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*DOI 10.3310/MDTT6530*

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Extended Research Article

# Enhanced recovery pathway for older people with hip fracture and cognitive impairment in acute hospitals: the PERFECTED research programme including an RCT

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## This article

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# Abstract

**Background:** Hip fracture has a substantial impact on the health, well-being and independence of patients and their families. In the 12 months after fracture, patients *are* at increased risk of cognitive and functional decline, admission to long-term care institutions and higher mortality. People with cognitive impairment are among the most vulnerable in acute hospital settings. They have lower short-term survival, with 24% mortality during admission. They are susceptible to suboptimal and inconsistent care standards that contribute to cognitive deterioration, increase risk of postoperative complications, prolong their length of stay and cause loss of independence.

**Objectives:**

1. Establish best-practice from a systematic review of literature, observations of practice, perspectives of service users, carers, healthcare professionals, health service managers and experts in the field.
2. Design the care pathway.
3. Determine cultural/organisational changes necessary to implement and maximise adherence to the enhanced recovery pathway in hospital settings. Develop staff training and a training manual.
4. Undertake a feasibility randomised controlled trial and collect outcomes to identify potential clinical and cost-effectiveness of the enhanced recovery pathway.
5. Disseminate the findings and develop a definitive trial bid.

**Design:** A programme to develop an enhanced recovery pathway for people with hip fracture and cognitive impairment, tested for implementation and refined in the clinical environment. This refined enhanced recovery pathway was then tested in a feasibility study in 10 hospitals across the UK.

**Setting:** Acute care.

**Participants:** Hospital staff, people with cognitive impairment and hip fracture, carers and national and international experts in hip fracture or dementia.

**Interventions:** An enhanced recovery care pathway with checklist and an implementation process.

**Main outcome measures:** Mortality, patient and carer quality of life, cognition, activities of daily living.

**Data sources:** Clinical trial.

**Results:** A total of 284 participants were recruited, 132 to the PEFECT-ER intervention arm and 150 to the control arm, had good retention in the study and provided data for analysis. There was no evidence of any systematic between group difference at either the point of discharge from hospital or at 1-month follow-up. However, at 3 months, a relatively small effect of around one quarter of a standard deviation (0.071 units), was evidenced with respect to the health-related quality of life of the patient based on the EuroQol-5 Dimensions, five-level version by proxy in the intervention group (95% confidence interval 0.018 to 0.124; $p = 0.009$). A difference of 0.099 units in favour of the intervention group was also seen at the 6-month follow-up (95% confidence interval 0.001 to 0.198; $p = 0.047$). 'Timed Up and Go' and the Suitable Informant EuroQol-5 Dimensions, five-level version showed a no statistically significant difference except the model for length of stay. Those individuals in the intervention group had significantly longer lengths of stay, on average 1.22 times longer (95% confidence interval 1.02 to 1.45; $p = 0.028$). Mortality was similar in both groups, with a 6.1% mortality rate by 30 days post surgery.

The process evaluation found that patients and carers were unable to comment on receiving the intervention.

**Limitations:** This was a feasibility study and was not designed as a definitive evaluation of the intervention.

Lack of direct access to patient notes meant that researchers were unable to verify the Perioperative Enhanced Recovery hip FracturE Care of paTiEnts with Dementia-Enhanced Recovery check listing results. The relationship between changes in documentation of practices and changes in care practices is also unclear. Patient and suitable informants did not assist understandings of implementation, mechanisms of action or experiences of interacting with the intervention.

Client Services Receipt Inventory data collection burden was an issue.

**Conclusions:** The Perioperative Enhanced Recovery hip FracturE Care of paTiEnts with Dementia-Enhanced Recovery feasibility trial demonstrated mean recruitment of 1.87 participant per centre per month. Retention at 1 month was over 80% and at 6 months approximately 50%. This information is useful for those wishing to design a definitive clinical trial. Although 30-day mortality was the same in both groups, the potential for reduction, by Perioperative Enhanced Recovery hip FracturE Care of paTiEnts with Dementia-Enhanced Recovery being implemented, exists from cumulatively increased good practices across a range of care domains. To compare longer-term survival of patients who received the intervention, we would recommend measuring 3-month (110-day) mortality in addition to 30-day mortality. These data are readily available from National Hip Fracture Database and are thus ideal for efficient trial design. Client Services Receipt Inventory can be reduced for a definitive trial, removing equipment questions and some community health use questions. Qualitative interviews with Perioperative Enhanced Recovery hip FracturE Care of paTiEnts with Dementia-Enhanced Recovery trial patient and carer should not take place.

**Future work:** Work to date shows that the intervention pathway for Perioperative Enhanced Recovery hip FracturE Care of paTiEnts with Dementia-Enhanced Recovery required considerable input from champions for delivery. We are exploring further funding options to facilitate work to understand these mechanisms and further test, pilot and produce the Perioperative Enhanced Recovery hip FracturE Care of paTiEnts with Dementia-Enhanced Recovery manual.

**Trial registration:** This trial is registered as Current Controlled Trials ISRCTN99336264.

**Funding:** This award was funded by the National Institute for Health and Care Research (NIHR) Programme Grants for Applied Research Programme (NIHR award ref: DTC-RP-PG-0311-12004) and is published in full in *Programme Grants for Applied Research*; Vol. 13, No. 1. See the NIHR Funding and Awards website for further award information.

# Contents

# List of tables

# List of figures

# List of supplementary material

**Report Supplementary Material 1** Study data

Supplementary material can be found on the NIHR Journals Library report page (https://doi.org/10.3310/MDTT6530).

Supplementary material has been provided by the authors to support the report and any files provided at submission will have been seen by peer reviewers but not extensively reviewed. Any supplementary material provided at a later stage in the process may not have been peer reviewed.

# List of abbreviations

| | |
|---|---|
| BADLS | Bristol Activities of Daily Living Scale |
| CI | cognitive impairment |
| CSRI | Client Services Receipt Inventory |
| DeNDRoN | Dementias and Neurodegeneration Diseases Research Network |
| DMEC | data monitoring ethics committee |
| ED | emergency department |
| EQ-5D-5L | EuroQol-5 Dimensions, five-level version |
| ERAS | enhanced recovery after surgery |
| FOI | freedom of information |
| GCP | good clinical practice |
| GP | general practitioner |
| HRE | hospital records extraction |
| HRQoL | health-related quality of life |
| NHFD | National Hip Fracture Database |
| NIHR | National Institute for Health Research |
| PAG | programme advisory group |
| PDSA | plan, do, study, act |
| PERFECTED | Perioperative-Enhanced Recovery hip FracturE Care of paTiEnts with Dementia |
| PERFECT-ER | PERFECTED- Enhanced Recovery |
| PLICS | patient-level information and costing system |
| PMG | programme management group |
| PPI | patient and public involvement |
| PPL | PERFECTED process lead |
| PSC | programme steering committee |
| QALY | quality-adjusted life-year |
| RCT | randomised controlled trial |
| SIL | service improvement lead |
| SIR | suitable informant-reported |
| WP | work package |

# Plain language summary

## What was the problem?

Hip fracture and thought/memory ('cognitive') impairments, such as dementia and delirium, are major challenges for older patients, their families/carers and the National Health Service and social care. The outcomes of medical treatment for elderly patients with hip fracture are often poor, and worse when patients have memory and thinking problems. There is little research on how best to look after this patient group in hospital. Our previous work shows that patients, families, carers and staff repeatedly seek more sensitive ways to look after this patient group. Staff have also highlighted the need for training to help them work more appropriately to meet these patients' needs.

## What did we do?

We have created, adapted and piloted a set of care actions called Perioperative Enhanced Recovery hip FracturE Care of paTiEnts with Dementia-Enhanced Recovery. Perioperative Enhanced Recovery hip FracturE Care of paTiEnts with Dementia-Enhanced Recovery comprises a best practice checklist, a staff training manual, staff time to put the checklist into practice and to train colleagues, and a process to improve care of this patient group continuously. We tested Perioperative Enhanced Recovery hip FracturE Care of paTiEnts with Dementia-Enhanced Recovery in five hospitals and asked whether staff found it acceptable. We wanted to find out if Perioperative Enhanced Recovery hip FracturE Care of paTiEnts with Dementia-Enhanced Recovery could be used in a bigger trial, testing whether Perioperative Enhanced Recovery hip FracturE Care of paTiEnts with Dementia-Enhanced Recovery improved outcomes for older people with hip fracture and memory problems.

## What did we find?

We found that Perioperative Enhanced Recovery hip FracturE Care of paTiEnts with Dementia-Enhanced Recovery was practical to use, both in the trial and by ward staff. Some measures we planned to use to calculate its costs were not completed by enough people to analyse in the study, suggesting that a future trial should have different measures. We found that measuring the number of people dying and people's quality of life should be considered for the trial.

## What does this mean?

Our evidence suggests that Perioperative Enhanced Recovery hip FracturE Care of paTiEnts with Dementia-Enhanced Recovery can be used in hospitals and was acceptable to staff. There remains a need for a larger evaluation to investigate whether Perioperative Enhanced Recovery hip FracturE Care of paTiEnts with Dementia-Enhanced Recovery provides benefit for this patient group.

# Scientific summary



## Background

This programme of research aimed to develop a best practice care pathway for people with dementia and hip fracture in hospital using the enhanced recovery framework. As the programme progressed, the intervention was adjusted to include all people with cognitive impairment (CI) as we learnt about implementation in practice.

## Objectives

What is the best care practice for people in hospital with dementia who fracture their hip? [work package (WP) 1 phases 1–4]

Can an optimised care pathway Perioperative Enhanced Recovery hip FracturE Care of paTiEnts with Dementia-Enhanced Recovery (PERFECT-ER) be developed for people in hospital with dementia who fracture their hip? (WP1 phase 5)

What are the staff training and cultural/organisational changes required to implement and maximise adherence to the optimised care pathway-enhanced recovery pathway (PERFECT-ER) in hospital settings? (WP2)

What are the components of a training manual for the enhanced recovery pathway (PERFECT-ER) promoting cultural and organisational changes and maximising adherence? (WP2)

What is the feasibility of undertaking a randomised clinical trial (RCT) to assess the clinical and cost-effectiveness of the enhanced recovery pathway (PERFECT-ER) to inform a definitive RCT? (WP3)

## Methods

### *Work package 1: evidence for best practice*

This WP generated evidence for best practice from peer-reviewed and grey literature including access to national and international initiatives. We undertook a Cochrane review (CRD42012002047; WP1, phase 1a and b). We collected front-line national and international healthcare professional perspectives on best practice, current practice and explanations for implementation gaps between 'best' and 'current' practice (WP1, phase 2). We undertook observations of care of delivery (WP1, phase 3) to understand 'usual care' and collected the views and opinions of patients, carers and healthcare professionals of regarding current care (WP1, phase 4).

From WP 1 phases 1–4 we identified and synthesised components to inform consensus development events attended by a number of experts (both by profession and experience) to develop the PERFECT-ER checklist (WP1, phase 5).

### *Work package 2: optimising care for patients with dementia and hip fracture*

We used an action research approach, with a mixed-methods case study design to study implementation on an orthopaedic ward in each of three hospitals, using a series of plan, do, study, act (PDSA) cycles.

### *Work package 3: feasibility trial*

We undertook a feasibility, multicentre, cluster RCT with integral economic evaluation. In line with Medical Research Council guidance for complex interventions, we also conducted an integrated multimethod multiperspective (from patients, suitable informants and NHS professionals) process evaluation. The trial ran from November 2016 to August 2018 in 11 hospitals in England and Scotland.

## Results (research findings)

### *Work package 1 key findings*

#### Work package 1 phase 1a

Our systematic review indicated that there was insufficient quality research on the rehabilitation of people living with CI following hip fracture surgery. Of the literature reviewed, the majority focused on people with mixed CI status and/or people with CI and hip fracture as a subgroup of larger studies. Studies lacked power to detect differences between intervention groups. The review suggested that models of rehabilitation could decrease the length of hospital stay and reduce admissions to care. No cost-effectiveness studies were located. We found that people living with CI are at greater risk of postoperative complications and higher mortality 12 months postoperatively. We also found uncertainty around rehabilitation provision, with no guidelines based on UK or international policy on how to deliver care to people living with CI following hip fracture. Components of enhanced care identified included screening for delirium and assessing pain for people with CI and hip fracture.

#### Work package 1 phase 1b

Our Freedom of Information Act survey highlighted the policy priorities that NHS trusts emphasised for people with dementia and hip fracture in March 2014. Numerous hospitals disclosed global dementia strategies and geriatric acute hip fracture pathways. However, no hospital disclosed an integrated dementia and hip fracture pathway or other documentation.

Major themes affecting care elements were identified: antipsychotics, behaviours that challenge, cost consequences, communication (between staff and patients, between staff and carers/family, between staff), consenting, constipation, delirium, dementia assessment, deprivation of liberties, discharge processes, end-of-life care, falls, hydration, identification of patients with dementia, incontinence, involving carers, manual handling, minimising ward changes, non-pharmacological interventions, nutrition, pain relief, pressure ulcers, safeguarding vulnerable adults, training in dementia care and ward environment. These themes were then aligned with corresponding elements described in the enhanced recovery after surgery literature (admission, preoperative, intraoperative, postoperative, rehabilitation, discharge).

#### Work package 1 phase 2

The telephone survey investigated domestic and international healthcare professionals' perspectives on the care pathways and costs, length of stay in hospital and discharge destinations for people with dementia and hip fracture. The participants identified diverse needs for patients with dementia in acute settings but supplied documentation that was largely dementia or hip fracture focused but not integrated. Participants described that training to provide colleagues with the skills to care for this patient group was generic and 'tick box'. They also found that outcome metrics such as length of hospital stay did not help in recognising recovery in this patient group.

The documents received through the survey were coded using a developed coding matrix to identify potential intervention components. This provided initial insights into what participants perceived as current and best practice. Implementation gaps they identified helped generate the observation topic guides used in WP1 phase 3.

#### Work package 1 phase 3

Key themes identified specific interruptions ('disjunctures') in routines or planned sequences in caregiving as:

Disruptions – when usual or expected practices were interrupted impacting on the ease with which staff manage care delivery.

Discontinuities – when divisions in culture, spaces and timing interrupt the smooth delivery of tasks.
Dispersions – occasions when environment artefacts [object(s) and/or people] are displaced from designated space.

### Work package 1 phase 4

The staff focus groups and interviews reported emotive experiences, fatigue and constraints that staff reported experienced on a daily basis. Many participants identified failing to deliver appropriate care to patients with dementia in several ways, including:

- lack of staff and/or time required
- combined organisational barriers
- care spaces not fit for these patients care needs.

Carer experiences supported these staff views. Some carers felt under pressure to assist staff, whom they perceived as needing help, to relieve shortages. Carers did not view this as empowering them to produce co-delivered care.

The patients were mostly full of praise for staff efforts, in improvising to meet ongoing disjunctures in workflow by re-prioritising tasks.

### Work package 1 phase 5

The intervention PERFECT-ER was developed through stakeholder consensus events.

### *Work package 2 key findings*

In WP2 we identified common barriers, facilitators, underlying mechanisms and work of service improvement leads (SILs) and PERFECTED process leads (PPLs) entailed in embedding PERFECT-ER across distinct hospital settings. While this proved challenging, staff found different ways to implement changes within their settings. It became clear that the practices surrounding such changes could easily break down. Components of PERFECT-ER that aligned to context-specific motivations, including the National Hip Fracture Database (NHFD) best practice tariff or trust policies, were easier to implement and longer lasting. WP2 enabled us to refine the PERFECT-ER intervention and develop its training manual, understanding the requirements of the SIL, PPL roles and using the checklist as part of the PDSA cycle. This informed implementation aspects of the trial (WP3) and the process evaluation.

