Multifactorial intervention after a fall in older people with cognitive impairment and dementia presenting to the accident and emergency department: randomised controlled trial

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Abstract

Objective To determine the effectiveness of multifactorial intervention after a fall in older patients with cognitive impairment and dementia attending the accident and emergency department.
Design Randomised controlled trial.
Participants 274 cognitively impaired older people (aged 65 or over) presenting to the accident and emergency department after a fall: 130 were randomised to assessment and intervention and 144 were randomised to assessment followed by conventional care (control group).
Setting Two accident and emergency departments, Newcastle upon Tyne.
Main outcome measures Primary outcome was number of participants who fell in year after intervention. Secondary outcomes were number of falls (corrected for diary returns), time to first fall, injury rates, fall related attendances at accident and emergency department, fall related hospital admissions, and mortality.
Results Intention to treat analysis showed no significant difference between intervention and control groups in proportion of patients who fell during 1 year's follow up (74% (96/130) and 80% (115/144), relative risk ratio 0.92, 95% confidence interval 0.81 to 1.05). No significant differences were found between groups for secondary outcome measures.
Conclusions Multifactorial intervention was not effective in preventing falls in older people with cognitive impairment and dementia presenting to the accident and emergency department after a fall.

Introduction

Older people with cognitive impairment and dementia are at increased risk of falls, with an annual incidence of around 60% (twice that of cognitively normal older people).[1 2] They are also at increased risk of a major injury such as a fracture.[2] Falls are a common reason for attending the accident and emergency department.[3] Previous work from our centre found that a quarter of older patients presenting to the accident and emergency department after a fall had cognitive impairment.[3] In the United Kingdom the national service framework for older people makes prevention of further falls in older people who attend the accident and emergency department after a fall a priority.[4] We aimed to determine the effectiveness of multifactorial assessment and intervention after a fall compared with conventional care in older patients with cognitive impairment and dementia presenting to the accident and emergency department.

Participants and methods

We recruited older people (aged 65 or over) with cognitive impairment and dementia (mini-mental state examination score <24[5]) presenting to the accident and emergency department after a fall. A fall was defined as an event reported by either the person who fell or a witness, resulting in the patient inadvertently coming to rest on the ground or at another lower level with or without loss of consciousness or injury.[6] To minimise the confounding effects of acute illness we recruited patients only if the mini-mental state examination score (2 weeks after presentation to the accident and emergency department or hospital discharge) remained less than 24.

We excluded patients who were unable to walk, had a medical diagnosis that was a likely attributable cause of index fall (for example, cerebrovascular accident), were unfit for investigation within 4 months, were unable to communicate for reasons other than dementia, were living outside a 15 mile radius of site of recruitment, and had no major informant, defined as someone in contact with the patient at least twice a week.

Design

We conducted a prospective single centre randomised controlled trial of multifactorial assessment and intervention after a fall compared with assessment followed by conventional care. We recruited patients from two inner city accident and emergency departments, which were screened for 52 weeks. Our study was

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At baseline interviews we recorded personal details, previous falls, current medical diagnoses, and research criteria for dementia according to the ICD-10 (international classification of diseases, 10th revision).[7] We sought consent or permission for entry into the study from three people: patient, immediate carer, and next of kin, following ethical principles.[8] The patients underwent multifactorial clinical assessment (medical, physiotherapy, occupational therapy, and cardiovascular) at baseline. Those randomised to the intervention group received intervention for all identified risk factors for falls.

We collected data on falls, injuries, attendance at accident and emergency department, hospital admission, and mortality prospectively for 1 year. At 3 months we repeated physiotherapy and occupational therapy assessments and cardiovascular tests if they were abnormal. We also assessed compliance with the multifactorial intervention at 3 months.

Outcome measures

The primary outcome measure was number of participants who fell at least once in the year after intervention. Secondary outcome measures were number of falls (corrected for diary returns), time to first fall, injury rates, fall related attendance at accident and emergency department, fall related hospital admissions, and mortality.

We recorded data on falls prospectively by asking informants to complete a weekly diary in the form of a postcard. If we received no postcard for two consecutive weeks, we contacted the informants by telephone. We collected additional data on injuries from accident and emergency department records. We obtained data on attendance at accident and emergency department and hospital admission at monthly intervals from computerised records.

