

Effect of enhanced psychosocial care on antipsychotic use in nursing home residents with severe dementia: cluster randomised trial

Jane Fossey, Clive Ballard, Edmund Juszcak, Ian James, Nicola Alder, Robin Jacoby, Robert Howard

Editorial by
Andrews

Oxford University
and Oxford Mental
Healthcare Trust,
Oxford

Jane Fossey
consultant clinical
psychologist

King's College
London, Institute of
Psychiatry, MRC
Centre for
Neurodegeneration
Research, London
SE5 8AF

Clive Ballard
professor of age
related illnesses

Robert Howard
professor of old age
psychiatry

Centre for Statistics
in Medicine,
Wolfson College,
University of
Oxford

Edmund Juszcak
senior medical
statistician

Nicola Alder
medical statistician

Centre for the
Health of the
Elderly, University
of Newcastle upon
Tyne

Ian James
consultant clinical
psychologist,

Department of
Psychiatry,
University of
Oxford

Robin Jacoby
professor of old age
psychiatry

Correspondence to:
Robert Howard
r.howard@
iop.kcl.ac.uk

BMJ 2006;332:756-8

Abstract

Objective To evaluate the effectiveness of a training and support intervention for nursing home staff in reducing the proportion of residents with dementia who are prescribed neuroleptics.

Design Cluster randomised controlled trial with blinded assessment of outcome.

Setting 12 specialist nursing homes for people with dementia in London, Newcastle, and Oxford.

Participants Residents of the 12 nursing homes; numbers varied during the study period.

Intervention Training and support intervention delivered to nursing home staff over 10 months, focusing on alternatives to drugs for the management of agitated behaviour in dementia.

Main outcome measures Proportion of residents in each home who were prescribed neuroleptics and mean levels of agitated and disruptive behaviour (Cohen-Mansfield agitation inventory) in each home at 12 months.

Results At 12 months the proportion of residents taking neuroleptics in the intervention homes (23.0%) was significantly lower than that in the control homes (42.1%): average reduction in neuroleptic use 19.1% (95% confidence interval 0.5% to 37.7%). No significant differences were found in the levels of agitated or disruptive behaviour between intervention and control homes.

Conclusions Promotion of person centred care and good practice in the management of patients with dementia with behavioural symptoms provides an effective alternative to neuroleptics.

Introduction

A large proportion of nursing home residents with dementia receive major tranquillisers for behavioural symptoms,^{1,2} despite evidence of only modest efficacy, high placebo response,^{3,4} and serious adverse events.⁵ Good practice guidelines recommend that psychological or environmental management options should be the first line approach and that drugs should be stopped after symptoms have been absent or minimal for three months.⁶ We carried out a cluster randomised controlled trial to determine whether behavioural symptoms in people with severe dementia could be safely managed with focused intervention training and support to reduce the proportion being treated with neuroleptics.

Methods

We used a cluster trial design primarily to avoid contamination but also for practical purposes. The intervention was aimed at changing clinical practice in the nursing home, and hence the home was the unit of

randomisation and analysis. See bmj.com for the calculation of sample size.

We recruited residents within 12 nursing homes, four each in London, Newcastle, and Oxford. Eligible homes had to have a minimum of 25% of residents with dementia who were taking neuroleptics.

Research assistants carried out baseline assessments before randomisation. The statistician then randomly assigned the homes to intervention or control, stratified by region and baseline neuroleptic use (owing to an imbalance in prescribing levels between groups, two homes in each region were assigned low use and two high use).

After completion of the baseline assessments but before randomisation a psychiatrist (RH, CB, and RJ) and a senior member of each home's nursing staff reviewed the drug prescriptions of the residents. This review included recommending stopping psychotropic drugs that had been prescribed for more than three months and discontinuing drugs when behavioural problems had resolved. Reviews took place every three months. Homes randomised to the intervention arm agreed to the trial's clinician working with them for two days a week for 10 months. Homes randomised to the control arm received treatment as usual.

The package was delivered by a clinician in each of the three centres. These staff received training in the delivery of person centred care and skills development in training and supervision. They were supervised weekly over the study period. The package involved a systemic consultation approach,⁷ tackling "whole home" issues, such as attitudinal factors. The clinicians supported the use of activities through didactic training, skills modelling, and supervision of groups and individual staff. Key elements in the programme involved initial skills training, behavioural management techniques, and ongoing training and support (see bmj.com for details of each).

