Additional file 1

Box 1 Search strategy: Our full identification strategy optimised for PubMed .

#1: (randomized trial) AND (clinical trial) [All Fields]

#2: ((long term care facility) OR (long term care) OR (assisted living) OR (group homes) OR (homes of aged) OR (Residential facilities) OR (nursing home) OR (retirement homes) OR (retirement communities)) [All Fields]

#3: ((cluster randomization) OR (cluster randomisation) OR (cluster) OR (clustered) OR (clustering) OR (clusters) OR (group-randomized) OR (group-randomised) OR (randomisation unit) OR (randomization unit)) [All Fields]

#4: #1 AND #2 AND #3

Table A. Quality criteria and other data extracted from publications

| Reported eligibility criteria for participants Reported eligibility criteria for participants? Reported eligibility criteria for clusters Reported eligibility criteria for clusters? Item 3 (4) Was a sample size calculation reported? Use of intra-cluster correlation coefficient, k or design effect to allow for clustering? Evidence of variation in cluster size Increased sample size to account for this (any method acceptable)? Team decision | Quality criteria | Data extracted (mostly yes/no) | Source ⁱ |
|--|--|---|----------------------|
| Design type specified Reported eligibility criteria for participants Reported eligibility criteria for clusters Reported eligibility criteria for clusters? Litem 3 (4) Litem 7 (72 calculation Reported variation in cluster size Considered Reported method used to generate random Reported method used to generate random Allocation sequence Minimisation Minimised identification/ recruitment bias Reported on blinding of outcome assessors Were outcome assessors (for primary outcome) reported as blind to assessment? (Note: if it was not applicable, e.g. recorded from routine data, the question was answered as 'Yes') Clustering accounted for in analysis Reported number of clusters randomised Reported number of individuals Reported number of clusters analysed Reported number of clusters in each arm for analysis of primary outcome Reported number of clusters analysed Reported number of clusters in each arm for analysis of primary outcome Reported number of individuals analysed Reported number of individuals analysed Reported number of individuals analysed Reported number of individ | Term 'cluster' included in title or abstract | Was the term 'cluster' included in title or abstract? | Item 1 |
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| Reported eligibility criteria for clusters Sample size calculation reported Was a sample size calculation reported? Clustering accounted for in sample size considered Reported method used to generate random allocation sequence Minimised identification/ recruitment bias Reported on blinding of outcome assessors Clustering accounted for in analysis Reported method used for generate random allocation sequence Minimised identification/ recruitment bias Reported on blinding of outcome assessors Reported number of clusters randomised Reported number of individuals Reported number of individuals Reported number of clusters randomised Reported number of individuals Reported number of clusters nandysed Reported number of clusters nandysed Reported number of individuals analysed Reported number of clusters analysed Reported number of individuals analysed Reported | Design type specified | Parallel, factorial, cross-over, other | Team (3a) |
| Clustering accounted for in analysis minimisation were recruiters blinded to allocation? Clustering accounted for in analysis calculation reported? Evidence of variation in cluster size considered Reported method used to generate random allocation sequence minimisation Minimised identification/ recruitment bias Were participants identified/recruited prior to randomisation, or were recruiters blinded to allocation? Reported on blinding of outcome assessors Reported number of clusters randomised Reported number of individuals Reported number of individuals Respected number of individuals Respected individuals Respected number of individuals Respected number of clusters reported Baseline characteristics of individuals Respected number of clusters reported Comparison between intervention and control? Pervalues not calculation reported? Number of clusters in each arm for analysis of primary outcome Reported number of individuals analysed Number of clusters in each arm for analysis of primary outcome Reported number of individuals analysed Number of clusters in each arm for analysis of primary outcome Reported number of individuals analysed Number of adverse events (or statement that none) reported Number of dusters in each arm for analysis of primary outcome Number of individuals in each arm for analysis of primary outcome Number of adverse events (or statement that none) reported Number of adverse events (or statement that none) reported Number of adverse events (or statement that none) reported Number of adverse events (or statement that none) reported Number of adverse events (or statement that none) reported Number of adverse events (or statement that none) reported Number of adverse events (or statement that none) reported Number of adverse events (or statement that none) reported Number of adverse events (or statement that none) reported Number of advers | Reported eligibility criteria for participants | Reported eligibility criteria for participants? | Item 3 (4) |
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| Adverse events reported Other information Data extracted Was a statistician, epidemiologist or other quantitative researcher a co-author in the report? Primary outcome measure Number of adverse events (or statement that none) reported Source Source Team decision Team | Reported number of individuals analysed | Number of individuals in each arm for analysis of primary outcome | Item 16 |
| Other informationData extractedSourceStatistician involvementWas a statistician, epidemiologist or other quantitative researcher a co-author in the report?TeamPrimary outcome measureas designated by the authors, or the one used in sample sizeTeam | ICC reported | ICC reported for at least one outcome? | Item 17 |
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| | | a co-author in the report? | decision |
| calculation, or the first outcome reported in the abstract decision | Primary outcome measure | as designated by the authors, or the one used in sample size | Team |
| | | calculation, or the first outcome reported in the abstract | decision |

