離床警報系統能降低住院病人跌倒嗎？

105年3月8日

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Effects of an Intervention to Increase Bed Alarm Use to Prevent Falls in Hospitalized Patients: A Cluster Randomized Trial

Ann Intern Med. 2012 November 20; 157(10): 692–699

Impact factor:13.9

步驟 1：研究探討的問題為何？

P (Population/ Problem)：Hospitalized Patients/Falls Prevention

I (Intervention)：Bed alarm systems(Education, training, and technical support)+Usual Care

C (Comparison)：Usual care
      1.Fall risk assessment(adapted Morse Fall Scale (125).
      2. General safety measures
      3. Bed alarms were available to patients

O(Outcomes)：
1.Pre–post difference in change in falls per 1000 patient-days
2. number of patients who fell, fall-related injuries
3. number of patients restrained

步驟 2：研究的品質有多好(內在效度)？

1.招募(Recruitment) - 受試者是否具有代表性？

- Methodist Healthcare-University Hospital, an urban,academically affiliated community hospital in Memphis, Tennessee, on *16 medical–surgical nursing units with 349 beds.*
- *All patients* became eligible for study *participation at the time of admission*
- to 1 of the 16 study units, and eligibility ended with discharge from 1 of the 16 study units.
- * Methodist Healthcare institutional review board reviewed and *approved the research protocol* and granted a *waiver of informed consent.*

評讀結果： ■是 □否 □不清楚

步驟 2：研究的品質有多好(內在效度)？

2.分派(Allocation) - 分派方式是否隨機且具隱匿性...？

A Cluster Randomized Trial

8 pairs

The first in the pair was randomly assigned to the intervention or control group

Units were allocated by using a random-number sequence in SAS software,version 9.2

* *Patients* were blinded to unit assignment.

評讀結果： ■是　□否　□不清楚

分派(Allocation):每個組別，在研究開始時的情況是否相同？

Table 1

Characteristics of Intervention and Control Nursing Units During Baseline and Study Periods*

Variable	Control Units		Intervention Units	
	Baseline Period	Study Period	Baseline Period	Study Period
Unit-level characteristics				
Units, n	8	8	8	8*
Patient-days	35 377	83 604	30 113	59 011
Mean fall risk score (SD)[†]	61.4 (25.5)	61.1 (19.8)	62.8 (24.7)	63.2 (20.2)
Median proportion of patient-days (IQR), by patient-level characteristic				
Age ≥75 y	0.17 (0.10–0.20)	0.25 (0.14–0.30)	0.20 (0.18–0.26)	0.30 (0.26–0.32)
Female sex	0.53 (0.49–0.57)	0.53 (0.51–0.55)	0.59 (0.55–0.61)	0.58 (0.55–0.59)
White race	0.31 (0.27–0.40)	0.32 (0.26–0.44)	0.31 (0.20–0.37)	0.32 (0.21–0.37)
Psychotropic drug use	0.25 (0.19–0.30)	0.22 (0.18–0.24)	0.26 (0.25–0.29)	0.26 (0.21–0.27)
Primary insurance				
Medicare	0.61 (0.49–0.67)	0.57 (0.50–0.67)	0.64 (0.61–0.66)	0.59 (0.57–0.65)
Medicaid	0.13 (0.10–0.17)	0.12 (0.10–0.14)	0.11 (0.10–0.12)	0.12 (0.10–0.13)
Other insurance	0.28 (0.22–0.33)	0.30 (0.21–0.39)	0.24 (0.22–0.29)	0.30 (0.23–0.33)
Median proportion of hours per patient-day (IQR), by staffing				

分派(Allocation):每個組別，在研究開始時的情況是否相同？

Median proportion of hours per patient-day (IQR), by staffing

Registered nurse	5.2 (4.1–6.1)	4.3 (3.9–4.8)	4.3 (4.0–4.6)	3.8 (3.6–4.2)
Licensed practical nurse	1.5 (1.0–2.4)	1.2 (1.03–1.7)	2.4 (2.2–2.8)	1.9 (1.4–2.0)
Nursing assistant	2.8 (2.7–3.1)	2.2 (2.0–2.3)	3.0 (2.8–3.2)	2.3 (2.0–2.5)

IQR = interquartile range.

* Two units unexpectedly closed during the study period and provided data only for 3 mo.