Clinical assessment and intervention protocol

Table 1 outlines the multifactorial assessment and intervention protocol. Participants in the control group received conventional care from all health professionals who were or became involved in their management during the year's follow up.

Cooperation with each component of assessment was judged clinically. Compliance with intervention was assessed at 3 months by direct questioning of the informant, inspection of drugs, review of physiotherapy documentation, and observation of the environment and patient. The same criteria were used to assess treatment received by controls.

Statistical analysis

Our sample size was based on the primary outcome measure of the number of patients who fell during the year's follow up. We judged a 30% reduction in the proportion of patients who fell over 1 year as clinically significant and similar to that of cognitively normal older people.[14 15] We estimated that at the 5% level we would require 90 patients in each group to give an 80% power of detecting a reduction of 30% (from an estimated 66%[1] to 46%) in the proportion of patients who had at least one fall. The actual proportion of the control group that fell was 80%. The sample size of 90 participants per group therefore gave a 90% power at the 5% level of detecting a 30% reduction (from 80% to 56%) in the proportion of patients who fell.

We used SPSS statistical software for our analysis. We calculated the weekly rate of falls for each patient by dividing the number of recorded falls by diary returns and used this when comparing differences in number of falls between control and intervention groups. We compared categorical variables between groups with Fisher's exact test, and we calculated a relative risk ratio. For variables that were at least ordinal, we used the Mann-Whitney U test to compare independent groups, and we calculated an estimated mean difference. For normally distributed data we used the independent samples *t* test. We used the log rank test to compare the two groups for time to first fall. We analysed data on an intention to treat basis.

Table 1 Multifactorial assessment and intervention protocol

Assessment	Risk factors identified	Intervention
Medical: history and examination, including review of drugs, visual acuity assessment, 12 lead electrocardiograph, short geriatric depression scale	General medical, drugs (psychotropic, culprit‡, polypharmacy), vision, depression, epilepsy, cerebrovascular	Appropriate investigation and management of untreated medical problems. Review and modification of psychotropic drugs, other culprit drugs, and polypharmacy. Optical correction by an optician or referral to an ophthalmologist. Formal psychogeriatric assessment
Cardiovascular*: measurement of morning orthostatic blood pressure, carotid sinus massage supine and tilted upright, prolonged head-up tilt[9]	Cardiovascular (orthostatic hypotension, cardioinhibitory carotid sinus hypersensitivity, vasodepressor carotid sinus hypersensitivity, vasovagal syncope)	Advice on avoiding precipitants and modification of drugs. Postural hypotension: compression hosiery, fludrocortisone, or midodrine.[9 10] Cardioinhibitory carotid sinus hypersensitivity: permanent pacemaker.[9] Symptomatic vasodepressor carotid sinus hypersensitivity or vasovagal syncope: fludrocortisone or midodrine[9 10]
Physiotherapy†: modified version of performance orientated mobility assessment,[11] assessment of walking aids, feet, and footwear[12]	Feet and footwear, gait and balance	Supervised home based exercise programmes for 3 months (structured gait retraining, balance, transfer and mobility interventions; functional limb strengthening and flexibility exercises),[12] to be continued by informant for duration of study. Provision of appropriate walking aids and footwear. Chiropody referrals as required
Occupational therapy: assessment of environmental fall hazards using a standard checklist[13]	Environmental fall hazards	Home hazard modification using standard protocol[13]

*Blood pressure measured by digital photoplesthysmography using Finapres (Ohmeda). Heart rate changes recorded by continuous surface electrocardiography.
†Assessment modified to allow normal gait or balance achieved using walking aid to count as normal score. Gait and balance components scored separately: gait scored out of 18, abnormal score >9; balance scored out of 39, abnormal score >13. Physiotherapy assessment conducted in patient's home environment.
‡Known to cause abnormal heart rate or blood pressure responses.

Group assignment and blinding

We randomised patients by block randomisation using computer generated random numbers either to assessment plus targeted multifactorial intervention (intervention group) or to assessment plus conventional care (control group). Randomisation was stratified by mini-mental state examination score at study entry: 20 to 23 (mild cognitive impairment); 12 to 19 (moderate cognitive impairment); 4 to 11 (severe cognitive impairment); 0 to 3 (very severe cognitive impairment). Group allocation was performed by a researcher who was independent of the recruitment process and blind to baseline interview data. Data from the postcards (primary outcome) were processed and coded off site by a researcher who was blind to group allocation and otherwise unconnected with the study. Data on secondary outcomes, compliance with intervention, treatment received by control group, and objective effects of intervention, were by necessity recorded and coded by members of the study team, who were not blind to randomisation.

