Developing a multidisciplinary rehabilitation package following hip fracture and testing in a randomised feasibility study: Fracture in the Elderly Multidisciplinary Rehabilitation (FEMuR)

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Scientific summary

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Scientific summary

Background

Proximal femoral fracture, commonly known as hip fracture, is a common major health problem in old age. It is strongly associated with decreased bone mineral density, increased age, prior fragility fracture, cognitive impairment, other health problems, undernutrition, frailty, poor physical functioning, vision problems and weight loss. Mortality is high, with 25% of patients dying within the following 12 months. A review of the long-term disability associated with proximal femoral fracture found that 29% did not regain their level of functioning after 1 year in terms of restrictions in activities of daily living (ADL). Many who were living independently before their fracture lose their independence afterwards and so a large cost burden on society is imposed, amounting to about £2.3B per year in the UK.

The National Institute for Health and Care Excellence has issued guidelines for the management of hip fracture. As well as prompt surgical treatment and the management of associated medical needs, the guidelines recommend a programme of multidisciplinary rehabilitation. Such rehabilitation starts while in hospital during post-operative recovery, continues in the community following hospital discharge and has the potential to maximise recovery, enhance quality of life and maintain independence. Although individual components of such programmes show promise, there is insufficient evidence of overall clinical effectiveness or cost-effectiveness.

Objectives

Phase I: developing the intervention

1. To undertake a realist review to identify the important components of a multidisciplinary rehabilitation programme following surgical treatment for hip fracture in older people and to understand the mechanism, context and outcome of successful interventions.
2. To assess the current provision of rehabilitation programmes following hip fracture surgery in the NHS throughout the UK.
3. To assess the views of patients, their carers and health professionals in multidisciplinary rehabilitation teams on the rehabilitation that they received or provided following surgical repair of a proximal hip fracture; how the programmes could be improved; and the findings from the realist review and survey.
4. To design a rehabilitation programme based on the findings from the realist review, survey and focus groups.

Phase II: feasibility study

1. To assess the feasibility of a future definitive randomised controlled trial (RCT) by assessing the number of eligible patients, monitoring recruitment and retention rates and exploring the willingness of patients to be randomised and the willingness of patients and carers to complete process and outcome measures.
2. To produce means and standard deviations of the quantitative measures so that effect sizes can be calculated for planning the future RCT.
3. To assess the acceptability of, and compliance with, the rehabilitation programme among patients, carers and clinicians and the fidelity of its delivery, and to identify any adverse events.
4. To explore the methodological issues associated with conducting an economic evaluation alongside a future RCT and to conduct an exploratory economic analysis.

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Methods

Phase I

The development of the community-based rehabilitation package was informed by three complementary work packages.

Realist review

A realist review of the rehabilitation literature was performed to determine the mechanisms behind multidisciplinary rehabilitation and to establish which components were effective for specific patient groups and in which circumstances.

Survey

A survey was carried out of a sample of physiotherapists, occupational therapists and hip fracture centre therapy service managers from throughout the UK to determine current rehabilitation practice.

Focus groups

Three focus groups were carried out with members of multidisciplinary teams and three focus groups were carried out with hip fracture patients and their carers. These involved semistructured discussions regarding their experiences, perceptions and beliefs about rehabilitation following hip fracture. The discussions were digitally recorded, fully transcribed and thematically analysed using the framework approach.

Phase II

Randomised feasibility study

Design

This pragmatic randomised feasibility study and concurrent economic evaluation had two parallel arms – an intervention group and a control group that received usual rehabilitation care. Assessments, blind to treatment allocation, were carried out at baseline and after 3 months. Randomisation was by a dynamic allocation method stratifying for hospital and gender.

Participants

Participants, aged $\geq$ 65 years, were recruited from the orthopaedic wards of all three acute hospitals in the Betsi Cadwaladr University Health Board (BCUHB), North Wales, while recovering from surgical treatment for proximal femoral fracture. They had been living in their own home prior to hip fracture rather than in a nursing or residential home and had the capacity to give informed consent. We also recruited their carers.

Interventions

Usual care consisted of multidisciplinary rehabilitation delivered by the acute hospital, community hospital and community services depending on need and availability. The intervention consisted of a patient-held information workbook and goal-setting diary and six additional therapy sessions available to patients once they returned home. It was designed to enhance usual rehabilitation by improving patients' self-efficacy and increasing the amount and quality of patients' practice of physical exercise and ADL.

