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The impact of a pain assessment intervention on pain score and analgesic use in older nursing home residents with severe dementia: A cluster randomised controlled trial

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ABSTRACT

Background: Pain is highly prevalent in older adults, especially those in institutional settings such as nursing homes. The presence of dementia may increase the risk of underdiagnosed and undertreated pain. Pain assessment tools are not regularly used in clinical practice, however, there are indications that the regular use of pain assessments tools may influence the recognition of pain by nursing staff and thereby affect pain management.
Objectives: To assess whether regular pain assessment using a pain assessment tool is associated with changes in i) pain scores and ii) analgesic use in nursing home residents with severe dementia.
Design: Cluster-randomised controlled trial.
Setting: The study was conducted in 16 nursing homes in four counties in Norway.
Participants: A total of 112 nursing home residents aged 65 years and older with dementia who lacked the capacity for self-reporting pain or were non-verbal.
Methods: The experimental group were regularly assessed pain with a standardised pain scale (the Doloplus-2) twice a week for a 12-week intervention period. The control group received usual care. The primary outcome was pain score measured with the Doloplus-2, and the secondary outcome was analgesic use (oral morphine equivalents and milligram/day paracetamol). Data on the outcomes were collected at baseline and at the end of week 12. The nursing staff in both the experimental and the control groups received training to collect the data. Linear mixed models were used to assess possible between-group difference over time.
Results: No overall effect of regular pain assessment was found on pain score or analgesic use. The mean score of Doloplus-2 and analgesic use remained unchanged and above the established cut-off in both groups.
Conclusion: The current intervention did not change analgesic use or pain score compared with the control condition. However, there is not sufficient evidence to conclude that regular pain assessment using a pain assessment tool is not clinically relevant. Furthermore, our results indicated that pain continued to be inadequately treated in nursing home residents with severe dementia. Therefore, further research on how standardised pain assessment can be used to support effective pain management in this population is needed.

What is already known about the topic?

- Pain is a frequently reported symptom in older adults with dementia, and research has shown that it is often ineffectively managed.
- Pain assessment tools have the potential to influence the recognition of pain by nursing staff and thereby affect pain management.
- In general, pain assessment tools are not regularly used in clinical practice.

What this paper adds

- Regular pain assessment using a pain assessment tool did not affect the pain score or analgesic use of nursing home residents with severe dementia.
- The mean pain score and analgesic use remained unchanged in both

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groups.
- The pain scores were above the established cut-off in both groups; this result indicates insufficient pain management in nursing home residents with severe dementia.
- Further research is needed on how pain assessment tools can be implemented to support pain management.

1. Introduction

Many studies have reported alarmingly high pain prevalence in older nursing home residents (NHR) with dementia, estimating that ≥50% experience pain (Zwakhalen et al., 2009; Torvik et al., 2009; Björk et al., 2016; Rostad et al., 2017a). The estimates vary considerably because of patients' characteristics, methodological differences and assessment tools used. Evidence suggests that pain remains under-assessed, under-diagnosed and inadequately managed in this vulnerable population (Gibson and Lussier, 2012; Hadjistavropoulos et al., 2014; Achterberg et al., 2013). The presence of dementia may increase the risk of under-diagnosis and under-treatment of pain, as the reduced ability to verbally communicate may cause healthcare professionals to wrongly assume that pain is not present (Hadjistavropoulos et al., 2014).

Pain assessment is the first step to adequate pain management (Hadjistavropoulos et al., 2014; Achterberg et al., 2013; Torvik et al., 2015; McAuliffe et al., 2012), but assessing pain in this population remains challenging because of patients' impaired memory, changes in cognitive processing and a reduced ability to communicate verbally (Achterberg et al., 2013; Lichtner et al., 2014). The other barriers in establishing good pain management practice for patients with dementia are inaccurate beliefs about pain management, poor knowledge and training of staff (Achterberg et al., 2013) and difficulties with, and lack of, pain assessment in this population (Achterberg et al., 2013; Martin et al., 2005; McAuliffe et al., 2009; Kaasalainen et al., 2007).

Standardised assessment tools have the potential to structure documentation, guide clinical decision making and facilitate effective clinical communication of patient needs. Over the past decade, a number of tools have been developed to assess pain in non-verbal older adults (Lichtner et al., 2014; Herr et al., 2006). In general, pain assessment tools are not regularly used in clinical practice (Hadjistavropoulos et al., 2014; Torvik et al., 2015; Lillekroken and Slettebø, 2013). Previous research found that pain assessment in older adults with dementia usually depends on the subjective impression of healthcare professionals (McAuliffe et al., 2009; Zwakhalen et al., 2007a).

