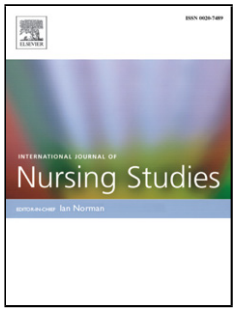

Title: Does participating in a clinical trial affect subsequent nursing management? Post-trial care for participants recruited to the INTACT pressure ulcer prevention trial: A follow-up study

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Title: Does participating in a clinical trial affect subsequent nursing management? Post-trial care for participants recruited to the INTACT pressure ulcer prevention trial: A follow-up study

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Abstract

Background: Participation in a clinical trial is believed to benefit patients but little is known about the post-trial effects on routine hospital-based care.

Objectives: To describe 1) hospital-based, pressure ulcer care-processes after patients were discharged from a pressure ulcer prevention, cluster randomised controlled trial; and 2) to investigate if the trial intervention had any impact on subsequent hospital-based care.

Methods: We conducted a retrospective analysis of 133 trial participants who developed a pressure ulcer during the clinical trial. We compared outcomes and care

processes between participants who received the pressure ulcer prevention intervention and those in the usual care, control group. We also compared care processes according to the pressure ulcer stage.

Results: A repositioning schedule was reported for 19 (14.3%) patients; 33 (24.8%) had a dressing applied to the pressure ulcer; 17 (12.8) patients were assessed by a wound care team; and 20 (15.0%) were seen by an occupational therapist. Patients in the trial's intervention group were more likely to have the presence of a pressure ulcer documented in their chart (odds ratio (OR) 8.18, 95% confidence intervals (CI) 3.64 to 18.36); to be referred to an occupational therapist OR 0.92 (95% CI 0.07; 0.54); to receive a pressure relieving device OR 0.31 (95% CI 0.14; 0.69); or a pressure relieving mattress OR 0.44 (95% CI 0.20; 0.96). Participants with Stage 2 or unstageable ulcers were more likely than others to have dressings applied to their wounds ($p = < 0.001$) and to be referred to an occupational therapist for protective devices ($p = 0.022$).

Conclusion:

Participants in the intervention group of a clinical trial were more likely to receive additional post trial care and improved documentation compared with those in the control group but documentation of pressure ulcer status and care is poor.

Keywords: Follow-Up Studies; Pressure Ulcer; Nursing; Outcome and Process Assessment (Health Care).

What is already known about the topic:

- Pressure ulcers continue to occur among patients with limited mobility
- Few interventions have shown to be effective in preventing pressure ulcers in this cohort
- There is a dearth of information about the impact of participating in a randomised controlled trial on subsequent pressure ulcer management.

What this paper adds:

- Participation in the intervention arm of a clinical trial increases care provided after the trial ends
- Participation in the intervention arm of a clinical trial improves documentation of care in clinical notes
- Processes of pressure ulcer care is very poorly reported in clinical notes.

BACKGROUND

Despite expensive prevention programs (1) and payment-removal penalties (2), pressure ulcers (PUs) continue to occur among patients admitted to acute care facilities. Incidence and prevalence rates of hospital acquired pressure ulcers vary depending on the practice setting between 0.0 to 72.5% (3), with highest rates among critical care, spinal cord injury and other patients with limited mobility (4, 5). The cost of PU prevention is substantial, ranging from €2.65 to €87.57 per patient per day. Costs associated with PU treatment are even higher with estimates from €1.71 to € 470.49 (6). In Australia, a recent cost-of-illness study estimated 121,645 cases of PUs per year contributed to 524,661 bed days lost for an estimated cost of AUD $983 million per year (based on 2012/2013)(7). More importantly, pressure ulcer-related pain is often severe and its presence increases the likelihood of developing a higher stage ulcer (8).

Although potentially preventable, there is a paucity of high level PU research to guide practice. For example, in the recent authoritative clinical guideline document we found only six of the 558 recommendations for pressure ulcer prevention and treatment were supported by Level A evidence (3); that is, a recommendation supported by “direct scientific evidence from properly designed and implemented controlled trials on pressure ulcers in humans” (p.3). Moreover, of the six recommendations with Level A evidence, only one, the recommendation relating to the use of high specification reactive foam mattresses, was supported by studies showing that the intervention was beneficial (9). For the other five recommendations, although high quality studies existed, the body of evidence from

those studies indicated that the effectiveness of the intervention remained unclear; for example evidence around diet (10) and repositioning (11).

