

# Psychosocial interventions for reducing antipsychotic medication in care home residents (Protocol)

Richter T, Meyer G, Köpke S



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[Intervention Protocol]

# Psychosocial interventions for reducing antipsychotic medication in care home residents

Tanja Richter<sup>1</sup>, Gabriele Meyer<sup>2</sup>, Sascha Köpke<sup>1</sup>

<sup>1</sup>Unit of Health Sciences and Education, University of Hamburg, Hamburg, Germany. <sup>2</sup>Institute of Nursing Science, Faculty of Medicine, Witten/Herdecke University, Witten, Germany

Contact address: Sascha Köpke, Unit of Health Sciences and Education, University of Hamburg, Martin-Luther-King-Platz 6, Hamburg, D-20146, Germany. [Sascha.koepke@uni-hamburg.de](mailto:Sascha.koepke@uni-hamburg.de).

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## ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

1. To evaluate the effectiveness of psychosocial interventions to reduce antipsychotic medication in care home residents.
2. To describe the components and the developmental process of the complex interventions used.
3. To highlight the quality and quantity of research evidence available about the effectiveness of psychosocial interventions to reduce antipsychotic medication in order to highlight effective interventions that could be implemented in practice or to set an agenda for future research in this field.

## BACKGROUND

### Description of the condition

Dementia is common in care home residents. Mean prevalence rates of over 60% have been reported from different countries (Matthews 2002, Rovner 1990). In addition to cognitive impairment dementia is often characterized by neuropsychiatric symptoms or so called 'Behavioural and Psychological Symptoms of Dementia' (BPSD) i.e. agitation, aggression, restlessness, wandering, repetitive vocalisations, shouting and many other symptoms (Zuidema 2007, Howard 2001). This frequently results in distress to patients and carers (Black 2004). Therefore, a number of pharmacological interventions aim at treating BPSD (Sink 2005). Several different classes of psychotropic drugs including antipsychotics are used for the treatment of BPSD, even though evidence is weak and ambiguous for most classes of psychotropic drugs. Practice guidelines on agitation in dementia recommend that psychosocial options should be the first line approach for the treatment of BPSD and that psychotropic drugs should be stopped after symptoms disappear (Howard 2001). The reality is different: Psychotropic drugs i.e. antipsychotics, hypnotics, tranquilizers and anti-depressants are regularly prescribed in care homes as first line treatment (Ruths 2008). Especially antipsychotic medication is often used to control BPSD (Mann 2009, Schneider 2006, Schmidt 1998), with studies having reported prescription rates between 20,9% and 45,9% (Mann 2009, Rochon 2007, Molter-Bock 2006). Antipsychotic drugs include all drugs allocated in class N05A of the ATC-classification system recommended by the World Health Organization (ATC-Index 2009). A common clinical classification differentiates between the subcategories of typical (or conventional) and atypical (second-generation) antipsychotics. An earlier meta-analysis indicated that atypical antipsychotics are the only effective psychotropic drugs for treatment of BPSD (Ballard 2006, Sink 2005). High placebo response rates have been reported (Ballard 2006, Schneider 2006) and also antipsychotic drugs are of only moderate efficacy and cause significant adverse effects such as sedation, falls, extrapyramidal, cardiovascular, and anticholinergic symptoms (Hartikainen 2007, Kolanowski 2006, Rochon 2005, Sink 2005). Recent studies also indicate increased risk of mortality for both, atypical and typical antipsychotics (Ballard 2008, Douglas 2008, Gill 2007). Prescribing of antipsychotic medication is influenced by a number of factors e.g. organisational factors, staff training, and patient characteristics (Fossey 2006, Hughes 2000). Considering the current evidence, it is questionable whether prescribing antipsychotics can be justified in terms of controlling BPSD. The potential harm of antipsychotic drugs in persons with dementia highlights the need to seek less harmful alternatives (Ballard 2009, Schneider 2006).