 $^{^{&#}x27;}$ Items refer to 2004 extended CONSORT statement; numbers in parentheses are CONSORT items from the updated 2010 main CONSORT statement.

^k We extracted more detail than simply whether or not the recruiter/identifier of participants was blind to allocation status, see Figure 1 for decision-aid.

Table B Basic characteristics of primary reports included in review

| Author | Year | Journal | Country | Outcome measure | Individuals analysed [*] | Clusters randomised* |
|----------------|------|----------------------------------|---------------------|---|--------------------------------------|----------------------|
| Avorn[1] | 1992 | N Engl J Med | USA | psychoactive drug use | 678 | 12 |
| Rimer[2] | 1992 | Public Health Rep | USA | use of mammograms | 412 | 8 |
| McMurdo[3] | 1993 | Age and Ageing | UK | battery of physical measures | 41 | 4 |
| Evans[4] | 1997 | J Am Geriatr Soc | USA | use of physical restraints | 463 | 16 |
| Meador[5] | 1997 | J Am Geriatr Soc | USA | antipsychotic use | 1152 | 12 |
| Ray[6] | 1997 | JAMA | USA | recurrent fallers | 482 | 14 |
| Schmidt[7] | 1998 | J Am Geriatr Soc | Sweden | psychotropic drugs use | 1805 | 36 |
| Morris[8] | 1999 | J Gerontol A Biol Sci Med Sci | USA | activities of daily life summary scale | 392 | 6 |
| Proctor[9] | 1999 | Lancet | UK | Crichton Royal Behaviour rating scale | 105 | 12 |
| McMurdo[10] | 2000 | Gerontology | UK | number of residents sustaining a fall | 133 | 9 |
| Furniss[11] | 2000 | Br J Psychiatry | UK | Crichton Royal Behaviour rating scale | 294 | 14 |
| Molloy[12] | 2000 | JAMA | Canada | residents' and families' satisfaction with health care and health care services utilization | n/r | 6 |
| Roberts[13] | 2001 | Br J Clin Pharmacol | Australia | continuous drug use | n/r | 52 |
| Naughton[14] | 2001 | J Am Geriatr Soc | USA | antibiotic use | n/a | 10 |
| Frenkel[15] | 2001 | Community Dent Oral Epidemiol | UK | denture plaque scores | 378 | 22 |
| Jensen[16] | 2002 | Ann Intern Med | Sweden | number of residents sustaining a fall | 384 | 9 |
| Midlov[17] | 2002 | Eur J Clin Pharmacol | Sweden | Short Form-36 | n/r | 48 |
| Lee[18] | 2002 | J Am Geriatr Soc | Hong Kong | Barthel index score | 89 | 45 |
| Lord[19] | 2003 | J Am Geriatr Soc | Australia | falls | 508 | 20 |
| Wolf[20] | 2003 | J Am Geriatr Soc | USA | falls | 286 | 20 |
| Becker[21] | 2003 | J Am Geriatr Soc | Germany | rate of falls | 981 | 6 |
| Meyer[22] | 2003 | BMJ | Germany | hip fracture | 942 | 49 |
| O'Halloran[23] | 2004 | Age and Ageing | Northern Ireland | fractured proximal femur | n/a | 127 |
| Crotty[24] | 2004 | Age and Ageing | Australia | Medication Appropriateness Index | n/r | 10 |
| Dyer[25] | 2004 | Age and Ageing | UK | number of falls per person | 196 | 20 |
| Crotty[26] | 2004 | BMC Health Serv Res | Australia | fall rate | 715 | 20 |
| Gold[27] | 2004 | J Am Geriatr Soc | USA | trunk extension strength | 122 | 9 |
| Sloane[28] | 2004 | J Am Geriatr Soc | USA | care recipient behaviour assessment | 69 | 15 |
| Kerse[29] | 2004 | J Am Geriatr Soc | New Zealand | proportion of residents sustaining a fall | 547 | 14 |

