The Prevention of Delirium system of care for older patients admitted to hospital for emergency care: the POD research programme including feasibility RCT

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Scientific summary

POD research programme including feasibility RCT

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Scientific summary

Background

Delirium is a common and serious condition in older people and is associated with adverse outcomes. Evidence suggests that it could be prevented in about one-third of patients using multicomponent interventions, but these are not yet routinely available in the NHS. We therefore undertook a programme of work to investigate delirium prevention for older people in hospital in which we developed and tested a novel delirium prevention system of care: the Prevention of Delirium programme. The programme was based on the previously evaluated Hospital Elder Life Program developed in the USA, within which there is a prominent role for hospital volunteers, and on the National Institute for Health and Care Excellence 2010 guidelines [National Institute for Health and Care Excellence. *Delirium: Diagnosis, Prevention and Management. Clinical Guideline 103*. London: National Clinical Guideline Centre; 2010].

Objectives

- To review and adapt the Hospital Elder Life Program for use in the UK health service (Hospital Elder Life Program-UK).
- To identify strategies to support the implementation of the Hospital Elder Life Program that take account of the potential barriers to change.
- To determine the optimum methods for delivering the Hospital Elder Life Program in routine care.
- To conduct a feasibility study to:
    - assess the implementation and acceptability of the adapted Hospital Elder Life Program to patients and their relatives, clinicians, support staff and volunteers
    - refine the content and delivery of the intervention
    - determine preliminary estimates of clinical effectiveness and cost-effectiveness
    - gather data to inform recruitment, appropriate outcome measure selection and sample size to design a large-scale trial.

Methods

Project 1: review and adapt the Hospital Elder Life Program for use in the UK, and identify candidate implementation and delivery strategies

Project 1 comprised five workstreams:

- Workstream 1: content review of the existing Hospital Elder Life Program protocols.
- Workstream 2: investigate effective integration of the Hospital Elder Life Program-UK into existing ward systems of care.
- Workstream 3: explore the role of hospital volunteers.
- Workstream 4: determine the methods of delivering training in the Hospital Elder Life Program-UK to volunteers and ward staff.
- Workstream 5: identify strategies to optimise implementation of the Hospital Elder Life Program-UK.

For workstream 1, we organised a content review of the existing Hospital Elder Life Program protocols with experts to examine applicability to the NHS, and visited active Hospital Elder Life Program sites in the USA and Canada to examine the delivery of the Hospital Elder Life Program in its real-life context.

For workstreams 2–5, we used a participatory action research approach involving staff, volunteers, and patient and carer representatives in three NHS hospital trusts in the north of England. Data were gathered through a sequence of practitioner workshops, interviews and ward observations. We used normalisation process theory to explore knowledge and ward practices on delirium prevention. We used grounded theory strategies in analysing and synthesising data.

Project 2: pilot study to test implementation feasibility and acceptability of the Prevention of Delirium system of care

The pilot study was to test implementation feasibility and acceptability of the Prevention of Delirium system of care in terms of:

- take-up of the intervention protocols
- impact of the intervention on staff workload
- impact on patient satisfaction with care
- acceptability to patients, carers, staff and volunteers.

We used a case study approach with data collection during a 6-month baseline/implementation period, and a 6-month delivery period to assess the feasibility and acceptability of the Prevention of Delirium programme (version 1), and to refine its content and delivery. We recruited four elderly-care wards and two orthopaedic wards in four NHS local trusts not involved in project 1. Following an initial preparatory workshop, we asked each site to establish a delirium prevention implementation team. Training and implementation in the Prevention of Delirium programme (version 1) was led by the local implementation team, supported by the research team as participant observers. Data collection included facilitated workshops, patient ward profiles, ward documentation/records, interviews and focus groups, observation and questionnaire surveys from multiple sources, and perspectives of all potential stakeholders. Qualitative data (interviews, focus groups and ethnographic observation) were analysed using established qualitative analytic procedures. Quantitative data were analysed using appropriate parametric and non-parametric statistical methods. Staff workload data analysis included investigation of the relationship between dependency/acuity, activity and other variables.

Project 3: preliminary testing of the Prevention of Delirium system of care

We aimed to conduct a pragmatic, multicentre, cluster randomised, controlled, feasibility trial to explore the potential clinical effectiveness and cost-effectiveness of the Prevention of Delirium (version 2) system of care, compared with standard care, among older patients admitted to hospital for emergency care. The primary objectives related to gathering data to inform the feasibility of conducting a definitive randomised controlled trial:

- Estimate recruitment and follow-up rates.
- Assess fidelity of the Prevention of Delirium system of care and the degree of contamination at ward level due to between-ward staff movements.
- Assess the completeness of data collection.
- Provide a preliminary estimate of the effectiveness of the Prevention of Delirium system of care, compared with standard care, as measured by the incidence of new-onset delirium within 10 days of recruitment (anticipated primary outcome for a definitive trial).
- Assess the variability in the incidence of delirium within 10 days of recruitment between the hospital sites.
- Assess fulfilment of criteria for progression to a future definitive trial.
- Investigate differences in financial costs and benefits between the Prevention of Delirium system of care and standard practice.
- Estimate the sample size for a future definitive trial.