Each patient's daily dose of drugs was translated into chlorpromazine daily equivalents. The Cohen-Mansfield agitation inventory⁸ was used to measure reported agitated and disruptive behaviours. Dementia care mapping was used to develop the practice of person centred care.⁹ Baseline assessments were carried out by the trial's clinicians and psychology research assistants. Assessments at 12 months were carried out by a psychology research assistant who had not been employed during the intervention period. This member of staff was blind to the homes' intervention.

Data analysis

Primary outcomes (at the cluster level) were the proportion of patients receiving neuroleptics at 12



This is the abridged version of an article that was posted on bmj.com on 16 March 2006: <http://bmj.com/cgi/doi/10.1136/bmj.38782.575868.7C>

months and the mean dose. Secondary outcomes were agitation, patient level quality of life, proportion of patients taking other psychotropic drugs, adverse events (including documented falls), and incidents involving irritable behaviour towards staff or other residents.

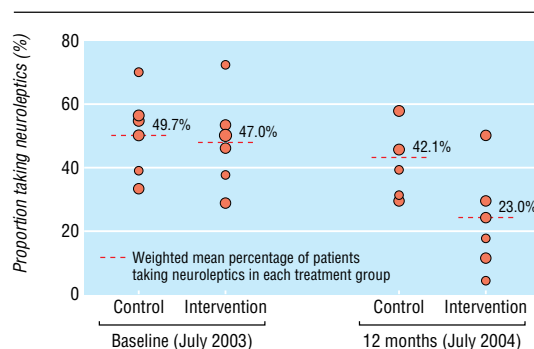
Analysis followed a prespecified plan based on an intention to treat basis; all clusters with available data were analysed in the groups to which they were allocated. All primary analyses were carried out at the cluster level using a weighted two sample *t* test, weighted by the number of patients in each home. With only six clusters in each group, we used the non-parametric Wilcoxon signed rank test as a sensitivity analysis to test for differences between the groups. For primary outcomes we used a weighted (by cluster size) linear regression analysis as a sensitivity analysis, to adjust for stratification factors. Subsequent analyses for the coprimary and secondary outcomes were based on the 12 cluster specific proportions for dichotomous outcomes, and the means or medians, depending on normality, for continuous outcomes. We used the weighted *t* test to compare the appropriate summary measures obtained for each cluster.

Results

Six care homes were randomised to the training and support intervention and six to treatment as usual (control homes; see [bmj.com](#)). All residents, not just those present, were analysed at each time point. This did not affect the primary analyses, carried out on the follow-up data at 12 months only. Personal and clinical characteristics of the residents in both arms were similar at baseline (see [bmj.com](#)).

Neuroleptic use and dose

At 12 months, 40 of 174 (23.0%) residents in the intervention homes were taking neuroleptics compared with 69 of 164 (42.1%) in the control homes: average reduction 19.1% (95% confidence interval 0.5% to 37.7%). Little or no overlap was found in the proportion of residents using neuroleptics in each home across the treatment groups (figure). To examine



Neuroleptic use at baseline and 12 months in homes allocated to training and support intervention or to treatment as usual (size of circle proportional to size of cluster). As control homes have almost identical proportions of residents taking neuroleptics at 12 months, points overlap and appear to be only five

the robustness of this result, a sensitivity analysis was carried out excluding residents with conditions that precluded the withdrawal of neuroleptics. After exclusion of these residents from analysis, 28 of 161 (17.4%) residents in the intervention group were taking neuroleptics at 12 months compared with 60 of 155 (38.7%) in the control group: average reduction 21.3% (4.3% to 38.3%). A further sensitivity analysis, adjusting for stratification variables (baseline neuroleptic use and region), gave an average reduction in neuroleptic use of 19.4% (-3.0% to 41.7%).

At 12 months the mean dose of neuroleptics was 107.1 in the control group and 102.1 in the intervention group: average difference 4.9 (-20.0 to 29.9). Adjusting for stratification variables confirmed this result (average difference 4.0, -22.0 to 29.9). After excluding those residents for whom withdrawal of neuroleptics would have been contraindicated, this difference increased to 19.3 (-7.0 to 45.7), with a mean dose of 114.3 in the control group and 94.9 in the intervention group.

