The detection and management of pain in patients with dementia in acute care settings: development of a decision tool: Research protocol.

Aims and Objectives of the overall study

The aim of this study is to identify how pain is currently detected and managed for patients with dementia in acute care settings and to assess the feasibility of introducing decision support tools to assist with the process. The study will address the following research questions:

1. How are clinicians detecting, managing and documenting pain in people with dementia in acute care settings?
2. What is the clinical utility of existing tools to assist with the detection and management of pain in people with dementia in acute care settings?
3. What is the role of carers in supporting the detection of pain in people with dementia in acute care settings?

The study has the following research objectives:

1. To identify the evidence base for existing tools that focus on the detection and management of pain in patients with dementia.
2. To explore current processes for the detection and management of pain in patients with dementia across acute care settings.
3. To provide strategies for incorporating carers' expertise into the detection and management of pain in people with dementia in acute care settings.

Methods

The MRC framework for the development and evaluation of complex interventions will be used to guide the study design (1). In this study we are following a technology development process where we are focusing on developing the intervention (bench testing) before field testing it through the development of associated implementation strategies and assessing its feasibility for use in clinical practice.

The study has two components:

1. A systematic reviews of systematic reviews of existing evidence. This is designed to provide an overview of existing pain assessment tools for use with individuals who have any form of cognitive impairment. It will provide an overview of existing tools to map out potential available assessment tools, and the settings and populations in which they have been evaluated.

Search Strategies: Search strategies will be based on the approach adopted by the JBI. An initial search using key words derived from Zwakhalen (2) including (Pain) AND (Scale OR assessment OR measure) AND (Elderly OR geriatric OR cognitive impairment OR dementia OR Alzheimer) will be

entered into a number of databases. These will include (but not be limited to) MEDLINE, CINAHL EMBASE and PSYCHINFO using both MeSH headings and keywords. Retrieved papers will be analysed for key terms and a full search strategy developed in consultation with information specialists. The Cochrane collaboration and JBI libraries of systematic reviews and the Centre for reviews database will also be searched. Following a full search, the references of the retrieved papers will be reviewed for any papers not already identified. A hand search will be conducted of key journals and conference abstracts and thesis. *Study Inclusion:* Papers will be included if they are reviews carried out systematically and address the use of pain assessment tools in older adults with any degree of cognitive impairment. Reviews addressing studies of clinical utility and psychometric properties of any tool using any measures will be included. While verbal report is acknowledged as the gold standard for pain assessment and some studies have compared verbal report with behavioural assessment in those with mild impairment, comparisons with staff assessment have also been reported. There is no clear agreement on the best approach to the assessment of accuracy in pain assessment tools for older adults with cognitive impairment so reviews addressing all approaches will be included. Case reports or secondary sources/reviews and papers not available in English will be excluded. Whilst we recognise that it is best practice to review world-wide literature, given our understanding of the strength of pain research in the English language journals we have decided it would not be a fatal flaw of the study to restrict to studies published in English.

Reviews will be reviewed for the inclusion criteria by two reviewers initially on the basis of titles and abstracts. Included papers will be retrieved and read by two reviewers to confirm their inclusion in the review. Any disagreements will be referred to a third reviewer. Critical appraisal will be will be carried out by two independent reviewers, using a tool based on the AMSTAR (3) systematic review critical appraisal tool and the PRISMA (http://www.prisma-statement.org/) statement.

Data extraction: Data extraction will be conducted by two reviewers using a data extraction form developed for the study based on the standardised tools developed by JBI. This will include inclusion/exclusion criteria, total sample size, assessment of methodological quality, results of meta-analyses or narrative summary, measures of sensitivity, specificity and accuracy, measures of clinical utility and overall conclusion of the authors.

Data Analysis Data from the papers will be synthesised using a narrative synthesis.

2. A multiple case site study with embedded units of analysis (individual, ward, organisation). Case studies are an empirical design which focuses on describing phenomena within their real life context (4). In this study we will be using the case studies to identify:

- Information currently used by clinicians when detecting and managing pain in patients with dementia,
- The existing processes of decision making for detecting and managing pain in patients with dementia,
- The role (actual and potential) of carers in detecting and managing pain in patients with dementia,
- The organisational context in which clinicians operate, with regard to the detection and management of pain in patients with dementia,
- How decision tools could be introduced into acute care settings to assist with the detection and management of pain in patients with dementia.

Case site selection
Four case sites (hospitals) will be theoretically sampled to provide varying settings of acute care. Criteria for sampling will include type of hospital (tertiary referral centre/secondary care) and type of service provision available to health care professionals (HCP) in the hospital (e.g. a specialist pain management team, dementia outreach team). In each site two wards will be selected for data collection. Selection of wards will also be theoretically driven to ensure that across the sample we have representation from a variety of clinical settings in acute care where patients with dementia may be cared for (e.g. orthopaedic, acute medicine, care of the elderly). This is to ensure that we derive a detailed comparative overview of how pain is currently detected and managed in patients with dementia in acute care settings.