Results

We recruited 53% (308/576) of eligible patients (figure). The median contact between informant and participant was 7 days a week (interquartile range 7-7). We excluded only six potential participants because of lack of informant. Patients who declined to be in the study were more likely to live in the community (51% (130/257) *v* 34% (105/306), relative risk ratio 1.47, 95% confidence interval 1.21 to 1.79) and less likely to have had a head injury in the index fall (20% (53/268) *v* 32% (100/308), 0.61, 0.46 to 0.81).

We report on 274 of the 308 patients; data on initial multifactorial assessment or outcome of falls (diary returns) were not obtained on 34 patients who died (n=24) or withdrew (n=10) shortly after recruitment. These patients were older (mean age 87 (n=34, 95% confidence interval 75 to 99) *v* 84 (n=274, 70 to 98), mean difference 2.69, 0.33 to 5.05) and more likely to be male (41% (14/34) *v* 20% (55/274), relative risk ratio 2.05, 1.29 to 3.27).

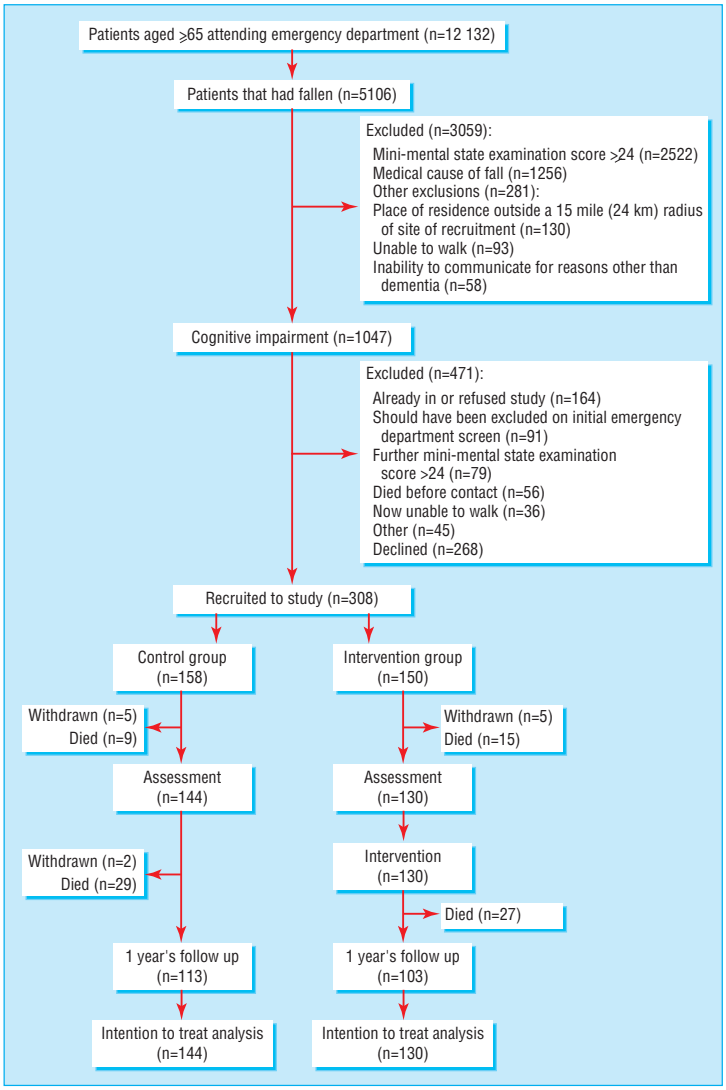
Overall, 88% of diaries were returned (11 095/12 542). We found no difference in median return rates between intervention and control groups (94% (interquartile range 83%-98.5%) and 92% (81%-98%), respectively; estimated mean difference 0.02%, −0.01% to 0.11%).

