

Effectiveness of post-operative management strategies for adults with dementia following hip fracture surgery (Protocol)

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[Intervention Protocol]

Effectiveness of post-operative management strategies for adults with dementia following hip fracture surgery

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ABSTRACT

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

To assess the effects of different post-operative management strategies for people with dementia following hip fracture surgery, with a bias towards dementia and cognitive or behavioural outcomes.

BACKGROUND

Description of the condition

The hip joint is the articulation between the thigh bone (femur) and the pelvis. The term 'hip fracture' encompasses all fractures of the upper (proximal) part of the thigh bone (femur). Hip fractures are commonly divided into two types: intracapsular fractures, which represent those that occur within or proximal to the attachment of the hip joint capsule to the femur; and extracapsular, which represent fractures occurring outside or lower (distal) to the hip joint capsule (Parker 2010). Hip fracture is a common injury in the elderly population.

The majority of people undergo hip surgery following hip fracture (Uzoigwe 2012). The location of the fracture, stability and degree

of comminution (number of pieces the bone breaks into) determine which operative procedure should be undertaken in order to repair the hip fracture. The aim of surgery, irrespective of the type of operation, is to reduce pain, facilitate early weight-bearing mobility to improve outcomes, and to facilitate independence in activities of daily living, such as bathing, dressing, and continence (Handoll 2009). A delay in surgical intervention is known to be a key factor in producing poorer outcomes (Vidal 2012).

The annual hip fracture incidence rate has been estimated as 1.29/1000 person-years in males and 2.24/1000 person-years in females (Adams 2012). This figure is likely to rise over the next few years as the population is increasing in age (Cummings 2002). It is the most common physical rehabilitation condition for older adults (Lenze 2007), seen in both those who are cognitively intact and those with all degrees of cognitive impairment, and is associated with

significant pain and loss of independence and function (Morrison 2000). Thirty-three per cent to 37% of patients return to their prior level of function by six months, including those needing assistance, but only 24% are independent in locomotion at by six months (Magaziner 2002).

Dementia is a global loss of cognitive and intellectual functioning, which gradually interferes with social and occupational performance (Lieberman 2006; McGilton 2012). It is a common condition with a significant impact on society. Hip fracture is nearly three times more common in people with dementia than in people without dementia (Zhao 2012). It is expected that the incidence of patients with dementia and hip fracture will increase during the next 25 years (Adunsky 2003; Knapp 2007). Health and social care expenditure in England on people with dementia in the year following admission for fractured neck of femur has been estimated to be in excess of GBP 1 billion (GBP 1037 million in 2005 to 2006 prices), about GBP 0.4 billion higher than expenditure on those without dementia (Henderson 2007). This was estimated as equating to approximately GBP 34,200 per person per annum for those without dementia and GBP 40,300 per person per annum for people with dementia (Henderson 2007).

Description of the intervention

The provision of high-quality care for people following hip fracture has been identified as a major clinical need in the United Kingdom and elsewhere. This has been exemplified in the United Kingdom through the development of national guidelines (NICE 2011), the introduction of specific financial incentives for high-quality care through the 'Best Practice Tariff' (NICE 2011), and the national audit of standards of care provision to this population through the National Hip Fracture Database (National Hip Fracture Database 2013). For all hip fracture patients, initial management is usually provided in an acute hospital setting, where the person undergoes an operation for their hip fracture. Best practice often includes shared orthopaedic and geriatric (sometimes termed ortho-geriatric) care pre- and post-operatively to ensure that patients are medically fit for surgery and to monitor and manage any post-operative medical complications that may develop (Dy 2012). These may include pneumonia, anaemia, dehydration, pressure sores, or cardiovascular complications (Dy 2012; Jameson 2012). During the initial hip fracture admission, or index admission (Drummond 2005), health professionals such as nurses, pharmacists, occupational therapists, physiotherapists, social workers, and dieticians may be involved in the patient's recovery and rehabilitation (Kammerlander 2010; Stenvall 2012). Depending on their home circumstances and their post-operative functional capabilities, patients may be discharged directly to the residential setting they lived in, with or without community or out-patient rehabilitation, or may be transferred to an in-patient rehabilitation unit to receive continued multi-professional rehabilitation. Patients will remain in this rehabilitation setting until

they are sufficiently independent to be discharged to their pre-admission residence or, if this is not achievable, they may be provided with residential or nursing home care (Hashmi 2004).