| Author | Year | Journal | Country | Outcome measure | Individuals analysed* | Clusters randomised* |
|------------------------------|--------------|-----------------------------|-----------------------|--|--------------------------|----------------------|
| Eisses[30] | 2005 | Br J Psychiatry | Netherlands | geriatric depression scale GDS-15 | 360 | 10 |
| Loeb[31] | 2005 | BMJ | Canada and USA | antimicrobials prescription | 3754 | 24 |
| Ray[32] | 2005 | Arch Intern Med | USA | serious fall-related injuries | n/r | 112 |
| Bravo[33] | 2005 | Int J Qual Health Care | Canada | quality of care scores (QUALCARE Scale) | 122 | 40 |
| Testad[34] | 2005 | Int J Geriatr Psychiatry | Norway | use of physical restraints | 142 | 4 |
| Law[35] | 2006 | Age and Ageing | UK | incidence of falls | 3717 | 223 |
| Hayward[36] | 2006 | BMJ | UK | all-cause mortality | 2572 | 50 |
| Nijs[37] | 2006 | BMJ | Netherlands | quality of life using validated questionnaire | 178 | 10 |
| Rosendahl[38] | 2006 | Aust J Physiother | Sweden | Berg Balance scale. | 172 | 34 |
| Huizing[39] Loeb[40] | 2006 2006 | BMC Geriatr JAMA | Netherlands Canada | use of physical restraints hospital admissions rates | 126 661 | 5 22 |
| Fossey[41] | 2006 | ВМЈ | UK | neuroleptics prescription | 346 | 12 |
| Monette[42] | 2007 | J Am Geriatr Soc | Canada | adherence to the recommendations | n/r | 10 |
| Kovacs[43] | 2007 | Spine (Phila Pa 1976) | Spain | Roland-Morris questionnaire | 584 | 12 |
| Kiel[44] | 2007 | JAMA | USA | adjudicated hip fractures | 1042 | 37 |
| Sloane[45] | 2007 | J Am Geriatr Soc | USA | night-time sleep using wrist actigraphy and daytime activity using non-obtrusive daytime observations | 66 | 3 |
| Colon- Emeric[46] | 2007 | Am J Med | USA | prescription of osteoporosis pharmacotherapy or hip protectors | n/r | 67 |
| Orrell[47] | 2007 | Int J Geriatr Psychiatry | UK | Camberwell Assessment of Needs in Elderly | 192 | 24 |
| Simmons[48] | 2008 | J Am Geriatr Soc | USA | residents' weight | 76 | 4 |
| Gurwitz[49] | 2008 | J Am Geriatr Soc | USA and Canada | adverse drug events | 1118 | 29 |
| Riemersma-van der Lek[50] | 2008 | JAMA | Netherlands | Mini Mental State Examination | 189 | 12 |
| Kerse[51] | 2008 | ВМЈ | New Zealand | elderly mobility scale and time to fall. | 473 | 41 |
| Bouwen[52] | 2008 | Age and Ageing | Belgium | number of participants with at least one accidental fall requiring an intervention by a physician or a nurse | 379 | 10 |
| Peri[53] | 2008 | Age and Ageing | New Zealand | Short Form-36 | n/r | 10 |
| Bentzen[54] | 2008 | Osteoporos Int | Norway | adherence between people offered soft and hard hip protectors | n/r | 18 |