### *Work package 3 feasibility key findings*

We recruited 282 participants, 132 from intervention sites and 150 from control sites. The average recruitment rates did not differ between intervention and control sites, ranging between 1.2 and 2.7 participants per month. Average recruitment of 1.87 per month contrasted with the expected 4 per site per month anticipated.

There was no evidence of any systematic between group difference at either the point of discharge from hospital or at 1-month follow-up. At 3 months, however, a potential beneficial effect of the intervention over control was evidenced for patient health-related quality of life (HRQoL) based upon the EuroQol-5 Dimensions, five-level version (EQ-5D-5L) by proxy: those in the intervention group had a mean EQ-5D utility score 0.071 units higher than control [95% confidence interval (95% CI) 0.018 to 0.124; $p = 0.009$], a relatively small effect of around one quarter of a standard deviation. A difference of 0.099 units, in favour of the intervention group, was also seen at the 6-month follow-up (95% CI 0.001 to 0.198; $p = 0.047$). Examination of the residuals from each of the models appeared to show violation of the normal distribution assumption for the length of stay, 'Timed Up and Go' and the Suitable Informant EQ-5D-5L models. Logarithmic transformation was applied to these data and the models refitted. None then showed any statistically significant difference except the model for length of stay. The individuals in the intervention group had significantly longer lengths of stay, on average 1.22 times longer (95% CI 1.02 to 1.45; $p = 0.028$).

Over the trial's duration, 57 participants (20.2%) died. A higher rate of all deaths was observed in the intervention group than in the control group (22.7% vs. 18.0%). Death in hospital was determined from the NHFD data and only available for participants in England, thus excluding 59 Scottish participants. Eleven participants (3.9%) died in hospital, with a higher rate in the control group (4.7% vs. 3.0%). Seventeen (8 intervention, 9 control) patients were known to have died within 30 days of surgery and 52 (28 intervention and 24 control) within 6 months.

## Process evaluation

The process evaluation demonstrated that, under particular conditions, the PERFECT-ER intervention package can be implemented in diverse NHS contexts. General barriers to implementation including: staffing issues, low staff morale, staff sickness, staff movement between wards and lack of senior staff, impacted negatively on implementation. However, the protected SIL resource, PDSA processes, networking, and using key staff members and trust processes, along with the resourcefulness, determination, commitment and ingenuity of SILs, PPLs and others with whom they worked, were facilitators.

We demonstrated that implementing an intervention encouraging more standardised practice and its documentation to improve patient, carer and staff outcomes via consistently amalgamating marginal gains was welcomed, necessary and seen as valuable.

## Health economics

Data completeness was comparable between suitable informant-reported (SIR) and hospital records but slightly higher in the SIR data. Comparing agreement in the data, we found sources agreed on 'non-use', but suitable informant over- and under-reporting of 'use' compared with hospital records did not follow a consistent pattern. Comparing SIR 'hospital use' over the 3-month periods pre-baseline and pre-6-month follow-up were identical at both assessments. Data suggest that sources yielded inconsistent estimates for inpatient days and for emergency department visits but more consistent estimates for outpatient attendances. Total hospital costs yielded inconsistent estimates. Individual items of resource use were relatively well completed, with missing rates below 12%. However, the cumulative impact of missing data decreased the availability of complete costs at all-time points.

A combination of missing resource use and unpaid care data from participants/suitable informants completing the trial and high attrition rates led to small or very small samples available for calculating 6-month costs. Low completion of self-reported HRQoL instruments (EQ-5D-5L and DEMQOL) and attrition led to small samples available for calculating 6-month participant-reported quality-adjusted life-year (QALY). There were 64 intervention participants and 79 controls at 6 months but on combinations of societal costs and self-completed HRQoL measures, only 25 cases were available for analysis. In line with the original proposal, cost-effectiveness estimates were produced. The evidence of these analyses points to substantial uncertainty as to the size of the incremental cost-effectiveness ratios produced. No assumptions were made as to the costs and QALY of participants that had died during the trial; instead, complete cases were analysed. The mechanisms underlying incomplete data were not necessarily observed or recorded and so no imputation strategy was possible.

## Conclusions

The PERFECT-ER feasibility trial demonstrated mean recruitment of 1.87 participant per centre per month. Retention at 1 month was over 80% and at 6 months approximately 50%. In patients with CI and hip fracture, we estimated that 10–20% died within 30 days of sustaining a hip fracture. Our data suggest that short-term mortality could be reduced with implementation of PERFECT-ER from a culmination of increased good practice across a range of care domains. Thirty-day mortality is more commonly used as an outcome measure in the evaluation of enhanced recovery pathways; discussion with the patient and public involvement group indicated that this was an appropriate primary outcome in future trials. The process evaluation found patients and carers unable to comment on receiving the intervention, so did not assist in answering questions about PERFECT-ER implementation. Equipment costs contributed little to overall costs and these questions should be removed. Hospital records-extracted data were used to estimate costs for use in the cost-effectiveness analyses presented here. These are the 'gold-standard' source compared with SIR data. However, records did not include information on hospital stays outside the trusts providing the records, so use of other hospitals might have been omitted.

The feasibility PERFECT-ER trial provided valuable information and evidence to future work.

1. Thirty-day post-surgery mortality is appropriate primary outcome for future trials, but to compare longer-term survival, we recommend also measuring 3-month mortality.
2. In a definitive PERFECT-ER trial, patient and carer interviews should not be undertaken.
3. Community health use questions should be reduced, removing health care that might be routine and little affected by the intervention, such as dentistry.
4. We consider that hospital records extraction proformas and trial database design in a definitive trial could address potential shortcomings. We would not recommend comparing SIR and hospital records sources in a larger study.

## Trial registration

This trial is registered as Current Controlled Trials ISRCTN 99336264.

## Funding

This award was funded by the National Institute for Health and Care Research (NIHR) Programme Grants for Applied Research Programme (NIHR award ref: DTC-RP-PG-0311-12004) and is published in full in *Programme Grants for Applied Research*; Vol. 13, No. 1. See the NIHR Funding and Awards website for further award information.

# Synopsis

## Background

Hip fracture is strongly associated with advancing frailty and has substantial impact on the health, well-being and independence of patients and their families.[1,2] In the 12 months after fracture, patients are at increased risk of cognitive and functional decline, admission to long-term care institutions and higher mortality.[3] People with cognitive impairment (CI) are among the most vulnerable in acute hospital settings.[4] They have worse short-term survival, and 24% mortality during admission.[3] They are susceptible to suboptimal and inconsistent care standards that contribute to cognitive deterioration, increase risk of postoperative complications, prolong length of hospital stay and cause loss of independence.[5]

Approximately 19% of older adults with hip fractures have dementia, and up to 42% have some degree of CI that may not meet criteria for a dementia diagnosis.[6] This combination of hip fracture and CI is associated with particularly poor outcomes.[7–9] People experiencing CI and hip fracture are cared for in environments designed to deliver excellent hip fracture care but less skilled in caring for people with CI.[10,11] Care of patients hospitalised with CI remains an ongoing area of concern.[4] Systemic failures in the care of older people have repeatedly been identified.[12] Hospital workers may lack the knowledge and skills needed to identify and assess CI. Under-identification of CI can negatively affect access to rehabilitation services, supported discharge planning, person-centred care plans and involvement of families and carers.[13–16]

Recent initiatives aimed to increase the quality and consistency of acute care of people with CI.[12,17–22] Complex relationships exist between hospitalisation, pre-admission cognitive frailty, post-admission cognition, functional decline and higher mortality.[5,23–25] The literature suggests that addressing deficiencies in care must be addressed at both the employee and organisational levels. This workforce has a limited understanding of the assessment methods and care needs of patients hospitalised with CI.[10,26] Staff education is a key factor in changing care practices.[27–32] Deficiencies in available training, in communication, behaviour management and carer involvement are linked to documented failures of care.[10,12,26] Training should be multifaceted, addressing skills in assessment, developing empathy and person-centred care.[31,33,34]

Attempts to increase the quality and consistency of acute care processes have focused on staff training and have not addressed contextual barriers (clinical rotations and blame cultures) or facilitators (professional socialisation, flexible care models).[35–37] Critically, evidence indicates that organisational conditions restrict the implementation of excellent practice even when staff are well trained.[38] Organisational conditions to overcome suboptimal practices and routines include strong leadership, adaptive strategies and care models.[39]

Deficiencies in the quality of care for patients with hip fracture and CI also includes poor access to rehabilitation and underinvolvement of family and other carers. The delivery of better integrated care for patients with CI through new models of care should be prioritised; integrated care is a key element of Department of Health and Social Care strategy.[40] The evidence suggests that an effective intervention to improve the care of patients with CI would not only implement person-centred care practices but also drive positive organisational change to facilitate those practices.[41–44] The intervention would build on learning from previous evaluations of acute care rehabilitation models and would use educational components addressing the needs of people with CI. This would encourage patient and carer involvement in shared decision-making and incorporate a mechanism for implementation at organisational level. To generate evidence on the effectiveness of a service improvement intervention in hospital care for hip fracture patients with CI, the National Institute for Health and Care Research (NIHR) funded the Perioperative Enhanced Recovery hip FracturE Care of paTiEnts with Dementia (PERFECTED) programme.

## Aims and objectives

Perioperative Enhanced Recovery hip FracturE Care of paTiEnts with Dementia was a real-world, mixed-method, multisite, multi-stakeholder applied research programme (*Figure 1*).

The aims of the programme were:

- To improve acute care delivery to people with dementia who have surgery after hip fracture using an enhanced recovery after surgery (ERAS) informed intervention[45]
- To develop and implement a complex intervention
- To examine the feasibility, acceptability and potential clinical and cost-effectiveness of the intervention

## Changes during the programme

As the research progressed we became aware that many older people with hip fracture and poor cognitive scores lack a dementia diagnosis.[23,46] For the PERFECTED-Enhanced Recovery (PERFECT-ER) intervention to make a positive

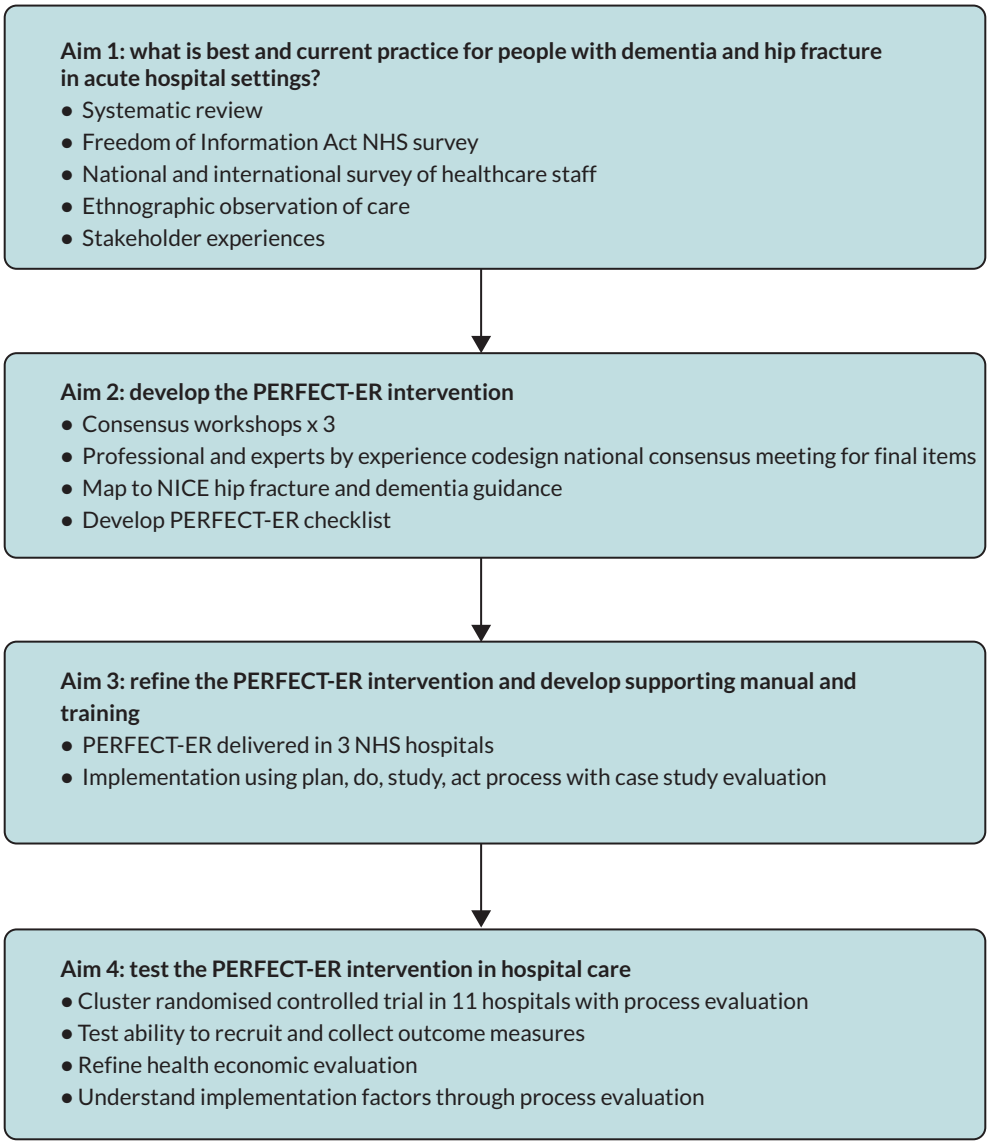


**FIGURE 1** Perioperative Enhanced Recovery hip FracturE Care of paTiEnts with Dementia research pathway. NICE, National Institute for Health and Care Excellence; PERFECTED-ER, PERFECTED-Enhanced Recovery.

impact on the care of older people with possible dementia it needed to encompass those displaying CI without a formal dementia diagnosis. Throughout this report we use CI to include diagnosed or assumed dementia and/or delirium and mild CI. We use 'dementia' when addressing this condition directly. Others have used the term 'cognitive spectrum disorder' for any combination of delirium, known dementia or abbreviated mental test score < 8/10 to label this patient group.[47] However, our patient and public involvement (PPI) and clinical stakeholder groups agreed that CI is a more relevant and accessible label. This research has demonstrated that many current dementia-sensitive practices and initiatives require a confirmed dementia diagnosis, so are not available to this population with CI, and an acute setting is not an appropriate environment in which to diagnose dementia due to cognitive suppressive elements, such as noise, unfamiliar environment and routines.[48]

Perioperative Enhanced Recovery hip FracturE Care of paTiEnts with Dementia aimed to use available evidence to identify components to include in developing an enhanced recovery intervention to optimise care delivery. The paucity of evidence required us to develop an additional strategy to determine current clinical practice and service strategies by submitting a Freedom of Information Act request to all UK NHS acute trusts. This was not part of our application but became work package (WP) 1 phase 1b.

Work packages were designed to:

- Establish best practice from a systematic review of literature and from the perspectives of service users, carers, healthcare professionals, health service managers and experts in the field (WP1 phases 1–4).
- Develop the optimised care pathway (WP1 phase 5).
- Determine the staff training and cultural/organisational changes required to implement and maximise adherence to the enhanced recovery pathway in hospital settings (WP2).
- Produce a training manual promoting cultural and organisational changes and maximising enhanced recovery pathway adherence (WP2).
- Undertake a feasibility study to assess the clinical and cost-effectiveness of the enhanced recovery pathway to inform a future large randomised controlled trial (RCT) (WP3).
- Disseminate the findings and develop a definitive trial bid (WP4).

## Work package 1: what is best and current practice for people with dementia and hip fracture in acute hospital settings?

### *Systematic review of best practice in hospital care for people with dementia and hip fracture*

#### Methods

We undertook a systematic review of best practice in hospital care for people with dementia and hip fracture with a comprehensive, systematic search strategy to identify empirical evidence regarding critical ingredients in caring for this group (PROSPERO CRD42012002047). We examined effectiveness in terms of cognitive function, functional performance, behaviour, quality of life, pain, mortality, clinical complications, health and social care service use and costs.