Major risk factors for PUs are well known and include 1) immobility; 2) physiological conditions that limit blood flow to vulnerable tissue, such as diabetes and vascular disease; and 3) skin condition or existing pressure ulcer status (12). Similarly, costs of treating PUs (6) and incidence/prevalence are well reported (12). There are also numerous studies describing outcomes from PU prevention programs (1, 13) but few of these provide information about processes of care; such as the use of preventive dressings, mattress type, frequency of referrals to wound-care experts or other specialist. Of the 24 studies included in a review of PU programs, only seven reported the rate of adherence to planned care processes and none describe strategies for treating new PUs (13).

We were able to find only one study, in an acute hospital setting, describing the day-to-day management subsequent to the identification of a PU (14). In this study, conducted in one community hospital in the USA, the medical records of 100 patients with a PU on admission or who developed a PU during their hospital stay were reviewed. Information was provided about bed/mattress type, use of topical applications, frequency of turning and referrals to surgical services; but other interventions, like use of dressings and other pressure relieving devices and referrals to other specialists, such as podiatrists or occupational therapists were not reported (14). One further study included a medical record review of patients who had developed a PU during their acute hospital stay but the only process indicator was referral to a specialist skin integrity nurse (15).

As there is a dearth of information in this area, the extent to which guidelines for PU treatment (3) are followed is unclear. We recently completed a multi-site, cluster randomised trial that evaluated a patient-centred, PU prevention care bundle intervention (16). Details of the intervention are reported elsewhere (16) but, briefly, the intervention consisted of a short DVD and an information leaflet and poster. The poster and information leaflet contained three main messages1) keep moving; 2)

look after your skin; and 3) eat a healthy diet. These messaged were reinforced orally, while the intervention was being delivered to the patient. Nursing staff also received education sessions about the intervention and were asked to support the messages during their patient contact. The study end-point was the development of a new PU. However, when the end point was reached, no further information was collected. Subsequently, we sought permission to conduct a follow-up study, to explore the care participating patients in both arms of the study received following the development of a PU.

The aim of the present study was two-fold: 1) to describe the care processes implemented by hospital staff following identification of a PU and 2) to investigate if the intervention had any impact on subsequent care.

MATERIALS AND METHODS

Patients

In this follow-up study, we retrospectively evaluated the follow-up care of the 133 adult patients who developed a PU, of any stage during a recent cluster randomised controlled trial (16). The trial was conducted at eight hospitals in three Australian states between June 2014 and May 2015. Inclusion criteria for the trial involved having reduced mobility, expected hospital stay of >24h; admitted to hospital within the past 36h; and able to provide informed consent. The follow-up study of patients from both arms of the trial was approved by the Ethics Committees of the administering university and the participating hospitals.

Patient record review

Using a purposefully designed data extraction tool, developed by the investigators, trained registered nurses and one dietitian retrospectively reviewed the nursing, medical and allied health entries in each patient's medical record. Where available, other materials, such as daily care plans and wound care pathways were also reviewed. We extracted information about the stage of the PU identified in the original trial (target PU); interventions to treat the target PU; interventions implemented and/or recommended by hospital staff to prevent further PU development (such as a turning regime); incidence of any new PU and any treatment

(for example dressings or topical agents) associated with any new PU. We also extracted data about any post-discharge referrals associated with follow-up care for PUs or PU related re-admissions. After the medical record review was completed we added demographic and risk factor data, such as comorbid conditions (diabetes, vascular disease) and body mass index (BMI) from the INTACT trial database. We also included the stage of the target PU at the trial endpoint.

Statistical analysis

Descriptive statistics are reported as frequencies (%) or mean and standard deviation (SD). To test for any differences between the subsequent PU management of original trial groups; and for any differences between the subsequent PU management by PU stages, all categorical data were analysed using the Chi-squared test or two-tailed Fisher's exact test if one of the cells had a very small expected count. Continuous variables were not normally distributed so we used the Mann-Whitney U Test to assess for differences in continuous variables. Between group comparisons are presented as odds ratios (OR) or mean difference (MD). Data were analysed using IBM SPSS Statistics 23 and significance was defined as $p = 0.05$. Sample characteristics, preventive interventions, treatments and post-discharge referrals are reported in two ways: 1) by the group to which participants were assigned in the original cluster RCT; and 2) by the pressure ulcer stage on discharge from the trial.