Other psychotropic drugs and falls

At 12 months the average proportion of residents taking other psychotropics was 109 of 174 (62.6%) in

Main outcomes at 12 months. Values are numbers (percentages) of nursing home residents unless stated otherwise

Outcome	Control homes (n=6; 170 residents)	Intervention homes (n=6; 176 residents)	Weighted mean difference (95% CI)*	P value*	Intracluster correlation coefficient
Taking neuroleptics	69/164 (42)	40/174 (23)	19.1 (0.5 to 37.7)	0.045	0.10
Mean† (SD) median dose in chlorpromazine equivalents (No of patients)	107.1 (15.4) (n=69)	102.1 (23.1) (n=40)	4.9 (-20.0 to 29.9)	0.67	0‡
Taking other psychotropics	92/162 (57)	109/174 (63)	-5.9 (-27.2 to 15.5)	0.56	0.080
At least one fall in past 12 months	90/165 (55)	91/175 (52)	2.6 (-18.7 to 23.8)	0.27	0.061
Mean† (SD) Cohen-Mansfield agitation inventory§ total (No of patients)	42.0 (5.9) (n=162)	41.6 (7.2) (n=172)	0.3 (-8.3 to 8.9)	0.94	0.087
At least one episode of aggression in past 12 months	16/165 (10)	14/173 (8)	1.6 (-12.7 to 15.8)	0.25	0.10
Mean† (SD) wellbeing¶** (No of patients)	0.9 (0.35) (n=153)	1.1 (0.04) (n=149)	-0.2 (-0.5 to 0.2)	0.29	0.075
Spending some time (>0%) asleep**	114/153 (75)	110/149 (74)	0.7 (-8.5 to 9.9)	0.87	0‡
Spending some time (>0%) withdrawn**	71/153 (46)	56/149 (38)	8.8 (-25.2 to 42.8)	0.58	0.22

*Adjusted for clustering (estimated from weighted *t* test).

†Mean of medians (data skewed, therefore median appropriate as summary statistic for each cluster).

‡Truncated at zero.

§Range 29-203; higher scores mean more agitation (scores >40 usually accepted as clinically significant).

¶Range -5 to 5.

**Estimated using dementia care mapping.

the intervention group and 92 of 162 (56.8%) in the control group (table): a non-significant difference (5.9%, -27.2% to 15.5%) suggesting that neuroleptics were not simply replaced with other psychotropic drugs. Similar proportions of residents had at least one fall in the past 12 months—91 of 175 (52.0%) in the intervention group and 90 of 165 (54.6%) in the control group: average difference 2.6%, -18.7% to 23.8%.

Agitation and aggression

No significant differences were found between the intervention and control groups in levels of agitation at 12 months (mean difference 0.3, -8.3 to 8.9).

At least one episode of aggression was recorded for 14 of 173 (8.1%) residents in the intervention group compared with 16 of 165 (9.7%) in the control group: average difference 1.6% (-12.7% to 15.8%).

Quality of life and wellbeing

Ratings for wellbeing in residents in the intervention group were similar to those in the control group (1.1 v 0.9, mean difference -0.2, -0.5 to 0.2). A marginal advantage was shown for the intervention group in the proportion of residents spending at least some time withdrawn during the six hour observation period (37.6% v 46.4%, average difference 8.8%, -25.2% to 42.8%). The proportion of residents who spent at least some time asleep was similar between the groups: 110 of 149 (73.8%) for the intervention arm v 114 of 153 (74.5%) for the control arm.

Discussion

An intervention offering support with individualised psychological intervention as part of a programme promoting person centred care and good practice provides a viable alternative to neuroleptics for treating behavioural symptoms in patients with dementia.

In both intervention and control homes, psychiatrists reviewed the prescriptions of the residents and recommended withdrawal of neuroleptics in accordance with best clinical practice, yet significantly fewer residents in the intervention homes remained taking these drugs. The percentage of residents who were still prescribed neuroleptics at the end of 12 months was less than half that in the control homes. Levels of agitation and episodes of aggressive behaviour did not increase in homes with reduced prescribing of neuroleptics.