#### Key findings

- Most literature included participants with mixed CI status and/or people with CI and hip fracture as a subgroup of a larger study and lacked power to detect differences between intervention groups.
- Enhanced care models of rehabilitation could decrease the length of hospital stay and reduce admissions to care.
- No cost-effectiveness studies were located.

This evidenced uncertainty around rehabilitation provision with no documented guidelines based on UK or international policy regarding care for people living with CI following hip fracture. Components of enhanced care included screening for delirium and assessing pain for people with CI and hip fracture.

### Limitations
This paucity of evidence necessitated an additional WP (WP1 phase 1b) to determine current clinical practice using a Freedom of Information Act request to all UK NHS acute trusts.

### Most recent version
Smith TO, Gilbert AW, Sreekanta A, Sahota O, Griffin XL, Cross JL, *et al*. Enhanced rehabilitation and care models for adults with dementia following hip fracture surgery. *Cochrane Database Syst Rev* 2020;(**2**):CD010569. https://doi.org/10.1002/14651858.CD010569.pub3

## *Freedom of information requests to access current clinical dementia strategies*

### Aims
To understand current clinical practice and documented service strategies of UK NHS trusts for delivering care to people with dementia and hip fracture.

### Methods
The Freedom of Information Act 2000 and the Freedom of Information (Scotland) Act (2002)[40,49] enable the public to obtain defined information from UK government departments and public bodies. We developed freedom of information (FOI) requests in partnership with clinical stakeholders and refined these with four NHS trust FOI departments (one in each devolved nation). After piloting, we issued FOI requests to UK NHS trusts (see *Appendix 2* for FOI request).

### Results and analysis
We contacted 160 acute trusts in England. Six were excluded (we were unable to find an e-mail for one trust; five were specifically for children or women and babies).

We received 343 documents (England 280, Scotland 49, Wales 7 and Northern Ireland 7) from this request.[50] Data were analysed using thematic analysis.[51] We coded a random selection of data inductively to develop an coding framework identifying 'care elements' and ERAS treatment phases (admission, preoperative, intraoperative, postoperative, rehabilitation, discharge).[45,52]

### Key findings
Findings highlighted policy priorities in NHS trusts for people with dementia and hip fracture. Hospitals shared global dementia strategies and geriatric acute hip fracture pathways but no integrated dementia and hip fracture pathway or documentation.

From the documents, 25 themes (care elements) were identified: antipsychotics, behaviours that challenge, cost consequences, communication (between staff and patients, between staff and carers/family, between staff), consenting, constipation, delirium, dementia assessment, 'deprivation of liberties', discharge processes, end-of-life care, falls, hydration, identification of patients with dementia, incontinence, involving carers, manual handling, minimising ward changes, non-pharmacological interventions, nutrition, pain relief, pressure ulcers, safeguarding vulnerable adults, training in dementia care and ward environment. These were located within elements described in the ERAS literature.

### Limitations

- FOI requests are subject to how they are interpreted and handled by organisations and are thus constrained by the subjectivity of the recipient and who within the organisation should (and is able) to respond. Our FOI request may have gone to geriatricians, orthogeriatricians, orthopaedic surgeons, dementia champions and/or senior nurse ward managers, which may be a strength. However, their response depends on how both they and the organisation decide to respond. While many responders provided information, others asked that we withdrew the request, suggesting they would respond informally outside the 21-day time limit of the FOI legislation; however, information was not forthcoming. We discuss this in Hammond *et al.*[50] [green open access available at University of East Anglia (UEA) Digital Repository: https://ueaeprints.uea.ac.uk/id/eprint/61054].

### *National and international telephone survey of healthcare workers*

#### Aims

- To provide an overview of NHS and international initiatives for improving hospital dementia care.
- To identify potential components for the intervention.

#### Methods

We generated a four-item telephone survey using our review findings[53] and the National Audit of Dementia Care in Hospital.[54] We sought to identify potential care bundle components by locating relevant grey literature, unpublished data, policy documents, audit standards, treatment protocols and care procedures including initiatives to improve patient and carer/family experiences. The telephone survey enabled responders to contextualise documents, highlight gaps between best and current practice and indicate implementation difficulties.

Ethical consent was received from the UEA Faculty of Medicine and Health Science Research Ethics Committee on 24 January 2014 (Ref: 2013/2014 – 24). Verbal informed consent was also obtained.

#### Results

We conducted 90 surveys, 50 with participants from English NHS trusts and 40 with international healthcare workers from 18 different countries (see *Appendix 3*, *Tables 1–3*).

We elicited 187 documents (82 UK, 105 international) and analysed them thematically with the coding matrix from the FOI request.

#### Key findings

We established domestic and international healthcare professionals' perspectives on care pathways and costs, hospital length of stay and discharge destinations for people with dementia and hip fracture. Participants recognised the differing needs of this population but documentation was dementia or hip fracture focused, not both. Training for caring for this population was generic with a 'tick box feel'. Further outcomes, such as length of stay, were unhelpful in terms of recognising recovery. We discuss these findings this more fully in Gill *et al*.[16]

Analysed documents identified potential intervention components and insights into perceptions of current and best practice. These findings were used in observation guides for WP1 phase 3.

#### Limitations

A significant proportion of participants were academic clinicians. In the UK, it was difficult to access those with little control of their clinical time (nurses, allied health professionals). Internationally, we were restricted by language and the availability of professionals.

### *Focused ethnographic observations of care in acute orthopaedic wards (July 2014 to March 2015)*

#### Aims

To describe usual care practices on orthopaedic wards, focusing on care of people who may have CI, to identify 'usual care'.

#### Methods

We used a focused ethnographic approach drawing on features of institutional ethnography,[55] to observe interactions involving individuals who may be cognitively impaired. This facilitated in-depth understanding of how relationships, lived experiences and everyday ward activities were situated in their contexts.

We observed shared spaces on orthopaedic wards and emergency departments (EDs) in three NHS hospitals in England selected to vary in size, geographical region and location on the rural–urban continuum.[56]

Ethical consent received from Leicester Research Ethics Committee (number 14/EM/1020).[57]

We recruited, trained and supported PPI colleagues as 'lay' researchers. Researchers adopted a 'marginal role'[58] focusing on interactions with ad hoc discussions to clarify understandings about events witnessed. Field notes provided thick descriptions of what was seen and heard, with reflective comments in a distinct typeface.

### Results and analysis

We undertook 48 observations over 3 months spending a month in each site. Across the sites, 424 participants provided informed consent. Observation periods of 3 hours spanned 24 hours across 7 days of the week. This produced 144 hours of observation, 24 hours of which were by PPI researchers.

Field notes were imported into Nvivo (QSR International, Warrington, UK) for data management. Analysis used multiple researchers and PPI members to test analytical themes, identify interpretive problems, which were reframed by returning to the data set, reassessing fit and applicability of themes.

### Key findings

Analysis provided insights into workflow, how staff delivered care to and was received by patients and carers in conflicting and pressurised settings.

We found multiple types of disruptions, discontinuities and dispersions affecting patients and staff. Patients with CI posed particular and specific challenges to practice. These practice dilemmas are known, but not well-captured in this setting.

Publication: Cross JL, Backhouse T, Hammond SP, Penhale B, Scheibl F, Lambert N, *et al*. Disjunctures in practice: ethnographic observations of orthopaedic ward practices in the care of older adults with hip fracture and presumed cognitive impairment. *Ageing Soc* 2022:1–22. https://doi.org/10.1017/S0144686X22000927

## *How face-to-face care delivery to patients occurs within the wider work of the ward*

We used these data to map out the work sequences in care. Sequences began with a care act initiated by a staff member or a patient, or the routines established in the ward. Preparation work followed, where staff modified the environment and assembled the people/equipment necessary to deliver care. Direct care was then undertaken, before staff restored the environment to its premodified state, then undertook follow-on tasks including documentation. We found that physical and cognitive work underpinning face-to-face care took place away from the patient but was intrinsic to delivering successful care. Thus, interventions to improve care must attend to ward and organisational practices, not simply face-to-face delivery of care.

This work identified potential intervention components and added contextual data which may inhibit rather than promote best practice for care elements within the enhanced recovery pathway. Publication: Backhouse T, Hammond SP, Cross JL, Lambert N, Varley A, Penhale B, *et al*. Making body work sequences visible: an ethnographic study of acute orthopaedic hospital wards. *Sociol Health Illn* 2020;**42**:1139–54. https://doi.org/10.1111/1467-9566.13085

### Limitations

Ethnographic fieldwork in clinical settings presented ethical challenges and some methodological limitations. Unlike many ethnographic studies, the observed community changed as NHS staff, patients and visitors moved. Symptoms of CI were observable but not confirmed.

## *Exploration of stakeholder views of care experiences*

### Aims

To explore stakeholder (patients, carers/families' and healthcare staff) views of care experiences, best practice and priorities.

## Methods for data collection

We undertook semistructured interviews with patients and carers, and interviews and focus groups with healthcare staff, from three different geographical regions across England. Interview schedules and focus group topic guides were developed in partnership with PPI members, informed by previous work.

Interviews explored stakeholder experiences with meanings and priorities they attached to them.[59] Interviews with patients were undertaken according to their capacity to participate.[57] We recruited and trained PPI members as co-interviewers for carer interviews. Focus groups explored healthcare staffs' collective and divergent perspectives.[60] Interviews with front-line staff were added once it transpired that focus groups were unfeasible.

Ethical consent was received from the Cambridge and Hertfordshire Research Ethics Committee, number 15/EE/0007.

## Results and analysis

We recruited 74 participants: 10 patients, 14 carers and 50 staff. Recruiting patient and carer participants shortly before or after busy, confusing and sometimes chaotic discharge processes was difficult. Thus, some study packs were distributed in subacute/community settings. Eligible staff from a range of disciplines delivering care to patients with hip fracture were recruited via posters and internal e-mail bulletins.

Data were digitally recorded, transcribed verbatim and imported into Nvivo for data management. Analysis began with readings and application of the coding matrix from previous WP1 work. All staff data were analysed for the consensus phase (WP1 phase 5). Patient and carer interview data were limited by slow recruitment, so we added specific PPI elements to the consensus process (described in the WP1 phase 5).

Two themes informed WP2 development:

1. Expectations, gaps and inadequate solutions experienced by patients, carers and staff.
2. Workplace interruptions; causes, consequences and how they were negotiated by stakeholders.

## Key findings

Staff focus groups/interviews identified emotive experiences, fatigue and constraints experienced on a daily basis. They described failing cognitively impaired patients with lack of staff and/or time to deliver appropriate care, and organisational barriers such as unsuitable care spaces. Carers supported these views, perceiving staff as needing help to relieve shortages and feeling under pressure to assist. However, this was not perceived as empowering them to co-deliver care. They were full of praise for staff efforts, improvising to meet disjunctures in workflow. Sometimes staff re-prioritising tasks impacted on patients experience and, while they understood the need, they felt its impact beyond the acute setting.

## Limitations

Recruiting patients and carers was difficult and we adjusted who, how and when eligible patients were given information about the study, how they could express an interest and how this was followed up to reduce perceived burden. We doubled the number of recruitment centres (threee to six) and enabled carers to give telephone interviews instead of face to face. Despite this adjustment, we recruited fewer patients and carers than planned, but we did achieve sufficient data for analysis.

Interviewing people with mild CI about their hospital experiences around 1 month after admission was challenging. The unfamiliar surroundings, busyness of acute settings and the impact of analgesia and anaesthesia, especially in the presence of cognitive issues, made recalling events and placing them in recognised sequence, extremely challenging.

For carers, anxieties about hospital care, liaising with numerous support services and relevant personnel, as well as sometimes trying to adjust the patient's living arrangements and dealing with the emotional impact of these factors, was exhausting. The perceived burden of research was excessive and contributed to an unwillingness to participate.

Recruiting front-line NHS staff was problematic despite provision for wards to use financial payments from the study to 'backfill' staff or to use these funds to offer overtime payments to staff as compensation for participating in focus groups after their shifts.

## *Developing the intervention*

### Aims

To develop an ERAS-informed care pathway for hip fracture patients experiencing CI on acute orthopaedic wards.

### Methods for developing consensus

We found limited, low-quality of evidence about enhanced recovery pathways for people with hip fracture and dementia.[53] Thus, the consensus process needed level 4 evidence, 'expert committee reports, opinions and/or clinical experience of respected authorities'.[61]

We proposed 3 regional consensus meetings of 30 people. However, with significant volumes of data from WP1, we used regional events to synthesise these and develop materials for a national consensus event.

### Pre-consensus work

Analysis produced 25 major themes, 'care elements' involved in delivering or receiving care related to patients with hip fracture and CI, which were mapped to ERAS phases admission, preoperative, intraoperative, postoperative, rehabilitation, discharge (an intraoperative care bundle was impossible as there was minimal relevant information available). These care elements were sent to national and international experts who were asked to track their changes (to provide an audit trial) to select, focus and distil that care element.[62] They removed duplication (e.g. of cognitive tests) to make materials more manageable in the consensus process.

#### *Regional events*

Perioperative Enhanced Recovery hip FracturE Care of paTiEnts with Dementia-Enhanced Recovery development events were in Norfolk, East Midlands and Cambridgeshire with a range of NHS stakeholders from across the patient pathway and service user advisory groups in Norfolk and Nottinghamshire. Participants considered why two mock ERAS-informed pathways (developed in pre-consensus work) 'would not work'. These insights were used to refine materials for the national consensus meeting.

#### *National consensus event*

Thirty appropriate stakeholders were selected including relevant professions, multidisciplinary representatives and PPI.[63] We used consensus development methods for mixed-methods data and provided a synthesis of evidence to group members.[64]

### Method

Attendees, in five groups, considered care elements most closely related to their professional expertise. Each group identified components for the PERFECT-ER intervention and located these into the relevant ERAS phase. Participants were then regrouped according to where, in the ERAS pathway, they had most influence; for example, in the rehabilitation phase group, physiotherapists were joined by occupational therapists, discharge co-ordinators and psychiatric liaison nurses. Each group considered components now populating their portion of the ERAS pathway, to identify missing elements and rank the three most important care elements. Finally, a whole group discussion ensured components of the pathway fitted together to represent the complete patient journey.

### After the event

Researchers scrutinised the prototype intervention and developed an audit checklist – the PERFECT-ER checklist. The programme steering committee (PSC) considered the intervention, to identify where standardisation was not possible. For example, while pre-operative analgesia regimes could not be standardised, the PERFECT-ER could highlight how analgesia regimens might impact on a patient's CI to hamper or facilitate postoperative rehabilitation.

The developed checklist and training manual can be found in *Report Supplementary Material 1*.

### Limitations

We pragmatically applied rigorous consensus strategies, but these relied on expert committee reports, opinions and clinical experience of experts.[61] No PERFECT-ER component was supported by strong research evidence and we proceeded assuming that, by implementing a number of smaller changes, potentially several marginal gains could improve patient outcomes, patient and carer experience, staff satisfaction and competence.[65]

## Work package 2: optimising care for patients with hip fracture and cognitive impairment

### *Aims*

To refine PERFECT-ER checklist and determine staff training needed to implement and develop a PERFECT-ER manual for staff training to implement the intervention in WP3.

### *Study design*

Case study assesses complex practices within real-world contexts,[66–68] using multiple case studies to facilitate comparison between cases and promote stronger theory building.[68,69] Implementing new ways of working in complex, multidisciplinary settings is challenging and understanding this was essential before the feasibility trial. We took an action research approach, with multi-site, mixed-methods case studies,[70] which has been successfully used to study implementation in differing settings.[66,70,71]

### Defining cases

We purposively selected three NHS hospitals of different size and location on the urban–rural continuum, to enable theory and knowledge to potentially be transferable to other clinical contexts.[67] Each hospital selected an orthopaedic ward to implement PERFECT-ER. The 'case' was defined as the contextual setting of the ward, the hospital and the actions and records of the researchers engaged with that site (*Figure 2*).