Criteria for progression to a definitive trial were a minimum of six wards (75%) completing the Prevention of Delirium manual milestone checklist and an overall recruitment rate of at least 10% of the potential recruitment pool.

The secondary objectives were to investigate differences in the severity and duration of delirium episodes (including persistent delirium), length of stay in hospital, in-hospital mortality, destination at discharge, health-related quality of life and health resource use, physical and social independence, anxiety and depression, and patient experience.

Health economic study

An embedded economic study assessed overall cost-effectiveness from the perspective of health and social care providers. Specific objectives were to:

- determine the feasibility of collecting the assessments needed (quality of life and health-care resource use) for an economic evaluation in this patient group
- determine the number of missing data in assessments
- determine the validity and responsiveness of quality-of-life assessments in this group
- determine the feasibility of collecting and of using/interpreting proxy-completed assessments
- estimate the cost of the Prevention of Delirium intervention
- provide estimates of the cost-effectiveness of the Prevention of Delirium system of care, compared with usual care
- compare these estimates with those from the earlier evaluation based on decision modelling.

A lifetime horizon decision-analytic model was developed to estimate the cost-effectiveness of the Prevention of Delirium programme. We tested the feasibility of conducting an economic evaluation in this group and setting. Trial analyses were conducted, which included updating the decision model to provide preliminary estimates of the cost-effectiveness of the Prevention of Delirium system of care, compared with usual care, from the perspective of the NHS. The economic evaluation relied on utility data from participant-completed EuroQol-5 Dimensions, three-level version, questionnaires and from resource use captured using a survey designed for the study. A cost–utility analysis was conducted on the trial data after adjustment for baseline imbalance and imputation of missing data. Incremental cost-effectiveness ratios were calculated, when appropriate, yielding cost per quality-adjusted life-year during the trial period.

Results

Project 1

The content of the Hospital Elder Life Program intervention was similar to the National Institute for Health and Care Excellence guidelines, with the exception that the latter include four additional risk factors. Site visits to the USA and Canada indicated that the content and style of the Hospital Elder Life Program varied between sites. We observed that ward nurses seemed to have little involvement in its delivery at some sites. Implementation of the Hospital Elder Life Program required a large team of volunteers and additional ward staff (1.25 whole-time equivalent staff for 500 at-risk patients per annum during the start-up year, then declining over time). These additional resources represented potential barriers to implementation; therefore, the development of a system of care capable of integration into routine practice in the NHS without the need for new staff was initiated.

Working with clinical teams in three acute hospital sites, we found that delirium prevention was poorly understood by frontline ward staff and that care practices aimed at reducing delirium risk were rarely carried out. It was also evident that systematic engagement in practices consistent with delirium prevention involved a complex interplay of cultural, interdisciplinary and organisational change at ward and hospital level, and that these practices related to care quality. The challenge of implementation,

therefore, was at the core of securing care practice change, not only to reduce delirium but to improve care quality, particularly with respect to patients whose resilience is compromised by severe illness, cognitive impairment and frailty in advanced older age.

The resulting Prevention of Delirium (version 1) system of care combined a multicomponent delirium prevention intervention that targeted 10 delirium risk factors and an implementation process that was organised in two manuals. The system of care aimed to integrate and embed delirium prevention activities into routine care without the need for additional staff.

Project 2

Five of the six wards implemented or partially implemented the Prevention of Delirium (version 1) system of care; one ward failed to do so. The model of delirium prevention that we adopted included a potential role for hospital volunteers, but most wards were unable to recruit or sustain the number of volunteers needed; therefore, we undertook a reassessment of the role of volunteers. We also concluded that certain conditions needed to be present to implement and deliver the Prevention of Delirium system of care. These 'readiness to change' criteria were summarised as:

- commitment of senior nurse, ward manager and voluntary services manager
- named person to drive implementation forward
- dedicated time (1 day per week) of an experienced nurse to lead implementation
- adequate ward staffing levels.

Overall, the intervention was acceptable to staff, volunteers, patients and carers. Reassuringly, delivery of the Prevention of Delirium (version 1) system of care did not increase nursing staff workload. The baseline audits of care were considered useful to stimulate practice changes. The impact on patient satisfaction was mixed, being large for some items (e.g. choice of food, confidence and trust in doctors and nurses, enough nurses on duty to care for the patient) and small for other items (e.g. noise at night, communication). Carers particularly valued staff spending time with their relatives and getting to know what was important to them.

The Prevention of Delirium (version 2) system of care was developed to include a more concise presentation of material, improvements in the structure and clearer descriptions of implementation checkpoints to support successful implementation, and incorporation of the 'readiness to change' criteria.