### Description of the intervention

Psychosocial interventions are non-pharmacological approaches to challenging behaviour in dementia, using a variety of methods. They may target patients, staff or whole organisations and they may be delivered to individuals or groups. A number of randomised trials investigated psychosocial interventions aiming at the reduction or substitution of antipsychotic medication have been published (e.g. Nishtala 2008, Cohen-Mansfield 2007, Fossey 2006, Lai 2004, Rovner 1996, Ray 1993, Avorn 1992). Interventions are designed as complex interventions, consisting of different components. Two components frequently included are (1) educational sessions aiming at changing nurses' attitudes to prescription of antipsychotics and (2) implementation of alternatives to antipsychotics in managing BPSD. Some interventions address members of different professions, e.g. physicians, nurses and pharmacists, most address nurses only (Nishtala 2008).

### How the intervention might work

Psychosocial interventions and their mode of functioning have to be distinguished depending on the target group: 1. Interventions directly targeting residents. 2. Interventions targeting nursing staff. Interventions targeting residents such as e.g. psychoeducative interventions or behavioural therapy may result in consolidation of affect and behaviour of the residents, thereby making the use of antipsychotic unnecessary. The goals of these interventions are to enable residents to reorganize themselves, replace inadequate coping with adequate coping, and reduce emotional distress (Solomon 1992). Another possible aim is to challenge residents' negative cognitions in order to reduce distortions and to enable them to generate more adaptive ways of viewing specific situations and events. A secondary aim is to enhance sense of control (Teri 1991). Interventions which target nursing staff aim to strengthen the expertise of nursing staff for handling persons with BPSD. Interventions aim to reduce staff members' distress and/or resolve management difficulties by identifying the underlying unsatisfied need or cause, or antecedents, or consequences of persons' behaviour (Moniz Cook 2008). In this context they are intended to improve management of behaviour problems and to minimize or abolish the use of antipsychotic drugs in care home residents. As a starting point interventions often try to increase staff's awareness of the limited effectiveness and possible adverse effects of antipsychotic drugs. These interventions may also support the shift from the biomedical model of acute care, focussing on physical conditions and ADL, to person-centred care targeting psychosocial and emotional needs of the residents.

### Why it is important to do this review

The best evidence for the efficacy of psychosocial interventions to reduce psychotropic medication in long term care homes should

stem from large, well-conducted randomized controlled trials. As even single large randomized controlled trials can be biased, it is always important to perform systematic reviews and, if possible, meta-analyses. In this case, a systematic review is required to identify the large number of trials in this area and summarise the evidence for health care professionals, researchers and others with an interest in this topic. There are several kinds of psychosocial interventions with varying results for different interventions. Even for similar interventions results may vary between studies. A systematic review of the risks and benefits of psychosocial interventions to reduce antipsychotic drugs is therefore needed to provide care givers and policy makers with the current, best evidence for alternative, less harmful interventions to reduce antipsychotics in care home residents with dementia.

## OBJECTIVES

1. To evaluate the effectiveness of psychosocial interventions to reduce antipsychotic medication in care home residents.
2. To describe the components and the developmental process of the complex interventions used.
3. To highlight the quality and quantity of research evidence available about the effectiveness of psychosocial interventions to reduce antipsychotic medication in order to highlight effective interventions that could be implemented in practice or to set an agenda for future research in this field.

## METHODS

### Criteria for considering studies for this review

#### Types of studies

The review will include all individual randomised controlled trials or cluster-randomised controlled trials including groups of care home residents allocated either (a) to a programme aiming to reduce the prescription rate of antipsychotics by one or more psychosocial interventions (the intervention group), or (b) to (optimised) regular care (the control group). Studies will only be included if the primary aim is the reduction of antipsychotic medication i.e. the primary endpoint being related to prescription of antipsychotic medication. Non-blinded studies will be included in the review as it seems unrealistic to expect blinding of the participating caregivers. Also, studies without blinding of outcome assessors will be included, as the risk of detection bias seems small

considering the primary outcome measures (i.e. prescription of antipsychotics). However, blinding will be considered for the quality assessment (see below). No language restrictions will be applied.