Data collection: In each case site a variety of data collection methods will be used to provide multiple sources of evidence for addressing the research questions. Non-participant observation of HCPs interacting with patients who have dementia will be used to identify how information appears to be used to detect and manage pain and the care processes that are currently used (e.g. how and where pain is documented, interactions between HCPs, patients and carers, interactions between members of the multi-disciplinary team (MDT) and availability of resources). An observation protocol derived from the theoretical framework will be used to guide data collection.

Semi-structured interviews will be carried out with clinical staff (nurses, doctors, other members of the MDT) and carers to explore their perceptions of how pain is currently detected and managed, how carers are currently involved in the process, how the process may be improved and what an effective tool would look like (e.g. format, content, resources). In addition, we will interview managers (at unit and organisational level) to gain a wider organisational perspective on the importance attached to the detection and management of pain in patients with dementia, and organisational policies/procedures in place or currently being planned to deal with the issue. Where possible we will also obtain copies of existing policies and procedures in place in the unit and/or organisation that are specifically focused on the detection and management of pain in patients with

dementia. We will also audit the medical and nursing notes for documentation of pain assessment, action taken and pain reassessment.

Sample: There is no consensus regarding how many periods of observation or interviews are necessary to provide an adequate overview. Based on our previous case site work (5), a sample of 40 periods of observation per case site provided a detailed insight into relevant decision processes. We therefore intend to carry out non-participant observation of 40 shifts per case site where HCPs interact with patients who have dementia (total n=160) and collect outcome data for these patients. We anticipate carrying out approximately 15 interviews with clinical staff per site, although the number may vary depending on whether interviews are revealing new data (total n = 60). Similarly we anticipate interviewing 10 carers (total n = 40) and 5 managers per case site (total n = 20). Again this number may vary depending on the type of data being obtained.

Data Analysis: Data for analysis will consist of verbatim transcripts of observation sessions, field notes and interviews, together with copies of existing policies and procedures. Data will be analysed with the assistance of the specialised software NVivo, using thematic analysis. Themes for the analysis will be derived both from the theoretical framework (e.g. information used to inform pain management decisions, sources of information, types of judgements, types of pain management decisions) and inductively from the data. Transcripts will be read and re-read to identify themes or categories, which will be used to code the data (6). Data in each theme will then be examined to ensure that all manifestations of each theme have been identified, before interconnections between themes are explored (6). To increase transparency in the analytic process, a minimum of two researchers will be asked to verify the identification of themes and assignment of text to analytic codes.

3. Development of decision tools

The themes derived from the data will be used to develop a new intervention to improve the assessment and management of pain for people with dementia in acute settings.

Following stages 1 and 2 we will have identified existing evidence based tools that are currently available for the detection and management of pain in patients with dementia; together with a detailed picture of how pain is currently managed; the role of carers in the process; and insights into how care processes could be improved in acute hospital settings. Using the theoretical framework as a guide, we will produce a synthesis of the findings to provide a structure for decision tool design. The exact nature of the format of the tool(s) will be decided upon, on the basis of the findings from stages 1 and 2; however, it is likely that it will include the following elements:

• A framework for identifying relevant information to be used to assist with detecting whether or not a patient is in pain. This will include identification of appropriate pain assessment tools, observational cues, information derived from carers and from the multidisciplinary team.

• Mechanisms for evaluation and feedback to ensure that if strategies are ineffective, pain is reassessed and different pain management approaches are put into place.

When designing the tool we will draw on evidence into the effectiveness of decision support interventions which suggest that tools should be integrated into a clinician's practice, provide guidance at the point of decision making and provide care recommendations (7).

We would expect the decision tool(s) to then be assessed for feasibility and acceptability in acute hospital settings. This should include an economic sub-study to inform a full RCT of the decision support tools, providing they are evaluated as feasible and acceptable. Both will be the basis of a follow-on study. In preparation for this, we will develop technical specifications for the design of the tool and data collection instruments, such as questionnaires.

4. Dissemination and research utilisation

The outcomes of this research will initially be disseminated through academic channels including publication in a peer reviewed journal and presentation of findings at national and international conferences. This will particularly focus on events targeted to clinical and nursing professionals.

The primary deliverable of this research will be the design of a new decision support tool for professionals in acute care settings based on robust evidence and stakeholder consultation. The tool design will be developed with a view to further evaluation in a randomised controlled trial.

5. Patient and Public Involvement

Patient and Public Involvement for this research will be led by the Alzheimer's Society through one of the co-applicants (Corbett). The experiences and opinions of people with dementia and their carers will be integral in the information gathering stage and in the development of the decision support tool and guidance which are the key deliverables from the research. It will be particularly important to consider any challenges or opportunities identified by these consultations to ensure the accuracy and success of the research. This work will be done through focus groups and interviews with these important stakeholders. In addition to the case study sites Alzheimer's Society's Research Network, a group of people with dementia, carers and former carers, will be involved in this work. The Network is experienced in reviewing, prioritising and monitoring research. Care will be taken to ensure that participants from the Network have had experience of the issues raised by this research to ensure their involvement is timely and relevant.

To ensure a stakeholder perspective across the programme of research, lay representatives will be involved on the Project Management Group and Local Management Groups. A member of the Alzheimer's Society Research Network will provide oversight for the full programme via the advisory group.

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