Baseline characteristics and identified risk factors for falls

Table 2 shows the baseline characteristics of the patients. Overall, 73% (n=199) of participants cooperated with multifactorial assessment (medical 86% (236), cardiovascular 73% (201), physiotherapy 78% (214), occupational therapy 79% (216)). We identified 1011 risk factors for falls (485 in intervention group, 526 in control group); for both groups, median number 4 (interquartile range 3-5; table 3). We found no significant differences in baseline characteristics or risk factors for falls between intervention and control groups.

Effect of intervention

The intervention group had 652 falls and the control group 728 falls during the year's follow up. Table 4 shows the results of the intention to treat analysis. We found no significant differences between the intervention and control groups for any study outcomes.



Recruitment and attrition rates

Table 2 Baseline characteristics. Values are medians (interquartile ranges) unless stated otherwise

Variable	Intervention group (n=130)	Control group (n=144)
Mean age (years) 95% CI	84 (71 to 97)	84 (71 to 97)
No (%) female	101 (78)	118 (82)
No (%) resident in community at study entry	34 (26)	26 (18)
Mini-mental state examination score*	14 (6-18)	12 (6-18)
No (%) with dementia†	118 (91)	128 (89)
Chronic conditions	3 (2-5)	3 (2-5)
Falls in previous 6 months	2 (0-4)	2 (0-4)
Environmental risk factors	2 (1-4)	2 (1-3)
Gait score‡	16 (13-17)	15 (12-17)
Balance score‡	28 (20-33)	27 (19-35)

*Higher score better—less cognitively impaired.
†ICD-10 research criteria for dementia.
‡Gait and balance components of modified performance orientated mobility assessment; lower score better.

Implementation of intervention

Objective effects of intervention were shown for the risk factors of gait, environmental fall hazards, and car-

Table 3 Risk factors for falls. Values are numbers (percentages) of patients

Risk factor for falls	Intervention group (n=130)	Control group (n=144)
Balance or gait:	129 (99)	142 (99)
Balance	129 (99)	142 (99)
Gait	122 (94)	137 (95)
Environmental fall hazards	108 (83)	118 (82)
Drugs:	96 (74)	99 (69)
Psychotropic drugs	55 (42)	53 (37)
Culprit drugs	83 (64)	88 (61)
Polypharmacy	58 (45)	52 (36)
Cardiovascular risk factor:	76/122 (62)	78/133 (59)
Orthostatic hypotension	47/122 (38)	55/133 (41)
Cardioinhibitory carotid sinus hypersensitivity	18/89 (20)	18/110 (16)
Vasodepressor carotid sinus hypersensitivity	23/89 (26)	29/110 (26)
Vasovagal syncope	7/94 (7)	4/108 (4)
Feet and footwear	37 (28)	45 (31)
Medical problem	35/123 (28)	36/134 (27)
Vision*	23/93 (25)	28/103 (27)
Depression	9/93 (10)	16/101 (16)
Cerebrovascular	15/123 (12)	9/134 (7)

*Department of Health criteria for partial sight.
Incomplete data due to lack of patient cooperation with assessment.

Table 4 Intention to treat analysis. Values are numbers (percentages) of patients unless stated otherwise

Outcome	Intervention group (n=130)	Control group (n=144)	Relative risk ratio (95% CI)
Patients falling in 1 year	96 (74)	115 (80)	0.92 (0.81 to 1.05)
Median No of falls (interquartile range)*	3 (0, 7)	3 (1, 8)	–0.02 (–0.32 to 0.09)†
Median time (weeks) to first fall (interquartile range)	11 (2, 41)	11 (2, 33)	P=0.459‡
Major injury	37 (28)	31 (21)	1.32 (0.87 to 2.00)
Fractured neck of femur	6 (5)	12 (8)	0.55 (0.21 to 1.43)
Fall related accident and emergency department attendance	52 (40)	46 (32)	1.25 (0.91 to 1.72)
Fall related hospital admission	19 (15)	19 (13)	1.11 (0.61 to 2.00)
Mortality	27 (21)	29 (20)	1.03 (0.65 to 1.64)

*Corrected for diary returns.
†Estimated mean difference (95% confidence interval).
‡Log rank test.

dioinhibitory carotid sinus hypersensitivity (table 5). In patients who had orthostatic hypotension on active standing at baseline, at 3 months' follow up those in the intervention group showed a smaller fall in blood pressure on active standing than did controls, but the difference was not significant. Table 6 details the proportion of the intervention group complying with key components of the multifactorial intervention strategy at 3 months' follow up (when all interventions were completed) and the proportion of control patients receiving treatment meeting criteria for compliance with these interventions.

