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Optimal care for the management of older people with frailty non-weight bearing after lower limb fracture: a consensus study protocol

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East Midlands Research into Ageing Network (EMRAN) is a research collaboration across the East Midlands to facilitate collaborative applied clinical research into ageing and the care of older people. EMRAN was set up by NIHR CLAHRC East Midlands and is supported by the NIHR Clinical Research Network.

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ABSTRACT

Introduction

Older people who are non-weight-bearing after a low velocity, lower limb fracture are usually frail with multi-morbidity and are at risk of poor outcomes such as failing to return to pre-morbid function. Our aim is to produce a guideline for the optimal management of this group of patients. We will base this guideline upon the findings of our scoping review of the literature and, as described in this paper, a consensus exercise to take account of those elements of management that do not have a strong research evidence base.

Method

A three-round e-Delphi technique will be conducted using the online JISC survey tool with multidisciplinary health professionals, patients and patients' representatives with a minimum of (n>10 per stakeholder group), with consensus requiring >/= 70% agreement with clinical management statements.

Discussion

A consensus exercise is needed given the lack of research evidence to guide the overall clinical management of these patients. Delphi techniques have the advantage over informal opinion seeking processes because they are systematic and can take account of multiple opinions. The involvement of patients and public in this proposed study will help ensure that the research outcomes are both relevant and patient-focussed. To reduce bias, it is necessary to ensure adequate participation of all relevant stakeholders with knowledge and expertise, and for their biases and conflicts to be acknowledged. To ensure comprehensiveness of the output of this exercise, we conducted a prior scoping review. The level of consensus chosen is arbitrary although in line with other studies, but unlike many other studies, we have justified our sample size on statistical grounds, aiming to be 95% confident that a consensus statement is a majority view.

Key words

Lower limb fractures, non-weight bearing, Delphi process, elderly.

INTRODUCTION

Many people with lower limb fractures are advised not to bear weight for 6-12 weeks on their affected limbs until they heal [1]. These people will usually have fallen and be frail and have multi-morbidity before their fracture, and the period of immobility consequent to being non-weight-bearing (NWB) can lead to further deterioration. This group of patients has not been well studied and no clear, comprehensive guideline for their care exists. Without such a guideline, it is difficult to assure high quality care for these patients and, without being able to demonstrate high quality care, it is difficult to conduct research into novel interventions to improve their outcomes. We aim to produce such a guideline. To do this we will draw upon the findings of our scoping review and conduct a consensus exercise to determine what practitioners and patients believe to be optimal or best practice care.

METHOD

Design

A modified Delphi technique will be used [2]. The Delphi technique was selected because it is suitable for the nature of this proposed study where there is little in the literature about the optimal care for these patients yet considerable amount of professional and patient-held tacit knowledge from experience.

Duration of the study

Data collection will be completed between August and December 2020.

Sampling

A purposive sampling strategy will be developed to recruit participants for our panel who have clinical experience of the management of this patient group.

Selection of the panel

Inclusion criteria

Medical and health care professionals eligible to participate in the panel will be those who have extensive experience of managing elderly patients who are non-weight bearing after a lower limb fracture

- Geriatric medicine consultants
- Orthopaedic medicine consultants
- Registered nurses
- Clinical specialist physiotherapists
- Clinical specialist occupational therapists
- Clinical dieticians
- Pharmacists

Patients eligible to participate are those older people who have had personal experience of being non-weight bearing after lower limb fracture. Our patient and public involvement group for research in older people and dementia will also be invited.

Sample size

To ensure that a statement with agreement of 70% in our sample will have a 95% probability of reflecting a majority (>50%) in the wider population of potential informants, a sample size of 80 participants is required in round three. We expect attrition risk among panel members, despite measures used in previous studies to minimise it [3], due to the length duration of the study. We aim to recruit 210 participants (30 from each of the seven clinical disciplines plus patients/PPI).

Recruitment process of the panel

Relevant organisations and special interest groups will be sought and asked if they will send a letter of invitation to this study, by email, to people in their membership lists:

- Older patients will be approached through existing database and online support within organisation such as: NIHR INVOLVE (https://www.invo.org.uk/), International PPI network (https://www.theppinetwork.com), Primary Research Network (https://www.nihr.ac.uk) and UK Ageing (https://www.ageuk.org.uk).