† Derived from the Morse Fall Scale (15) and scored from 0 to 125. This element was included in the electronic medical record only in the last month of the baseline period but in all 18 mo of the intervention period.

分派(Allocation):每個組別，在研究開始時的情況是否相同？

Appendix Table

Admission Characteristics of Patients on Intervention and Control Nursing Units During Baseline and Study Periods

Variable	Control Units		Intervention Units	
	Baseline Period	**Study Period**	**Baseline Period**	**Study Period**
Patients, *n*	7327	16 911	5272	10 761
Demographic characteristics				
Mean age (SD), *y*	59.3 (16.6)	59.1 (16.8)	60.1 (17.6)	59.6 (17.3)
Female sex, %	53.7	53.8	55.7	54.7
White race, %	32.5	32.9	28.6	30.5
Psychotropic drug use, %	30.3	28.0	29.5	27.5
Primary insurance, %				
Medicare	54.7	53.9	58.3	57.2
Medicaid	13.7	13.2	12.3	11.9
Other insurance	25.7	25.0	23.4	23.3

評讀結果： ■是　　□否　　□不清楚

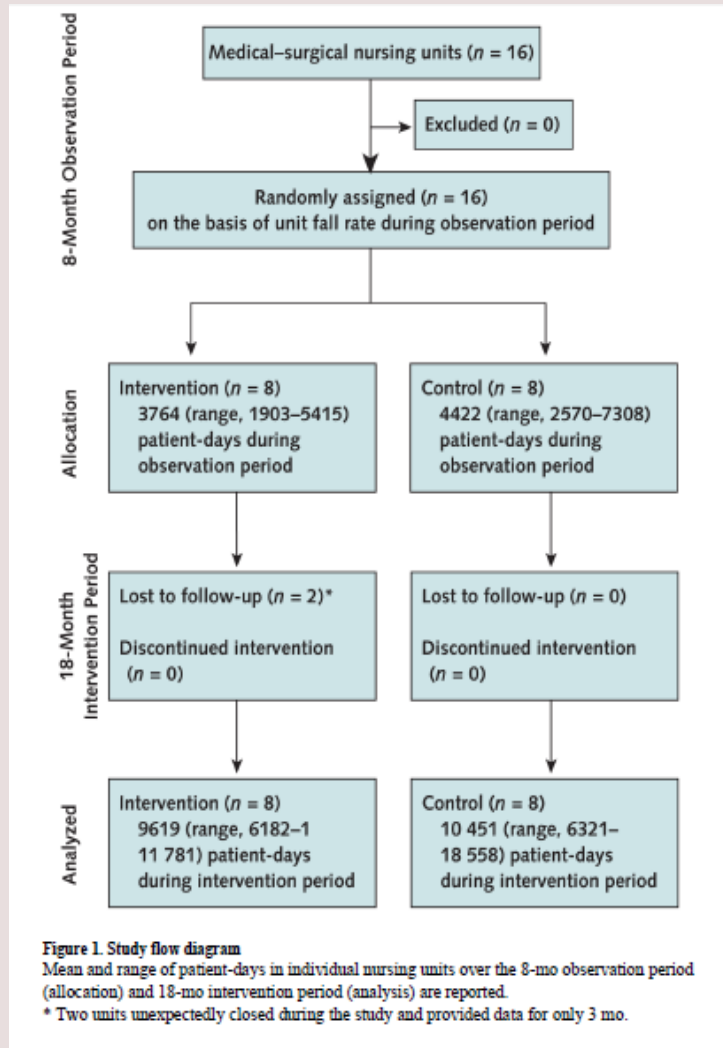# 維持(Maintenance) – 各組是否給予相同的治療？

Control:

- The study interventionist also *did rounds for approximately 15 minutes once or twice per week* on control units, promoting the hospital's fall prevention protocol but *without emphasizing the use of bed or chair alarms*

Intervention:

- 1. *did rounds every weekday for approximately 15 minutes*
- 2.The study interventionist and the principal investigator conducted *extensive educational sessions on the use of the alarm system at each intervention unit.*
- 3.The study interventionist *encourage* the use of bed alarms by delivering them and setting them up on patients selected for their use, address technical issues related to use of the alarms, and provide training on device use.