A few studies have investigated the impact of regular pain assessment on pain score and pain management strategies (Fuchs-Lacelle et al., 2008; Zwakhalen et al., 2012; Monacelli et al., 2013; Ando et al., 2016) with differing results. The regular use of a pain assessment tools resulted in increased usage of pro re nata (PRN) analgesics (Fuchs-Lacelle et al., 2008), analgesic therapy in general (Monacelli et al., 2013; Ando et al., 2016) and a reduced pain score (Fuchs-Lacelle et al., 2008; Monacelli et al., 2013; Ando et al., 2016). Other studies demonstrated that the regular use of pain assessment tools did not result in the increased use of regularly scheduled analgesic (Fuchs-Lacelle et al., 2008) or in the frequent use of pain management interventions (Zwakhalen et al., 2012). Therefore, if and to what extent regular pain assessment results in changes in pain management strategies applied and in a subsequent reduction in pain scores in NHR with dementia remains uncertain. Furthermore, many previous studies were of relatively short intervention duration (Zwakhalen et al., 2012; Ando et al., 2016) and used small sample sizes (Zwakhalen et al., 2012; Monacelli et al., 2013; Ando et al., 2016). Only one study was a randomised controlled trial (Fuchs-Lacelle et al., 2008). Therefore, more studies are warranted.

We hypothesised that nursing home staff who regularly assess residents for pain using a pain assessment tool would have increased knowledge of and focus on how to recognise pain, which in turn support clinical decision-making affecting analgesic administration and subsequently lowering pain scores. Thus, this study aimed to assess the effectiveness of regular pain assessment on analgesic use and pain score in NHRs with severe dementia. Specifically, the following research questions were formulated:

1) Are there differences in pain score between the experimental and the control group?
2) Are there differences in analgesic use between the experimental and the control group?

2. Materials and method

2.1. Trial design

A single-blinded, parallel cluster randomised controlled trial was used to evaluate the effectiveness of regular pain assessment on pain prevalence and analgesic use in Norwegian NHRs with severe dementia. A cluster was defined as a single nursing home (NH). The reason for using a cluster design was the risk of contamination if individual randomisation was used. The intervention was carried out by the NH staff, and the outcomes were measured on the individual NHR. This clinical trial is registered at ClinicalTrials.gov (ref. no: NCT02945865). The Regional Ethics Committee approved the procedure of this study (ref. no. 2014/1431, REC South East) prior to the recruitment of the clusters. Written consent was obtained from the residents' next of kin before the residents were included in the study. If the registered nurses (RN) considered study participation to be a potential burden for the resident, the resident would be withdrawn from the study. Reporting adhered to the CONSORT extension for cluster trials (Campbell et al., 2012) and the TIDieR checklist (Hoffmann et al., 2014).

2.2. Randomisation, allocation and blinding

An independent statistician randomised (computer generated allocation) every NH in four counties in the southeast part of Norway (N = 161 in November 2014). Random allocation to one of two study arms was performed before the invitation to participate was e-mailed to the NHs. The NHs were consecutively invited according to the computer-generated allocation sequence from November 2014 to January 2016. We stopped inviting NHs after reaching the required number according to the sample size calculation. Ninety-seven NHs were invited and 16 participated (Fig. 1).

The NHs, the individual residents and their next-of-kin were blinded to group allocation. Owing to ethical issues and the risk of contamination, the participating parties were told that the study was to be conducted on two groups receiving different study procedures rather than to test the effectiveness on an intervention. Information was given on the overarching aim of the study: To obtain more knowledge of the importance of pain and pain assessment in people with severe dementia in NHs. Written consent was obtained from the individual participants' next-of-kin after randomisation and before each resident was enrolled in the study.

2.3. Sample

Data were collected in 16 NHs. The only eligibility criterion for the clusters was that they did not routinely use a pain assessment tool. The eligibility criteria for the NH staff delivering the intervention were as follows:

i) RN or nursing assistant with a course in drug administration (i.e. he or she could obtain the delegated responsibility form RNs use to administer medication)
ii) Worked at the NH for a minimum of six months