Multiple cases enabled 'cross-case' analysis and produced conclusions supporting a standardised implementation of PERFECT-ER in trial sites.[72] The process and data collected are represented in *Figure 2*.

### Ethical approval

Ethical approval was received from South Central – Oxford C Research Ethics Committee: rec. ref. no 15/SC/0294.

### Analysis

#### *Quantitative data*

Perioperative Enhanced Recovery hip FracturE Care of paTiEnts with Dementia-Enhanced Recovery scores were analysed descriptively and compared across implementation cycles and between sites.

#### *Qualitative data analysis*

We examined how staff responded, positioned, embedded or rejected the PERFECT-ER intervention. Data from three sites across the action research cycles were coded inductively drawing on normalisation process theory.[73,74]

### Results and analysis

Checklist items were not weighted nor were service improvement leads (SILs) instructed which practices to change or how. Different items in different sites scored well or not, suggesting that they were context specific. This approach enabled flexible implementation while identifying commonalities and distinctive experiences.

#### *Refining PERFECT-ER through action research*

Action research enabled us to work with sites to refine PERFECT-ER for real-world contexts. This led to 4 organisational and 11 patient-items being added to PERFECT-ER. Three arose from separating original items into 2, better reflecting specific practices; 12 came from suggestions from SILs. However, these modifications were made only if supported by scientific evidence or expert consensus opinion from WP1 phase 5.

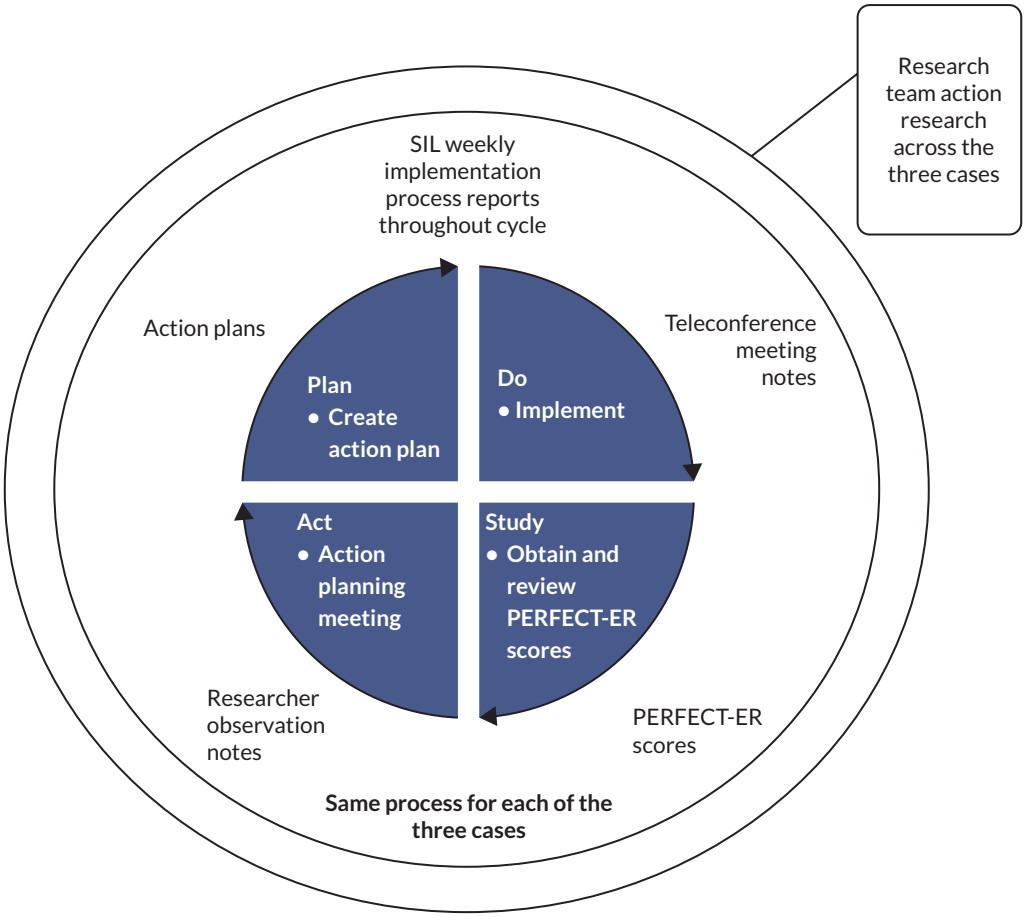


**FIGURE 2** Work package 2 process and data collection activities.

Service improvement leads began by developing understanding the context within which they were conducting the implementation and the tool they were implementing. Sometimes they found PERFECT-ER recommended practice was already occurring but not documented, so some score changes resulted from changing recording practices.

### *Implementing PERFECT-ER*

Findings show site A scoring lowest at baseline, with the highest score change in both organisational (36–57%) and patient (43–87%) items across the cycles. Site B showed steady score increases across organisational (73–93%) and patient level (69–86%) and site C scored highest at baseline but demonstrated least change over time.

## *Key findings*

- Links to existing trust policies facilitated implementation.
- Role modelling change behaviours assisted sense making and cognitive participation.
- Encouraging others' participation takes ongoing work.
- Embedding new practices and officially endorsing them may provide lasting change.
- SILs and/or the PERFECTED process lead (PPL) should preferably be ward based; if not, they must work closely with key stakeholders.
- Embedding new practices using documentary change may deliver implementation but this may not be effective in isolation.

Publication: Fox C, Hammond SP, Backhouse T, Poland F, Waring J, Penhale B, Cross JL. Implementing PERFECT-ER with Plan-Do-Study-Act on acute orthopaedic hospital wards: building knowledge from an implementation study using Normalization Process Theory. *PLOS One* 2023;**18**:e0279651. https://doi.org/10.1371/journal.pone.0279651

### *Limitations*

While implementation of the multicomponent intervention occurred across time and place in acute hospitals, reliability and validity of checklist scores and interrater reliability remain unknown.

Service improvement leads were qualified nurses (as in most ERAS studies) but with varying knowledge, experience and ward environments. Clinical guidelines suggest that ERAS change agents can be staff from other disciplines, but this has not been demonstrated in research, nor tested in this study.

## Work package 3: a feasibility cluster randomised controlled trial of Perioperative Enhanced Recovery hip FracturE Care of paTiEnts with Dementia-Enhanced Recovery with cost-effectiveness and process evaluations

### *Aim*

To use a cluster RCT to test acceptability and feasibility.

### *Methods*

A feasibility, multicentre, cluster RCT was undertaken with integrated multi-method multi-perspective (patients, suitable informants and NHS professionals) process evaluation.[75]

Ethical approval was received from Camden and Kings Research Ethics Committee (reference number: 16/LO/0621) and Scotland Research Ethics Committee A (reference number: 16/SS/0086). Trial registration number: ISRCTN 99336264.

Publications: protocol – Hammond SP, Cross JL, Shepstone L, Backhouse T, Henderson C, Poland F, *et al*. PERFECTED enhanced recovery (PERFECT-ER) care versus standard acute care for patients admitted to acute settings with hip fracture identified as experiencing confusion: study protocol for a feasibility cluster randomized controlled trial. *Trials* 2017;**18**:1–10. https://doi.org/10.1186/s13063-017-2303-y; trial paper – Cross JL, Hammond SP, Shepstone L, Poland F, Henderson C, Backhouse T, *et al*. PERFECTED enhanced recovery pathway (PERFECT-ER) versus standard acute hospital care for people after hip fracture surgery who have cognitive impairment: a feasibility cluster randomised controlled trial. *BMJ Open* 2022;**12**:e055267. https://doi.org/10.1136/bmjopen-2021-055267

#### Design

A cluster randomised feasibility trial and economics analysis.

#### Settings and participants

Patients over 60 years of age with a proximal hip fracture requiring surgical fixation and identified CI in 11 NHS hospitals across the UK.

#### Intervention

Perioperative Enhanced Recovery hip FracturE Care of paTiEnts with Dementia-Enhanced Recovery, an enhanced recovery pathway, had 15 quality targets for health professionals to meet for proposed better practice. These were grouped into three stages (admission and preoperative, postoperative and rehabilitation, discharge) supported by a PERFECT-ER checklist and manual, a service improvement lead and PPL. They used the plan, do, study, act (PDSA) model to implement change.

#### Measurements

We collected feasibility outcomes: recruitment and attrition, intervention acceptability and fidelity, completion of participant reported outcome measures, preliminary estimates of potential effectiveness using mortality, EuroQol Five Dimensions, Five-Level version (EQ-5D-5L), economic and clinical outcome scores.

### Results
Two hundred and eighty-four participants were recruited (132 PEFECT-ER intervention; 150 control). In eligible participants with capacity, 30% provided consent; agreement was provided for 50% of eligible participants requiring consultee consent. Mean recruitment rates were the same in intervention and control sites (range 1.2 and 2.7 participants per month). At 3 months a relatively small effect [one quarter of a standard deviation (SD)] on health-related quality of life (HRQoL) of the patient measured with EQ-5D-5L by proxy in the intervention group.

### Outcomes
This trial design was feasible with modifications to the recruitment of participants. The mechanisms for delivering consistency in the PERFECT-ER intervention and for reducing the challenges of participant retention also need to be addressed. The results provide valuable insights into overcoming these challenges. However, a RCT may not be the optimal research design to evaluate this perioperative intervention because of the complexity of caring for people after hip fracture with CI, and the contextual factors impacting on their care and outcomes.

## *Health economics*

### The evaluation examined
Incremental cost per 3.5-unit change in Bristol Activities of Daily Living Scale (BADLS) score of the participant
Incremental cost per quality-adjusted life-year (QALY) of the participant, computed from DEMQOL-U, completed by participants and again by proxy
Incremental cost per QALY of the participant, computed from EQ-5D-5L, completed by participants and again by proxy

We computed utilities using societal weights (DEMQOL-U from the DEMQOL; DEMQOL-Proxy-U from the DEMQOL-Proxy; EQ-5D-5L). QALYs over the intervention period were derived using the trapezoid method to approximate the area under the quality-of-life curve, with linear interpolation between time-points.

We examined the systems in place for collecting activity and cost data in participating NHS trusts to assess the usefulness of using administrative data on inpatient and outpatient service costs. To inform measurements of intervention-related variations in hospital costs in a definitive trial, qualitative data collected in the process evaluation were examined to explore how time is used to provide appropriate care to people with CI and hip fracture.

Further details of the health economics analysis are available in *Appendix 7*, including *Tables 4–22* and *Figures 4–15*.

### *Key findings*
The feasibility trial provided valuable evidence to inform a definitive trial.

Particularly:

1. The mean recruitment was 1.87 participants per centre per month. Retention at 1 month was over 80% and at 6 months approximately 50%.
2. Short-term mortality may be reduced by implementing PERFECR-ER, from cumulatively increased good practice across a range of care domains. This aligns to other evaluations of enhanced recovery pathways where 30-day mortality is more commonly used as the primary outcome. To compare longer-term survival we recommend measuring 3-month (110-day) mortality. These data are readily available from National Hip Fracture Database (NHFD), potentially providing an efficient trial design.
3. Patient and carer qualitative interviews should not take place.
4. Client Services Receipt Inventory (CSRI) data collection should be reduced. Equipment questions will be removed and other sections reduced, including community health use questions, such as dentistry, that are less relevant to the intervention.
5. The hospital records extraction (HRE) approach is feasible and avoids participant burden; however, proformas should be adapted to address the shortcomings identified. We would not recommend repeating the comparison of the suitable informant-reported (SIR) and hospital records data.

## *Process evaluation*

### Aim

A mixed-methods process evaluation investigated how the intervention was implemented and contextual factors influencing this.[5] Process evaluation designs need to take into account that complex interventions like PERFECT-ER are usually implemented in diverse, changeable and dynamic circumstances. This evaluation used Medical Research Council guidance for the process evaluation of complex interventions.[75]

### Objectives

To Identify facilitators and barriers to delivering the intervention.
To evaluate whether and how staff behaviour changed.
To gather staff views of PERFECT-ER.

Publication: Backhouse T, Fox C, Hammond SP, Poland F, McDermott-Thompson V, Penhale B, Cross JL. Implementing an intervention to enhance care delivery and consistency for people with hip fracture and cognitive impairment in acute hospital wards: a mixed methods process evaluation of a randomised controlled feasibility trial (PERFECTED). *BMJ Open* 2023;**13**:e064482. https://doi.org/10.1136/bmjopen-2022-064482

## *Key findings*

### Recommendations for service improvement lead role

Service improvement leads are key to implementation and several factors that facilitate or impede this implementation are modifiable. Being able to secure protected SIL time improved implementation. SILs reported 0.2 full-time equivalents (FTE) during the maintenance phase was not enough to maintain implementation due to contextual barriers (shift patterns and clinical rotations). SILs who were outsiders to ward environments faced additional challenges and had fewer resources with which to address these challenges. Being from a non-nursing background meant that aspects of ward practices were difficult to understand, compounded by also being new to the context and not working there on non-SIL days. Conversely, being an outsider and not being allocated to other clinical duties on the ward (site 03 SIL) was advantageous in terms of not being conflicted by urgent staff shortages. These factors suggest an increase in SIL time during the 'maintenance/recruitment' phase from 0.2 to 0.4 FTE in any definitive trial would help to mitigate these factors, particularly if staff appointed to this role have or have had a role on the study ward similar ward.

### Recommendations for the ward environment

Despite NHS pressures, SILs and ward staff managed to successfully implement PERFECT-ER to varying degrees:

1. For wards with changing staffing, new staff and agency staff, it is advantageous for SILs to use a PERFECT-ER staff leaflet and or regular ward meetings to cascade messages about the intervention.
2. Reduce the administrative burden on SILs by providing administrative support.

### Recommendations for aligning to wider trust initiatives

When in post and prior to implementation, SILs should network to identify trust initiatives, document changes which could be aligned to (or undermine) PERFECT-ER items. SILs can plan to maximise advantages and mitigate threats.

### Recommendations of behaviour change approaches for service improvement leads

A variety of approaches were used by SILs, each appropriate to the context in which they were deployed. Thus, there are a range of strategies that SILs may find useful, these will be integrated into the 'best practice' PERFECT-ER manual for future use:

provide welcome packs to new staff highlighting PERFECT-ER as the 'norm' for the ward
continually engage/re-engage communicating with staff regarding PERFECT-ER. Consider using action planning meetings
provide regular group and/or one to one education sessions
promote responsibility, participation and ownership using PERFECT-ER champions

conduct ad hoc spot checks of implementation
support staff members struggling to implement changes
recognise and reward implementation success and consistency

### Staff views of Perioperative Enhanced Recovery hip FracturE Care of paTiEnts with Dementia-Enhanced Recovery

Service improvement leads reported that PERFECT-ER was a valuable tool which had a positive impact on their wards.
Staff reported the positive impact of PERFECT-ER on patient care, with some items becoming part of their, daily routines.
Staff felt that PERFECT-ER ensured consistency, standardising care and formalising information that needed to be re-corded. This was particularly useful for staff new to wards.
Staff supported the notion that successfully implementing PERFECT-ER might raise the standard and consistency of hip fracture care processes for patients with CI.

#### *Limitations*

Lack of direct access to patient notes meant that researchers were unable to verify the PERFECT-ER checklisting results. The relationship between changes in documentation practices and changes in care practices is also unclear. Patient and suitable informant interviews revealed that patients and carers were largely unable to comment on receiving the intervention and thus did not assist understandings of implementation, mechanisms of action, or experiences of interacting with the intervention.

## Work package 4: dissemination and planning of Phase III trial

### *Planning and writing of Phase III trial*

### Bid development

The PERFECT-ER feasibility study indicated it was feasible to undertake a definitive trial and economic evaluation using the developed and refined recruitment and consenting practices.