Results

Of the 133 participants included in the follow-up study, 67 (50.4%) were female. The mean age of participants was 75.7 years (SD 14.3); mean BMI was 28.23kg/m^2 (SD 8.94; range 13.1 to 69.4) and average length of stay was 12.6 days (SD 11.97). A total of 128 (94%) were assessed for PU risk on admission and, of the 103 patients who were assessed with the Waterlow scale, 99 (96.1%) scored > 9 (i.e. were at risk of PU). The majority, 73 (54.9%) were receiving internal medicine care, 58 (43.6%) were surgical patients and two (1.5%) were receiving cancer care. Less than half, 63 (47.4%) were living independently; the majority, 90 (67.7%) reported more than one co-morbidity and 37 (27.8%) had a PU on admission to hospital.

A repositioning schedule was reported for 19 (14.3%) patients and 33 (24.8%) had a dressing applied to the PU. In terms of referrals, 17 (12.8%) patients were assessed by a wound care team, two (1.5%) saw a dietitian; 20 (15.0%) were seen by an occupational therapist and two (1.5%) had an orthotics referral. At hospital discharge the outcome for 99 (74.4%) PU was not recorded; 17 (12.8%) were recorded as healed; 11 (8.3%) were Stage 1; five (3.8%) were Stage 2; and one (0.8%) was Stage 3. Documentation at discharge was more likely if the patient had a Stage 2 PU ($p = 0.006$). There was no record of any referral to a care provider for PU management following hospital discharge and no indication that any participant returned to an outpatient clinic for PU care.

Overall, 60 (45.1%) PUs identified during the INTACT trial were documented in the patient's medical record. Documentation varied, depending on the group to which the patient had been assigned during the trial. A PU was 8-times more likely to be reported in the medical record of those who had been assigned to the INTACT trial's intervention group ($p = < 0.001$) compared with the trial's control group. Those in the intervention group were also more likely than those in the control group to have the stage of the PU recorded when the patient was discharged from hospital ($p = 0.007$); a record that a dressing had been applied to the target PU ($p < 0.04$); been referred to a wound care team ($p < 0.001$) or an occupational therapist ($p = 0.001$); and a prophylactic pressure relieving device ($p = 0.005$) or mattress ($p = 0.03$) as part of their care (Table 1).

The stage of a PU also influenced whether the lesion would be reported in the medical record, with Stage 2 being the most frequently recorded ($p < 0.02$). Participants with Stage 2 or unstageable ulcers were more likely than others to have dressings applied to their wounds ($p < 0.001$) and to be referred to an occupational therapist for protective devices ($p = 0.022$). PU stage had no influence for any other interventions. Fifteen (11.3%) patients developed an additional PU during their subsequent hospital stay (Table 2).

Discussion

Under trial conditions, interventions are carefully administered, monitored and reported but less is known about the effect of the intervention once a patient has been discharged from the trial. Our study is the first, prospectively designed investigation into the management of PUs in an acute care setting following participation in a randomised controlled trial. We undertook a medical record review, using a purposefully designed data extraction tool, to follow-up 133 patients who developed a PU during our recently completed clinical trial. We recorded subsequent treatment for any PU that developed during the trial and any intervention aimed at preventing development of a new PU. Whilst not pre-specified in the original INTACT trial, this post-hoc analysis has been undertaken to identify PU prevention and management strategies following a PU prevention intervention, in order to generate hypotheses for future trials.

Although unexpected, we have shown considerable post-trial differences in both the documentation of PU care and the management of PUs between the INTACT trial intervention and control groups. Whether these differences (such as higher rate of dressing use or referral to an occupational therapist) were due to a real effect of the intervention or to differences in the capacity of hospitals in the control group to provide these interventions is unclear. The trial was a cluster randomised trial with hospitals randomised according to their baseline PU rate; so it was possible that differences existed in access to resources in some hospitals (for example all public hospitals employ occupational therapists whereas some private hospitals may not). However, private and public hospitals were evenly distributed in the control and intervention groups. Consequently, we hypothesise that differences were due to the intervention, which was aimed at raising patient, carer and nurse awareness about PU prevention and patients participating in this. There is some evidence to support a favourable effect on outcomes through participation in clinical trials (17, 18) but at least one study has shown that, although processes of care may improve; outcomes between intervention and controls remained similar (19). Our study was too small to test if the improved processes of care in the intervention group affected the

outcome (incidence of new PUs) but the data we do have, suggests that further investigation into this proposition is warranted.