#### Types of participants

Participants will be care home residents of either gender requiring long-term nursing care. We aim to include all residents included in the primary studies, irrespective of their cognitive status. Although the target group for antipsychotic medication is predominantly people with dementia and BPSD, in practice, such people are not easy to determine. The percentage of individuals with dementia and BPSD is often high in care homes, however not all of these individuals have an established diagnosis; on the contrary, not all residents with a diagnosis are clearly suffering from dementia and BPSD. Furthermore, residents' status may change during follow-up. Also, studies may use different diagnostic measures to categorise residents as suffering from dementia or BPSD. Therefore, we include all residents, assuming that most of those who receive antipsychotic medication do so because of BPSD. Care homes are defined as institutions where long-term care is provided by professional care workers for residents requiring nursing care i.e. mostly frail elderly.

#### Types of interventions

For the purposes of this review, psychosocial interventions are defined as: 'any intervention that emphasizes psychological or social factors rather than biological factors' (Ruddy 2005). Psychosocial intervention programmes may consist of different non-pharmacological elements. This definition allows for the inclusion of interventions with components of psychological therapies and health education, as well as interventions with a focus on social aspects, such as social support and networking. A psychosocial intervention must comprise an interpersonal dialogue i.e. 'talking' in the form of a verbal dialogue at least as a part of a complex intervention. This dialogue can take place between different dialogue partners:

1. An individual resident or a group of residents and a trained member of nursing staff.

2. An individual resident or a group of residents and a person from outside the institution e.g. a trainer for cognitive therapy or behavioural therapy.

3. An individual staff member or a group of staff members and somebody who is coming from outside to implement the intervention e.g. a trainer for social skills or coping skills.

Interventions combining psychosocial elements with biological components will also be included, as well as studies comparing two types of interventions. The psychosocial interventions may be provided in any format, e.g. in groups or individually, and in any scope, e.g. as a single training session or as training programmes over a period of time. We expect that studies included in the review may use a wide variety of psychosocial interventions for reducing BPSD.

Interventions that do not include psychosocial components will be excluded e.g. placebo-controlled or uncontrolled withdrawal of antipsychotic drugs or sole pharmacological interventions. Also interventions based only on biological factors will be excluded, which are defined as physical or sensational activities as e.g. physical activity, massage, aroma-therapy, music-therapy. Also interventions which provide information without a personal contact and dialogue as e.g. leaflets, educational videotapes will be excluded. Lastly, structural interventions, as e.g. changing organisational policies and bringing in more staff will be excluded.

## Types of outcome measures

### Primary outcomes

Use of regularly prescribed antipsychotic medication measured at the unit of randomisation level (the resident or the nursing home)

### Secondary outcomes

- Type, dosage, number and duration of regularly prescribed antipsychotic medication measured at the unit of randomisation level (the resident or the nursing home)
- Antipsychotic drugs administered “as needed”, measured at the unit of randomisation level (the resident or the nursing home)
- Prescribing of any regularly psychotropic medication, measured at the unit of randomisation level (the resident or the nursing home)
- Adverse effects of the interventions employed (e.g. falls, injuries, hospitalisation and deaths)
- Cognitive status such as the reduction of the prescribing rate that could result in an improvement of residents’ cognitive status
- Any BPSD measured with a validated scale e.g. Neuropsychiatric Inventory (NPI), Cohen-Mansfield-Agitation-Inventory (CMAI), Behavioural Pathology in Alzheimer’s Disease (BEHAVE-AD)
- Physical restraints as a possible substitute for antipsychotic medication to control BPSD
- Costs

Antipsychotic agents are defined according to the Anatomical Therapeutic Chemical (ATC) classification as drugs listed under the ATC-category N05A. Regular prescription is defined as continuous (i.e. daily or weekly) administration of the drug over a period of time in contrast to drugs administered “as needed”.

## Search methods for identification of studies

### Electronic searches

We will search ALOIS ([www.medicine.ox.ac.uk/alois](http://www.medicine.ox.ac.uk/alois)), the Cochrane Dementia and Cognitive Improvement Group’s Specialized Register.

