Complex Interventions, Development and Evaluation in Nursing

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Complex interventions are ...

- „built up from a number of components, which may act both independently and interdependently.“
- „more than the sum of their parts, and interventions need to be better theorised to reflect this.“ (Craig et al. 2008, BMJ; Hawe et al. 2004, BMJ)

**Box 1. What makes an intervention complex?**

- Number of interacting components within the experimental and control interventions.
- Number and difficulty of behaviours required by those delivering or receiving the intervention.
- Number of groups or organisational levels targeted by the intervention.
- Number and variability of outcomes.
- Degree of flexibility or tailoring of the intervention permitted.

(Craig et al. 2012; IJNS)
The MRC framework

Developing and evaluating complex interventions: new guidance

Figure 1 Key elements of the development and evaluation process

- **Feasibility/piloting**
  1. Testing procedures
  2. Estimating recruitment/retention
  3. Determining sample size

- **Development**
  1. Identifying the evidence base
  2. Identifying/developing theory
  3. Modelling process and outcomes

- **Evaluation**
  1. Assessing effectiveness
  2. Understanding change process
  3. Assessing cost-effectiveness

- **Implementation**
  1. Dissemination
  2. Surveillance and monitoring
  3. Long term follow-up
Introduction of such a system did not significantly reduce the incidence of our study outcomes. Possible explanations for our findings are that the MET system is an ineffective intervention; the MET is potentially effective but was inadequately implemented in our study; we studied the wrong outcomes; control hospitals were contaminated as a result of being in the study; the hospitals we studied were unrepresentative; or our study did not have adequate statistical power to detect important treatment effects.
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Development of clinically meaningful complex interventions – The contribution of qualitative research
Key challenges to systematic reviews of complex interventions
Fig. 1. Substantive features of a complex intervention that can lead to heterogeneity of results.
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One-day workshop
- for skilled nurses
- Aim: to prepare for the role as multipliers and for the implementation of the intervention.

Module 1: Introduction and preparation of role as a multiplier.

Module 2: Knowledge on evidence on joint contracture development and treatment.

Module 3: Knowledge on relevant measures to support nursing home residents in participation and quality of life.

Module 4: Methods of collegial consulting and training.

Insufficient evidence for effectiveness of preventive interventions

Known negative impact on social participation.

Resource-oriented promotion of physical activity combined with a personal goal on participation level.

Skilled nurses can be trained to support necessary changes → Theory of planned behavior (TPB).

Intervention components and process

Information presentation
- In-house presentation (40 minutes) for nursing home staff, residents, relatives and public.

Assistive Peer-Review
- Friendly visit (4 hours) to discuss practical resident-related issues in case conferences.

Telephone Consulting
- Demand-oriented, regularly support by telephone-hotline to discuss practical needs or problems.

Behavioral change (TPB)

Attitude
- Multipliers have an positive attitude towards intervention components and aims.

Subjective norm
- The intervention addresses an important issue from nursing and care managers’ perspective.

Perceived behavioral control
- Multipliers believe, that they are able to implement the intervention.

Intention

Behavior

Intermediate impacts

Identification of need for changes.

The multipliers support their colleagues by advice and guidance.

The multipliers collaborate with relatives, therapists and physicians.

Support of residents considering environmental and personal factors.

Implementation of all needs for changes on organizational and individual level.

Health Outcome

Improved quality of life and social participation in nursing home residents.

Behavioral change (TPB)

Evidence base

Insufficient evidence for effectiveness of preventive interventions

Known negative impact on social participation.

Resource-oriented promotion of physical activity combined with a personal goal on participation level.

Skilled nurses can be trained to support necessary changes → Theory of planned behavior (TPB).
Cluster randomised controlled trials (cRRTCs) are experiments in which (interacting) social units rather than individuals are randomly allocated to study groups: communities, schools, families, hospitals, nursing homes ...
Challenges of cRCT

- Cluster baseline imbalance (allocation techniques)
- Post-randomisation recruitment bias
- Attrition bias
- Blinding
- Ethical issues (e.g. waiver solutions)
  - ...


