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# Understanding the relationship between process and outcome in complex intervention trials


## Professor Lisette Schoonhoven

Fundamental Care & Safety - Skin Health Group

L.Schoonhoven@soton.ac.uk

# Complex interventions

- Intervention: any action taken by health care workers (including people working in social care and public health situations) with the aim of improving well-being of people with health and/or social care needs

- Complex
  - What is simple?
  - Not the intervention but the question is complex: does it work/ how does it work/ what would work in this situation/how can we optimise it?

# Components of intervention complexity

| Type of complexity | Sub-themes |
|---|---|
| Behaviours | Number of different behaviours |
| | Parameters of behaviours |
| | Methods of organising and delivering behaviours |
| | Interactions between behaviours |
| | Difficulty of these behaviours for clinicians and recipients |
| Outcomes | Number and variability |
| Delivery | Degree of flexibility and tailoring |

MRC (2000, 2008) taken from Richards and Hallberg 2015

# Process evaluation

- Can be used to:
  - Assess fidelity and quality of implementation
  - Clarify causal mechanisms
  - Identify contextual factors associated with variation in outcome

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# Process evaluation: implementation fidelity (integrity)

- Refers to the degree to which an intervention is delivered as intended by the intervention developers (fidelity)
- Fidelity influences how far the intervention actually affects the outcomes
- The effectiveness of a carefully developed intervention depends on the degree in which it is delivered (dose)

# Process evaluation: what to measure?

*Target group/participants*

- Professional, patients, aimed at individuals or group, size of group, motivation participation

*Implementer*

- Professional status, opinion leader, authority

*Intensity*

- Frequency, time intervals, duration

*Information provided*

- Type of information about performance, presentation form, medium

# Process evaluation: how to measure?

- On-site observation
- Self-report techniques (interviews and questionnaires)
- Existing data sources or records

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# SAFE or SORRY? an evidence based inpatient safety program for the prevention of adverse events

*Betsie van Gaal*

*Lisette Schoonhoven*

*Raymond Koopmans*

*George Borm*

*Joke Mintjes-de Groot*

*Theo van Achterberg*

(Van Gaal et al. BMC Health Serv Res. 2009)

# SAFE or SORRY?

- Background – Project tiredness and a lack of comprehensive safety thinking
- Aim - to develop and test a patient safety program that addresses several AEs simultaneously in hospitals and nursing homes
- The program addresses three AEs: pressure ulcers, falls and urinary tract infections

# Intervention

- Developed with experts, using existing guidelines & supplementary material
- Consensus about the essence of the guidelines and formulated bundles of key recommendations
- Bundles and indicators discussed with the user group (n=17)
- Implementation strategy consisting of
  * education
  * patient involvement
  * feedback through a computerized registration program