Over the past 15 years, developments in the management of people with hip fracture have been advanced (Cameron 2000). This has particularly been seen for those with dementia, who have specific and complex care needs (Cameron 2000; Dy 2012). Over this period, research reports and subsequent clinical guidelines have recommended a number of interventions to improve outcomes for this group of patients (NICE 2011). These have included specific medical management by an ortho-geriatrician on specified hip-fracture wards, which is considered to enhance interdisciplinary team working; improvement of communication between health and social agencies (Kammerlander 2010; Stenvall 2012); provision of dedicated functional rehabilitation interventions across acute hospital and community rehabilitation settings (Al-Ani 2010; Huusko 2000); monitoring of post-operative complications including pressure sores (Söderqvist 2007); and optimisation of nutritional levels for this group of patients (Hershkovitz 2010). Specific rehabilitation strategies for this population have included enhanced rehabilitation with respect to orientation to the environment, clues, reminiscence and structured, familiarised routines. Such interventions can be delivered in a variety of health-care and domiciliary settings.

How the intervention might work

The interventions that have been proposed to improve the management of people with dementia who have suffered a hip fracture have been advocated to improve communication between health-care professionals and provide generic and wider healthcare expertise than may conventionally be found on an orthopaedic ward or in a rehabilitation setting (Söderqvist 2007). Recommended interventions have also included specifically targeting interventions and resources for this population, who have greater and more complex healthcare needs (Söderqvist 2007). These factors are acknowledged as possible explanations why a specific, targeted management programme for people with dementia following hip fracture may be advantageous over conventional, non-specific post-operative management (Handoll 2009).

Why it is important to do this review

More than three quarters of a million people in the UK have dementia. One in four National Health Service (NHS) beds are occupied by someone with dementia. Fractured hips and falls are the commonest reasons for hospital admission. People with dementia who sustain a hip fracture have more complex health problems with complications, disabilities, and social needs. Whilst previous reviews have examined the rehabilitation of people following hip fracture, none have specifically assessed the specialist rehabilitation

strategies for those who have dementia. Since this population has complex care needs, and makes a major demands on healthcare services, this focused review of the literature is warranted.

In this population, factors such as depression, motivation, pain, and cognitive impairment have been cited as impacting on clinical outcomes (Lenze 2007). Pain has been acknowledged as a particular problem since if pain management is inadequate, due to poor assessment, negative post-operative outcomes and complications such as pneumonia, atrophy, and thromboembolism can occur (Egbert 1996; Feldt 1998; Morrison 1998). These factors may adversely impact on the ability of a person to return to functional independence, the discharge destination, the length of their in-patient hospital stay and rehabilitation requirements. The resulting negative consequences, therefore, have a health economic impact, at a personal and a systems level. People who sustain a hip fracture and have dementia experience longer hospitalisations with poorer outcomes, such as higher mortality and morbidity rates, and have a greater risk of requiring nursing home placement and poorer functional recovery (Gruber-Baldini 2003; Magaziner 1990; Steiner 1997). However, whilst various interventions have been supported for the targeted rehabilitation of people with dementia who experience a hip fracture (Al-Ani 2010; Huusko 2000), these are more expensive than conventional post-operative management following hip fracture (Lenze 2007). More evidence is needed on the relationship between the processes and outcomes of post-operative care, length of stay, and costs in the general population of hip fracture patients (Hunt 2009), and in particular in the subpopulation of people with dementia (Henderson 2007). Decisions as to whether to allocate limited health and social care resources to these new interventions can be informed by economic evaluation, the comparative analysis of outcomes and the costs of alternative treatment programmes (Drummond 2005).