Discussion

The United Kingdom national service framework for older people identifies prevention of falls as a priority and recognises cognitive impairment as an important risk factor for falls.[4] It recommends that services for fall prevention should target falls resulting in injury or attendance at an accident and emergency department and those occurring in residential or nursing homes.[4] Our study is the first randomised controlled trial to evaluate multifactorial intervention to prevent falls in older patients with cognitive impairment and dementia who present to the accident and emergency department after a fall. Most (80%) participants resided in residential or nursing homes. Intention to treat analysis showed no difference between intervention and control groups for proportion of participants who fell (74% and 80%), number of falls (median 3 for both), or time to first fall (median 11 weeks for both). We also found no difference in injury, fall related attendance at the accident and emergency department, fall related hospital admission, or mortality.

The most commonly identified risk factors for falls were impairments of gait and balance (postural instability), environmental hazards, drugs, and cardiovascular diagnoses. Multifactorial intervention directed at this group of risk factors has been successful in preventing falls in older patients living in the community, patients attending the accident and emergency department, and the residents of nursing homes, half of whom had cognitive impairment.[14–16] We showed objective effects of intervention on gait, environmental hazards, and cardioinhibitory carotid sinus hypersensitivity, but we were unable to replicate the reductions in falls and the proportion of patients who fell.

About 10% fewer patients fell in our intervention group than in our control group. As the sample size was calculated to detect a 30% difference in fall rates, similar to outcomes achieved by multifactorial intervention in cognitively normal older patients, this was not significant.[14 15] When calculating the sample size, we judged that routine clinical implementation of any positive findings would require us to show similar effectiveness of multifactorial intervention after a fall in older patients both with and without dementia.

Strengths and limitations

It is unlikely that contamination of the control group was a major factor in the negative outcome. The control and intervention patients lived in the same residential or nursing homes, and all received a comprehensive assessment of risk factors at baseline. However, although 14% of control patients had changes in drugs meeting criteria for compliance with intervention, for all other key risk factors less than 10% of control patients received intervention outwith the study. Fall rates in the control group were equivalent to the highest reported rates of nursing home populations including residents with dementia.[2 17] Poor compliance with intervention was anticipated, yet compliance with key interventions at 3 months was similar to that reported in studies where multifactorial intervention had been successful in preventing falls.[15 16]

Our study is limited by lack of generalisability—there was relative under-recruitment of participants from the community, and recruitment was from a specific population in a single centre. A further limitation is that effective single blinding was feasible for only the primary outcome measure (number of participants who fell) and the secondary outcome measures of number of falls and time to first fall.

Neurodegenerative process

The neurodegenerative process is a probable source of much of the increased risk of falls in patients with cognitive impairment and dementia. Studies of postural instability have found particular impairments in patients with Alzheimer's disease when central processing of conflicting information is required, and neuropathological studies show degeneration in parts

Table 5 Objective effects of intervention. Values are medians (interquartile ranges)

Variable	Intervention group			Control group			Between group significance*
	Baseline	3 months	Change	Baseline	3 months	Change	
Gait score†	16 (13 to 17) (n=130)	14 (13 to 16) (n=117)	–1 (–5 to 4) (n=117)	15 (12 to 17) (n=144)	15 (13 to 17) (n=125)	0 (–4 to 4) (n=125)	Baseline P=0.431, 3 months P=0.215, change in score P=0.022
Environmental risk factors	2 (1 to 4) (n=130)	1 (0 to 2) (n=124)	–1 (–4 to 3) (n=124)	2 (1 to 3) (n=144)	2 (1 to 3) (n=135)	–0 (–2 to 2) (n=135)	Baseline P=0.575, 3 months P=0.027, change in score P<0.001
Drop in orthostatic pressure on active standing (mm Hg)‡	–36 (–54 to –27) (n=40)	–12 (–25 to 4) (n=36)	27 (–41 to 92) (n=36)	–38 (–54 to –31) (n=39)	–22 (–43 to –4) (n=34)	19 (–54 to 93) (n=34)	Baseline P=0.388, 3 months P=0.086, change in score P=0.186
Asystole (s)§	4.9 (4.0 to 6.3) (n=18)	0.8 (0.8 to 1.5) (n=14)	–3.5 (–8.1 to 1.1) (n=14)	5.1 (4.6 to 6.3) (n=18)	2.2 (2.0 to 3.3) (n=15)	–1.8 (–5.0 to 1.3) (n=15)	Baseline P=0.834, 3 months P=0.004, change in score P=0.026

