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Research paper

Feasibility and baseline findings of an educational intervention in a randomized trial to optimize drug treatment among residents in assisted living facilities

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ABSTRACT

Purpose: To describe the baseline findings and feasibility of a cluster randomized controlled trial of staff training to optimize the use of drugs among older residents in assisted living facilities.
Methods: Participants ($n = 227$) were recruited from assisted living facilities in Helsinki, Finland. Their wards were randomized into two arms: 1) intervention wards in which staff received training (2×4 hours) to identify prescribing of harmful drugs; 2) control wards in which staff received training after completion of the intervention. Cognition, health-related quality-of life (HRQoL) by 15D and psychological well-being (PWB) were assessed of all participants. Demographics, diagnoses and drug use were verified from medical records. Drugs were categorized using anatomical therapeutic chemical (ATC) codes. The prevalence of anticholinergic, multiple psychotropic and Beers Criteria drugs was computed.
Results: The mean age of participants was 83 years, 71% were females and 93% had dementia. The intervention and comparison groups did not differ with respect to cognition or PWB. However, the proportion of females and HRQoL was lower, and the Charlson comorbidity index higher in the intervention than in the control group. In addition, the prevalence of pro re nata (PRN) drugs, and the proportion using any harmful drug was higher in the intervention than in the control group. Staff training was received favourably by staff participants in the intervention wards. However, not all nurses participated in the training sessions, and there was some resistance to change working habits.
Conclusions: We have successfully randomized wards of assisted living facilities and trained staff in the intervention arm.

1. Introduction

Institutionalized older people have a high prevalence of multimorbidity and polypharmacy. Polypharmacy is associated with the use of potentially inappropriate drugs [1]. Beers Criteria are widely used explicit criteria including a list of potentially inappropriate drugs both independent and dependent on a patient's diagnoses or medical conditions [2]. In institutional settings, 34–46% of residents are administered Beers Criteria drugs [1]. The use of psychotropic drugs is highly prevalent in older nursing home residents and varies from 48.5% to 80% [3]. Use of psychotropic drugs has been associated with an increased risk of falls [4], stroke and mortality [5].

There is increasing awareness of the adverse events associated with drugs with anticholinergic properties [6]. Use of anticholinergic drugs is also associated with impaired cognitive

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function [7] and risk of hospitalisations [8]. Older people with dementia are especially vulnerable to these side effects. Furthermore, Swedish criteria highlight that the long-term use of non-steroidal anti-inflammatory drugs (NSAIDs) and tramadol is inappropriate for older people [9]. There are also studies suggesting that use of proton-pump inhibitors (PPIs) among predominately frail older institutionalized residents is associated with diarrhea, infections, hip fractures and higher mortality [10].

A number of randomized controlled trials of interventions to reduce the use of potentially inappropriate drugs have been performed in nursing homes [11]. This includes successful educational interventions to decrease the use of psychotropic drugs [12–17] and to improve the quality of drug prescribing [18,19]. However, many studies have been of low quality and few have investigated the effects of educational intervention on older peoples' quality of life or their use of health services [20].

This cluster randomized controlled trial investigates the impact of staff training on the use of drugs among older residents in assisted living facilities in Helsinki. We will also clarify the effects of the intervention on quality of life (QoL), cognition and use and costs of health services of the participating residents. In this article, we describe the baseline findings and describe the feasibility of the educational intervention in institutional settings.

2. Methods

The study was approved by the Ethics Committee of the Helsinki University Central Hospital. Each participating resident was provided with information about the study and gave written informed consent to participate. If a resident had cognitive decline (MMSE < 20), his or her closest proxy (spouse or relative) provided informed consent before any study procedures took place.

2.1. Participants and randomization

All participants were recruited from wards of assisted living facilities in Helsinki, Finland. The resident inclusion criteria were:

- living permanently in an assisted living facility in Helsinki;
- able to provide written informed consent (the resident or closest proxy);
- age ≥ 65 years, native Finnish speaking;
- using at least one drug;
- having an estimated life expectancy ≥ 6 months.