Project 3

The target number of hospitals ($n = 8$) and wards ($n = 16$) were recruited (two wards in each hospital). A total of 4449 patients were screened; 3274 (73.6%) were eligible, of whom 1537 were assessed for prevalent delirium and 713 (16.0% of those screened, 99.0% of the 720 trial participant target) were recruited and registered to the trial. Thirty-three (4.6%) participants withdrew. The populations of screened and registered participants were similar. The cluster randomisation led to an imbalance between groups for ward type (elderly care and orthopaedics); this resulted in an imbalance for some characteristics: cognitive impairment and/or dementia, highest National Early Warning Score, visual impairment, and prescribed opiates and antihistamines.

All eight wards allocated to the intervention group completed the milestone checklist and went on to deliver the Prevention of Delirium system of care, with a median time of 18.6 weeks needed for implementation. Overall fidelity to the intervention was assessed as high in two wards, medium in five wards and low in one ward. Between-ward intervention contamination was minimal.

Of the expected 5645 delirium assessments (using the Confusion Assessment Method), 5065 (89.7%) were completed during the first 10 days of admission. At 30 days, 513 (81.6%) out of an expected 629 Confusion Assessment Method assessments were completed. The rates of return of the questionnaire booklets were 98.0% at baseline, 81.8% at 30 days and 70.5% at 3 months.

Fifty-seven (8.0%) participants developed new-onset delirium within 10 days of providing consent: 24 (7.0%) in the Prevention of Delirium group and 33 (8.9%) in the control group. Delirium incidence in the eight hospital sites ranged between 4.6% and 10.6%.

Multilevel logistic regression analysis showed that participants in the Prevention of Delirium group had non-statistically significant lower odds of developing delirium (odds ratio 0.68, 95% confidence interval 0.37 to 1.26; $p = 0.2225$).

Severity, duration and time to first delirium episode were similar between the two groups, as were falls in hospital, length of hospital stay, deaths and discharge destination, patient-reported outcomes and poor outcomes.

The criteria for continuation to a future definitive randomised controlled trial were met. Using data obtained from our study, we estimate that such a trial would need to recruit 5200 patients in 26 hospital clusters (200 patients per cluster). This assumes a significance level of 5%, a study power of 90% and a delirium incidence reduction of 30%.

Health economic study

The return rate of the EuroQol-5 Dimensions, three-level version, questionnaire was 98.6%, 77.5% and 65.3% at baseline, 1 month and 3 months, respectively (94–98% fully completed). The completion rate of the resource use questionnaire was lower (48.7%). The average cost of the Prevention of Delirium intervention was estimated as £10.98 per patient. The mean costs for the Prevention of Delirium and usual-care groups were £5332 and £4412, respectively. Despite the fewer cases of delirium in the Prevention of Delirium group, there were negligible between-group differences in quality-adjusted life-years, although, in all analyses, these were in favour of the control group. Using a threshold of £20,000 per quality-adjusted life-year gained, the probability that the Prevention of Delirium programme was cost-effective, based on the trial data, was 0.01 (1% chance) in a simulation using adjusted quality-adjusted life-years and complete-case and imputed items. The decision-analytic model was updated using the trial data. The probabilistic sensitivity analyses yielded mean incremental costs and quality-adjusted life-years of £1774 and 0.11, respectively, and an incremental cost-effectiveness ratio of £15,454. At a willingness-to-pay threshold of £20,000 per quality-adjusted life-year gained, the Prevention of Delirium programme was cost-effective in 100% of simulations, indicating that the Prevention of Delirium programme is a cost-effective strategy. Thus, trial and model results provided conflicting evidence regarding cost-effectiveness. Given this, and in view of the significant issues with the data (i.e. in terms of the number of missing data) and low confidence regarding a treatment effect, the economic evaluation results are highly uncertain. Further research is recommended to identify optimal data collection strategies in this population.

Conclusions

A multicomponent Prevention of Delirium system of care suitable for widespread use in NHS acute hospital wards was successfully developed. A multicentre, cluster randomised, pragmatic, feasibility trial ($n = 714$ participants; 16 wards; 8 hospital sites) showed that the intervention can be implemented and delivered in routine care. Fidelity to the intervention and preliminary estimates of clinical effectiveness were acceptable. Estimates of cost-effectiveness should be treated with caution. Greater levels of intervention adherence might have influenced the effectiveness estimate of the Prevention of Delirium programme. However, the trial was purposefully designed as a pragmatic trial, that is ward changes were led by existing ward staff, rather than research staff. The findings are therefore likely to be generalisable to delirium prevention in routine care and to form a more reliable basis for planning future studies.

Recommendation

The findings from this research programme indicate that a definitive multicentre, cluster randomised, pragmatic trial evaluation of the Prevention of Delirium system of care should be designed and conducted in the NHS to obtain robust estimates of clinical effectiveness and cost-effectiveness.

Trial registration

This trial is registered as ISRCTN28213290 (project 1), ISRCTN65924234 (project 2) and ISRCTN01187372 (project 3).

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