Previous reviews have examined the literature on the use of management strategies for people with dementia who experience a hip fracture (Allen 2012; Handoll 2009). These have focused on clinical and functional outcomes. No reviews have specifically assessed the impact of such management programmes on behavioural, cognitive, or dementia-related outcomes for this population, nor on the relationship between these outcomes and resource use and costs. The purpose of this review is therefore to answer these important questions.

OBJECTIVES

To assess the effects of different post-operative management strategies for people with dementia following hip fracture surgery, with a bias towards dementia and cognitive or behavioural outcomes.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised, quasi-randomised (method of allocating participants to a treatment which is not strictly random, for example by hospital number) or cluster-randomised controlled clinical trials published in any language, evaluating the effectiveness of different post-operative management strategies for people with dementia following hip fracture surgery. We will include studies of costs and cost-effectiveness accompanying eligible effectiveness studies of post-operative management strategies for people with dementia following hip fracture surgery (Shemilt 2008).

Types of participants

We will include all people if they are aged 65 years or over, have been diagnosed with any form of dementia, and have undergone hip fracture surgery for a proximal femoral fracture. We will exclude studies where over 30% of participants presented with a mid-shaft or distal femoral fracture. Dementia should have been diagnosed using a validated instrument such as the Diagnostic and Statistical Manual IV (American Psychiatric Association 1994) or International Classification of Diseases 10th revision (ICD-10) (World Health Organization 2007). We will contact corresponding authors for further information if the method of diagnosing dementia is not stipulated in the original study. Participants may be resident in the community, in care homes, or hospitals for short- or long-term care.

Types of interventions

We will include any form of post-operative management or rehabilitation programme following a hip fracture that is intended specifically for people with dementia or cognitive impairment. This may include post-operative recovery on a specialist orthogeriatric ward and enhanced rehabilitation with respect to: orientation to the environment, clues, reminiscence and structured, familiarised routines undertaken. Interventions may be delivered in acute hospital environments, community health or rehabilitation centres, in community centres or non-health settings, or domiciliary in people's homes and residences.

For comparison, we will compare study interventions to routine post-operative and rehabilitation management. Neither the intervention nor the control will be known until the search is conducted.

Types of outcome measures

Primary outcomes

- Cognitive function as assessed using (for example): Alzheimer's Disease Assessment Scale Cognitive Subscale (ADASCOG) (Rosen 1984), Mini-Mental State Examination (MMSE) (Folstein 1975), Abbreviated Mental Test (Hodkinson 1972), Addenbrooke's Cognitive Examination Revised (ACE-R) (Mathuranath 2005), Montreal Cognitive Assessment (MoCA) (Nasreddine 2005), Hopkins Verbal Learning Test (HVLT-R) (Brandt 1991), the Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE) (Jorm 1989).

Secondary outcomes

- Cognitively determined function as assessed with tools such as the: Barthel Index (Mahoney 1965), Nottingham Extended Activities of Daily Living Scale (Nouri 1987), Oxford Hip Score (Dawson 1996), and the Bristol Activities of Daily Living Score (Bucks 1996).

- Behaviour as assessed using: Neuropsychiatric Inventory (NPI) (Cummings 1994), Cohen-Mansfield Agitation Inventory (CMAI) (Cohen-Mansfield 1986).

- Quality of Life as assessed using: the Short Form-36 (Ware 1992), Bath Assessment of Subjective Quality of Life in Dementia (BASQID) (Trigg 2007), DEMQOL (Smith 2005), Short Form-12 (Ware 1996), EuroQol (EQ)-5D (EuroQol Group 1990), and Health Utility Index (Feeny 2002) instruments.

- Tools assessing pain, from any cause, using methods suited to patients with dementia, such as the Pain Assessment in Advanced Dementia (PAINAD) (Warden 2003).

- Mortality.
- Complications such as deep vein thrombosis, pressure sores, pneumonia.

