COSMOS: Improving the quality of life in nursing home patients
Effectiveness-implementation cluster randomized clinical hybrid trial

Irene Aasmul, PhD candidate
The leprosy bacterium first microbe to be identified as causing disease in humans (Armauer Hansen, 1873)
NHs: largest institution form in Norway

- 900 NHs with 41,000 places for 5 million inhabitants
- 80% of NH-patients have dementia
- 70,000 people with dementia; number will double in 20 years
- 300 working years for physicians (1 physician per 130 patients)
- Ethical challenges
- 48% die in a NH, 35% in hospital, 6-15% at home
Medical challenges in NHs

- Dementia, stroke, heart failure, muscle-skeletal, cancer
- Behavioural disturbances (>90%): agitation, depression, apathy
- Pain (40-60%)
- Polypharmacy and harmful psychotropic drugs
- Significant need of advance care planning (ACP)
- Significant need of meaningful activities
- Research programs/calls encourage researchers to develop complex, large-scale intervention studies
Aims of the COSMOS trial

• Primary objective: to improve QoL in NH patients
  – Enhanced Advance Care Planning (ACP)
  – Proactive assessment and treatment of pain
  – Discontinuation of unnecessary medication
  – Organization of activities

• Secondary objective is to determine the effectiveness
  – Mental and physical health
  – Pain
  – Sleep
  – Safety
  – Total drug use
  – Hospital admission
  – Cost-effectiveness

• Investigate implementation, staff attitude and distress
Method

- Effectiveness hybrid trial
- NH units are treatment
- Hybrid trial education across process, to evaluate
- Participants blinded
- Lack of blinding requires increased sample size!
Systematic pain assessment and treatment

Communication

Safety

Medication review

Organization of activities

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MOBID 2 Pain Scale

Mobilization - Observation - Behaviour - Intensity

Patient’s name: ___________________________ Date: __________

MOBID 2-M: Pay attention to the patient’s pain behaviour during morning care. Observe clearly what is going to happen. Guide the patient carefully through the activities 1–5. Pain is perceived. Rate your observation after each activity:

**Pain Behaviour**

Tick the boxes for Pain noises, Facial expression and Defence, whenever you observed such pain behaviour.

1. Guide to open both hands, one hand at a time
2. Guide to stretch both arms towards head, one arm at a time
3. Guide to stretch and bend both knees and hips, one leg at a time
4. Guide to turn in bed to both sides
5. Guide to sit at the bedside

**YOU MAY TICK SEVERAL BOXES FOR EACH ACTIVITY**

**HOW INTENSE IS 0 no pain?**

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**Impact of a stepwise protocol for treating pain on pain intensity in nursing home patients with dementia: A cluster randomized trial**

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**Abstract**

Background: Mobilization-Observation-Behavior-Intensity-Dementia 2 (MOBID-2) pain scale is a staff-administered pain tool for patients with dementia. This study explores MOBID-2's test-retest reliability, measurement error and responsiveness to change.

Methods: Analyses are based upon data from a cluster randomized trial including 132 patients with advanced dementia from 18 Norwegian nursing homes. 78% of the patients were female, average age 82.2 (±13.1). In weeks 1 and 2 (n = 159) and weeks 2 and 4 (n = 199) the test-retest reliability was assessed using intra-class correlation coefficients (ICCs). Minimal detectable change (MDC) was calculated using ICCs and minimal important change (MIC) was assessed using MDC and responsiveness was evaluated using the Mann-Whitney test.

Results: ICCs of the test-retest reliability were 0.81 (2 weeks) and 0.85 (4 weeks) for the total score, 0.56 (2 weeks) and 0.70 (4 weeks) for the intervention arm and 0.81 (2 weeks) and 0.80 (4 weeks) for the control arm. The total MIC was 5.3 for the intervention and 4.7 for the control arm. The responsiveness was significant for the intervention arm (p = 0.003) but not for the control arm (p = 0.08).
Communication

Systematic pain assessment and treatment

Safety

Medication review

Organization of activities

Protocol development and implementation strategy

1. Development of COSMOS intervention
   - Guidelines and manuals are based on:
     - Results from clinical research projects
     - Literature review
     - Education for health care staff, people with dementia and relatives
     - Collaboration

2. Development of education program
   - Power-point
   - Handouts
   - Flash cards
   - Flyer
   - Poster
   - Entrance placard

3. Education of COSMOS implementors
   - 2-day seminar
   - Teach the teachers
   - 2.5-hour lecture for each domain
   - Lecture with power point
   - Feedback
   - Role play
   - Patient centered discussion

4. Implementation in NHs
   - Weekly education of staff by COSMOS ambassadors
     - Red (communication)
     - Blue (pain treatment)
     - Yellow (drug review)
     - Green (activity) weeks in the NH
   - Face-to-face medication review
   - Patient log of implementation

5. Follow-up
   - Info to municipalities, NH managers, staff, relatives
   - Data collection at baseline, month 4 & 9
   - Midway evaluation
     - 2 x/month telephone interview
   - Telephone hot-line
   - Final conference
Protocol development and implementation strategy

Guidelines and manuals are based on:
Results from clinical research projects
Literature review
Education for health care staff, people with dementia and relatives
Collaboration

Background:
Nursing home (NH) patients have complex health problems, disabilities and needs for Advance Care Planning (ACP). The implementation of ACP in NHs is a neglected research topic, yet it may optimize the intervention efficacy, or provide explanations for low efficacy. This scoping review investigates methods, design and outcomes and the implementation of ACP (i.e., themes and guiding questions, setting, facilitators, implementers, and promoters/barriers).