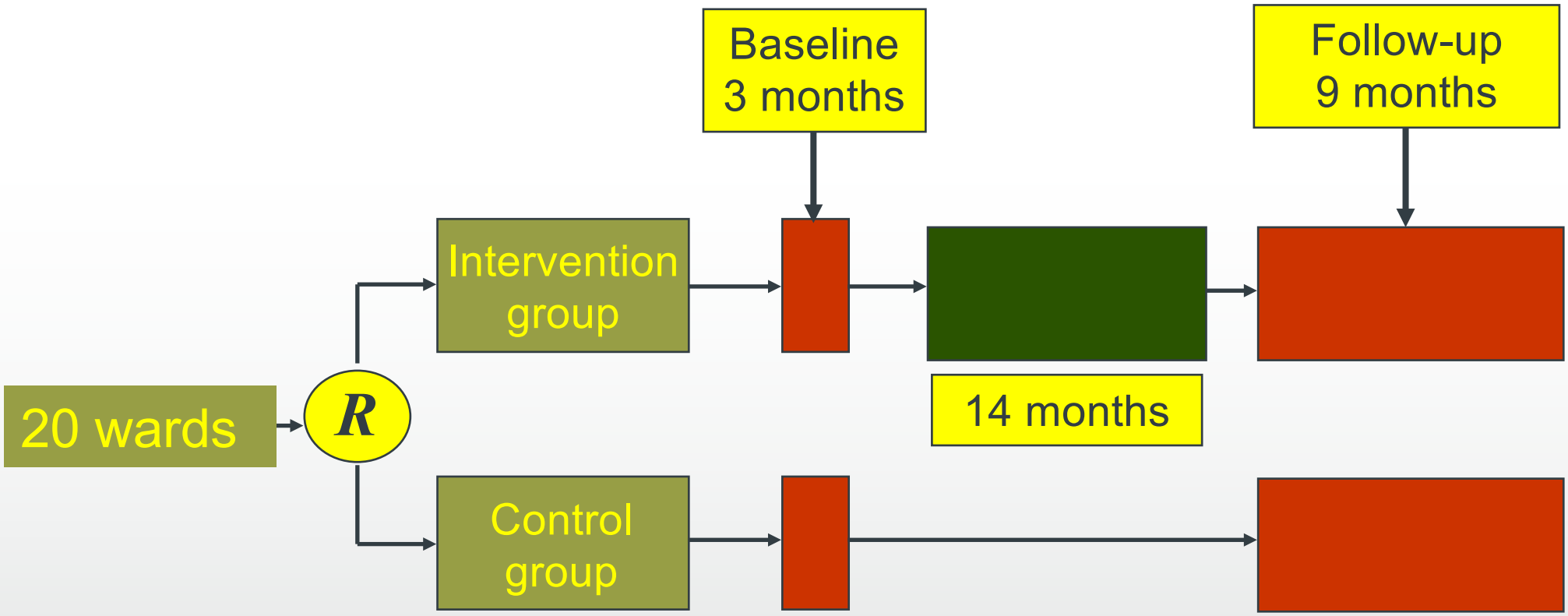
# Aim

*Was the SAFE or SORRY? program effective in hospitals and nursing homes?*

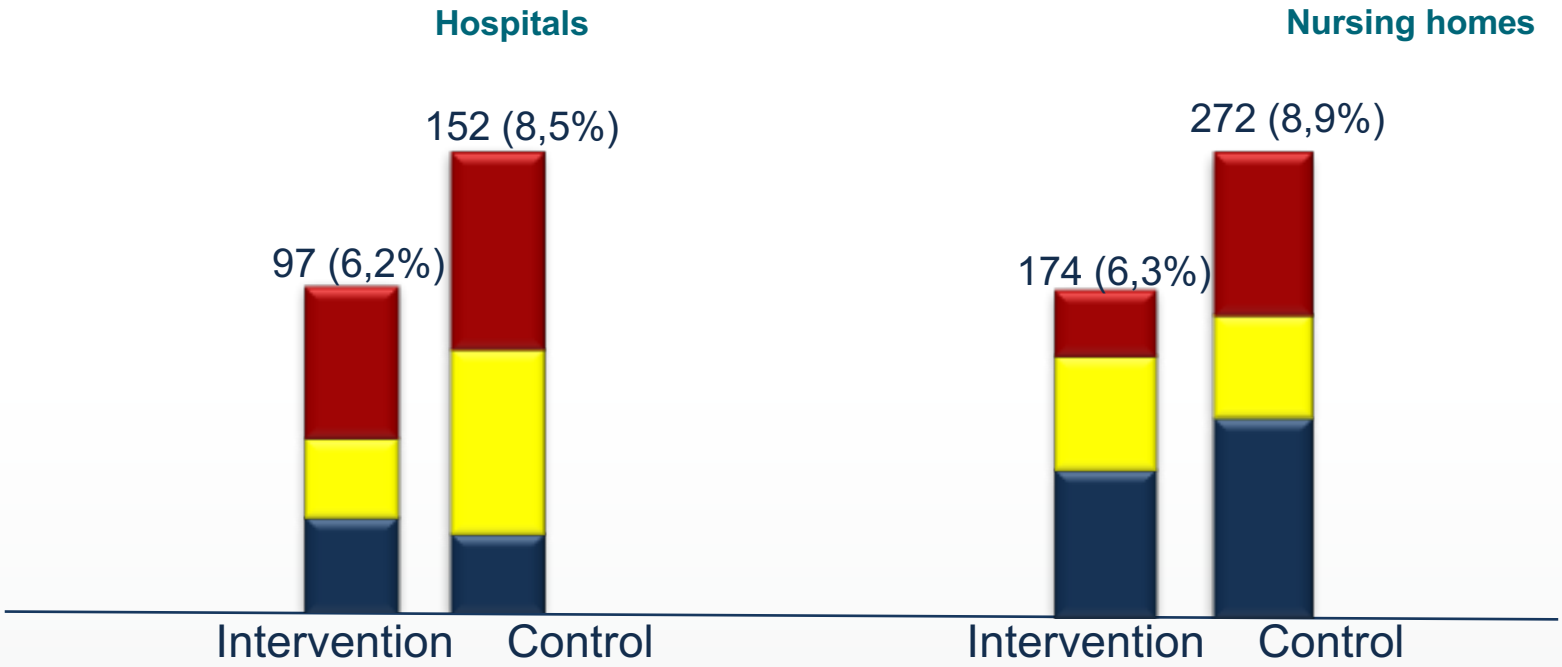
- Did it decrease the incidence of adverse events
- Did it increase preventive care