*Mann-Whitney U test.
†Gait component of modified performance orientated mobility assessment; lower score better.
‡Only patients with orthostatic hypotension on active standing at baseline.
§Only patients with cardioinhibitory carotid sinus hypersensitivity at baseline; paced rhythm counted as 0.8 s.

Table 6 Compliance with intervention at 3 months' follow up. Values are numbers (percentages) of patients

Risk factor	Compliance in intervention group*	Treatment received by control group meeting criteria for compliance*
Balance	76/125 (61)	5/134 (4)
Gait	75/117 (64)	5/125 (4)
Environmental fall hazard	41/105 (39)	8/111 (7)
Drugs	46/92 (50)	13/92 (14)
Cardiovascular risk factor:	58/74 (78)	6/75 (8)
Orthostatic hypotension†	37/46 (80)	5/53 (9)
Cardioinhibitory carotid sinus hypersensitivity	12/14 (86)	0/15 (0)

*Denominator is patients with risk factor at baseline completing 3 months' follow up.
†On either active standing or head-up tilt.

of the brain controlling cardiovascular (autonomic) reflexes.[18 19] A high prevalence of autonomic dysfunction, manifest as orthostatic hypotension and cardioinhibitory carotid sinus hypersensitivity has been shown in older people with dementia.[20] It may be that for effective prevention of falls in patients with cognitive impairment and dementia, different strategies are required to those used in cognitively normal older people. For example, physiotherapy may need to be delivered for longer, and intervention to modify cardiovascular risk factors may be relatively more important.

Practical implications and conclusion

The recommendations for fall prevention within the national service framework for older people are broadly similar to a guideline issued in 2001 by a joint panel of the American Geriatrics Society, British Geriatrics Society, and American Academy of Orthopaedic Surgeons.[21] Implementation of these recommendations will have considerable resource implications for the NHS in the United Kingdom. It seems appropriate, particularly in areas where effective services for falls do not yet exist, to target scarce resources where benefit is proved. Research data support multifactorial intervention in cognitively normal older people living in the community with risk factors for falls and those who present to the accident and emergency department after a fall.[14 15] Several studies also support the use of exercise as a single intervention in cognitively normal older people living in the community.[22 23] Although one randomised controlled trial of multifactorial intervention showed a reduction in recurrent falls in residents of nursing homes, most studies in this setting have been unable to prevent falls.[6 16 24]

We did not show a significant reduction in the proportion of patients who fell or in number of falls by using a multifactorial assessment and intervention strategy after a fall in patients with cognitive impairment and dementia presenting to the accident and emergency department. This suggests multifactorial intervention after a fall is less effective in these patients than in cognitively normal older people. Limited resources may be used more effectively if targeted towards cognitively normal older people who fall. However, as older people with cognitive impairment and dementia are at particularly high risk of falls and their associated morbidity, it is important that prevention of falls remains a research priority in this patient group. Further work is required in patients with cognitive impairment and dementia who fall to determine optimal delivery of interventions and to identify the most important modifiable risk factors.

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Contributors: FES was the principal investigator and coordinated the project under the supervision of JB, IGMcK, and RAK. PD provided expertise for physiotherapy and occupational therapy sections of the trial protocol. FES and DAR collected the data. FES and INS analysed the data. All authors contributed

What is already known on this topic

Multifactorial intervention prevents falls in cognitively normal older people living in the community and in those who present to the accident and emergency department after a fall

Fall prevention strategies have not been tested by controlled trials in patients with cognitive impairment and dementia who fall

What this study adds

No benefit was shown from multifactorial assessment and intervention after a fall in patients with cognitive impairment and dementia presenting to the accident and emergency department

The intervention was less effective in these patients than in cognitively normal older people

to the study design and preparation of the paper. FES and RAK wrote the paper. RAK will act as guarantor for the paper.

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