A decision was made to use 3-month mortality as the primary outcome. Data from the NHFD for 2018 indicated that 64,000 fractures were seen in 170 hospitals in a 12-month period, that is, a rate of 31.4 fractures per hospital per month. Assuming that 45% of patients have CI, 40 hospitals recruited into the study and a 16-month recruitment phase, over 9000 subjects would be available for study. Using routinely collected data, it was argued that consent would not be required for study entry and all subjects could therefore participate. Using an assumed small intraclass correlation coefficient for this outcome from the clustering of hospitals of no more than 0.005, the design effect would be 2.12, that is providing an effective sample size of around 4245. This sample size would provide 90% statistical power to detect a 20% relative risk reduction in deaths, from an assumed 15% to 12%, using a Cox's proportional hazards model.

Building on the PERFECTED programme, the team developed and submitted a Programme Grants for Applied Research bid for a definitive trial to the NIHR. This application was rejected. Review provided by PGFAR drew attention to the outcomes tested in PERFECTED that did not demonstrate statistically significant benefits for patients and that the precise mechanisms of benefit were unclear.

Work to date highlighted that the intervention pathway for PERFECT-ER required considerable input from champions for delivery, suggesting that systematic staff support (i.e. 'coaching') was important. Building on this learning around the role of coaching champions to support better outcomes for patients, we submitted a Health and Social Care Delivery Research bid in September 2020. This submission was also rejected. The committee acknowledged that the topic was important and relevant to the funding stream. The expertise and skills of the team were also highlighted, but the bid was seen to lack coherence in terms of the method, scope of the literature review and how it built on PERFECT-ER.

Owing to the difficulty in obtaining further funding required to test the intervention to establish its effectiveness, the team has been hesitant to put the intervention forward as a 'training manual'. We are currently considering funding options to facilitate a programme of work dedicated to the testing, piloting and production of this manual.

## Dissemination

Plans to disseminate findings from PERFECTED via workshops and training materials (project protocol) were put on hold due to the onset of the COVID-19 pandemic in February 2020. The ongoing nature of restrictions on social gatherings into summer and autumn of 2021 prevented the resumption of the latter strategy, in view of which, we realigned the dissemination strategy to focus on the direct accessibility of online platforms leading to the development and launch of an online webinar, hosted at the UEA on 21 September 2021.

The online webinar provided a platform for:

- the study team to present an overview of the key messages and findings of the PERFECTED study
- three invited expert clinical researchers (Professor Alasdair Maculloch, University of Edinburgh, Professor Louise Allen, University of Exeter, and Dr Joe Buchart, University of Exeter) to present 'state of the art' knowledge about dementia and delirium diagnostics in the acute setting and recovery following discharge
- signposting directions for future research
- public reading of the poem '*A story of falling*' commissioned from Dr Rebecca Goss (https://rebeccagoss.wordpress.com) by the PERFECTED team. The poem (reproduced in full below) was inspired and created in response to ethnographic data collected in phase 1. The team considered this to be a creative approach to PPI and would also serve to increase awareness of the fundamental role of nursing care for patients living with dementia on acute wards
- the launch of the updated and expanded PERFECTED website www.perfected.ac.uk.

### *Poem commissioned by Perioperative Enhanced Recovery hip FracturE Care of paTiEnts with Dementia team for dissemination event*

**A Story of Falling**

A slip, a stumble, a shifting of earth and the ground
is suddenly close. No longer righted in air
but carried to a bay, its waiting bed of cloud.
*Oh nurse, can you give me your hand for a minute?*
Nurse weaving pathways between the prone,
criss-crossing a ward, making lacework of the floor,
falling now suspended in the mesh.
Caught in the song of *so many human beings*
*close together.* Rituals of tending veiled from sight,
from family who come to *give him his lunch sometimes*
*or help him with drinks.* A stitching of routine into
bewilderment. Night, and privacy is a diaphanous state,
brings a trespass into dreams. The need to lift and turn a body
sends its night stories tilting. Waking to cupboards
different from home *sputum containers; pressure cuffs;*
*netty pants; thermometers; body bags; combs.*
This is healing but not quite mending,
*a patient is shouting very loudly*
*Oh nurse, can you give me your hand for a minute?*
People are tumbling here, but they are held.

*Rebecca Goss 2021*

The event also provided a showcase for the update of the project website (www.perfected.ac.uk) which (as explained in more detail below) involved expanding sections; on PPI involvement in the study; providing links to high impact scientific papers presented across a range of conferences in the UK and internationally (see *Appendix 9*). Dissemination at grassroots level has included production of an educational 'ward leaflet' for orthopaedic wards to increase awareness of dementia for all ward users (see in more detail below). This is also available as a downloadable resource on the

new website. Updates and development of the website is ongoing and incomplete sections will be populated in the coming months.

### Website updates and development

In September 2021, we updated the reporting of key findings on the project website (www.perfected.ac.uk) to include key publications/conferences and work undertaken to build networks and collaborations across academia and PPI. Strapline areas for the update included:

- PERFECTED laid the groundwork for the development of an evidence-based intervention to improve the hospital care of physical and mental health problems in people with dementia.
- Further work is required to advance the development of an enhanced recovery pathway for the care and rehabilitation of people with dementia who break their hip.
- PERFECTED drew on extensive PPI consultations, shaping the topic, methods, research implementation (including co-research and analysis) and project governance at all levels.

### Dissemination on wards

Reproduced in *Appendix 9* is draft text from the ward leaflet. This resource is also available as a download on the project website.

### *Perioperative Enhanced Recovery hip FracturE Care of paTiEnts with Dementia public profile*

Perioperative Enhanced Recovery hip FracturE Care of paTiEnts with Dementia remained publicly accessible by engaging and informing members of the public about the programme through the programme's website (www.perfected.ac.uk) and X (formerly Twitter) account @perfected. These platforms were provided insights into the research programme, developments, progress and findings. A programme newsletter informed people who gave us permission to keep their contact details on our database. This included patients, carers and a range of national and international health and care professionals. We created a YouTube (YouTube LLC, San Bruno, CAS, USA) channel and posted short audiovisual clips about the research, putting faces and voices to names, titles and responsibilities to develop transparency in project workings. We maintained the public profile of PERFECTED throughout the programme, although limited allocated resources made this difficult. If funders want to prioritise public engagement, then we recommend a clear strategy and appropriate allocated resources are articulated in funding applications.

## Patient and public involvement

Perioperative Enhanced Recovery hip FracturE Care of paTiEnts with Dementia promised a thorough and ongoing commitment to public involvement in development, design and delivery of this research. We documented PPI in processes from the application stage, scoping and initial surveys, interviews, observations of practice, the feasibility trial and process evaluation and dissemination. Acute orthopaedic hospital care for people living with dementia was prioritised PPI groups in the Dementias and Neurodegeneration Diseases Research Network (DeNDRoN) in 2010, then, once funded, its delivery was supported by the Alzheimer's Society. This ensured a wide range of PPI perspectives were included in development, governance and research delivery. Representatives were recruited from several local and national voluntary organisations, including the Alzheimer's Society, Dementia UK, Norfolk and Suffolk Public and Patient Involvement in Research Group, DeNDRoN, Age UK and community dementia support groups.

Patient and public involvement members, recognised as experts by experience, were members of the PSC, programme advisory group (PAG) and data monitoring ethics committee (DMEC). Having at least one PPI representative on each committee ensured that their perspectives were considered throughout the programme. As PSC members, PPI representatives shared responsibilities for project governance and reporting to the sponsor. PPI members on the PAG and PSC worked with the study team, and external advisors, to provide advice during the project. PPI members helped committees ensure perspectives of people affected by dementia remained central to committee processes and were incorporated into advice they gave. To facilitate PPI views and active contribution were facilitated, each panel had a research team member providing support to PPI individuals before and after meetings of the PSC, PAG and DMEC meetings, affirming the value of their contributions and supporting their input to these meetings.

Three regional (Norfolk, Bradford and Nottingham) service user advisory groups helped shape development and data collection for WP1 and WP2, contributing to research protocols and NHS research ethics committees applications. They met to regularly review the relevance and accessibility of public-facing documents.

We recruited and trained some service user advisory group members as 'peer researchers' to work with the research team during data collection, analysis and dissemination during WP1, WP2 and WP3. Together, the research team and PPI members co-produced practices to enable this, encountering some issues, which led to recommendations, for both the NIHR and INVOLVE, relating to inclusive involvement (standard 1).[86] These findings underpin the following recommendations to enable future successful PPI involvement in research programmes.

### *Key findings for successful patient and public involvement*

#### National Health Service and Health Research Authority

Across the programme, PPI members advised on public-facing documentation, contributed to ethical applications and acted as experts by experience on management and governance committees. PERFECTED also involved PPI members in novel ways, including as co-researchers in data collection activities, which highlighted research practices and real costs implications for participants and projects that need to be met efficiently and appropriately.

In WP1, some PPI members became co-researchers, contributing to data collection activities in ethnographic observations of acute hospital wards (WP1 phase 3) and co-interviewing carers of people living with dementia (WP1 phase 4). In 2014, when applying for permissions to conduct this work, research and development departments insisted that, as co-researchers, our PPI members must fulfil the same governance checks as academic researchers. Thus, to undertake two 3-hour research observation sessions, PPI members had to secure NHS research passports, which required them to undertake several hours of good clinical practice (GCP) training; to gain occupational health clearances and up-to date-inoculations, which entailed a appointments with their general practitioner (GP) to obtain their inoculation history; to provide a signed and dated curriculum vitae; undergo a Disclosure and Barring Services check; secure a temporary contract as an employee at the UEA, and thus covered by their indemnity insurance; and to undertake PERFECTED specific training to enable to undertake the specific research activities. These requirements were more burdensome than the designated research activity but imposed as necessary before contributing to the research.

Working with all PPI representatives across the programme, we raised these issues with the NIHR (see *Appendix 8*) and received correspondence we could later use in later ethical submissions to highlight to recruiting sites that they needed not to seek disproportionate checks and balances for PPI members (see *Appendix 2*). Despite this reassurance, we still encountered similar challenges and barriers during WP1 phase 4 (2014–5) and WP2 (2015–6).

#### Higher education institutions

During PERFECTED, a recurring procedural challenge was to ensure that PPI members could be efficiently and promptly contracted and paid for their contributions. While INVOLE offers some guidance (www.invo.org.uk/wp-content/uploads/2016/05/CCF_Public_Payment_Guide-1.pdf), higher education institution human resource procedures have not developed flexible approaches in these cases. These issues are echoed in subsequent publications.[50] Higher education institutions face challenges in providing proportionate contractual responses to increasing number and types of infrequent but long-term engagements which characterise PPI involvement in research programmes.

#### National research ethics committees

National research ethics committees reviewed and subsequently approved the various ethical submissions and protocols over the duration of the PERFECTED research programme. They provided a review which was forward-thinking and risk-aware rather than risk-averse. Compared with NHS research and development departments and higher education institutions, research ethics committees reviewed in open-minded and proportionate ways.

#### Key findings for researchers

For programmes like PERFECTED, we recommend an initial PPI meeting to agree PPI members' commitments and expectations. Consistent and timely communication using a single point of contact could be achieved with a PPI-specific

administrative support role. Often, meetings were via teleconference; however, face-to-face meetings were favoured by our PPI members. Pre meetings with PPI members enabled clearer understandings of expectations and the views of PPI members' views to be more fully expressed. Providing a single point of contact was important.

## Reflections

The PERFECTED programme was successful. It developed and tested an enhanced recovery pathway for hip fracture patients with CI. The intervention development phases delivered the intervention and in-depth understandings of the complexity of the environment for patients with hip fracture and CI which goes someway to developing understandings of the poorer outcomes for this group.

Work programme 2 used NHS quality improvement methods to test implementation and has delivered insights into the difficulties faced by implementors of change within the NHS context, which does not prioritise service improvement and where the efforts required for this task are often perceived as illegitimate.

Work programme 3 tested the final intervention in a large cluster randomised feasibility trial with embedded process evaluation. This showed that it was feasible to undertake a definitive trial and economic evaluation in the future, deploying the developed and refined recruitment and consenting practices. It also indicated that mortality is a feasible primary outcome measure which could be collected economically.

The process evaluation demonstrated that PERFECT-ER can be implemented in differing NHS contexts. Barriers to implementation include staffing issues, low staff morale, staff sickness, staff movement between wards and lack of senior staff impacted negatively on implementation. However, facilitators were identified as the protected SIL resource, PDSA processes, networking with key staff members and trust processes, resourcefulness, determination, commitment and ingenuity of SILs, PPLs and others with whom they worked. Findings demonstrated that implementing PERFECT-ER was both welcomed, necessary and viewed as having value.

### *Recommendations for future research*

Complex interventions such as PERFECTED need to be implemented in the complex and changing world of clinical practice. Implementation is a key factor influencing testing such interventions, potentially compromising potential effectiveness in clinical trials. Outcome measures in such studies need to be easily and reliably collectable challenging the priority given to patient reported outcomes in such circumstances.

### *Implications for practice*

Implementing change in the NHS is fraught with difficulty – competing and changing demands on staff impact on implementation potential. Political drivers, such as best practice tariff, override other motivations for change, reinforced by organisations financial targets.

## Key learning

- PERFECT-ER feasibility indicates the intervention had potential impact.
- Given the complexity of the setting, further research is necessary to establish effectiveness and achieve full impact.
- Efforts to attract further funding have not been supported.
- Research into improving care is not simply quality improvement, successful change appears dependent on money motivating change.
- The care of people with CI and hip fracture poses a 'wicked problem' and definitive research using a RCT will probably not provide evidence of effectiveness due to the complexity of the patient group and acute care settings. Other evaluation methods should be considered.

## Perioperative Enhanced Recovery hip FracturE Care of paTiEnts with Dementia programme management

*Figure 3* provides an overview of PERFECTED governance structures. To deliver programme management and co-ordination, we formed a programme management group (PMG) in November 2013. Chaired by Professor Chris Fox (chief investigator), including all co-applicants (in their roles as methodological, WP or site leads) and delivery teams based at the UEA, this group was responsible for delivering the programme and reporting to oversight committees (see *Figure 3*). Regular meetings and telephone conferences enabled co-ordination across sites.

The PSC, which became the trial steering committee from January 2016, was responsible for governance, reporting to the sponsor (UEA) and funder (NIHR) as appropriate. Formed in September 2014, the group included three PPI colleagues and an independent chair, Professor Cameron Swift. It received progress reports from the PMG, the PAG) and the DMEC, which was formed in January 2016. The group met biannually, with face-to-face meetings once a year.

The PAG was formed in September 2014 with three PPI colleagues and chair Professor Cornelius Katona. The group received reports from the PMG and was responsible for offering advice to the PMG and PSC on methodological or analytical issues including personal expertise, experience and knowledge. This group offered international, perspectives on protocol development and implementation and met biannually.

An independent DMEC formed in January 2016. Chaired by Dr Claudia Cooper and following DAMOCLES (Data Monitoring Committees: Lessons, Ethics, Statistics) guidelines, it received reports from the PMG[87] and provided oversight to safeguard the interests of trial participants, monitor the main outcome measures (including safety and efficacy) and of the conduct of the trial. The group met biannually and included a PPI member.

Three regional service user advisory groups were set up, assisted by Dr Nigel Lambert, an experienced PPI facilitator (research team). He liaised with PPI representatives from each group, the PSC and PAG. These groups were replaced by a national-level service user advisory group in WP3. This group continued to be supported by specific contacts in the research team.