# Methods

## Cluster randomised trial



# Results




- In hospitals 43%↓ adverse events & in nursing homes 33%↓ adverse events

**Conclusion:** Simultaneous implementation of multiple guidelines seems feasible and effective

# Methods

## Outcome

- Primary: incidence of PUs
- Secondary: utilisation of preventive care

## Data collection

- Weekly visits
- 5-hours observation

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# Results: General

| Hospitals | Baseline | | Follow up | |
|---|---|---|---|---|
| | Intervention | Control | Intervention | Control |
| Included patients | 346 | 341 | 1081 | 1120 |
| Female | 184 (53%) | 204 (60%) | 570 (53%) | 646 (58%) |
| Age (mean (st dev) | 66 (14.5) | 64 (16.9) | 66 (14.7) | 67 (16.1) |

| Nursing homes | Baseline | | Follow up | |
|---|---|---|---|---|
| | Intervention | Control | Intervention | Control |
| Included patients | 114 | 127 | 196 | 196 |
| Female | 70 (61%) | 89 (70%) | 131 (67%) | 126 (64%) |
| Age (mean (st dev) | 78 (9.9) | 78 (10.8) | 80 (9.2) | 79 (10.5) |

# Results: incidence pressure ulcers

| Hospitals | Baseline | | Follow up | |
|---|---|---|---|---|
| | Intervention (n=346) | Control (n=341) | Intervention (n=1081) | Control (n=1120) |
| Patient weeks | 496 | 534 | 1576 | 1782 |
| Incidence PUs | 14 | 18 | 45 | 66 |
| Incidence Rate PU/week | 2.8% | 3.4% | 2.9% | 3.7% |

**Multilevel analysis: 0.92 (95% CI: 0.39 to 2.15)**

| Nursing homes | Baseline | | Follow up | |
|---|---|---|---|---|
| | Intervention (n=114) | Control (n=127) | Intervention (n=196) | Control (n=196) |
| Patient weeks | 933 | 1058 | 2754 | 3045 |
| Incidence PUs | 29 | 30 | 36 | 97 |
| Incidence Rate PU/week | 3.1% | 2.8% | 1.3% | 3.2% |