| Author | Year | Journal | Country | Outcome measure | Individuals analysed [*] | Clusters randomised* |
|--------------------------------|------|--------------------------|---------------------|---|--------------------------------------|----------------------|
| Cox[55] | 2008 | Age and Ageing | UK | hip fractures | 5637 | 230 |
| Gopal Rao[56] | 2009 | Epidemiol Infect | UK | proportion of compliance with infection control guidelines | n/a | 12 |
| Field[57] | 2009 | J Am Med Inform Assoc | Canada | appropriate drug orders within alert categories | 833 | 22 |
| Huizing[58] | 2009 | J Am Geriatr Soc | Netherlands | use of physical restraints | 241 | 15 |
| Kuske[59] | 2009 | Int Psychogeriatr | Germany | GEROLF - staff knowldege in dealing with dementia | 210 | 6 |
| Lemaitre[60] | 2009 | J Am Geriatr Soc | France | all-cause mortality | 3400 | 40 |
| Resnick[61] | 2009 | J Am Geriatr Soc | USA | Barthel index score | n/r | 12 |
| Meyer[62] | 2009 | Age and Ageing | Germany | number of residents sustaining a fall | 1125 | 58 |
| Patterson[63] | 2009 | J Am Geriatr Soc | Northern Ireland | inappropriate psycho- active prescriptions | 253 | 22 |
| Sackley[64] | 2009 | BMJ | UK | Barthel index score | 243 | 24 |
| Eggermont[65] | 2009 | Behav Brain Res | Netherlands | neuropsychological tests, mood questionnaires and actigraphy | 61 | n/a |
| Neyens[66] | 2009 | Age and Ageing | Netherlands | falls | 518 | 12 |
| Marcantonio[67] | 2010 | J Am Geriatr Soc | USA | persistence of delirium | 370 | 8 |
| Testad[68] | 2010 | J Clin Psychiatry | Norway | Cohen-Mansfield Agitation Inventory | 145 | n/r |
| Pellfolk[69] | 2010 | J Am Geriatr Soc | Sweden | use of physical restraints | 288 | 40 |
| Ward[70] | 2010 | Med J Aust | Australia | fracture neck of femur | 5391 | 88 |
| Baldwin[71] | 2010 | J Hosp Infect | Northern Ireland | methicillin-resistant staphylococcus aureus prevalence in residents and staff | 478 | 32 |
| van Gaal[72] | 2010 | Int J Nurs Stud | Netherlands | score on a knowledge test regarding 3 topics: pressure ulcers, urinary infection, falls | 102 | 10 |
| Looijmans-van den Akker[73] | 2010 | Vaccine | Netherlands | proportion of health care workers vaccinated against influenza | 6636 | 36 |

^{*} n/a not applicable; n/r not reported.

Table C Basic characteristics of secondary reports included in review

| Author | Publicati on year | Related to reference | Journal | Primary outcome measure for this publication |
|----------------|----------------------|----------------------|--------------------|--|
| Jensen[74] | 2003 | Jensen[16] | J Am Geriatr Soc | time to first fall |
| Warnke[75] | 2004 | Meyer[22] | Z Gerontol Geriatr | quality of life assessment: fear of falling |
| Warnke[76] | 2004 | Meyer[22] | J Am Geriatr Soc | time to first fall without hip protector |
| Jensen[77] | 2004 | Jensen[16] | Aging Clin Exp Res | functional ambulation categories |
| Sattin[78] | 2005 | Wolf[20] | J Am Geriatr Soc | Activities-Specific Balance Confidence Scale and the Fall Efficacy Scale |
| Bentzen[79] | 2008 | Bentzen [54] | Inj Prev | hip fractures |
| Rapp[80] | 2008 | Becker[21] | J Am Geriatr Soc | time to first fall |
| Rosendahl[81] | 2008 | Rosendahl[38] | Aging Clin Exp Res | fall rate |
| Huizing[82] | 2009 | Huizing [58] | Int J Nurs Stud | use of physical restraints |
| Littbrand[83] | 2009 | Rosendahl[38] | J Am Geriatr Soc | Barthel index score |
| Conradsson[84] | 2010 | Rosendahl[38] | Aging Ment Health | geriatric depression scale GDS-15 |