ALOIS is maintained by the Trials Search Co-ordinator for CD-CIG and contains dementia and cognitive improvement studies identified from:

1. Monthly searches of a number of major healthcare databases: Medline, Embase, Cinahl, Psycinfo and Lilacs
  2. Monthly searches of a number of national and international trial registers: ClinicalTrials.gov, Current Controlled Trials, the WHO Portal (which covers Chinese Clinical Trials Register; German Clinical Trials Register; Iranian Registry of Clinical Trials and the Netherlands National Trials Register, plus others), and Umin - Trials Register of Japan
  3. Monthly searches of a number of pharmaceutical industry trial registers: AstraZeneca Clinical Trials, Bristol-Myers Squibb Clinical Trial Registry, Eil Lilly and Company Clinical Trials Registry, Forest Clinical Trial Registry, GlaxoSmithKline Clinical Trial Register, NovartisClinicalTrials.com, Pfizer Clinical Trials, Wyeth Clinical Trial Listings, and more
  4. Monthly searches of a number of grey literature sources: ISI Web of knowledge Conference Proceedings; Index to Theses; Australasian Digital Theses
- To view a complete list of all sources searched for ALOIS see [About ALOIS](#) on the ALOIS website.
- Additional separate searches will be run in many of the above sources to ensure that the most up-to-date results are retrieved. The search strategy that will be used for the retrieval of reports of trials from MEDLINE (via Ovid SP) can be seen in [Appendix 1](#).

### Searching other resources

- Reference lists of published reviews and retrieved articles will be checked for additional trials.
- Experts in the field will be contacted to identify unpublished or ongoing studies.

## Data collection and analysis

### Selection of studies

Two reviewers will independently perform searches and screen the abstracts of identified studies, rejecting any which are obviously irrelevant. The same two reviewers will then independently select randomised controlled trials meeting the predefined inclusion criteria. Disagreements will be resolved by discussion or, if necessary, consulting a third reviewer.

## Data extraction and management

Data extraction will be performed using a standardised data collection sheet and entered in the current version of RevMan. Data will be sought per participant or randomized cluster (care home), on all of the outcome measures of interest from all assessment times (including baseline). Data will be extracted for: characteristics of participants, baseline data, interventions, duration of intervention, length of follow-up, outcome measures, and adverse events. For cluster randomised trials estimates of the intra-cluster correlation coefficient (ICCC) will be extracted if possible. Data from included studies will be extracted independently by two reviewers, using a standardised form and checked for accuracy. Study names will not be masked. The results will be discussed between the two reviewers. Disagreement will be resolved by discussion or, if necessary, referred to a third author, to reach consensus.

Required data for each trial and each outcome for continuous data are the mean change from baseline, the standard error of the mean change, and the number of residents for each cluster at each assessment. Where changes from baseline were not reported, the mean standard deviation and the number of residents in each cluster at each time point will be extracted if available.

## Assessment of risk of bias in included studies

Quality assessment will follow the Cochrane Handbook for Systematic Reviews of Interventions, version 5.0.2 (Higgins 2009). Two authors will independently assess and score the studies' methodological quality in order to identify any potential sources of systematic bias. The internal validity of the studies will be determined by categorising individual studies into low or high risk of bias.

Cluster-randomised trials are associated with possible specific biases e.g. baseline imbalance caused by recruitment bias, loss of clusters, or lack of cluster adjustment.

To account for possible recruitment bias, baseline data of participants will be compared and method and time of randomisation of the clusters assessed. If there is an indication of imbalance between study arms, this will be considered in discussion of the results. Loss of clusters and lack of cluster adjustment in cluster-randomized studies will also be described.

As recommended in the Cochrane Handbook, we will use a two-part tool, addressing six domains (sequence generation, allocation concealment, blinding, incomplete outcome data, selective outcome reporting and other issues). The first part describes what has been reported in the study. In the second part a judgement concerning the related risk of bias is assigned for each entry, by asking for the adequacy of the study in relation to the entry, such that 'Yes' indicates low risk of bias, 'No' indicates high risk of bias, and 'Unclear' indicates unclear or unknown risk of bias. The domains of sequence generation, allocation concealment (avoidance of selection bias) and selective outcome reporting (avoidance of reporting bias) will be addressed in the tool by a single entry for

each study. Blinding of participants, staff and outcome assessors (avoidance of performance bias and detection bias) will be considered separately for objective outcomes and subjective outcomes. Incomplete outcome data (avoidance of attrition bias) will be considered separately for different length of follow up (shorter and longer follow up).