Irrespective of the higher use of PU prevention and treatment strategies in the INTACT intervention group participants, overall use of these strategies was low. This was despite clinical staff being notified when a PU was identified during the trial, providing an opportunity for staff to document and review their patients' PU treatment. One of the most predictive indicators for developing a PU is the presence of an existing PU (15). Consequently, all of the patients in our follow-up study were at high risk for developing a second PU, yet only 14.3% had a repositioning schedule documented, an intervention generally accepted as the most basic and fundamental PU prevention strategy (3). Similarly, only around one third of patients with an existing PU received a pressure relieving device or mattress as part of their care.

The study demonstrates that documentation of care following the development of a PU is poor. For example, although all of the patients in the study had an existing PU, any information about the PU was found in less than half of the patient's clinical notes. This result is almost identical to outcomes from a Swedish prevalence survey where only 47% of skin assessments were documented in the electronic medical record (20), and similar to findings from American acute care centres, where just 46% of PUs that were found on clinical examination were documented in the electronic medical record (21). Even more disappointing, by the time study participants were discharged from hospital, the outcome (healed or otherwise) was recorded for only 14% of all PUs. Whether poor documentation was due to low levels of skin inspection, or simply a failure to document the findings of skin inspections, is unclear. Never-the-less, poor reporting has a number of implications. Documentation is a means of conveying information from one health care provider to another, so care may be compromised if documentation is incomplete; especially if documentation is used to prompt PU prevention interventions. Additionally, when under-reporting is present, chart audits may reveal incorrect results and lead to a false sense of security around PU rates, preventing quality improvement activities from occurring. Similarly, only patients who had limited mobility and therefore

deemed as high risk of developing a PU were admitted to the INTACT trial. Arguably, failure to document any follow-up care on these high-risk individuals represents an important omission and may be damaging in the event of any future legal action against the organisation. It is reasonable to assume that ‘‘what was not documented was not done.’’(22) p100.

Limitations

The study was post-hoc, designed after completion of the main study. Consequently, it was not powered to find differences between groups. Confidence intervals were wide, indicating a great deal of uncertainty around the effect size. Even so, the study has raised some interesting questions for future research in this area (for example, ‘does improving processes of care result in improved outcomes?’). Secondly, the results relied on medical record reporting. We had no way of validating that all of the care provided was recorded in the patient’s record; some care may have been provided but not recorded. Our data extraction tool was based on the outcomes we wished to measure; the reliability of the tool was not assessed, for example by using a second person to validate the extracted data. In addition, data extractors were not directly informed of the allocation status of the hospital (intervention or control) but it is possible that they may have become aware of this status; thus compromising outcome blinding. Finally, results may not be generalized due to the small sample size, although participants were from a range of hospitals, which represented different levels of care.

Conclusion

Medical record evidence indicates that participants in the intervention arm of a randomised controlled trial received more ‘post-trial’ PU prevention-care compared with patients in the control arm. Irrespective of the PU stage, interventions among those with an existing PU were low. PU care of an existing or newly acquired PU is inadequately documented.

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Table 1. Demographic and risk factor data for patients who were included in the follow-up study. Results are reported by group allocation in the INTACT trial

Sample baseline characteristics	**ıtervention N=49) (%)**	**Control (N=84) n (%)**
Female	5 (51.0)	44 (52.4)
Aged care residence	(14.3)	13 (14.8)
Admission type		
Surgical	5 (51.0)	50 (39.3)
Medical	3 (46.9)	50 (59.9)
Cancer	(2.0)	1 (1.2)
Number of co-morbidities		
Less than two	7 (34.7)	26 (30.9)
Two or three	3 (57.1)	44 (52.4)
Four or more	(12.2)	14 (16.7)
Current Smoker	(10.2)	4 (4.8)
	Mean (SD[a])	Mean (SD)
Age in years	70.67 (15.01)	78.89 (13.11)
Body Mass Index	29.41 (10.43)	27.54 (8.01)
Length of stay	12.58 (10.83)	12.89 (15.85)

[a] Standard deviation

Table 2: Outcomes and interventions, documented in the medical record following discharge from the INTACT trial, for all patients who developed a pressure ulcer during the trial (n = 133). Results reported by group allocation in the INTACT trial