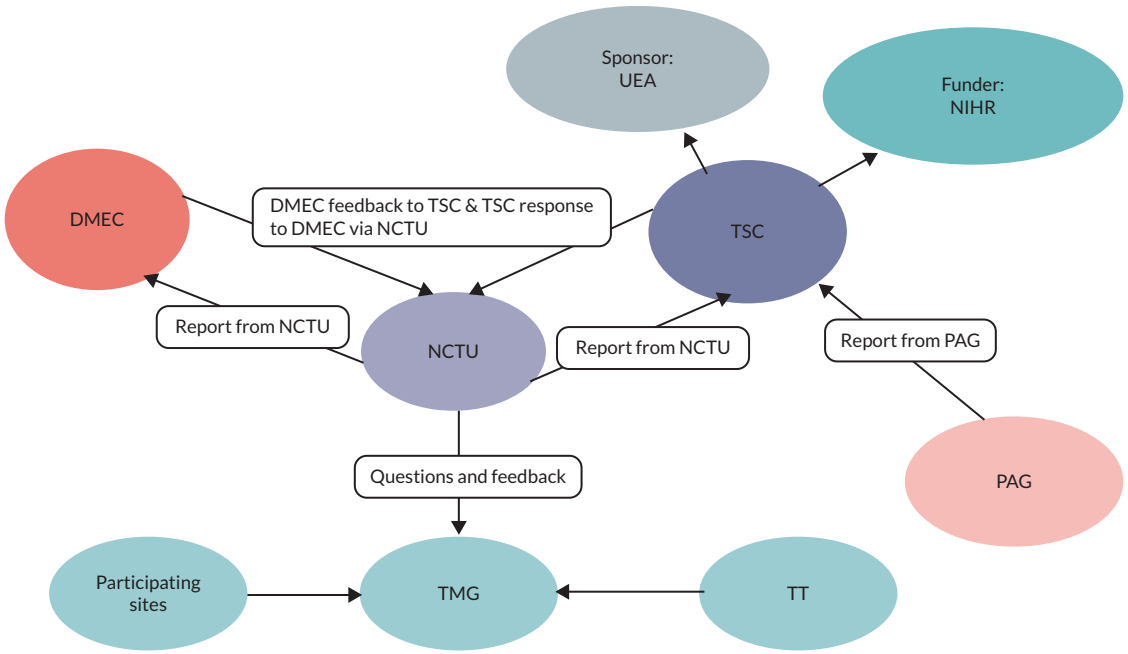


**FIGURE 3** Perioperative Enhanced Recovery hip FracturE Care of paTiEnts with Dementia governance. NCTU, Norwich clinical trials unit; TMG, trial management group; TSC, trial steering committee; TT, trial team.

# Additional information

## Contributions of authors

**Chris Fox (**https://orcid.org/**0000-0001-9480-5704)** Professor of Old Age Psychiatry. Was chief investigator and oversaw the programme, contributed towards the design and conduct of the study and was involved in editing and revisions of the report.

**Simon P Hammond (https://orcid.org/0000-0002-0473-3610)** Programme Manager, Research Fellow. Contributed to the design and analysis of the study and was involved in editing and revisions.

**Lee Shepstone (https://orcid.org/0000-0001-5524-7818)** Professor of Statistics. Contributed to the design and analysis of the study and the writing of the report.

**Fiona Poland (https://orcid.org/0000-0003-0003-6911)** Professor of Social Research Methods. Led the PPI, contributed to the design and analysis of the study and the writing of the report.

**Catherine Henderson (https://orcid.org/0000-0003-4340-4702)** Research Fellow – Health Economics. Contributed to the design and analysis of the study and the writing of the report.

**Tamara Backhouse (https://orcid.org/0000-0001-8194-4174)** Senior Research Associate. Contributed to the design, conduct and analysis of the study and the writing of the report.

**Bridget Penhale (https://orcid.org/0000-0002-8487-0606)** Reader. Contributed towards the design and conduct of the study and was involved in editing and revisions of the report.

**Simon Donell,** Honorary Professor. Suggested the study of hip fracture patients, provided the orthopaedic expertise, contributed towards the design and conduct of the study.

**Martin Knapp (https://orcid.org/0000-0003-1427-0215)** Professor of Health Economics. Contributed towards the design of the study and was involved in editing and revisions of the report.

**Douglas Lewins**, PPI member. Advised on the conduct of the study and was involved in editing and revisions of the report.

**Alasdair MacLullich (https://orcid.org/0000-0003-3159-9370)** Professor. Contributed towards the design and conduct of the study.

**Martyn Patel (https://orcid.org/0000-0002-9313-3894)** Consultant in Older People's Medicine, Norfolk and Norwich Hospital. Contributed towards the design and conduct of the study.

**Opinder Sahota (https://orcid.org/0000-0003-0055-7637)** Professor, Nottingham University Hospitals NHS Trust. Contributed towards the design and conduct of the study.

**Toby O Smith (https://orcid.org/0000-0003-1673-2954)** Senior Lecturer. Led the research synthesis programme in WP1, contributed to the conduct of the study and the writing of the report.

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**Jane L Cross (https://orcid.org/0000-0002-7003-1916)** Senior Lecturer. Led WP1 and WP2, contributed to the design, conduct and analysis of the study including writing and revisions of the report.

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Patient and public involvement members contributed to this programme and had to engage with a steep learning curve while having limited time in their lives to give to this project. The PERFECTED team acknowledge and give particular thanks for the patience, expertise and enthusiasm shown by our PPI members in providing oversight on committees, regional service user advisory groups and as front-line co-researchers. We thank Marion Shoard, Doug Lewins, Marianne Vincent, Angela Clayton-Turner, Sylvia Wallach Squire, Alan Caswell, Lynne Chambers, Fiona Hardy, Esther Harris, Dave Gudgeon, Ian Robertson, Marilyn Roberston, Liz Magem, Lorraine Reddington, Sue Tucker, Isla Dowds, Stevie Vanhegen, Denise Day, Sara Gregson and Dominic Tye.

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## Patient data statement

This work uses data provided by patients and collected by the NHS as part of their care and support. Using patient data is vital to improve health and care for everyone. There is huge potential to make better use of information from people's patient records, to understand more about disease, develop new treatments, monitor safety and plan NHS services. Patient data should be kept safe and secure to protect everyone's privacy, and it is important that there are safeguards to make sure that they are stored and used responsibly. Everyone should be able to find out about how patient data are used. *#datasaveslives* You can find out more about the background to this citation here: https://understandingpatientdata.org.uk/data-citation

## Data-sharing statement

All available requests should be submitted to the corresponding author. Access to anonymised data may be granted following review.

## Ethics statement

* Care delivery in acute hospital settings: an observational study :
REC name: East Midlands - Leicester Central Research Ethics Committee
REC reference: 14/EM/1020
Date of REC Opinion: 9 Jun 2014
REC opinion: Favourable Opinion
IRAS ID: 146744

* PERFECTED WP1 P4: A qualitative exploration of lay and professional stakeholder views of care delivery in hospitals for patients with hip-fracture & memory difficulties :
REC name: East of England - Cambridgeshire and Hertfordshire Research Ethics Committee

REC reference: 15/EE/0007
Date of REC Opinion: 28 Jan 2015
REC opinion: Further Information Favourable Opinion
IRAS ID: 146746

* PERFECTED WP2: Implementing optimised hospital care:
REC name: South Central - Oxford C Research Ethics Committee
REC reference: 15/SC/0294
Date of REC Opinion: 3 Jun 2015
REC opinion: Favourable Opinion
IRAS ID: 179797

* PERFECTED WP3: Care of patients experiencing hip fracture & confusion: PERFECTED CRCT :
REC name: London - Camden & Kings Cross Research Ethics Committee
REC reference: 16/LO/0621
Date of REC Opinion: 4 Jul 2016
REC opinion: Further Information Favourable Opinion
IRAS ID: 186320
Scottish approvals:
REC: Scotland A REC
REC reference: 16/SS/0086
Date of REC opinion: 28 June 2016
IRAS ID: 205905

## Information governance statement

The University of East Anglia (UEA) is committed to handling all personal information in line with the UK Data Protection Act (2018) and the General Data Protection Regulation (EU GDPR) 2016/679.

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## Disclosure of interests

***Full disclosure of interests:*** Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/MDTT6530.

***Primary conflicts of interest:*** Lee Shepstone: EME Funding Committee member 2010–4.

Toby O Smith: HS&DR commissioned Associate Board member 2012–6 and HS&DR Associate Board member 2012–8.

Jane Cross: HTA EESC Methods Group 2014–6, HTA EESC Panel 2012–7.Justin Waring: HS&DR researcher-led board member 2013–6.

## Publications

Gill N, Hammond S, Cross J, Smith T, Lambert N, Fox C. Optimising care for patients with cognitive impairment and dementia following hip fracture. *Z Gerontol Geriatr* 2017;**50**:39–43. https://doi.org/10.1007%2Fs00391-017-1224-4. ***Among the highest-scoring outputs from this source (#33 of 154)***

Hammond SP, Cross JL, Shepstone L, Backhouse T, Henderson C, Poland F, *et al.* PERFECTED enhanced recovery (PERFECT-ER) care versus standard acute care for patients admitted to acute settings with hip fracture identified as experiencing confusion: study protocol for a feasibility cluster randomized controlled trial. *Trials* 2017;**18**:1–10. https://doi.org/10.1186/s13063-017-2303-y. ***In the top 25% of all research outputs scored by Altmetric***

Hammond SP, Cross JL, Poland FM, Patel M, Penhale B, Smith TO, Fox C. Freedom of information act: Scalpel or just a sharp knife? *J Med Ethics* 2017;**43**:60–2. https://doi.org/10.1136/medethics-2016-103609 (green open access: https://ueaeprints.uea.ac.uk/id/eprint/61054). ***In the top 25% of all research outputs scored by Altmetric***

Fox C, Howard RJ, Ballard C, Cross J, Poland F, John Knapp MR, *et al*. Peri-operative enhanced recovery hip fracture care of patients with dementia (PERFECTED): RCT results. *Alzheimers Dement* 2019;**15**:P1448. https://doi.org/10.1016/j.jalz.2019.06.4057. ***In the top 25% of all research outputs scored by Altmetric***

Backhouse T, Hammond SP, Cross JL, Lambert N, Varley A, Penhale B, *et al*. Making body work sequences visible: an ethnographic study of acute orthopaedic hospital wards. *Sociol Health Illn* 2020;**42**:1139–54. https://doi.org/10.1111/1467-9566.13085 (green open access Altmetric – Making body work sequences visible: an ethnographic study of acute orthopaedic hospital wards). ***In the top 25% of all research outputs scored by Altmetric***

Smith TO, Gilbert AW, Sreekanta A, Sahota O, Griffin XL, Cross JL, *et al.* Enhanced rehabilitation and care models for adults with dementia following hip fracture surgery. *Cochrane Database Syst Rev* 2020. https://doi.org/10.1002/14651858.CD010569.pub3. ***In the top 5% of all research outputs scored by Altmetric***

Cross JL, Backhouse T, Hammond SP, Penhale B, Scheibl F, Lambert N, *et al.* Disjunctures in practice: ethnographic observations of orthopaedic ward practices in the care of older adults with hip fracture and presumed cognitive impairment. *Ageing Soc* 2022. https://doi.org/10.1017/S0144686X22000927

Cross JL, Hammond SP, Shepstone L, Poland F, Henderson C, Backhouse T, *et al*. PERFECTED enhanced recovery pathway (PERFECT-ER) versus standard acute hospital care for people after hip fracture surgery who have cognitive impairment: a feasibility cluster randomised controlled trial. *BMJ Open* 2022;**12**:e055267. http://doi.org/10.1136/bmjopen-2021-055267

Backhouse T, Fox C, Hammond SP, Poland F, McDermott-Thompson V, Penhale B, Cross, JL. Implementing an intervention to enhance care delivery and consistency for people with hip fracture and cognitive impairment in acute hospital wards: a mixed methods process evaluation of a randomised controlled feasibility trial (PERFECTED). *BMJ Open* 2023;**13**:e064482. https://doi.org/10.1136/bmjopen-2022-064482

Fox C, Hammond SP, Backhouse T, Poland F, Waring J, Penhale B, Cross JL. Implementing PERFECT-ER with Plan-Do-Study-Act on acute orthopaedic hospital wards: building knowledge from an implementation study using Normalization Process Theory. *PLOS One* 2023;**18**:e0279651. https:// 10.1371/journal.pone.0279651

**Oral presentations**

**European Delirium Consortium British Society of Gerontology London 2015** Perioperative Enhanced Recovery hip FacturE Care of paTiEnts with Dementia (PERFECTED).

**European Union Geriatric Medicine Association Lisbon 2016** Caring for people with hip fracture and cognitive impairments: qualitative findings from the PERFECTED research programme.

**One hundred and ten years after Auguste Deter Marktbreit, Ochsenfurterstr. Germany 2016** Dementia care research International symposium. International co-design in hospital care of cognitive impairment: the PERFECTED programme.

**AGILE London 2016,** 360 Degree Hospital Care Design in Dementia and Delirium: PERFECTED?

**AAIC 2017** 'It's good care, but who is it good for, me?' A multi-perspective insight into stakeholder constructions of 'good care' for people living with dementia and hip fracture.

**Gerontological Society of America San Francisco 2017** 'Work is like a conveyor belt' but does this mean poor care?: findings from an ethnographic study of acute trauma wards.

**British Society of Gerontology Swansea Wales 2017** Getting on or getting better?

A multi-perspective insight into the provision of care to cognitively impaired patients.

**IAGG Global Aging and Health: Bridging Science, Policy, and Practice. Chicago 2018** 'Bribe Them With Cake'; Implementing Change in Acute Hospital Settings; An Action research Study.

**Alzheimer Europe Barcelona 2018** Acute Care for Patients with Cognitive Impairment: A Qualitative Study.

**FFN 2018** Trials in rehabilitation involving patients with dementia – the PERFECTED experience.

**British Geriatrics Society Spring Meeting. Cardiff, Wales 2019** *Age & Ageing*, *48*, ii20 ii22. https://doi.org/10.1093/ageing/afz059.01. Perioperative enhanced recovery hip fracture care of patients with dementia (PERFECTED): cluster randomised control trial.

**Alzheimer Society 2019** Enhancing recovery for people with hip fracture and dementia in acute hospital wards: a mixed methods process evaluation of the PERFECT-ER intervention.

**World Alzheimer's Day webinar with CRN Eastern and CPFT 2021** Professor Chris Fox Title: 'PERFECTED key findings and future directions'.

**Fragility Fracture Network Toronto Canada 2021. Rehabilitation Key Note invited speaker Dr Jane Cross Tile** 'Physiotherapy – but not here': an ethnography of acute orthopaedic wards with a focus on the 'cognitively impaired'.

**Posters**

**AAIC Conference London 2017.** Person-Centred Care Practices on Acute Trauma Wards Caring for People with Cognitive Impairments: An Ethnographic Study.

**FFN 2018** Disruptions, Discontinuities and Dispersions: An Ethnography of Disjunctures in Acute Orthopaedic Wards.

**Alzheimer Society Conference 2019** Enhancing recovery for people with hip fracture and dementia in acute hospital wards: a mixed methods process evaluation of the PERFECT-ER intervention.

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# **Appendix 1** Work package 1 phase 1a: systematic review of best practice in hospital care for people with dementia and hip fracture

## Methods

We undertook a systematic review of best practice in hospital care for people with dementia and hip fracture, with a comprehensive, systematic search strategy to identify empirical evidence regarding critical ingredients in caring for this group. We registered the protocol with PROSPERO (CRD42012002047). We examined effectiveness in terms of cognitive function, functional performance, behaviour, quality of life, pain, mortality, clinical complications, health and social care service use and costs.

## Outcomes: key findings

The systematic review found insufficient good-quality research on the rehabilitation of people living with CI following hip fracture surgery.[107] The majority of the literature reviewed studied people with mixed CI status and/or people with CI and hip fracture as a subgroup of larger studies. This means that they lacked power to detect differences between intervention groups. The review suggested that enhanced care models of rehabilitation could decrease the length of hospital stay and reduce admissions to care. No cost-effectiveness studies were located.