評讀結果： ■是 □否 □不清楚

Figure 1. Study flow diagram
Mean and range of patient-days in individual nursing units over the 8-mo observation period (allocation) and 18-mo intervention period (analysis) are reported.
* Two units unexpectedly closed during the study and provided data for only 3 mo.

2 units randomly assigned to *the intervention group unexpectedly closed* during the third month of the 18-month study.

Incomplete data were assumed to be missing at random.

評讀結果： □是　　■否　　□不清楚

評估(Measurement) – 受試者與評估者是否對治療方式及(或)評估目的維持盲法(blind)？

 * *statistical consultant* who was blinded to the identity of the units.
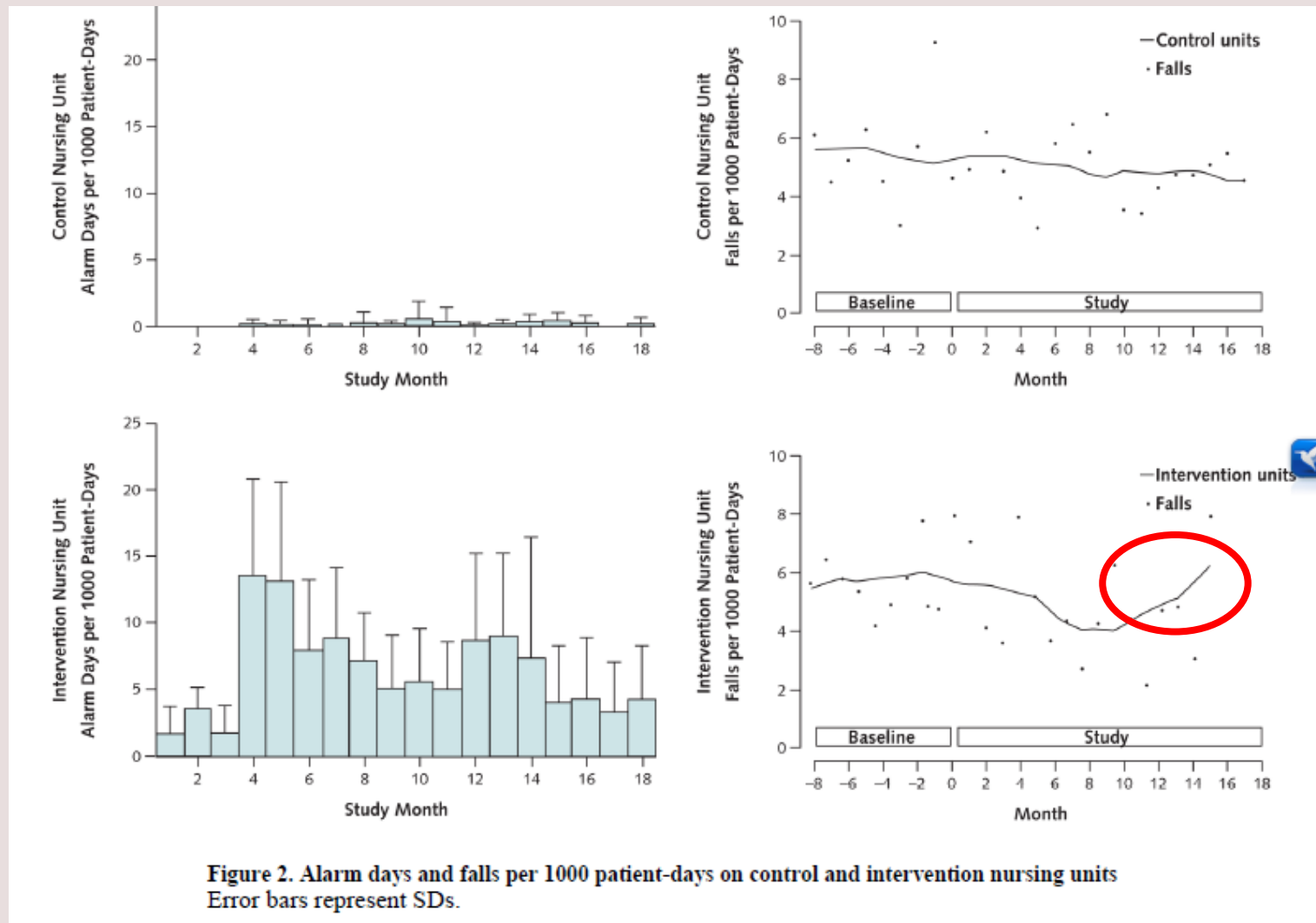
評讀結果： □是 ■否 □不清楚

步驟 3：研究結果的意義為何？

使用何種評估方式，療效有多大？

The *relative effect* of the intervention is expressed as a *risk ratio (RR),* defined as (fall event rate in the intervention units during the study period/fall event rate in the intervention units during the baseline period)/(fall event rate in the control units during the study period/fall event rate in the control units during the baseline period). *An RR less than 1.0 favors the intervention units*.