## Measures of treatment effect

Summary statistics will be required for each trial and each outcome. For dichotomous data (as the primary endpoint number of residents with at least one prescription of antipsychotics) the effect measure will be odds ratio (OR). For continuous data (e.g. dosage or duration of psychotropic medication use) the effect measure will be the weighted mean difference (WMD) or the standardized mean difference if different instruments are used for the same outcome measure

## Unit of analysis issues

It will be considered for each study whether groups of individuals were randomized in clusters or individually, whether individuals underwent more than one intervention or whether there were multiple observation times for the same outcome. As results from more than one time point per study cannot be combined in the meta-analysis, depending on included studies' reported follow-up periods, separate analyses will be performed to reflect short-term and long-term follow-up (Higgins 2009).

## Dealing with missing data

The total and kind of missing data related to participants' dropout, that cannot be retrieved from the original authors, will be described in the table 'Characteristics of included studies'. The impact of these missing data will be discussed. Their potential impact on the results will depend on the extent, the pooled estimate of the treatment effect and the variability of the outcomes. Variation between studies in the amount of missing data may also be considered as a potential source of heterogeneity. Where possible, intention-to-treat (ITT) analyses will be performed. Data will be sought whether or not clusters were subsequently deemed ineligible, or otherwise excluded from treatment or follow-up. Recognizing that statistical analysis cannot reliably compensate for missing data (Unnebrink 2001), the impact of any assumption will be assessed by trying more than one method as a sensitivity analysis. For example, for dichotomous data, it will first be assumed that all missing participants in the first group incurred the event and those in the second group did not, after which the opposite will be assumed. If intention-to-treat data are not available in the publications, "on-treatment" or the data of those who completed the trial will be sought and indicated as such. Data from non-randomized follow-on periods will not be used.

### Assessment of heterogeneity

Studies will be analysed and presented separately. Meta-analysis will only be performed when studies are sufficiently homogeneous in terms of participants, interventions and outcomes. Both clinical heterogeneity and statistical heterogeneity will be considered. Heterogeneity between trials included in each analysis will be tested using  $I^2$  with 95% confidence intervals (CI) (Ioannidis 2007). In case of evidence for statistical heterogeneity, this will be explored by identifying any results with non-overlapping 95% CI, creating a subgroup analysis, and seeking to confirm any statistically significant differences between subgroups by comparing the ratio of the difference in the natural logarithm of the relative risks and the standard error of the difference in log relative risks to the standard normal distribution (test for interaction).

### Assessment of reporting biases

In order to minimise the risk of publication bias, a comprehensive search in multiple databases, including searching for unpublished studies at trials registries, will be performed. To investigate the likelihood of overt publication bias, data from all identified trials will be entered into a funnel plot.

### Data synthesis

Meta-analysis requires the combination of data from trials that may not use the interventions in a similar manner. Meta-analysis will be performed according to the inverse-variance method making it possible to deal with dichotomous as with continuous data in random-effect or fixed-effect-models.

The effect measure for dichotomous data (e.g. number of residents with at least one prescription of antipsychotics) will be odds ratio (OR), for continuous data (e.g. duration of psychotropic medication use) the weighted mean difference (WMD) or the standardized mean difference (absolute mean difference divided by the pooled standard deviation), if different instruments are used for the same outcome measure.

For interventions of the same category meta-analysis will be conducted. Expecting some interventions will include elements of more than one category, comparable interventions (e.g. including educational and organisational elements) will be considered for meta-analysis. Meta-analysis of data from individually randomized and cluster randomized studies for which the ICCI is available or could be calculated will be conducted. Otherwise separate analyses will be conducted for individually and cluster-randomized trials. Presentation of meta-analysis will be carried out in forest plots, together with the results of the combined analysis. For this review these reports will be standardised by using the current version of RevMan. If it is not possible to pool the data, the results will be

presented in a descriptive review of different interventions and effects.

### Subgroup analysis and investigation of heterogeneity

Subgroup analyses will be performed for relevant and clinically meaningful subgroups if sufficient data are available.

Possible subgroup analyses will be carried out for:

- Study design (cluster randomised versus individual randomised participants)
- Target group of interventions (care givers versus residents)
- Cognitive status of participants (cluster with all residents versus cluster with residents suffering from dementia)
- Risk of bias (low versus high risk)
- Type of intervention

Subgroup analyses according to the type of intervention are possible for different aspects of content: interventions with a therapeutic focus versus social focus, educational programmes versus counselling, single component intervention versus multi component or individual interventions versus group sessions.