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**Evaluation**
1. Assessing effectiveness
2. Understanding change process
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• A process evaluation is often highly valuable – providing insight into
  • why an intervention fails unexpectedly or
  • has unanticipated consequences or
  • why a successful intervention works and
  • how it can be optimised
Figure 1. Key functions of process evaluation and relationships amongst them. Blue boxes represent components of process evaluation, which are informed by the causal assumptions of the intervention, and inform the interpretation of outcomes.
Figure 1 Key elements of the development and evaluation process

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„The results should be disseminated as widely and persuasively as possible, with further research to assist and monitor the process of implementation.”

MRC 2008
Criteria for Reporting the Development and Evaluation of Complex Interventions in healthcare: revised guideline (CReDECI 2)

Ralph Möhler, Sascha Köpke, and Gabriele Meyer

Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide

Paul Montgomery, Sean Grant, Evan Mayo-Wilson, Geraldine Macdonald, Susan Michie, Sally Hopewell, David Moher, on behalf of the CONSORT-SPi Group
An own example
(according to the MRC-Framework for developing and evaluating complex interventions; Craig et al. 2008)

**Feasibility and Piloting**
- Feasibility test of educational and study material within focus groups
- Cluster-randomised controlled pilot study with 4 nursing homes

**Development**
- Cross-sectional and cohort study with 30 nursing homes
- Surveys on attitudes and burden of nurses and relatives
- Cochrane review: reduction of physical restraints
- Evidence-based guideline on physical restraints

**Evaluation**
- Cluster-randomised controlled trial with 36 nursing homes
- Economic evaluation
- Process evaluation

**Implementation**
- Update of the evidence-based guideline
- 3-arm cluster-randomised controlled trial with 120 nursing homes
- Economic evaluation
- Process evaluation
Methodenpapier zur Entwicklung einer Praxisleitlinie zur Vermeidung von freiheits einschränkenden Maßnahmen in der beruflichen Altenpflege

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quantitative studies

Möhler Ralph², Meyer Gabriele¹²

*School of Nursing Science, Faculty of Health, Witten/Herdecke University, Witten, Germany
²Institute of Health and Nursing Science, Martin-Luther-University Halle-Wittenberg, Halle/Saale, Germany
(according to the MRC-Framework for developing and evaluating complex interventions; Craig et al. 2008)

**Development**
- Cross-sectional and cohort study with 30 nursing homes
- Surveys on attitudes and burden of nurses and relatives
- Cochrane review: reduction of physical restraints
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Effect of a Guideline-Based Multicomponent Intervention on Use of Physical Restraints in Nursing Homes
A Randomized Controlled Trial

Context Despite unambiguous legal regulation and evidence for lack of effectiveness and safety, physical restraints are still frequently administered in nursing homes.

Results All nursing homes completed the study and all residents were included in the analysis. At baseline, 30.6% of control group residents had physical restraints vs 31.5% of intervention group residents. At 6 months, rates were 29.1% vs 22.6%, respectively, a difference of 6.5% (95% CI, 0.6% to 12.4%; cluster-adjusted odds ratio, 0.71; 95% CI, 0.52 to 0.97; P = .03). All physical restraint measures were used less frequently in the intervention group. Rates were stable from 3 to 6 months. There were no statistically significant differences in falls, fall-related fractures, and psychotropic medication prescriptions.

JAMA. 2012;307(20):2177-2184
IMPRINT - Implementation of a Multicomponent Intervention to Prevent Physical Restraints in Nursing Homes
Design

- 3-arm pragmatic cluster-randomised implementation study (NCT02341898)
- Process evaluation
- Economic evaluation
- Large unselected sample
  - 4 regions in Germany
  - 120 nursing homes
  - No specific inclusion criteria
- Follow-up: 12 months
Updated original program

- Information sessions for all nurses (90 minutes)
- Training (1.5 days) for nominated key nurses
- Structured support for nominated key nurses (for three months)
- Provision of:
  - Information brochures
  - Updated guideline
  - Supportive material (poster, mugs and pencils with the guideline logo)
Concise version

- Information sessions for all nurses (90 minutes)
- Training (1.5 days) for nominated key nurses
- Train-the-trainer module
- Structured support for nominated key nurses (for three months)
- Provision of:
  - Information brochures
  - Updated guideline
  - Supportive material (poster, mugs and pencils with the guideline logo)
Control group