- PPI participants will be approached through NIHR INVOLVE network (https://www.invo.org.uk/).
- Geriatric medicine consultants will be approached through the British Geriatrics Society (https://www.bgs.org.uk), the Falls and Bone Health Special Interest Group (https://www.bgs.org.uk/falls-and-bone-health), European Geriatrics Community (https://www.eugms.org) and the European Falls and Fractures Special Interest Group (https://www.eugms.org/research-cooperation/special-interest-groups/falls-and-fractures.html).
- Orthopaedic medicine consultants will be approached through the Royal College of Surgeons (https://www.rcseng.ac.uk), Orthopaedic Surgeon Special Interest Group (https://www.abhi.org.uk/who-we-are/member-groups/special-interest-sections/orthopaedics/), Fragility Fracture Network (https://www.fragilityfracturenetwork.org) and The Orthopaedic Trauma Society (https://www.orthopaedictrauma.org.uk).
- Registered nurses will be approached through Royal College of Nursing https: (https://www.rcn.org.uk/), British Nurses' Association (https://www.bna.co.uk), Society of Trauma Nurses (https://www.traumanurses.org) and The Society of Trauma Nurses - Europe (https://www.traumanurses.org/about/stn-europe).
- Clinical specialist physiotherapists will be approached through the Chartered Society of Physiotherapy(https://www.csp.org.uk) and special interest groups such as Association of Chartered Physiotherapists in Orthopaedic Medicine and Injection Therapy (https://acpomit.csp.org.uk), Chartered Physiotherapists Working with Older People and Association of Trauma (https://agile.csp.org.uk), Orthopaedic-Chartered Physiotherapists (https://atocp.csp.org.uk) and the European Region of the World Confederation for Physiotherapy(https://www.erwcpt.eu).
- Clinical specialist occupational therapists will be approach through Royal College of Occupational Therapy(https://www.rcot.co.uk) and special interest groups such as the Occupational Therapy for elderly group (https://www.rcot.co.uk/about-us/specialist-sections/older-people-rcot-ss), Trauma and Musculoskeletal Health work group (https://www.rcot.co.uk/about-us/specialist-sections/trauma-and-musculoskeletal-rcot-ss/clinical-forums) and Council of Occupational Therapists Association for the European Countries (https://www.coteceurope.eu).
- Clinical dieticians will be approached through the British Dietetic Association (https://www.bda.uk.com), The Academy of Nutrition and Dietetics

(https://www.eatright.org) and The European Federation of the Associations of Dietitians (http://www.efad.org/en-us/about-efad/).

- Pharmacist will be approached through The General Pharmaceutical Council (https://www.pharmacyregulation.org), The United Kingdom Clinical Pharmacy Association (https://www.ukclinicalpharmacy.org), the European Association of Hospital Pharmacists (https://www.eahp.eu), the Pharmaceutical Group of European Union (https://www.pcne.org).

The letter of invitation will direct interested potential participants to the study website. The study website will provide participant information, the opportunity to consent to participate on line, and the ability to request further information from the study team. The study information will state that participation in all three rounds is expected, that only the names of medical and health professionals who participate in all three rounds will be listed in the final publication, and that their contact details will be held securely and used solely for this study. For those wishing to participate, the consenting process will require a declaration of suitable experience and a lack of significant financial conflict of interests. For patient participants, as advised by our PPI representatives, we will not publish their names - the reason being that revealing their names gives personal information about them and therefore compromises confidentiality.

Survey development

The study will be completed using the Jisc (formerly Bristol) online survey tool (https://www.onlinesurveys.ac.uk/). A paper copy will be made available on request to individuals who do not have access to sufficient equipment to complete the survey online.

Statement development

The study authors will generate the initial statements for this study, based upon the findings of the scoping review and their clinical experience. Statements will describe aspects of management, generated under each of the following headings, aiming to be comprehensive:

- Orthopaedic surgery
- Geriatric medicine

- Nursing & care
- Physiotherapy
- Occupational therapy
- Dietetics
- Pharmacist
- Patients
- Family / social network
- Teamwork

The statements will be entered into the Jisc platform and piloted with a convenience sample covering the range of the study target groups.

Design of Delphi rounds

A three round modified Delphi technique will be used to establish consensus.

Prior to the first round, brief descriptive demographic details of the participants will be collected.

In each round, panel will be asked to rate their agreement with each standard statement by marking 'agree' or 'disagree'. A box for free text comments will be provided for respondents to suggest amendments or clarifications.

The level of consensus will be set at 70%. Any statements that reach consensus, either for agreement or disagreement will be removed from subsequent rounds. Each participant will be asked to select either 'agree' or 'disagree' or "neither agree nor disagree" responses to each statement. Those opting for the latter will be asked to use the text box to explain this response and if any change of wording would allow them to choose one of the former two options. Statements without consensus will be modified in the light of participants' comments and included into the second and or third round.

Data analysis

The Jisc survey analysis tool will be employed and descriptive statistical analysis will be completed using SPSS/ Microsoft Excel. Non-response and response rates over the

ongoing iterations will be analysed and reported. Statements where there is and is not consensus as defined will be reported.

Data management

Data management plan will be in line with the Nottingham University research data management policy (https://uniofnottm.sharepoint.com/sites/DMPCollection).

Ethical Approval

Completion of the online survey by the panel will imply consent to participate. The protocol was approved by the University of Nottingham Faculty of Medicine and Health Sciences Research Ethics Committee [423-1911].

DISCUSSION

A consensus exercise is justified because of the lack of research evidence to guide the overall clinical management of these patients. Delphi techniques have the advantage over informal opinion seeking processes because they are systematic and can take account of multiple opinions. One of the strength of this study lies in the involvement of patients and public in the research process. They will be involved at two levels, as part of study research team involving in research design, data collection, data analysis and dissemination of the research outcomes and will be involved as participants in the study.

To obtain a generalizable result, it is necessary to ensure adequate participation of all relevant stakeholders with knowledge and expertise. We believe that recruitment via national and international bodies of interested professionals is most likely to do this. To reduce bias, their conflicts of interest also need to be acknowledged, which is why we have asked for these. To ensure that our sample size is sufficient at least to ensure that our consensus statements command at least a majority in the wider population from which the sample is drawn, we have used a statistical calculation. We note that this provides a sample size larger than many consensus exercises, which implies that the findings of many previous consensus studies may be unreliable.

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