The absolute effect of the intervention was expressed as the population *averaged difference in differences (DID),* which we defined as (fall event rate in the intervention units during the study period – fall event rate in the intervention units during the baseline period) – (fall event rate in the control units during the study period – fall event rate in the control units during the baseline period). *A DID less than 0 favors the intervention units.*

步驟 3：研究結果的意義為何？

Figure 2. Alarm days and falls per 1000 patient-days on control and intervention nursing units
Error bars represent SDs.

步驟 3：研究結果的意義為何？

Table 2

Outcomes per 1000 Patient-Days During the Baseline and Study Periods on Intervention and Control Nursing Units[*]

End Point, per 1000 Patient-Days	Adjusted Fall Rates During Baseline Period (95% CI)[†]	Adjusted Fall Rates During Study Period (95% CI)[‡]	Ratio (95% CI)	RR (95% CI)	Difference (95% CI)	DID (95% CI)[§]
Falls	C: 5.11 (4.07 to 6.75) I: 5.76 (4.31 to 7.86)	C: 4.56 (3.80 to 5.81) I: 5.62 (4.98 to 7.76)	C: 0.89 (0.75 to 1.03) I: 0.98 (0.77 to 1.39)	1.09 (0.85 to 1.53)	C: −0.55 (−1.48 to 0.14) I: −0.14 (−1.77 to 2.02)	0.41 (−1.05 to 2.47)
Patients who fell	C: 4.57 (3.83 to 5.92) I: 5.00 (3.76 to 6.75)	C: 4.01 (3.50 to 5.00) I: 5.04 (4.47 to 6.52)	C: 0.88 (0.74 to 1.01) I: 1.01 (0.82 to 1.31)	1.15 (0.92 to 1.49)	C: −0.56 (−1.44 to 0.05) I: 0.03 (−1.18 to 1.30)	0.59 (−0.50 to 1.84)
Injurious falls	C: 1.87 (1.44 to 2.35) I: 1.30 (0.89 to 1.84)	C: 1.32 (0.97 to 1.62) I: 1.30 (1.05 to 1.56)	C: 0.70 (0.46 to 0.94) I: 1.00 (0.61 to 1.60)	1.42 (0.77 to 3.34)	C: −0.55 (−1.24 to 0.09) I: 0.00 (−0.72 to 0.57)	0.56 (−0.32 to 1.67)
Patients restrained	C: 3.86 (2.83 to 5.34) I: 5.20 (3.76 to 8.59)	C: 5.65 (3.82 to 8.24) I: 6.29 (5.21 to 9.03)	C: 1.46 (1.16 to 1.78) I: 1.21 (0.85 to 1.55)	0.83 (0.56 to 1.18)	C: 1.79 (0.57 to 3.34) I: 1.09 (−1.23 to 2.47)	−0.69 (−3.77 to 1.03)

C = control unit; DID = difference in differences; I = intervention unit; RR = risk ratio.

[*] Adjusted rates are from a marginal model that accounts for the cluster randomized design; estimates are from a model adjusted for group assignment, period, and group assignment × period interaction ("base model"). For falls, an RR <1.0 and a DID <0 favor the intervention units.

[†] 65 490 patient-days.

[‡] 142 615 patient-days.

[§] Difference in change in intervention compared with control units (intervention units − control units).

