

Developing a nursing intervention, using the concept of Amalgamation of Marginal Gains, to improve fundamental nursing care for people living with dementia.

1. Background to the study:

Dementia:

Dementia is a syndrome, of many subtypes, where common effects can include cognitive and memory impairment, communication problems, changes to personality and loss of independence with daily activities (NICE, 2006). It impacts greatly on those who live with it and their relatives and carers and serves many challenges to healthcare professionals and the NHS (NICE, 2006; Alzheimer's Society, 2016). Along with the emotional and physical burden to individuals and their relatives and carers, there is also a large financial cost involved in the long-term care and support required (Department of Health, 2015).

It is estimated that twenty-five per cent of hospital inpatients and sixty-nine per cent of care home residents has a diagnosed dementia (Department of Health, 2015). In the year 2015-2016, in England alone, 427,000 people had a recorded diagnosed dementia although the estimated figure is thought to be much higher (Alzheimer's Society, 2016; Department of Health, 2015; Health and Social Care Information Centre, 2016). Dementia is a current, widespread and growing issue that justifies research being invested into it.

The James Lind Alliance has worked alongside the Alzheimer's Society to set out ten priorities for such research using input from those living with it, their relatives, carers and health care professionals (James Lind Alliance, 2013). These priorities included maintaining independence, putting research into practice, effective diagnosis, maintaining nutritional intake and best care in acute settings. Future research proposals should be guided by and designed to address these priorities.

Fundamentals of nursing care:

There are well publicised reasons why the fundamentals of nursing care is an area requiring further development and improvement. The publication of the Francis report in 2013, which investigated the widely publicised failings of care at the Mid-Staffordshire NHS trust, highlighted that one issue was the breakdown of these 'basics,' or fundamentals, of nursing care (Francis, 2013). Kitson et al. (2013) similarly argued that these basics appear to have been lost in modern healthcare and such failings have the potential to lead to further, and more extensive, poor practice and care.

Kitson et al. (2010) sought to define what these fundamentals of nursing care are. They identified 13 elements in their review of the literature, and the five most consistently acknowledged being hygiene, elimination, eating and drinking, mobility and communication. The Code for nursing behaviour and practice as set out by the Nursing and Midwifery Council (2015) sets out as its very first statement that the effective delivery of fundamental care is required of all nurses. It considers fundamental nursing care to include aiding needs associated with nutrition, hydration, elimination, mobility and ensuring this care is carried out in a hygienic environment. It states nurses must address these needs to provide individualised and dignified care (Nursing and Midwifery Council, 2015).

Failings in these elements of care have also been identified in the care of people living with dementia (Care Quality Commission, 2014). The Alzheimer's Society's campaign, Fix Dementia Care, described in their report on hospital care (Alzheimer's Society, 2016) stories where basic needs were not met. This has resulted in, amongst others, weight loss, incontinence, loss of communication and reduced mobility. They also stated that a poll they conducted found only 2% of those affected by dementia felt the needs of a patient with dementia were fully understood. This is an area of nursing care that requires more applied research to help professionals deliver high quality care to this growing population.

Amalgamation of Marginal Gains:

Amalgamation of Marginal Gains (AMG) is a term more widely recognised in the field of cycling. Sir David Brailsford used the term to describe the process he developed whilst coaching the British cycling team. He brought in a number of small changes to the training and care of the cyclists, and stated that the amalgamation of these small improvements helped to bring about the overall progression and winning success of the team (BBC, 2015).

There has been suggestion that this may be a valuable tool to use in healthcare settings, including in nursing care (Neirenberg et al., 2015; Richards, 2015). Some areas in healthcare have reported its use (NHS Improving Quality, 2013), but there has been no review into how widespread or effective it is in healthcare settings. Therefore there is an opportunity to explore AMG as a tool of implementing change in nursing care; in particular whether it could be utilised in an intervention where a number of small changes in nursing behaviours are made to deliver overall improved fundamental care to people living with dementia.

2. Hypothesis, aims and objectives:

The proposal for this PhD is to develop, and aim to test the feasibility and acceptability of, a nursing intervention targeting the improvement of fundamental nursing care delivery to people living with dementia. The intervention will be developed using the complex interventions framework developed by the Medical Research Council (2000) and since updated (Craig et al. 2008).