Outcome measures

The primary outcome measure was the Barthel Activities of Daily Living (BADL) index. The secondary outcome measures included the Abbreviated Mental Test Score, Nottingham Extended Activities of Daily Living (NEADL) scale, Hospital Anxiety and Depression Scale (HADS), visual analogue scale for hip pain intensity, General Self-Efficacy Scale, Falls Efficacy Scale – International (FES-I), Self-Efficacy for Exercise scale, visual analogue scale for fear of falling, EuroQol-5 Dimensions (EQ-5D), ICEpop CAPability measure for Older people (ICECAP-O) and Client Service Receipt Inventory. Physical function was assessed at baseline using the grip strength test; at 3 months, in addition to the grip strength test, physical function was assessed using the 30-second sit-to-stand test, 8-foot up-and-go test (also known as the Timed Up and Go test) and 50-foot walk test. Carers completed the Caregiver Strain Index.

Focus groups

Two focus groups were carried out with members of the multidisciplinary rehabilitation teams, two with patients and carers in the intervention arm and two with patients and carers in the control arm. The acceptability and feasibility of the different components of the new intervention, including its delivery and being in a randomised study, were assessed.

Cohort study

An anonymous cohort of all proximal femoral fracture patients admitted to the three acute hospitals in BCUHB over a 6-month period was followed up for 3 months. The following data were collected: the number admitted with proximal femoral fracture, the number who fulfilled the inclusion criteria for the feasibility study and the number of deaths, serious complications and readmissions.

Results

Phase I

Realist review

There were three programme theories described in terms of context, mechanism and outcome (CMO).

Improve patient engagement by tailoring the intervention according to individual needs and preferences

Elderly proximal hip fracture patients presenting with a range of pre-fracture physical and mental functioning and a variety of comorbidities (C) need a rehabilitation programme that is tailored to individual needs (M) to achieve appropriate outcomes such as improved physical functioning, greater mobility, reduced disability and independent living (O).

This tailoring involved:

- detailed assessment of patients' pre-fracture level of functioning, current cognitive status and other comorbid conditions
- collaborative decision-making through discussion and agreement with patients, family members and carers regarding the provision of enhanced support through active engagement of carers and rehabilitation professionals.

Reducing fear of falling and improving self-efficacy to exercise and perform activities of daily living

Proximal hip fracture results in poor physical functioning, fear of falling, low mood and lack of self-efficacy (C), requiring improved quality and increased amount of practice of physical exercises, ADL and psychological tasks (M) to gain mastery and control to improve confidence, mobility and physical functioning (O).

Enhancing the practice and quality of exercises and ADL has both physical and psychological components.

- The provision of coaching by health professionals to enhance the practice of skills and mastery to improve confidence for the transition to independent and unsupervised practice.
- The provision of supervision by physiotherapists or occupational therapists to increase the duration and frequency, and improve the quality and quantity, of exercises such as strength, balance, reverse and gait training and ADL.
- Adaptation of the physical environment for the safe practice of exercises and ADL.
- Addressing psychological concerns and needs to improve mood and reduce depression.
- Improving motivation to practise the exercises and ADL.

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Co-ordination of services and sectors delivering the rehabilitation

The diversity of services provided by different disciplines across sectors from a variety of funders (C) requires co-ordinated provision of the multidisciplinary rehabilitation programme (M) in order to deliver appropriate physical, functional and psychological interventions to patients in a timely manner (O).

This requires:

- multidisciplinary co-ordination of care, from the acute hospital into the community
- improved communication between rehabilitation professionals
- careful discharge planning.

Survey

The survey found that routine clinical practice was broadly in line with current guidance but that there was variability in the provision of services, especially in the community, and psychological mediators such as self-efficacy and fear of falling were not routinely assessed using validated tools. Good aspects of rehabilitation services included commonality of treatment goals, multidisciplinary team working and being responsive and flexible to tailor treatment to individual need. Areas for improvement included better liaison between acute hospitals and community services, access to rehabilitation beds and increased therapy and nursing resources.

Focus groups

Four themes emerged:

1. *Variation in rehabilitation care provided*. This occurred because of individual tailoring of treatment, geographical variation in resource availability, the variety of providers delivering programmes and lack of awareness by referring clinicians.
2. *The need for more information*. The complexity in programme provision meant that there was a strong need for more information for patients and their carers.
3. *Facilitators of and barriers to rehabilitation*. These included the reliance on patients' self-motivation to seek out and access services, their level of engagement in the rehabilitation programme, access to transport and good co-ordination between the different components of the programme.
4. *The psychosocial impact of hip fracture.* Falling and fracturing had an impact on fear of falling and independence.