步驟３：研究結果的意義為何？

Table 3

Relative and Absolute Effects of Alarm Intervention for the Primary and 3 Secondary End Points, Adjusted for Unit-Level Covariates

End Point	Covariate (95% CI)		
	Staffing[*]	Demographic Characteristics[†]	All[‡]
Falls	R: 1.18 (0.88 to 1.75) A: 0.79 (−0.77 to 3.11)	R: 1.08 (0.83 to 1.50) A: 0.33 (−0.77 to 3.11)	R: 1.17 (0.87 to 1.68) A: 0.69 (−0.88 to 3.01)
Patients who fell	R: 1.21 (0.98 to 1.64) A: 0.82 (−0.29 to 2.16)	R: 1.14 (0.95 to 1.45) A: 0.52 (−0.29 to 2.16)	R: 1.22 (1.01 to 1.55)[§] A: 0.81 (−0.12 to 1.89)
Injurious falls	R: 1.60 (0.84 to 3.70) A: 0.71 (−0.23 to 1.84)	R: 1.45 (0.81 to 3.65) A: 0.56 (−0.23 to 1.84)	R: 1.59 (0.81 to 3.57) A: 0.73 (−0.19 to 2.49)
Patients restrained	R: 0.83 (0.51 to 1.26) A: −0.70 (−3.99 to 1.06)	R: 0.84 (0.54 to 1.21) A: −0.79 (−3.99 to 1.06)	R: 0.82 (0.45 to 1.19) A: −0.81 (−5.34 to 0.87)

A = absolute, expressed as difference in differences; R = relative, expressed as risk ratio.

[*] Adjusted for base covariates (group assignment, time period, and group assignment × time period interaction) plus staffing covariates (registered nurse, licensed practical nurse, and nursing assistant hours per patient-day).

[†] Adjusted for base, demographic (age, sex, race, and insurance status), and psychotropic drug use covariates.

[‡] Adjusted for base, staffing, demographic, and psychotropic drug use covariates.

[§] $P < 0.05$.

其他的文章：Interventions for preventing falls in older people in care facilities and hospitals (Review)

Interventions for preventing falls in older people in care facilities and hospitals (Review)

Summary of main results

Despite the addition of 20 trials (35,270 participants) many of the results from the pooled analyses remain inconsistent.

Exercises

Thirteen trials in care facilities and two in hospitals investigated exercise as a single intervention.

In care facilities overall, there was no reduction in rate of falls or risk of falling. However, there appeared to be a trend towards an increase in rate of falls in facilities including high level nursing care and a trend towards a decrease in intermediate level care facilities. Of the various exercise components tested, only balance training using mechanical apparatus in intermediate level care facilities reduced rate of falls, but the adoption of these interventions may be problematic. Our subgroup analysis by level of care plus the subgroup analysis in Faber 2006, suggested that frail participants might be less likely to benefit from exercise interventions.

In hospitals there is some evidence that additional physiotherapy in subacute wards reduced risk of falling.

In summary, within each setting results relating to the effectiveness of exercise are inconsistent. This may relate to the type and intensity of exercise, differences in study populations, or possibly variation in methodological quality.

Medication (drug target)

Medication review by a pharmacist

Five studies tested vitamin D supplementation in care facilities, and one in a hospital. In addition, one placebo-controlled trial in a care facility investigated the effect of daily multivitamin supplementation which included vitamin D and calcium.

In care facilities, results showed a significant reduction in the rate of falls (five trials) but not risk of falling (six trials). Average serum vitamin D levels at baseline appeared to be low or very low in all six studies (see Characteristics of included studies), indicating that these results relate to the low vitamin D levels in residents of care facilities.

In hospital, one trial in an acute geriatric unit found no effect of vitamin D supplementation on risk of falling, despite the low levels of vitamin D at baseline. The median length of stay was only 30 days.

These results suggest that vitamin D supplementation in people living in care facilities is effective.

Environment/assistive technology

In one trial in a high level nursing care facility there was no effect on rate of falls from using a wireless position-monitoring patch (Clifton 2009).

Four trials in hospitals investigated environment/assistive technology interventions. Carpet flooring in a subacute ward appeared to significantly increase falls compared with vinyl flooring. There was no effect on falls of low-low beds or using identification bracelets for patients at high risk.

Social environment

Five trials in care facilities and five in hospitals targeted staff train-

6-PACK programme to decrease fall injuries in acute hospitals: cluster randomised controlled trial

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ABSTRACT

OBJECTIVE
To evaluate the effect of the 6-PACK programme on falls and fall injuries in acute wards.

DESIGN
Cluster randomised controlled trial.

SETTING
Six Australian hospitals.