- Use of health and social care resources: hospital length of stay, hospital re-admissions, discharge destination (to pre-injury setting, residential or nursing home care), use of primary and community care support services including general physician (GP) visits, medications and tests prescribed, also community and residential rehabilitation.

- Costs of hospitalisation, hospital re-admission, health and social care support in the community or in residential or nursing home care, and costs to people with dementia who have had a hip fracture and to their carers (such as travel, carers' lost production).

Search methods for identification of studies

We will perform the search methods in accordance with the latest version in the *Cochrane Handbook for Systematic Reviews of Interventions* (Lefebvre 2011).

Electronic searches

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

ALOIS is maintained by the Trials Search Co-ordinator and contains dementia and cognitive improvement studies identified from the following.

1. Monthly searches of a number of major healthcare databases: MEDLINE, EMBASE, CINAHL, PsycINFO, and LILACS.

2. Monthly searches of a number of trial registers: metaRegister of Controlled Trials; Umin Japan Trial Register; WHO Clinical Trials Registry Platform portal (which covers ClinicalTrials.gov; ISRCTN; Chinese Clinical Trial Register; German Clinical Trials Register; Iranian Registry of Clinical Trials; the Netherlands National Trials Register, plus others).

3. Quarterly search of the Central Register of Controlled Trials (CENTRAL) in *The Cochrane Library*.

4. Monthly searches of a number of grey literature sources: ISI Web of Knowledge Conference Proceedings; Index to Theses; Australasian Digital Theses.

5. Monthly searches of the NHS Economic Evaluation Database (NHS EED).

To view a list of all sources searched for ALOIS see [About ALOIS](#) on the ALOIS website.

We will run additional separate searches 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 the OvidSP platform) can be seen in [Appendix 1](#).

We will place no restriction on the search in respect to date of publication, risk of bias, or language of publication.

Searching other resources

We will review the reference lists of all potentially eligible papers identified and all review papers related to this topic. We will also ask the corresponding authors of each included paper to review the search results to identify any papers not initially identified from the previous searches.

We will search the conference proceedings and abstracts from the British Orthopaedic Association Annual Congress, the European Federation of National Associations of Orthopaedics and Traumatology (EFORT), the British Hip Society, and British Trauma Society meetings. We will access these through the Journal of Bone & Joint Surgery (British Volume) [Orthopaedic Proceedings](#). We will additionally search the [INSIDE](#) (British Library database of conference proceedings and journals).

Data collection and analysis

Selection of studies

Two review authors (TS and YH) will search the results of the search strategy. They will independently review the titles and abstracts of each citation. We will order the full text version of each potentially eligible trial. This will then be assessed independently by two review authors (TS and YH) in order to re-assess its eligibility. We will include all full text papers which still satisfy the eligibility criteria of the review. Any disagreements with regards to study eligibility will be discussed between the two review authors (TS and YH), and adjudicated by a third review author (CF).

Data extraction and management

We will review each study which satisfies the eligibility criteria and its data will be extracted from the original publication independently by two review authors (TS and YH). They will record the data on a pre-defined eligibility database. Data extracted will include: country of origin, publication date, number of participants receiving each intervention, gender, age, and dementia diagnosis for participants, classification or type of femoral fracture, fracture fixation method, interval between fracture and surgical management, location of rehabilitation and post-operative management for each intervention, the post-operative management allocated to each group assessed, duration of intervention, follow-up period, outcome measurements used, and results from each intervention group during each follow-up period.

Disagreements between the review authors (TS and YH) will be resolved through discussion. If agreement is not reached, this will be adjudicated by a third review author (CF). All agreed data will then be tabulated into a single document on Review Manager version 5.1.

Assessment of risk of bias in included studies

The quality of the included studies and their risk of bias will be evaluated using the Cochrane Collaboration 'Risk of bias' assessment tool (Higgins 2011). For each study, we will assess: sequence generation; allocation concealment; blinding; completeness of outcome data; and selective outcome reporting. For each domain, an assessment will be made of whether there is a low risk of bias (if the study matches the criteria), a high risk (if the study does not match the criteria), or unclear risk of bias (due to under-reporting).