Failure of the training and support intervention to have a significant effect on any of the secondary outcome measures may reflect difficulties inherent in affecting the culture of care within a nursing home enabling change to be measured in such a small scale trial.

In March 2004 the Committee on Safety of Medicines wrote to all doctors in the United Kingdom to advise against the prescription of risperidone and olanzapine in patients with dementia. Differences in the proportion of patients receiving neuroleptics at each review (see bmj.com) between the groups were sustained over the year, and similarly affected by the ruling of the Committee on Safety of Medicines.

The nursing homes reflected a typical range of care provision for people with dementia in the United Kingdom: three private individually owned and managed facilities, seven homes belonging to different large groups of care home providers, and two NHS

What is already known on this topic

A high proportion of nursing home residents with dementia are treated with neuroleptics

The long term efficacy of neuroleptics in the management of behavioural disturbance in dementia has not been proved and their use is associated with increased morbidity and mortality

Withdrawal of neuroleptics does not acutely worsen behavioural symptoms of dementia

What this study adds

The training and support of care home staff reduced neuroleptic use in residents with dementia in nursing homes without worsening behavioural symptoms

The reduction in neuroleptic use was sustained for 12 months

managed facilities. Despite such heterogeneity and the geographical spread of the study, the training and support intervention was accompanied by significant reductions in the numbers of residents prescribed neuroleptics across the country.

We thank the residents and their family carers and staff of the homes. Rosamund Weatherall provided statistical support. Barbara Carlton, Brenda Barber, and Cathryn Roblett acted as consumer monitors for the Alzheimer's Society. Katrina Gasson, Karen Hathaway, and Jill Sawyer were the research clinicians. Jessica Baker, Sarah Barrett, Roland Burke, Ruth Elvish, and Sarah Wilmarsh collected data.

Contributors: See bmj.com.

Funding: Grant from the Alzheimer's Society, funded by the Community Fund.

Competing interests: CB is director of research for the Alzheimer's Society and has received payment for attending advisory boards from Janssen, AstraZeneca, and Bristol-Myers Squibb. RH has spoken at educational events sponsored by Janssen and has acted as a paid consultant for Bristol-Myers Squibb.

Ethical approval: Northern and Yorkshire regional multicentre research ethics committee and local committees in Oxford, Newcastle, and London.

- McGrath AM, Jackson GA. Survey of prescribing in residents of nursing homes in Glasgow. *BMJ* 1996;314: 611-2.
- Margallo-Lana M, Swann A, O'Brien J, Fairbairn A, Reichelt K, Potkins D, et al. Prevalence and pharmacological management of behavioural and psychological symptoms amongst dementia sufferers living in care environments. *Int J Geriatr Psychiatry* 2001;16:39-44.
- DeDeyn PP, Rabheru K, Rasmussen A, Bocksberger JP, Dautzenberg PL, Eriksson S, et al. A randomised trial of risperidone, placebo and haloperidol for behavioural symptoms of dementia. *Neurol* 1999;53: 946-55.
- Street JS, Clark WS, Gannon KS, Cummings JL, Bymaster FP, Tamura RN, et al. Olanzapine treatment of psychotic and behavioural symptoms in patients with Alzheimer's disease in nursing care facilities: a double-blind randomised, placebo-controlled trial. *Arch Gen Psychiatry* 2000;57:968-76.
- Sink KM, Holden KE, Yaffe K. Pharmacological treatment of neuropsychiatric symptoms of dementia: a review of the evidence. *JAMA* 2005;293:596-608.
- Howard R, Ballard C, O'Brien J, Burns A. Guidelines for the management of agitation in dementia. *Int J Geriatr Psychiatry* 2001;16:714-7.
- Cohn MD, Smyer MA. Mental health consultation: process, professions and models. In: Smyer MA, Cohn M, Brannon D, eds. *Mental health consultation in nursing homes*. New York: New York University Press, 1990.
- Cohen-Mansfield J. Agitated behaviors in the elderly. II. Preliminary results in the cognitively deteriorated. *J Am Geriatr Soc* 1986;34:722-7.
- Kitwood T, Bredin K. *Evaluating dementia care the DCM method*. 7th ed. Bradford: Bradford Dementia Research Group, Bradford University, 1997.

(Accepted 23 February 2006)

doi 10.1136/bmj.38782.575868.7C