Box 2 Examples of interventions

Example 1: Activity for residents plus staff training (Sackley et al, 2009[64])

Activity for residents: Three-month physiotherapy and occupational therapy aimed at enhancing mobility and ability to perform activities of daily living, addressing components such as strength, flexibility, balance, and exercise tolerance, delivered by two qualified physiotherapists. Dose, frequency and duration were dependent on goals agreed by the individual participant and the therapists and on progress throughout the intervention.

Staff training: Programme aiming to promote residents' independence and use of therapeutic aids.

Example 2: Drug or technology aimed at individual residents (Law et al, 2006[35])

Ergocalciferol 2.5 mg every three months to prevent falls and fractures

Example 3: Staff training plus risk assessment tool use (Cox et al, 2008[55])

Staff training: Half-day training by specialist osteoporosis nurses organised for managers, nurses and health care assistants at central locations, aiming to support staff to recognise the importance of falls and fracture prevention and identify those at high risk.

Risk assessment tool use: The care home staff were trained to use the Black fracture risk assessment tool and the STRATIFY risk assessment tool. They used these on each resident and reported results to the specialist nurses who fed back to the care home staff and the resident's GP with an assessment of fracture and falls risk.

Example 4: Falls risk assessment tool plus information (Kerse et al, 2004[29])

Risk assessment: Each home appointed a falls coordinator to undertake risk assessment of all residents using an evidence-based falls risk assessment tool. High-risk residents had a logo attached to wall of their room.

Information: This was provided on specific fall-prevention strategies and environmental assessment of surroundings and hazards. In addition, all useful material was included in a manual.