Post study outcome	**Intervention (N=49) n (%)**	**Control (N=84) n (%)**	**OR[a] [95% CI[b]]**	***P-value[c]***
PU[d] reported in medical record at end of INTACT Trial	37 (75.5)	23 (27.4)	8.18 (3.64; 18.36)	< 0.001
PU stage reported at hospital discharge	19 (38.8)	15 (17.9)	2.91 (1.31; 6.49)	0.007
Turning regime for PU reported in the INTACT Trial	10 (20.4)	9 (10.7)	0.47 (0.18; 1.25)	0.101
Dressing for PU reported in the INTACT Trial	17 (34.7)	16 (19.0)	0.44 (0.20; 0.99)	0.036
Referral to wound team for PU reported in the INTACT Trial	16 (32.7)	1 (1.2)	0.03 (0.00; 0.16)	< 0.001
Referral to dietician for PU reported in the INTACT Trial	1 (2.0)	1 (1.2)	0.58 (0.04; 9.46)	0.603
Referral to occupationl therapist for PU reported in the INTACT Trial	14 (28.6)	6 (7.1)	0.19 (0.07; 0.54)	0.001
Prophylactic orthotics	2 (4.1)	1 (1.2)	0.28 (0.25; 3.20)	0.306
Prophylactic turning regime	19 (38.8)	19 (22.6)	0.46 (0.21; 0.99)	0.072
Prophylactic pressure relieving device	21 (42.9)	16 (10.0)	0.31 (0.14; 0.69)	0.005
Prophylactic pressure relieving mattress	18 (36.7)	17 (20.2)	0.44 (0.20; 0.96)	0.031
New PU after discharge from main study	8 (16.3)	7 (8.3)	0.47 (0.16; 1.38)	0.169
Dressing to treat new PU	6/8 (75.0)	4/7 (57.1)	0.44 (0.53; 4.26)	0.608

Turning regime for new PU	5/8 (62.5)	5/7 (71.4)	1.5 (0.17; 13.22)	1.000
Any other intervention to treat new PU	2/8 (25.0)	5/7 (71.4)	7.5 (0.76; 74.16	0.132

[a] Odds Ratio; [b] Confidence interval; [c] Chi Square or Fisher's Exact (2-sided); [d]Pressure Ulcer

Table 3: Outcomes and interventions, documented in the medical record following discharge from the INTACT trial, for all patients who developed a pressure ulcer during the trial (n = 133). Results reported by pressure ulcer stage during the INTACT trial.

Post study outcome	**Stage 1 N = 88**	**Stage 2 N = 35**	**Unstageable or suspected deep tissue injury N = 10**	**P-value[a]**
PU[b] reported in medical record at end of INTACT Trial	33 (37.5)	22 (62.9)	5 (50.0)	0.018
PU stage reported at hospital discharge	16 (18.2)	16 (45.7)	2 (20.0)	0.006
Turning regime for PU reported in the INTACT Trial	9 (10.2)	8 (22.9)	2 (20.0)	0.169
Dressing for PU reported in the INTACT Trial	13 (14.8)	17 (48.6)	3 (30.0)	< 0.001
Wound team referral for PU reported in the INTACT Trial	8 (9.1)	6 (17.1)	3 (30.0)	0.115
Referral to dietician for PU reported in the INTACT Trial	1 (1.1)	1 (2.9)	0 (0.0)	0.717
Referral to occupationl therapist for PU reported in the INTACT Trial	8 (9.1)	10 (28.6)	2 (20.0)	0.022
Prophylactic orthotics	3 (3.4)	0 (0.0)	0 (0.0)	0.456
Prophylactic pressure relieving device	25 (28.4)	11 (31.4)	1 (10)	0.402
Prophylactic pressure relieving mattress	18 (20.5)	13 (37.1)	4 (40.0)	0.098
Prophylactic turning regime	23 (26.1)	12 (34.3)	3 (30.0)	0.662
New PU after discharge from the INTACT Trial	9 (10.2)	4 (11.4)	2 (20.0)	0.651
Dressing to treat new PU	6/9 (66.7)	2/4 (50.0)	2/2 (100.0)	0.472

Turning regime for new PU	7/9 (77.7)	1/4 (25.0)	2/2 (100.0)	0.099
Any other intervention to treat new PU	3/9 (33.3)	3/4 (75.0)	1/2 (50.0)	0.739
	Mean (SD[c])	**Mean (SD)**	**Mean (SD)**	***P-value[d]***
Age in years	78.40 (12.11)	73.60 (16.43)	61.5 (16.36)	0.001
BMI	27.40 (7.51)	27.60 (7.79)	37.73 (17.08)	0.002
Length of stay	12.58 (10.83)	12.89 (15.85)	11.70 (3.92)	0.963

[a] Chi Square or Fisher's Exact (2-sided); [b]Pressure Ulcer; [c] Standard deviation; [d] Mann-Whitney U test