Rehabilitation intervention

An intervention was developed to enhance usual rehabilitation by improving patients' self-efficacy and increasing the amount and quality of patients' practice of physical exercise and ADLs to improve functional outcomes. The intervention consisted of a patient-held information workbook, a goal-setting diary and additional therapy sessions available to patients once they had returned home.

Phase II

Feasibility study

Between June 2014 and March 2015 593 patients with proximal femoral fracture were screened for eligibility, of whom 266 (45%) were eligible. The main reason for ineligibility was lack of mental capacity (49%). Of those who were eligible, 193 (73%) were invited to participate and 62 (23% of the eligible population) agreed to participate. The main reason for non-participation was the perceived burden of the study. From the recruited participants, 41 carers were identified, with 31 agreeing to participate (76%).

The two trial groups (intervention and control) were similar with regard to age, gender, living status, type of property, type of fracture, type of surgery and admitting hospital. The baseline scores for the outcome measures and physical function tests were similar between the two groups; however, the NEADL scale score was 2.4 points higher in the control group.

There were nine withdrawals, one before baseline and eight during the intervention (four from each group). Four patients could not be contacted at follow-up, resulting in a patient retention rate of 79% overall (intervention group 86%; control group 75%). Six of the carers withdrew during the study, seven were lost to follow-up and only 18 completed the follow-up questionnaire, giving a carer retention rate of 58%.

At 3-month follow-up there were minimal differences between the two groups for most of the outcome measures, including the main outcome measure, the BADL index, with an adjusted mean difference of 0.5 (Cohen's $d = 0.29$), but there was a trend towards a greater improvement in the intervention group, but with small effect sizes. However, the NEADL scale showed a medium effect size, also in favour of the intervention group, with an adjusted mean difference of 15.8 (Cohen's $d = 0.63$). On the other hand, in the physical function tests the 50-foot walk test was completed in a shorter time in the control group, with a medium effect size, with an adjusted mean difference of 12.2 second (Cohen's $d = 0.40$). This might be explained by the control group completing these physical function tests 3 weeks later than the intervention group.

The economic evaluation used a cost–consequences analysis. The cost of delivering the intervention was £231 per patient. Both the intervention group and the control group showed improvements in EQ-5D health utility index scores and ICECAP-O capability index scores from baseline to 3-month follow-up. The differences between groups were not statistically significant, but this small feasibility study was not powered to test such differences. The intervention group had slightly higher mean quality-adjusted life-year gains than the control group, which was also not statistically significant. The difference in QALY was 0.02 (95% CI –0.02 to 0.06). There was, however, a statistically significant difference in hospital costs between the groups because of longer inpatient stays in one group. The mean total service use costs were £43,999 higher in the intervention group (95% CI £4027 to £88,818). The discrete choice experiment found that two attributes were important to participants: participants preferred more time with health professionals and preferred unqualified therapy assistants to qualified therapists. Scoping the potential to conduct social return on investment analysis identified that outcome measures were well completed in the trial. Potential payer stakeholders included the patient and publicly funded health and social care services.

Cohort study

In total, 400 proximal femoral fracture patients were recruited to the anonymised cohort study. They were similar to those in the feasibility study with regard to gender, type of hip fracture and surgery. However, the cohort population was slightly older (mean age difference 4.5 years) and patients were more likely to be readmitted to hospital and more likely to die.

Focus groups

The key finding from the focus groups was that, in the context of variable usual rehabilitation care, the role of the therapist is extremely important in managing patients' needs and expectations. This was especially so at the beginning of rehabilitation, for giving permission about what physical activity was safe to do. Regular home visits allowed a relationship to build between patient and rehabilitation therapist, which was important for patient engagement. Patients valued the use of tailored care and personal goal setting as a motivational tool. These activities were well supported by the workbook and the goal-setting diary.

Conclusions

Recommendations for research

1. The trial methods for a full definitive RCT and economic evaluation were satisfactory. In particular, there were suitable rates of eligibility, recruitment, retention and outcome measure completion.
2. The sample size for a future RCT is 322 participants.

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3. The most suitable outcome measures for a definitive RCT are the NEADL scale as the primary effectiveness outcome, the EQ-5D as the primary health economic outcome and the Falls Efficacy Scale – International for measuring self-efficacy.
4. Health service use data should be obtained from both the patient-completed Client Service Receipt Inventory and routinely collected data in electronic records.

Trial registration

This trial is registered as ISRCTN22464643.

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