Risk of bias will be conducted independently by two review authors (TS and YH). Any disagreement on the risk of bias scoring will be resolved through discussion. If agreement cannot be reached, this will be adjudicated by a third review author (CF).

Measures of treatment effect

We will assess whether meta-analysis is appropriate based on the heterogeneity of the study characteristics. When there is consid-

erable variability between studies in respect to population, intervention, or follow-up procedure characteristics, we will perform a narrative review to summarise the treatment effect. When there is minimal or no heterogeneity between studies based on the study characteristics, we will conduct a pooled (meta-) analysis.

We will use a random-effects statistical model when I^2 equates to more than 20%, or the Chi^2 P value is greater than 0.1. We will undertake a fixed-effect statistical model when I^2 equates to less than or equal to 20% or Chi^2 has a P value less than or equal to 0.1. For each meta-analysis, we will calculate mean differences or standardised mean difference for continuous outcome data. We will calculate odd ratio statistics for dichotomous outcome data. We will present all meta-analysis results with 95% confidence intervals, and present forest plots.

Unit of analysis issues

The individual participant will be the unit of analysis in this review, with the exception of cluster-randomisation trial where the unit of analysis will be the specific, randomised cluster. Some grouping of follow-up periods is anticipated. Therefore, we will present the results of short-term outcomes (randomisation to six post-operative weeks), mid-term (three months to 12 months post-randomisation), and longer-term outcomes (18 months onwards). This will reduce the risk of multiplicity of results (Deeks 2011).

Dealing with missing data

We will contact corresponding authors regarding any missing data from trials included in the review. When data are unavailable after contacting the corresponding author, we will acknowledge this. We will not impute missing outcome data for any outcomes. In the event of a study only providing imputed data, we will request that the corresponding author provide data on outcomes only from the participants who were assessed rather than estimated through imputation.

Assessment of heterogeneity

We will evaluate study characteristic heterogeneity and statistical heterogeneity. We will assess study characteristic heterogeneity by examining the data extraction tables. Two review authors (TS and CF) will examine the data extraction table and assess the data for between-study variability with respect to population diagnosis, interventions (pre- and post-surgical), and outcome measurements. We will assess statistical heterogeneity for each meta-analysis through a visual assessment of the forest plot results in addition to evaluating the Chi^2 test and I^2 statistic. In accordance with Deeks et al (Deeks 2011), we will interpret a Chi^2 test as significant with a P value of 0.10. I^2 will be interpreted as: 0% to 40% not being important, 30% to 60% representing moderate heterogeneity, 50% to 90% representing substantial heterogeneity, and 75% to 100% representing considerable heterogeneity (Deeks

2011). As recommended by Deeks et al (Deeks 2011), we will interpret both the Chi² test and I² statistic together to inform an overall assessment of statistical heterogeneity.

Assessment of reporting biases

When data are available from at least 10 studies which form a meta-analysis for a specific outcome measurement, we will generate funnel plots to assess the risk of publication bias (Sterne 2011).

Data synthesis

Two review authors (TS and CF) will evaluate study characteristic heterogeneity using the data extraction tables. When substantial in respect to the intervention, population, or method of assessment, we will present a narrative review of the results. If study characteristics heterogeneity is deemed not substantial, with homogeneity in relation to the intervention, population, or method of assessment, we will conduct meta-analyses.

Subgroup analysis and investigation of heterogeneity

If heterogeneity is identified for a priori characteristics that are included in a meta-analysis, we will undertake subgroup analyses. This may include, when appropriate, an assessment of the difference in outcomes dependent on the following.