The work will link in with that currently be carried out by the ESSEnCE project team at the University of Exeter. They are investigating how the concept of the Amalgamation of Marginal Gains can be used to aid better delivery of fundamental nursing care. The main fundamentals of care the PhD proposes to focus on will be in line with the ESSEnCE project, who are focussing on the five most consistently acknowledged in the literature (Kitson et al. 2010);

- Hygiene
- Elimination
- Eating and drinking
- Mobility
- Communication

This PhD project will work within some of the James Lind Alliance (2013) dementia research priorities. It is expected it may address the priorities concerning;

- Maintaining independence

- Maintaining nutritional intake
- How to better put research findings into practice.

3. Proposed research methodology:

The plan for this PhD will follow a number of stages, as outlined below. These stages will follow the complex intervention framework (Medical Research Council, 2000; Craig et al, 2008).

STAGE ONE:

The proposed first step of the PhD will follow that of the Medical Research Council complex intervention framework of reviewing what is already known (Medical Research Council, 2000; Craig et al, 2008). Two systematic reviews will be undertaken; one looking at the Amalgamation of Marginal Gains, and the other looking at the literature investigating five main fundamentals of nursing care.

i) Systematic review on Amalgamation of Marginal Gains:

The first review will look at how effective the concept of AMG, or processes using the principles of it, is in delivering change in any healthcare setting. A protocol for the systematic review will be written as per the checklist and guidelines set out by Shamseer et al. (2015) in the PRISMA-P initiative. The protocol will clearly set out the PICOS question and the inclusion and exclusion criteria for the papers to be included.

A wide range of databases from healthcare, as well as ones from sport science, complementary health and grey literature, will be searched to ensure a good coverage of literature and to minimise publication bias. With the use of an independent second reviewer, the results from the searches will be checked against the inclusion and exclusion criteria, and it is hoped a number of papers that have used either used AMG, or the principles of it, will be included in the review.

Data extraction will then take place to establish the results from each study. Dependent on the quality and study design of the included papers, quantitative analysis may or may not be appropriate. If not, then a narrative analysis will be carried out.

ii) Systematic review on the fundamentals of nursing in dementia care:

The second review will ask questions of current literature concerning nursing interventions for fundamental nursing care for people living with dementia in all healthcare settings.

A subset of papers will be extracted from that of the ESSEnCE team, who are conducting separate systematic reviews into five main fundamentals of nursing care:

- Hygiene
- Elimination
- Eating and drinking,
- Communication
- Mobility

The papers making up the subset in this project will be fundamental care interventions involving individuals with dementia. The included papers will then undergo data extraction and analysis. The review will look at what components make up the interventions and how successful they are, as well as the barriers and facilitators in delivering them to this population. It is hoped that this will give a clearer idea as to what is preventing evidence based care being put into practice and what is leading to breakdown in care.

STAGE TWO:

The next step of intervention development will be to explore how acceptable an intervention in this area will be. There is the potential that qualitative interviews may be carried out, exploring barriers and facilitators in implementing change in this area. Interviews may include both individuals with dementia, their relatives as well as nursing staff who work with this population.

PPI:

There will be a Public and Patient Involvement (PPI) strategy developed for this project to ensure that the views of patients and relatives are included and to help gauge the acceptability of an intervention. PPI input would be especially valuable in this second stage of the project when designing the questions in the qualitative interviews, to help direct to topics of importance.

Any proposed intervention will be dependent of the acceptability and support from nursing staff to implement it. Therefore it is recognised that early input from service providers from nursing homes, for example managers and staff, will be vital in the development of the intervention.

Qualitative Methods:

The method by which the qualitative interviews are carried out may use a semi-structured interview approach (Kallio et al, 2016). This flexible approach asks a standard set of questions but allows follow-up questions to obtain further knowledge and views. Although this less consistent method could lead to the introduction of bias and difficulty in analysing responses, it would be a constructive method in this early investigative stage of the project. It gives the opportunity to explore views in depth and get a broader picture of the challenges of implementing an intervention may face (Mitchell and Jolley, 2001).

The questions asked will be guided by PPI and issues highlighted in the first stage of the project, however included questions may explore:

- What matters most to individuals receiving the care; is it the 'little things' that make the most difference in their experience of nursing care?
- What supports and what hinders the delivery of best practice in fundamental care?
- It could also give the opportunity to explore views on the role of who delivers the fundamentals of care; has it become the main responsibility of nursing assistants rather than registered nurses themselves?
- How feasible and acceptable would an intervention be to nurses in their area of work? What would be the barriers to this?