PARTICIPANTS
All patients admitted to 24 acute wards during the trial period.

INTERVENTIONS
Participating wards were randomly assigned to receive either the nurse led 6-PACK programme or usual care over 12 months. The 6-PACK programme included a fall risk tool and individualised use of one or more of six interventions: "falls alert" sign, supervision of patients in the bathroom, ensuring patients' walking aids are within reach, a toileting regimen, use of a low-low bed, and use of a bed/chair alarm.

MAIN OUTCOME MEASURES
The co-primary outcomes were falls and fall injuries per 1000 occupied bed days.

RESULTS

1.04, 0.78 to 1.37; P=0.796) and fall injuries (0.96, 0.72 to 1.27; P=0.766) were similar in intervention and control wards.

CONCLUSIONS
Positive changes in falls prevention practice occurred following the introduction of the 6-PACK programme. However, no difference was seen in falls or fall injuries between groups. High quality evidence showing the effectiveness of falls prevention interventions in acute wards remains absent. Novel solutions to the problem of in-hospital falls are urgently needed.

TRIAL REGISTRATION
Australian New Zealand Clinical Trials Registry ACTRN12611000332921.

Introduction

Falls remain a common cause of harm to patients in acute hospitals worldwide. In the United Kingdom, as many as 250 000 falls and more than 1000 fractures are recorded each year.[1] Recent epidemiological studies provide evidence that the harm from in-hospital falls is increasing. A Danish study that included national hospital data showed that the rate of fall related major injuries increased more than 11% between 2007 and 2012.[2] The

6-PACK programme to decrease fall injuries in acute hospitals : cluster randomised controlled trial

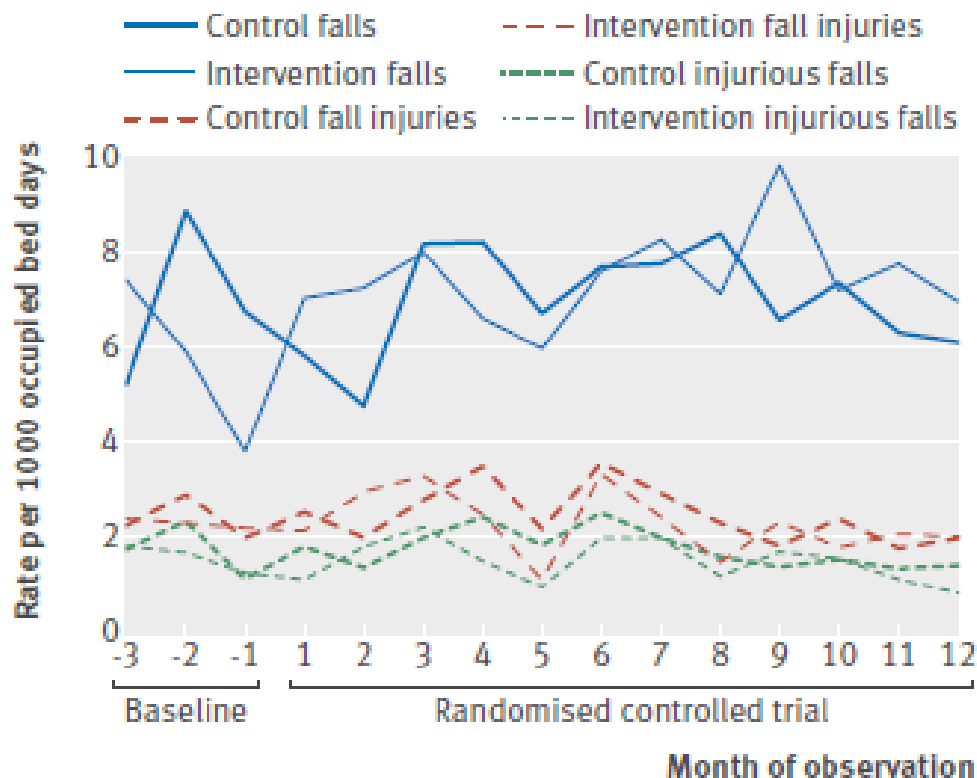Fig 3 | Use of 6-PACK programme components during randomised controlled trial period by group

Fig 4 | Fall outcomes by month and group

是否建議臨床使用離床警報器？

- 同意:1位
- 不同意:4位
- 待討論:11位