Methods: A systematic search using ACP MESH terms and keywords was conducted in CINAHL, Medline, PsychINFO, Embase and Cochrane libraries. We excluded studies on home-dwelling and hospital patients, including only specific diagnoses and/or chart-based interventions without conversations.

Results: Sixteen papers were included. There were large variations in definitions and content of ACP, study design, implementation strategies and outcomes. Often, the ACP intervention or implementation processes were not described in detail. Few studies included patients lacking decision-making capacity, despite the fact that this group is significantly present in most NHs. The chief ACP implementation strategy was education of staff. Among others, ACP improved documentation of and adherence to preferences. Important implementation barriers were non-attending NH physicians, legal challenges and reluctance to participate among personnel and relatives.

Conclusions: ACP intervention studies in NHs are few and heterogeneous. Variation in ACP definitions may be related to cultural and legal differences. This variation, along with sparse information about procedures, makes it difficult to collide and compare research results. Essential implementation considerations relate to the involvement and education of nurses, physicians and leaders.

Keywords: Advance care planning, Nursing home, Dementia, End-of-life care, Implementation, Barriers, Ethical decision making.
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2. Development of education program
3. Education of COSMOS implementors
4. Implementation in NHs
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Protocol development and implementation strategy

1. Development of COSMOS intervention
   - Evidence and consensus for based on
   - Evaluation of clinical research projects
   - Literature survey
   - Education for healthcare staff, people with
     chronic diseases, and relatives
   - Collaboration

2. Development of education program
   - 2.5-hour lecture for each domain
   - Lecture with power point
   - Feedback
   - Role play
   - Patient centered discussion

3. Education of COSMOS implementors
   - Presentation in NHs

4. Follow-up
   - Evaluation
   - Feedback
   - Training on implementation of COSMOS

5. Evaluation
   - Evaluation of effectiveness, process evaluation
   - Feedback
   - Training on implementation of COSMOS
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   - Data collection at baseline, month 4 & 9
   - Midway evaluation
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     - Final conference
Protocol development and implementation strategy

1. Development of COSMOS intervention
   - Baseline data collection
   - Identification of clinical research projects
   - Literature review
   - Ethics review

2. Development of education program
   - Lectures and workshops
   - Case studies

3. Education of COSMOS implementors
   - Weekly education of staff by COSMOS ambassadors
     - Red (communication)
     - Blue (pain treatment)
     - Yellow (drug review)
     - Green (activity) weeks in the NH
   - Face-to-face medication review
   - Patient log of implementation

4. Implementation in NHs
   - Plan and implementation
   - Follow-up and evaluation
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   - Midway evaluation
   - 2 x/month telephone interview
   - Telephone hot-line
   - Final conference
Protocol development and implementation strategy

1. Development of COSMOS intervention
   - Establish and coordinate the study
   - Establish the research project
   - Literature review
   - Establish the research project
   - Establish the research project

2. Development of education program
   - Plan and design
   - Plan the intervention
   - Plan the intervention
   - Plan the intervention

3. Education of COSMOS implementors
   - Plan and design
   - Plan the intervention
   - Plan the intervention
   - Plan the intervention

4. Implementation in NHs
   - Plan and design
   - Plan the intervention
   - Plan the intervention
   - Plan the intervention

5. Follow-up
   - Plan and design
   - Plan the intervention
   - Plan the intervention
   - Plan the intervention

Info to municipalities, NH managers, staff, relatives
Data collection at baseline, month 4 & 9
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Future directives

- Analyses and publications
- Collaboration between municipalities and universities; academic NHs; high top research, education, teaching, implementation of research results
- Attractive working conditions in NHs & municipalities
- National and international research collaboration
- Specialization in NH medicine for physicians
- Psychometric property studies to test different approaches
- Avoid therapeutic nihilism – balance between too much/little
- Academic disagreement important – talk to each other!
Köszönöm!
Optimal: Process orientated, repeated talks with GPs, early, or at admission to the NH, about values, wishes. Documentation

Optimal: Order of attorney. Will not make ethical decisions but have to be informed and advocate the patient (presumed consent): «In this situation, my mother’s wish would have been...». Documentation

Optimal: Change from curative to palliative approach. Physician is responsible for the treatment decision after multidisciplinary discussion, e.g. antibiotics, iv. fluid, DNAR, feeding tube, hospital. Documentation

Optimal: Last days and hours - competent assessment and treatment of pain and symptoms, such as death rattle, dyspnea, anxiety, nausea, agitation. Documentation