Our review agrees with previous literature, that people living with CI are at greater risk of postoperative complications and higher mortality at 12 months postoperatively. It evidenced uncertainty around rehabilitation provision with no documented guidelines based on UK or international policy on how to deliver care to people living with CI following hip fracture. Components of enhanced care included screening for delirium and assessing pain for people with CI and hip fracture.

## Limitations

Perioperative Enhanced Recovery hip FracturE Care of paTiEnts with Dementia aimed to use available evidence to identify components for inclusion in an enhanced recovery intervention to optimise care delivery. The paucity of evidence necessitated an additional strategy to determine current clinical practice and service strategies using a FOI request to all UK NHS acute trusts, not part of our original application, which became WP1 phase 1b.

# **Appendix 2** Work package 1 phase 1b: freedom of information requests to access current clinical dementia strategies

## Methods

The Freedom of Information Act 2000 and the Freedom of Information (Scotland) Act (2002)[40,49] enable the public to obtain defined information from UK government departments and public bodies. We developed FOI requests in partnership with clinical stakeholders and refined these with four NHS trust FOI departments (one in each devolved nation). After piloting, in January 2014 we issued FOI requests to UK NHS trusts using the FOI request letter reproduced below.

## Research tool: freedom of information request letter

To whom it may concern,

I am making a request for any current policies which you may have for treating people with dementia who get admitted to acute hospital trusts under the UK Freedom of Information Act. I would also like to know if these policies have been evaluated. As such my request is as follows:

Does your acute hospital(s) have specific policies for treating people with dementia who get admitted to hospital?
If so, please provide me with a list of acute hospitals which do have specific policies and those that do not.
Where specific policies are in place, please send me an electronic copy of this/these documents? (Ideally in a Word or PDF format)
Have these policies been evaluated in anyway, this may include discussion papers, audits, economic impacts or strategic planning?
If so can you please send me the evaluative documentation? (Ideally in a Word or PDF format)

I would like to take this opportunity to thank you for dealing with this request.

Yours sincerely

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## Outcomes: key findings

The FOI highlighted the policy priorities NHS trusts emphasised for people with dementia and hip fracture in March 2014. Numerous hospitals shared global dementia strategies and geriatric acute hip fracture pathways. However, no hospital shared an integrated dementia and hip fracture pathway or other documentation.

From the 343 documents, 25 major themes (care elements) were identified: antipsychotics, behaviours that challenge, cost consequences, communication (between staff and patients, between staff and carers/family, between staff), consenting, constipation, delirium, dementia assessment, deprivation of liberties', discharge processes, end-of-life care, falls, hydration, identification of patients with dementia, incontinence, involving carers, manual handling, minimising ward changes, non-pharmacological interventions, nutrition, pain relief, pressure ulcers, safeguarding vulnerable adults, training in dementia care and ward environment. These were then identified with the elements described in the ERAS literature (admission, preoperative, intraoperative, postoperative, rehabilitation, discharge). This created a coding matrix used to guide future developments in WP1 to frame and present data from the multiple sources across WP1 to the WP1 phase 5 consensus events.

## Limitations

The FOI exercise was used in response to the lack of high-quality peer-reviewed research literature. FOI requests are subject to how the request is interpreted and handled by each organisation. Unlike more systematic search strategies, researchers are constrained by the subjectivity of the recipient of the FOI request and who, within the organisation, should (and is able) to respond. Thus, our FOI request may have gone to geriatricians, orthogeriatricians, orthopaedic surgeons, dementia champions or senior nurse ward managers, which could have been a strength. However, the response is dependent on how the organisation and then the healthcare professional, tasked by their organisation, decides to respond. While most responders were happy to provide information to researchers, others asked that we withdraw our requests, suggesting that they were happy to respond more informally outside the 21-day time limit of the FOI legislation. However, we found that further contact with the sites was not forthcoming. We discuss these issues more fully in Hammond *et al.*[50] (green open access: https://ueaeprints.uea.ac.uk/id/eprint/61054).

# **Appendix 3** Work package 1 phase 2: national and international telephone survey of healthcare workers

## Methods

We generated a four-item telephone survey topic guide using our review findings,[53] and the National Audit of Dementia Care in Hospital.[54] We sought to identify potential care bundle components by locating relevant grey literature, unpublished data, policy documents, audit standards, treatment protocols and care procedures aiming to achieve quality care pathways, including initiatives to improve patient and carer/family experiences. The telephone survey method also enabled responders to contextualise documents they planned to share, highlight gaps between best and current practice and indicate implementation difficulties.

Ethical approval was provided by the UEA Faculty of Medicine and Health Science Research Ethics Committee on 24 January 2014 (REF: 2013/2014 – 24). Verbal informed consent was obtained at the beginning of each call with participants informed that data might be available for further investigations after the programme.

## Outcomes: key findings

Work package 1 phase 2 established domestic and international healthcare professionals' perspectives on the care pathways and costs, hospital length of stay and discharge destinations for people with dementia and hip fracture. Participants recognised the differing needs of patients with dementia in acute settings, but documentation tended to be dementia or hip fracture focused not both. They indicated that training to provide colleagues with the skills to care for this patient group tended to be generic and had a 'tick box feel', noting that outcome metrics such as length of stay, were unhelpful in terms of recognising recovery and what recovery means for this patient group. We discuss these this more fully in Gill *et al*.[16]

Analysed documents identified potential intervention components and provided insights into participants' perceptions of current and best practice and implementation gaps. This was used to generate guides for the observations in WP1 phase 3.

## Limitations

The international survey identified participants using recommendations from our co-applicants, using snowballing techniques to identify further participants. Thus, a significant proportion of participants were academic clinicians. In the UK, when saturation was reached in professional groups (e.g. consultants) we asked them to recommend colleagues from other professions within their trust and then contacted them to participate. It was more difficult to access those professions who had little control over their clinical time (nurses, associated health professionals). Internationally we were restricted by language and availability of front-line professionals.

While the disadvantages of chain-referral sampling within the domestic telephone survey were mitigated by simultaneously deploying our FOI exercise, this was not the case in the international survey.

**TABLE 1** National telephone survey by profession

| Profession | *N* |
|---|---|
| Dementia nurses | 11 |
| Consultant | 17 |
| Physiotherapists | 2 |
| Occupational therapists | 6 |
| Dieticians | 3 |
| Dementia pathway lead | 1 |
| Dementia practitioner | 1 |
| Director of nursing | 1 |
| Senior hip fracture nurse | 1 |
| Dementia services manager | 1 |
| Liaison psychiatrists | 3 |
| Social worker | 1 |
| Pharmacist | 2 |
| Total | 50 |

**TABLE 2** International telephone survey by profession

| Profession | *N* |
|---|---|
| Physician | 17 |
| Senior manager | 3 |
| Senior academic | 16 |
| Occupational therapist | 2 |
| Senior nurse | 2 |
| Total | 40 |

**TABLE 3** International telephone survey by location

| Country | *N* |
|---|---|
| USA | 9 |
| Italy | 2 |
| Scotland | 5 |
| Germany | 1 |
| Australia | 6 |
| Sweden | 1 |
| Portugal | 1 |
| Ireland | 1 |
| Switzerland | 2 |

**TABLE 3** International telephone survey by location (*continued*)

| Country | *N* |
|---|---|
| Norway | 4 |
| Canada | 1 |
| Denmark | 1 |
| Singapore | 1 |
| Malaysia | 1 |
| Hong Kong | 1 |
| Netherlands | 1 |
| France | 1 |
| Poland | 1 |
| Total | 40 |

# **Appendix 4** Work package 1 phase 3: focused ethnographic observations of care in acute orthopaedic wards

## Methods

We used a focused ethnographic approach to observe practices in acute orthopaedic wards and some EDs to observe usual care. Drawing on features of institutional ethnography,[55] we observed practice, including interactions, paying particular attention to individuals who may be cognitively impaired. Our ethnographic approach facilitated in-depth understanding of how relationships, lived experiences and everyday ward activities were situated in their contexts.

We observed shared spaces on orthopaedic wards and EDs in three NHS hospitals in England selected to vary in size, geographical region and location on the rural–urban continuum.[56]

The National Research Ethics Service Committee East Midlands – Leicester (number 14/EM/1020) provided ethical approval.

We recruited, trained and supported PPI colleagues as 'lay' researchers. During fieldwork, researchers adopted a 'marginal role',[58] meaning they focused on interactions and held ad hoc discussions with participants to pose questions about events witnessed. Observers recorded events as field notes, providing thick descriptions of what they saw and heard, noting their reflective comments in a distinct typeface.

## Outcomes: key findings

Analysis of these data provided insights into workflow in these conflicting and pressurised settings. We identified three, often-linked, interruptions ('disjunctures') to routines or planned sequences in caregiving. These were identified as disruptions, discontinuities and dispersions.

Disruptions – when usual or expected practices are interrupted – impacting on ways staff manage care delivery more or less easily.
Discontinuities – when divisions in culture, spaces and timing interrupt the smooth delivery of tasks.
Dispersions – occasions when environment artefacts [object(s) and/or people] are displaced.

This work identified potential intervention components and added contextual data, including organisational settings and systems, which may inhibit rather than promote best practice for care elements within the enhanced recovery pathway. Cross *et al*. report these findings.[108]

These data also address the increasing interest within health and social care to understanding the nature and centrality of body work. Relatively little is known about how and where body work specifically fits into the wider work relations that produce it in healthcare settings. Our data show body work interactions in acute care to be critically embedded within a context of initiating, preparing, moving and restoring and proceeding.[109] Shades of privacy and objectification of the body are present throughout these sequences. While accomplishing tasks away from the physical body, staff members must also maintain physical and cognitive work focussed on producing body work. Thus, patient care is necessarily complex, requiring much staff time and energy to deliver it. We argue that by making visible the microprocesses that hospital patient care depends on, including both body work and the work sequences supporting it, the complex physical and cognitive workload required to deliver care can be better recognised.

## Limitations

Using the clinical setting for ethnographic fieldwork presented numerous ethical challenges and some methodological limitations. Unlike many ethnographic studies, the observed community changed with the turnover of NHS staff, patients and visitors. The symptoms of CI (including dementia and/or delirium) were observable, but we did not confirm whether any observations included patients with a dementia diagnosis. Thus, we illustrate the needs of patients with assumed CI rather than confirmed dementia or delirium, acknowledging that any intervention must attend to the needs of all patients with hip fracture and any CI.

# **Appendix 5** Work package 1 phase 4: exploration of stakeholder views of care experiences

## Methods

We undertook semistructured interviews with patients and carers, and interviews and focus groups with healthcare staff from three different geographical regions across England. We created a semistructured interview schedules for patients, carers/families in partnership with PPI members and developed semistructured interview schedules and focus group topic guides for healthcare staff informed by the previous work.

Interviews enabled us to explore stakeholder experiences and the meanings and priorities they attached to them.[59] Interviews with patients were undertaken according to their capacity to participate.[57] We recruited and trained PPI members as co-interviewers for the carer interviews. Focus groups provided an opportunity to explore healthcare staffs' views and perspectives including collective and divergent viewpoints.[60] Interviews were also offered to front-line staff once it transpired that releasing staff from ward environments for a focus group was not feasible. The National Research Ethics Service Committee East of England – Norfolk provided ethical approval on 28 January 2015.

## Outcomes: key findings

Stakeholder perspectives and experiences illuminated the contextual features of the implementation context. Staff focus groups and interviews identified emotive experiences, fatigue and constraints experienced on a daily basis. They described failing cognitively impaired patients with:

lack of staff and/or time required to deliver care for such people
combined organisational barriers
care spaces not suitable for such people

Carer experiences supported these views, with some reporting feeling under pressure to assist staff, whom they perceived as needing help to relieve shortages. However, carers did not regard this as empowering them to co-deliver care. Patients who were interviewed were usually full of praise for the efforts of staff improvising to meet disjunctures in workflow. In some cases, re-prioritising tasks by staff impacted on patients experience and, while they understood the need for such reprioritisation, they acutely felt its impact beyond the acute setting.

## Limitations

Recruiting patients and carers was difficult and we deployed various strategies to improve recruitment. We adjusted who, how and when eligible patients were given information about the study, how they could express an interest and how this was followed up to reduce perceived burden. We doubled the number of recruitment centres (from three to six) and enabled carers to contribute via telephone interviews instead of face-to-face. Despite these measures we recruited fewer patients and carers than planned but achieved sufficient data for the analysis. Protocol changes were supported by the PSC and PAG.

Interviewing people with mild CI about their hospital experiences, around 1 month after admission, was challenging. The unfamiliar surroundings, busyness of acute settings and the impact of analgesia and anaesthesia, especially in the presence of cognitive issues, made recalling events and placing them in recognised sequence, extremely challenging.

For carers, anxieties about hospital care, liaising with numerous support services and relevant personnel, as well as sometimes trying to adjust the patient's living arrangements and dealing with the emotional impact of these factors,

was exhausting. This made the perceived burden of research excessive and contributed to their unwillingness to participate.

Recruiting front-line NHS staff was problematic despite provision for wards to use financial payments from the study to 'backfill' staff or to use these funds to offer overtime payments to staff as compensation for participating in focus groups after their shifts.

# **Appendix 6** Work package 1 phase 5: developing the intervention

## Method

Care elements were presented to attendees, divided into five groups constructed to consider care elements most closely related to their professional expertise. Each group was asked to identify components to include in the PERFECT-ER intervention and then locate these into the relevant ERAS phase. Participants were then regrouped according to where, in the ERAS pathway, they had most influence. For example, in the rehabilitation phase group, physiotherapists were joined by occupational therapists, discharge co-ordinators and psychiatric liaison nurses. Each group was asked to consider the components now populating their portion of the ERAS pathway to identify missing elements and rank the three most important care elements. Finally, a whole group discussion ensured components of the pathway fitted together to represent the complete patient journey.

## Outcomes: key findings

The research team scrutinised the prototype PERFECTED intervention, in terms of how actionable and auditable it was and an audit checklist was designed – the PERFECT-ER checklist. The PSC considered the items suggested in the intervention, to identify where standardisation was not possible. For example, while preoperative analgesia regimens could not be standardised, the PERFECT-ER could highlight how analgesia regimens might impact on a patient's CI to hamper or facilitate postoperative rehabilitation processes. The developed checklist is currently not included in this report to facilitate future research.

## Limitations

We pragmatically applied the most rigorous consensus strategies during WP1 P5, but they were relied on level 4 evidence, including expert committee reports, opinions and clinical experience of experts.[61] With no PERFECT-ER component supported by strong research evidence we proceeded assuming that, by bringing together several marginal gains and implementing a number of smaller changes, patient outcomes, patient and carer experience and staff satisfaction and competence could be improved.[65]

# **Appendix 7** Work package 3: cost-effectiveness evaluation

## Details of economic evaluation: qualitative and cost data mapping

We investigated how the service improvement intervention was implemented, whether hospital resource use changed and whether resultant changes would be detectable without resort to (expensive) microcosting methods in a definitive trial. The economic evaluation drew on the NHS reference costs to calculate patients' hospital costs and parallel work explored the feasibility of detecting finer-grained variations in costs related to the intervention. Reference costs are providers' average costs for each healthcare resource group, clinically meaningful case mix groupings of hospital activities that are based on both diagnoses and procedures.[88,89] A result of the pilot economic evaluation's costing strategy of attaching reference costs to inpatient days was that only variations in costs related to the length of the index admission could be measured. We therefore explored how time is used to provide appropriate care to people who are confused and have hip fracture to inform measurements of intervention-related variations in hospital costs.