Following the “framework for design and evaluation of complex interventions”, it will not be possible to extract the effective or ineffective components of the educational programmes (Craig 2008, Campbell 2000), but components of included programmes will be extracted and analysed descriptively. If, as is frequently the case, information about the intervention has not been reported sufficiently in the publication, we will try to acquire detailed information about the interventions used by contacting authors of the primary study.

### Sensitivity analysis

Many issues suitable for sensitivity analysis can only be identified during the review process when the individual peculiarities of studies under investigation are identified (Higgins 2009). To incorporate assessment of risk of bias in the review process, we will first plot intervention effects estimates stratified for risk of bias for each relevant domain. If differences in results will be present among studies at different risk of bias, we will perform sensitivity analysis, excluding studies with high risk of bias from the analysis.

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\* Indicates the major publication for the study

## APPENDICES

### Appendix I. MEDLINE search strategy

Source	Search strategy
MEDLINE (Ovid SP)	<ol style="list-style-type: none"> <li>1. antipsychotic*.mp.</li> <li>2. neuroleptic*.mp.</li> <li>3. risperidone.mp.</li> <li>4. olanzapine.mp.</li> <li>5. haloperidol.mp.</li> <li>6. prothipendyl.mp.</li> <li>7. methotrimeprazine.mp.</li> <li>8. clopenthixol.mp.</li> <li>9. flupenthixol.mp.</li> <li>10. clothiapine.mp.</li> <li>11. methylperon.mp.</li> <li>12. droperidol.mp.</li> <li>13. pipamperone.mp.</li> <li>14. benperidol.mp.</li> <li>15. bromperidol.mp.</li> <li>16. fluspirilene.mp.</li> <li>17. pimozide.mp.</li> <li>18. penfluridol.mp.</li> <li>19. sulpiride.mp.</li> <li>20. veralipride.mp.</li> <li>21. levosulpiride.mp.</li> <li>22. sultopride.mp.</li> <li>23. aripiprazole.mp.</li> <li>24. clozapine.mp.</li> <li>25. quetiapine.mp.</li> <li>26. thioridazine.mp.</li> <li>27. phenothiazine.mp.</li> <li>28. butyrophenone.mp.</li> <li>29. "antipsychotic agents".mp.</li> <li>30. Risperidone/</li> <li>31. Haloperidol/</li> <li>32. Methotrimeprazine/</li> <li>33. Clopenthixol/</li> <li>34. Flupenthixol/</li> <li>35. Droperidol/</li> <li>36. Benperidol/</li> <li>37. Fluspirilene/</li> <li>38. Pimozide/</li> <li>39. Penfluridol/</li> <li>40. Sulpiride/</li> <li>41. Clozapine/</li> <li>42. Thioridazine/</li> </ol>

(Continued)

43. Phenothiazines/  
44. Butyrophenones/  
45. Antipsychotic Agents/  
46. or/1-45  
47. Geriatric Nursing/  
48. Residential Facilities/  
49. Nursing Homes/  
50. "geriatric nurs\* ".mp.  
51. "residential facilit\* ".mp.  
52. "nursing home\* ".mp.  
53. "care home\* ".mp.  
54. "geriatric care ".mp.  
55. "residential facilit\* ".mp.  
56. or/47-55  
57. discontinu\* .mp.  
58. cessation.mp.  
59. reduc\* .mp.  
60. taper\* .mp.  
61. stop\* .mp.  
62. or/57-61  
63. randomized controlled trial.pt.  
64. controlled clinical trial.pt.  
65. randomi?ed.ab.  
66. placebo.ab.  
67. drug therapy.fs.  
68. randomly.ab.  
69. trial.ab.  
70. groups.ab.  
71. or/63-70  
72. (animals not (humans and animals)).sh.  
73. 71 not 72  
74. 46 and 56 and 62 and 73

## HISTORY

Protocol first published: Issue 8, 2010

## CONTRIBUTIONS OF AUTHORS

GM and SK initially planned the study. TR, GM & SK have written the study protocol.

## **DECLARATIONS OF INTEREST**

None known.

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