**Multilevel analysis: 0.34 (95% CI: 0.15 to 0.76)**

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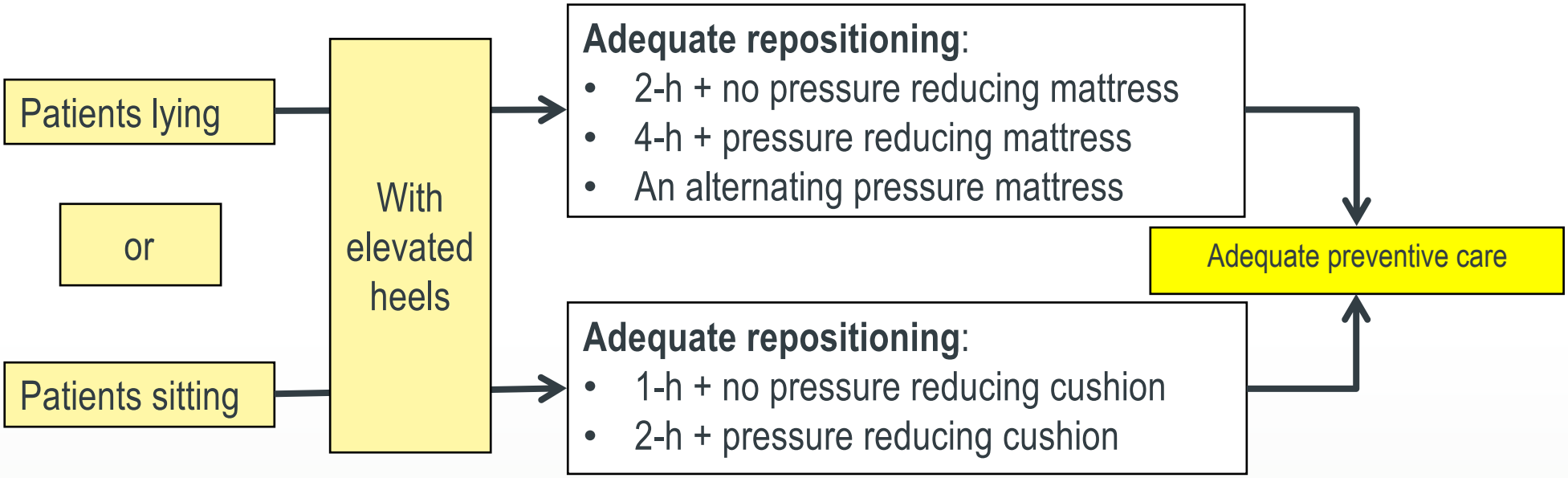
# Results: preventive material

| Hospitals | Baseline | | Follow up | |
|---|---|---|---|---|
| | I (n=346) | C (n=341) | I (n=346) | C (n=341) |
| % patients at risk PU[1] | 46% | 50% | 49% | 52% |
| Pressure-reducing mattress | 97% | 97% | 86% | 98% |
| Alternating pressure mattress | 2% | 3% | 1% | 1% |
| Pressure- reducing cushion | 1% | 2% | 2% | 2% |

| Nursing homes | Baseline | | Follow up | |
|---|---|---|---|---|
| | I (n=114) | C (n=127) | I (n=196) | C (n=196) |
| % patients at risk PU[2] | 71% | 62% | 58% | 71% |
| Pressure-reducing mattress | 36% | 25% | 38% | 57% |
| Alternating pressure mattress | 14% | 20% | 18% | 23% |
| Pressure- reducing cushion | 38% | 50% | 33% | 55% |

1: PrePURSE or Braden subscale mobility <3 or activity <3 / 2: Braden scale or Braden subscale mobility <3 or activity <3

# Results: preventive care




| Adequate preventive care | Follow up | | Estimate | 95% CI: |
|---|---|---|---|---|
| | Intervention | Control | | |
| **Hospitals** | 27% | 27% | 0.06 | -0.07 to 0.19 |
| **Nursing homes** | 19% | 13% | 0.04 | -0.05 to 0.13 |

# Discussion

- Risk assessment: probably to many patients at risk for PUs, but still not many patients did receive preventive care
- Data collection
  - Not missed:
    - Incidence of pressure ulcers
    - Preventive materials
  - Only an impression of the given prevention

# Conclusion

The SAFE or SORRY? program:

- Decreases the incidence rate of PU in nursing homes
- No measured increase the preventive care for patients at risk for PUs

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