The content of the interviews will likely be analysed using a thematic analysis approach using NVivo, a qualitative analysis software programme (Rapley, 2016). Transcripts of the interviews will be examined and coded according to participant views of the questions. Similar codes are then brought together to create and define overall themes that have come out of the interviews. Coding will be checked independently by another reviewer to minimise bias in the interpretation of the transcripts. The meanings of these themes are then explored in relation to the research question and fundamental nursing care for people living with dementia (Crowe et al., 2015).

It is hoped that along with the findings from the systematic review, the interviews will aid in developing an intervention that is feasible and could realistically be used by nursing staff in aiding the delivery of good fundamental care to people living with dementia.

STAGE THREE:

The final stage of the PhD project will be to design and then test the feasibility and acceptability of the intervention. The intervention itself and the method in which it is tested will be clearer as the project progresses. However methods may include a case study, a before and after study or possibly a small randomised controlled trial.

The intervention is intended to be based in a nursing home setting. The proposed feasibility study will be looking to address the uncertainties of basing an intervention in this setting, as well as the acceptability and effectiveness of the intervention. For example the use of the intervention will be dependent on nursing staff in this setting to implement it. The study would look at how acceptable the use of the intervention will be to nursing staff and how differences between nursing home management and practices may affect the ability for comparison. It would also give insight into how achievable it will be to recruit participants to be involved in the testing of the intervention (Giangregorio and Thabane, 2015).

ETHICAL CONSIDERATIONS:

Research involving a vulnerable population such as those living with dementia raises a number of ethical questions. Common symptoms of dementia, such as memory difficulties, can make it challenging to obtain informed consent of possible study participants (Office of the Public Guardian, 2007; Higgins, 2013). However, it is equally important that these challenges do not lead to this population having their opportunity to partake in research taken away. Their right to be included in research needs to be maintained (Medical Research Council, 2007). It will be ensured that any research involving individuals living with dementia will provide beneficial knowledge of dementia care that outweigh any risks to the participants, will be terminated if the individual does not wish to be further involved and will involve the relative or carer of the participant if they are unable to give informed consent (Office of the Public Guardian, 2007). Any research carried out will be in line with European and UK legislation and laws (Medical Research Council, 2007).

Process Consent is one method which may be utilised in ensuring an ethically planned study is achieved (Dewing, 2007; Higgins, 2013). This five stage method looks to create research that is centred towards the individual participant and takes into account that consent can fluctuate and may change during the course of the study (Dewing, 2007). Contact with individuals living with dementia is sought through permission of their relative or carer and information about the individual sought so it is easier to judge when they are comfortable with their surroundings. Consent is sought using appropriate information materials for the person with dementia and this process is repeated throughout the study to ensure the participant is still happy to be involved (Dewing, 2007; Higgins, 2013). This method may allow greater opportunity for individuals to participate in the research.

There are a number of ethical considerations that will need to be addressed before the second and third stages of the project. Ethical approval will be sought from the ethics

committee at the University of Exeter for the qualitative interviews and the feasibility study. Any further approval that may be required will also be sought; for example, if applicable, NHS ethical approval.

4. Relevance and significance:

An aging population and increasing numbers of people living with dementia requiring nursing care, make this a very relevant area of research. Over the course of the next three years this project aims to:

- Develop a nursing intervention, and test its feasibility and acceptability, using the Medical Research Council complex intervention framework (Craig et al. 2008).
- Use the concept of Amalgamation of Marginal Gains in the intervention as a method for driving better standards of fundamental nursing care for people living with dementia.
- Work in line with the priorities for dementia research as set out by the James Lind Alliance (2013).

This project will give opportunity for publication in peer reviewed journals as well as presentations at conferences. It will aim to give more insight as to how improved, evidence based nursing care can be better implemented into practice for people living with dementia and whether AMG is an acceptable and feasible method by which to do this.

5. Personal and professional development:

Throughout the course of this proposed project there will also be many professional development opportunities for career development in healthcare research. These will include:

- Development and experience of a variety of research skills. This will be aided by attending workshops and courses held by the Researcher Development Programme.
- Training and experience in a variety of research methodologies. For example attending modules within the MSc Applied Health Services Research programme and utilising a number of methods within the project.
- Experience in critical appraisal skills through attending NIHR workshops and through the systematic review process.
- Experience in academic writing and the project giving opportunity for publications in peer review journals.
- Experience in attending and presenting at conferences.
- Development of networking skills and presentation skills. For example attendance of the summer school and meetings held by the Research Capacity in Dementia Care Programme (RCDCP) between the different NIHR CLAHRCs.
- Experience of the ethical considerations of healthcare research and applying for approval for such work in the second and third stages of the project.

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