We utilized a cluster-randomized design by randomizing wards instead of individual to avoid contamination of intervention. All wards selected for this study used the Minimum Data Set (MDS)/ Resident Assessment Instrument (RAI) version 2.0 for home care [21]. The MDS provides the patient profile of the ward (often called the case-mix), and a measure of the mean level of residents' need for assistance.

Assisted living facilities in Finland are similar in level of care to traditional nursing homes but the environment is more home-like. They provide medical and nursing care to people who are unable to live independently in the community. Physicians act as visiting consultants to whom nurses can refer patients' problems.

Once the case-mix of each participating ward was assessed, the wards were paired into dyads with similar characteristics. Computer-generated random numbers were used to randomize wards from these dyads into one of two study arms. The first arm was the intervention group and received staff training. The second arm was the control group and received delayed staff training after completion of the intervention.

In total, we recruited 20 wards with 320 residents. Of these 320 residents, 227 met the inclusion criteria and gave informed consent. The intervention group included 118 participants and the control group included 109 participants.

2.2. Measures and study procedures

The participants were assessed at baseline, 6 months and 12 months. Drug use data were extracted directly from each resident's medication administration chart on the day when the study nurses performed the baseline assessments. Use of both regular and pro re nata (as-needed) drugs was recorded. Drug use data represented the point prevalence on the day of assessment.

Participants were assessed using the Clinical Dementia Rating scale (CDR) [22], Mini-Mental State Examination (MMSE) [23], verbal fluency test [24], and clock drawing test [24]. The Mini Nutritional Assessment (MNA) [25] was used to assess each resident's nutritional status, the 15D was used to assess health-related quality of life (HRQoL) [26], and the Psychological Well-being scale (PWB) [27] was used to assess well-being. Participants' active diagnoses were retrieved from medical records and Charlson's comorbidity index was computed [28].

Drugs were classified using the anatomical therapeutic chemical (ATC) classification system recommended by the World Health Organization [29]. Drugs were categorized using Beers Criteria [2]. The Anticholinergic Risk scale [6] was used in combination with previously published Swedish and Finnish lists to categorize drugs with anticholinergic properties [8,9]. For the purpose of the research, psychotropic drugs were deemed to include antipsychotics (ATC-code N05A), antidepressants (N06A), anxiolytics (N05B) and hypnotics (N05C). We also determined the prevalence of PPIs (A02BC) [30] and NSAIDs including COX2-inhibitors (M01A). Low-dose acetylsalicylic acid ≤ 250 mg (B01AC06) and topical NSAIDs were excluded when calculating the prevalence of NSAIDs [9]. For the purpose of the study, harmful drugs were defined as Beers Criteria drugs, anticholinergic drugs, use of multiple psychotropic drugs ($>$ two drugs) [9], PPIs and NSAIDs. The list of drugs considered harmful was described in our description of the study protocol [31].

3. Education intervention

The staff working in the intervention wards received specific training in geriatric pharmacotherapy by three geriatricians (ALJ, MPB, KHP). The education occurred over two afternoons (2×4 hours). It consisted of lectures on harmful drugs for which the risks may outweigh the benefits, particularly in older people. The staff also received information about clinically significant (D-class) DDIs [32] (Table 1).

Patient cases from their own and other wards were used as examples. This demonstrated the relevance of the training to each ward. Sessions were interactive with discussion. The staffs were instructed to work collaboratively with their colleagues to optimize drug regimens using the patient cases examples. This ensured that the training was learner-centred and adhered to constructive learning principles [33]. Each nurse was provided with a list of potentially harmful drugs to help identify whether these drugs were prescribed to residents of their wards. The nurses were encouraged to discuss the clinical appropriateness of drugs with physicians responsible for visiting the wards.

In Finland, only physicians are permitted to make changes to a resident's drug chart. Nurses are permitted to independently administer non-prescription drugs. However, physicians typically only visit the wards once a week and do not necessarily meet residents face-to-face. Therefore, physicians prioritize prescribing issues for those residents that are brought to their attention by the