- The severity of dementia presented, when appropriate. Through this, we will use an assessment of dementia based on, for example, the MMSE (e.g., mild: 19 to 16; moderate: 15 to 10; severe: 9 to untestable) to compare clinical outcomes for the post-operative recovery strategies for those with greater compared to less dementia.
- Age of participant in years e.g., 60 to 69; 70 to 79; 80 to 89; 90 years and older.
- The type of dementia e.g., Alzheimer's disease, vascular dementia, Lewy Body, or a rarer syndrome.

- Location of intervention provision e.g., in-patient, out-patient, or home-based.

We will assess heterogeneity through examination of the data extraction tables to evaluate study characteristic heterogeneity, and using I² and Chi² statistics to evaluate statistical heterogeneity. Two review authors (TS and CF) will do this.

Sensitivity analysis

We will conduct sensitivity analyses if there are sufficient data to explore the influence of the following factors.

- The risk of bias: the analysis of data with the exclusion of results from studies which demonstrated a high risk of bias based on the Cochrane Collaboration's risk of bias tool (Higgins 2011).
- The analysis of data solely from published, peer-reviewed papers.

'Summary of findings' Tables

We shall use the GRADE approach to assess the quality of the body of evidence related to the primary outcome measure and the first four secondary outcome measures identified in the [Types of outcome measures](#) section.

We will construct a 'Summary of findings' (SoF) table using the GRADE software (Schunemann 2011). Using this software, the quality of the evidence can be considered along with the magnitude of the intervention's effect for each outcome of interest (Schunemann 2011). This will be used to aid interpretation of the main findings of the review.

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* Indicates the major publication for the study

APPENDICES

Appendix I. MEDLINE search strategy

1. exp Dementia/
2. Delirium/
3. Wernicke Encephalopathy/
4. Delirium, Dementia, Amnesic, Cognitive Disorders/
5. dement*.mp.
6. alzheimer*.mp.
7. (lewy* adj2 bod*).mp.
8. deliri*.mp.
9. (chronic adj2 cerebrovascular).mp.

10. ("organic brain disease" or "organic brain syndrome").mp.
11. ("normal pressure hydrocephalus" and "shunt*").mp.
12. "benign senescent forgetfulness".mp.
13. (cerebr* adj2 deteriorat*).mp.
14. (cerebral* adj2 insufficient*).mp.
15. (pick* adj2 disease).mp.
16. (creutzfeldt or jcd or cjd).mp.
17. huntington*.mp.
18. binswanger*.mp.
19. korsako*.mp.
20. or/1-19
21. exp Femur/
22. exp Fractures, Bone/
23. exp Fracture Fixation/
24. exp Fracture Healing/
25. or/22-24
26. 21 and 25
27. (hip or hips or pertrochant* or intertrochant* or trochanteric or subtrochanteric or extracapsular*).ti,ab.
28. ((femur* or femoral*) adj3 (neck or proximal)).ti,ab.
29. 27 or 28
30. ((hip or hips or pertrochant* or intertrochant* or trochanteric or subtrochanteric or extracapsular* or ((femur* or femoral*) adj3 (neck or proximal)))) adj4 fracture).ti,ab.
31. randomized controlled trial.pt.
32. controlled clinical trial.pt.
33. randomi?ed.ab.
34. randomly.ab.
35. placebo.ab.
36. drug therapy.fs.
37. trial.ab.
38. groups.ab.
39. ("double-blind*" or "single-blind*").ti,ab.
40. (RCT or CCT).ti,ab.
41. or/31-40
42. (animals not (humans and animals)).sh.
43. 41 not 42
44. 29 or 30
45. 20 and 43 and 44

CONTRIBUTIONS OF AUTHORS

TS: drafted the protocol; develop and run the search strategy; reviewed and approved final protocol; act as guarantor.

YH: drafted the protocol; reviewed and approved final protocol.

CH: drafted the protocol; reviewed and approved final protocol.

JC: drafted the protocol; reviewed and approved final protocol.

OS: drafted the protocol; reviewed and approved final protocol.

CF: drafted the protocol; reviewed and approved final protocol.

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No conflicts of interests have been declared by any of the authors in relation to this protocol.

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