Table D. CONSORT endorsement by journals included in this review

| Journal | Strength of CONSORT endorsement | Quote from 'Instructions for authors' |
|--------------------|---------------------------------|---|
| Int J Geriatr | Low | No mention of CONSORT guidelines |
| Psychiatry | | |
| Behav Brain Res | Low | No reference found in guidelines for authors |
| Am J Med | Low | No mention of CONSORT in guidelines for authors |
| J Am Medical | Low | No mention of CONSORT in guidelines for authors |
| Informatics Assoc | | |
| Osteoporos Int | Low | No mention of CONSORT in instructions for authors |
| Int J Qual Health | Low | No mention of CONSORT in author guidelines |
| Care | | |
| Aging Clin Exp Res | Low | No mention of CONSORT in instruction for authors |
| Aging Ment Health | Low | No mention of CONSORT in instruction for authors |
| Vaccine | Low | Please refer to the CONSORT statement website at http://www.consort- |
| | | statement.org for more information. |
| Epidemiol Infect | Low | The requirements of the journal are in accordance with the International |
| | | Committee of Medical Journal Editors Uniform Requirements for Manuscripts |
| | | submitted to biomedical journals [British Medical Journal 1991; 302: 338–341 |
| | | and New England Journal of Medicine 1991; 324: 424–428.]. |
| Age and Ageing | Medium | For reporting of randomised trials, authors are advised to work to the |
| | | guidelines in the CONSORT statement. www.consort-statement.org |
| JAGS | Medium | To improve the quality of reporting randomized, controlled trials (RCTs), it is |
| | | recommended that authors adhere to the CONSORT (Consolidated Standards |
| | | of Reporting Trials) statement, which consists of a checklist and flow diagram |
| | | that authors can use to report RCTs. Authors should refer to the paper, Altman |
| | | DG, et al. The revised CONSORT statement for reporting randomized trials: |
| | | Explanation and elaboration. <i>Annals of Internal Medicine</i> 2001; 134:663-694 |
| BMC Geriatrics | Medium | (the journal) also supports initiatives aimed at improving the reporting of |
| | | biomedical research. Checklists have been developed for a number of study |
| | | designs, including randomized controlled trials (<u>CONSORT</u>). Authors are |
| | | requested to make use of these when drafting their manuscript and peer |
| | | reviewers will also be asked to refer to these checklists when evaluating these |
| Do I Do I I I | NA - dive | studies. |
| Br J Psychiatry | Medium | The Journal recommends to authors the CONSORT guidelines (1996, Journal of |
| | | the American Medical Association, 276, 637-639) and their basis (2001, Annals of Internal Medicine, 124, 663, 604) in relation to the reporting of randomised |
| | | of Internal Medicine, 134, 663-694) in relation to the reporting of randomised |
| | | controlled clinical trials; also recommended is their extension to cluster |
| Archives Intern | Himb | randomised controlled trials (2004, <i>BMJ</i> , 328, 702-708). Preparing Reports of Randomized Controlled Trials: |
| Med | High | The CONSORT Checklist should be completed and submitted with the |
| IVICU | | manuscript. In addition, a flow diagram illustrating the progress of patients |
| | | throughout the trial should be included as a figure in the manuscript (see |
| | | Figure for example). The checklist and flow diagram will be reviewed along |
| | | with the manuscript. |
| Australian Journal | High | Instruction for authors: Submit a CONSORT-like figure outlining the flow of |
| Physiotherapy | 111811 | participants through the trial, including reasons for dropouts |
| . Hysiotherapy | | Instruction for reviewers: Reviewers are asked to consult checklists where |
| | | appropriate. Specifically, reviewers of randomised controlled trials are asked to |
| | | consult the CONSORT e-checklist, |
| BMJ | High | If you are submitting a RCT please send with your manuscript a completed |
| | | checklist and flowchart in accordance to the appropriate CONSORT guidelines, |
| | | the trial protocol and the registration details of the trial. |
| JAMA | High | All randomized clinical trials should include a flow diagram and authors should |

provide a completed randomized trial checklist (see **CONSORT Flow Diagram** and Checklist) and a trial protocol. All manuscripts reporting randomized controlled trials should have the Int Psychogeriatr High following sent with them or they will be returned to the authors: A check list and flow chart in accordance with the CONSORT guidelines which can be found at http://www.consort-statement.org. Please send in the checklist as a supplementary file and include the flow chart as Figure 1 in the manuscript Med J Aust High RCTs must follow CONSORT guidelines (including checklist and flowchart, see www.consort-statement.org). Int J Nurs Stud High The editors require that manuscripts adhere to recognized reporting guidelines relevant to the research design used. These identify matters that should be addressed in your paper. These are not quality assessment frameworks and your study need not meet all the criteria implied in the reporting guideline to be worthy of publication in the journal. The checklists do identify essential matters that should be considered and reported upon. For example, a controlled trial may or may not be blinded but it is important that the paper identifies whether or not participants, clinicians and outcome assessors were aware of treatment assignments. You are encouraged (although not required) to submit a checklist from the appropriate reporting guideline together with your paper as a guide to the editors and reviewers of your paper. Randomised (and quasi-randomised) controlled trial - CONSORT http://www.equator-network.org/index.aspx?o=1032 For Clinical Trials and similar study designs, please adhere to the CONSORT Spine High statement (www.consort-statement.org/). Injury Prev High Please note that we require registration of clinical trials and reporting of randomized clinical trials according to the CONSORT guidelines. We also ask that authors follow the STROBE guidelines when reporting observational studies. Although not required for publication in Injury Prevention, authors are encouraged to review similar published guidelines for the reporting of systematic reviews, meta-analyses, and assessments of diagnostic test. Templates for CONSORT, STROBE and other reporting guidelines are available through the Equator Network (http://www.equator-network.org/)

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