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  - Information brochures
  - Updated guideline
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## Baseline characteristics of residents

<table>
<thead>
<tr>
<th></th>
<th>Intervention Group 1 (n=2972)</th>
<th>Intervention Group 2 (n=2523)</th>
<th>Control Group (n=3305)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age, mean (SD) [range], y</strong></td>
<td>83.7 (9.7) [34-108]</td>
<td>83.5 (10.0) [25-106]</td>
<td>82.5 (10.5) [24-105]</td>
</tr>
<tr>
<td><strong>Female sex, No. (%)</strong></td>
<td>2110 (71.2%)</td>
<td>1936 (76.9%)</td>
<td>2408 (73.0%)</td>
</tr>
<tr>
<td><strong>Length of residence, median (Min-Max.), mo</strong></td>
<td>36 (0-363)</td>
<td>40 (0-546)</td>
<td>39 (0-495)</td>
</tr>
<tr>
<td><strong>Care dependence category</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>31 (1%)</td>
<td>67 (3%)</td>
<td>32 (1%)</td>
</tr>
<tr>
<td>0</td>
<td>122 (4%)</td>
<td>83 (3%)</td>
<td>107 (3%)</td>
</tr>
<tr>
<td>I</td>
<td>1.164 (39%)</td>
<td>944 (38%)</td>
<td>1.293 (39%)</td>
</tr>
<tr>
<td>II</td>
<td>1.146 (39%)</td>
<td>940 (37%)</td>
<td>1.194 (36%)</td>
</tr>
<tr>
<td>III</td>
<td>489 (17%)</td>
<td>484 (19%)</td>
<td>669 (20%)</td>
</tr>
<tr>
<td>≥ 1 Fall in preceding 12 mo</td>
<td>1051 (40.7%)</td>
<td>840 (37.5%)</td>
<td>1116 (40.1%)</td>
</tr>
<tr>
<td>≥ 1 Fall-related fracture in preceding 12 mo</td>
<td>106 (3.6%)</td>
<td>85 (3.4%)</td>
<td>79 (2.4%)</td>
</tr>
<tr>
<td>Cognitive impairment</td>
<td>1683 (60.0%)</td>
<td>1401 (57.7%)</td>
<td>1957 (61.2%)</td>
</tr>
</tbody>
</table>
Prevalence of physical restraints per study group at baseline and follow-up

<table>
<thead>
<tr>
<th></th>
<th>Intervention Group 1 (n=40)</th>
<th>Intervention Group 2 (n=39)</th>
<th>Control Group (n=41)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any physical restraint</td>
<td>% (95% CI)</td>
<td>% (95% CI)</td>
<td>% (95% CI)</td>
</tr>
<tr>
<td>Baseline</td>
<td>17.4 (13.9-20.9)</td>
<td>19.6 (15.3-23.9)</td>
<td>18.8 (15.0-22.6)</td>
</tr>
<tr>
<td>12-Month Follow-up</td>
<td>14.6 (11.8-17.4)</td>
<td>15.7 (10.9-20.5)</td>
<td>17.6 (14.1-21.1)</td>
</tr>
<tr>
<td>Difference</td>
<td>-2.8 (-5.5 – -0.01; P=.042)</td>
<td>-3.9 (-6.8 – -1.0; P=.009)</td>
<td>-1.2 (-0.04 – 0.11; P=.294)</td>
</tr>
</tbody>
</table>
Conclusion

• Both versions of a guideline-based multicomponent intervention did not effectively reduce physical restraints in a large unselected sample of nursing home residents
• We found pronounced center differences in physical restraint prevalence between different nursing homes
• Educational interventions aiming at changing the culture of care regarding physical restraints seems to be less effective
• Other approaches, like legal or governmental policies, might be necessary to make clear that physical restraints are ineffective and ethically inadequate measures in nursing home care
Die Initiative zur Vermeidung freiheitseinschränkender Maßnahmen in der beruflichen Altenpflege

Mehr Freiheit wagen!

Startseite der Leitlinie FEM

Hier finden Sie alle Informationen und Materialien zum Projekt


Zur Leitlinie


http://www.leitlinie-fem.de/
Thank you very much for listening!