We asked hospital staff in the active sites to describe what differences might exist in ward care practices with patients with hip fracture and confusion and with patients with hip fracture (without confusion) as part of the process evaluation. We also examined the systems for collecting activity and costs data. In particular, we investigated whether patient-level information and costing systems (PLICS), could yield hospital service cost data accurately reflecting changes in patient service use resulting from PERFECT-ER better than the reference costing system. PLICS collections have evolved over recent years to the point of becoming mandated national collections in England, beginning in 2019.[90]

## Methods

### *Hospital costing systems*

Information was collected from finance staff in 7/9 trusts by telephone and a brief written response received from another trust. The remaining participating trust declined permission for this research activity due to costs. CH sought NHS costing guidance documents issued by NHS Improvement in England and the Information Services Division in Scotland and corresponded with the Information Services Division in Scotland and NHS Digital in England about their plans for warehousing PLICS collections and the availability of data extracts in future years.

### *Qualitative research*

The process evaluation included questions for individual NHS active sites' ward staff and focus groups. These covered:

- staff members' concept of confusion and confused behaviours
- staff perceptions of the proportion of patients on their ward exhibiting confusion
- whether staff adapted care practice to accommodate patients with confusion and how
- whether care provided might change on a ward in response to a higher proportion of confused patients on the ward

Anonymised excerpts of process evaluation transcripts were provided to the health economist for evaluation.

## Results

Hospital workers described various 'confused' behaviours, including disorientation, wandering, non-compliance with hip precautions, aggression, shouting and pulling out cannulas. The view that pain was a root cause of such behaviours was widely held. Staff members altered the way they provided care for patients with confused behaviours using one-to-one observation by unqualified nursing staff routinely. This left other nursing staff to cover the remaining workload during the shift or additional staff members (from the permanent or bank workforce) were called in. Wards

used 'dementia boxes' or 'activity boxes' of reminiscence and cognitive stimulation materials to engage and calm confused patients. These were used when a one-to-one observation worker or a volunteer was available. Non-verbal pain assessments (an element of PERFECT-ER) were said to raise staff awareness that people with confusion might be unable to communicate pain directly. Other strategies to care for confused patients included use of bedside signs to alert staff to particular patient needs, colour-coded meal trays and deployment of bed alarms monitoring patient movements. In general, providing care for confused patients was thought to increase nursing workloads. Instances were given of changes in the ward-wide organisation of care when the number of patients with significant confusion became substantial. A ward might move all confused patients of the same sex to a bay and assign one member of staff to continuously monitor patients in that bay.

We considered the potential for PLICS to detect intervention-related reductions in the intensity of nursing in the context of a definitive trial. A consistent picture emerged in that PLICS could yield detailed data on inputs for some aspects of patient journey (particularly time in theatre and recovery, volumes of tests) but would not yield detailed data on variations in ward staff time inputs. Any electronic systems (from trusts or NHS statistics bodies) would be unlikely to generate data that could be used to examine variations in ward staff time inputs related to individual patients' level of need.

### *Reference costs*

In preparation for a definitive trial, spell-level reference costs (England) and costs book data (Scotland) could be requested from NHS statistics agencies, obviating the need for time-consuming applications for research and development permissions and data-sharing agreements with individual trusts. PLICS data collected in 2019 by NHS Digital could also be requested. There were no Information Services Division in Scotland plans to collect these data so PLICS data would need to be requested from individual trusts, where available. PLICS data would yield more accurate costs of certain elements of individual patient pathways but, at the stage of most concern to the trial, the postoperative ward stay, would yield only the average cost across all ward patients regardless of their level of need.

## Costing methodology

### *Costs*

Study collections providing data for calculation of costs are summarised in *Table 4*.

### *Hospital use data extracted from medical records*

A set of proformas were devised to extract data from hospital records and included in the case report forms. Research nurses entered the dates of each occurrence of hospital use (e.g. inpatient admissions, A&E and outpatient department attendances, day cases) over the follow-up periods and over the 6 months prior to baseline. At each follow-up, preliminary to completing the hospital use section of the workbook, research nurses recorded whether the patient had been discharged from the baseline discharge time point into the baseline workbook. The study database automatically calculated a length of stay on the study ward.

### *Costing methods*

Units of resource input (e.g. GP contacts, ER attendances) were weighted by published, nationally applicable unit costs.[91,92] Details of unit costs are given in *Table 5*.

### *Hospital service costs*

Hospital service costs were calculated by attaching a unit cost based on a description of the reason for inpatient or outpatient attendances (recorded in both hospital-extracted and SIR collections). HRG4 subchapter codes (inpatient stays, day case or outpatient procedures) or clinical specialty codes (outpatient attendances) were assigned to each reason. An activity-weighted average cost per subchapter or per specialty derived from the NHS reference costs was then allocated to each unit of activity.[91] Where no reason was given, the weighted average cost across all adult specialties was assigned. In the case of admissions for the index fracture, a cost was assigned based on the weighted average of reference costs for the HRG codes associated with fragility hip fractures as defined in the best practice tariff.[102] Hospital costs in the 3 months prior to baseline were calculated from HRE data, for consistency with the

**TABLE 4** Overview of collections contributing data to economic evaluation

| Perspective | Data | Instrument | Source | Recorded | Time points |
|---|---|---|---|---|---|
| Health and social care | Primary and secondary health care, mental health care, medications, community day and home-based care, equipment | CSRI | Suitable informant | Suitable informant workbook | BL,[a] T1, T2, T3 |
| Health and social care | Secondary health care Medications | Extraction pro-forma | Health records | Patient workbook | BL,[b] T1, T2, T3 |
| Societal – suitable informant and participant | Carer time, out-of-pocket payment for travel, equipment | CSRI | Suitable informant | Suitable informant workbook | BL, T1, T2, T3 |
| Intervention costs | FTE of SIL and PIL; numbers of potentially eligible patients on the intervention study wards | – | Project team | Team communications | Study period |

BL, baseline; PIL, process implementation lead; T, time point.
a Excluded medications at baseline.
b Date–times of stay in the study ward were recorded separately in the baseline discharge workbook as part of the process evaluation data collection.

**TABLE 5** Unit costs

| Variable name | Unit cost, 2016–7 (£) | Unit | Source | Notes/assumptions |
|---|---|---|---|---|
| ***Respite and care home use*** | | | | |
| Private sector residential care for older people, cost of stay | 94 | Per day | PSSRU unit costs 2017, table 1.2[92] | Includes personal living expenses |
| Local authority residential care for older people, cost of stay | 162 | Per day | PSSRU unit costs 2017, table 1.3[92] | Includes personal living expenses |
| Private sector nursing home for older people, cost of stay | 119 | Per day | PSSRU unit costs 2017, table 1.1[92] | Includes personal living expenses |
| NHS continuing care | 443 | Per day | NHS reference costs 2016–7[91] | Mental health hospital stay: weighted average of CI clusters (18–21) Tab MHCC |
| NHS residential rehabilitation | 362 | Per day | NHS reference costs 2016–7[91] | Weighted average inpatient rehabilitation Tab Rehab |
| Residential intermediate care | 153 | Per day | PSSRU UC 2014, table 1.9[93] | Average cost across four Intermediate care based in residential homes; uprated using HCHS Pay and Prices Index |
| ***Community health and social care services*** | | | | |
| GP time, home visit average visit cost | 88 | Per visit | PSSRU unit costs 2017, table 10.3b for costs; PSSRU unit costs 2013 table 10.3b for ratios[92] | No information about home visits in the 2017 volume. Assumed ratio of clinic to home cost per minute remained the same and average duration of visit remained the same as given in 2013 volume. Home visit of 23.4 minutes |
| GP time, clinic visit | 28 | Per visit | PSSRU unit costs 2017, table 10.3b[92] | No direct care staff and no qualification costs, per surgery consultation of 9.22 minutes |
| Practice nurse, face-to-face time | 9 | Per consultation | PSSRU unit costs 2017, table 10.2[92] | Per 15.5 minutes consultation; excludes qualification costs |

continued

**TABLE 5** Unit costs (*continued*)

| Variable name | Unit cost, 2016–7 (£) | Unit | Source | Notes/assumptions |
|---|---|---|---|---|
| Community nursing time | 37 | Per contact | NHS reference costs 2016–7[91] | |
| Nurse (mental health), face-to-face contact | 44 | Per contact | PSSRU unit costs 2017, table 12.1[92] | Excludes qualification costs |
| Consultant: psychiatrist, face-to-face session | 232 | Per contact | PSSRU unit costs 2015, table 15.7[94] | Excludes qualification costs. Uprated using HCHS Pay and Prices Index. Assumes 50-minute visit |
| Social worker, face-to-face time | 59.00 | Per hour | PSSRU unit costs 2017, table 11.2[92] | Excludes qualification costs. Assumes 1 hour of client-related work |
| Physiotherapist | 53 | Per contact | NHS reference costs 2016–7 CHS tab[87] | |
| NHS occupational therapist | 13 | Per contact | PSSRU unit costs 2014, table 9[93] | Excludes qualification costs. Assumes 25-minute visit. Uprated using HCHS Pay and Prices Index |
| NHS community mental health team worker for older people with mental health problems, per team member | 44 | Per visit | PSSRU unit costs 2017, table 12.1[92] | |
| Home care – average of independent and social services | 27 | Per hour | PSSRU unit costs 2017, table 11.6[92] | Face-to-face time: average cost of private and social services costs; weighted average of weekday and weekend costs |
| Cleaner | £20 | Per visit | | Internet search (costs vary between this and higher). Assumes 2-hour visit |
| Meals on Wheels | 6 | Per meal | PSSRU compendium 2014, table 8.1.1[93] | Uprated using HCHS Pay and Prices Index |
| Sitting service that is Crossroads Carer support worker | 45 | Per visit | Evaluation of the East Sussex Carers' Breaks demonstrator site[95] | Cost of short break for carers of 2.5 hours. Uprated using HCHS Pay and Prices Index |
| Chiropodist | 44 | Per contact | NHS reference costs 2016–7 CHS tab[91] | |
| Optician | 21 | Per visit | | Cost of sight test |
| Dentist, general dental service | 85 | Per visit | NHS reference costs 2016–7 CHS tab[87] | |
| Day care for older people, per session | 56 | Per session | PSSRU unit costs 2017, table 1.4[88] | |
| Day care in NHS facilities, per attendance | 132 | Attendance | NHS reference costs 2016–7 CHS tab[87] | Day care facilities regular attendances – elderly |
| Day care for people with mental health problems, per session | 34 | Per session | PSSRU unit costs 2017, table 2.4[88] | |
| Lunch club | 8 | Per session | Romeo *et al.*[96] | Uprated using HCHS Pay and Prices inflator |
| Paramedic visit, see and treat and refer | 181 | Per attendance | NHS reference costs 2016–7[87] | ASS01 see and treat or refer |

**TABLE 5** Unit costs (*continued*)

| Variable name | Unit cost, 2016–7 (£) | Unit | Source | Notes/assumptions |
|---|---|---|---|---|
| ***Equipment and adaptations*** | | | | |
| Wheelchair (average of powered and self/attendant propelled), mean annual equipment cost | 62 | Per item | PSSRU unit costs 2017, table 7.2[88] | Annuitised over 10 years; annual cost |
| Outdoor rail | 5.40 | Per item | PSSRU unit costs 2017, table 7.2[88] | Annuitised over 10 years; annual cost |
| Stair/grab rail | 4 | Per item | PSSRU unit costs 2017, table 7.2[88] | Annuitised over 10 years; annual cost |
| Commode | 2 | Per item | PPSRU unit costs 2013, table 7.3.1[97] | Annuitised over 10 years; annual cost. Uprated using HCHS Pay and Prices inflator |
| Toilet frame/raised toilet seat | 4 | Per item | PPSRU unit costs 2013, table 7.3.1[97] | Annuitised over 10 years; annual cost. Uprated using HCHS Pay and Prices inflator |
| Chair/bed raisers | 4 | Per item | PPSRU unit costs 2013, figure 1 7.3.1[97] | Annuitised over 10 years; annual cost. Uprated using HCHS Pay and Prices inflator |
| All four-wheeled and four-footed walking frames | 9 | Per item | PPSRU unit costs 2013, table 7.3.1[97] | Annuitised over 10 years; annual cost. Uprated using HCHS Pay and Prices inflator |
| Bath seat | 10 | Per item | PPSRU unit costs 2013, table 7.3.1[97] | Annuitised over 10 years; annual cost. Uprated using HCHS Pay and Prices inflator |
| Bed rail | 4 | Per item | PSSRU unit costs 2017, table 7.2[88] | Annuitised over 10 years; annual cost. Uprated using HCHS Pay and Prices inflator |
| Individual alarm system | 410 | Per item | *Building Telecare in England*, pp. 1–21[98] | Annuitised over 5 years; annual cost; uprated using HCHS Pay and Prices inflator |
| ***Medications*** | | | | |
| Various | Range: 0.001–78 | Standard quantity units | Prescription cost analysis, England[99] | |
| ***Unpaid carer costs*** | | | | |
| National average wage – value of lost work time | 16.20 | Per hour | Annual Survey of Hours and Earnings table[100] | Gross mean wage for all employee jobs, 2017 |
| National average wage – value of lost leisure time | 5.67 | Per hour | Annual Survey of Hours and Earnings table[100] | 35% of gross mean wage for all employee jobs, 2017 |
| ***Travel costs*** | | | | |
| Cost per mile of travel for carer (car running costs), per mile | 0.16 | Per mile | Automobile Association[101] | |
| Ambulance to A&E | 247 | Attendance | NHS reference costs 2016–7, EM tab[91] | AMB tab: see and treat and convey |
| ***Hospital services*** | | | | |
| A&E attendances, weighted average of admitted attendances | 221 | Attendance | NHS reference costs 2016–7, EM lab[91] | EM tab |
| A&E attendances, weighted average of non-admitted attendances | 128 | Attendance | NHS reference costs 2016–7[91] | EM tab |

continued

**TABLE 5** Unit costs (*continued*)

| Variable name | Unit cost, 2016–7 (£) | Unit | Source | Notes/assumptions |
|---|---|---|---|---|
| A&E attendances, weighted average of admitted and non-admitted attendances | 148 | Attendance | NHS reference costs 2016–7[91] | EM tab |
| ***Inpatients*** | | | | |
| Subchapter AA: nervous system procedures and disorders | 478 | Day | NHS reference costs 2016–7[91] | NEL Tab |
| | 295 | Excess day | | NEL_XS Tab |
| Subchapter CA: ear, nose, mouth, throat and neck disorders | 521 | Day | NHS reference costs 2016–7[91] | NEL Tab |
| | 295 | Excess day | | NEL_XS Tab |
| Subchapter DZ: thoracic procedures and disorders | 402 | Day | NHS reference costs 2016–7[91] | NEL Tab |
| | 271 | Excess day | | NEL_XS Tab |
| Subchapter EB: cardiac disorders | 452 | Day | NHS reference costs 2016–7[91] | NEL Tab |
| | 291 | Excess day | | NEL_XS Tab |
| Subchapter FD: digestive system disorders | 453 | Day | NHS reference costs 2016–7[91] | NEL Tab |
| | 294 | Excess day | | NEL_XS Tab |
| Subchapter FD: digestive system open and laparoscopic procedures | 825 | Day | NHS reference costs 2016–7[91] | NEL Tab |
| | 343 | Excess day | | NEL_XS Tab |
| Subchapter GA: hepatobiliary and pancreatic system open and laparoscopic procedures | 880 | Day | NHS reference costs 2016–7[91] | NEL Tab |
| | 359 | Excess day | | NEL_XS Tab |
| Subchapter HT: orthopaedic trauma procedures | 724 | Day | NHS reference costs 2016–7[91] NEL Tab | NEL Tab |
| | 313 | Excess day | | NEL_XS Tab |
| Subchapter KA: endocrine system disorders | 461 | Day | NHS reference costs 2016–7[91] | NEL Tab |
| | 307 | Excess day | | NEL_XS Tab |
| Subchapter KB: diabetic medicine | 414 | Day | NHS reference costs 2016–7[91] | NEL Tab |
| | 273 | Excess day | | NEL_XS Tab |
| Subchapter LA: renal procedures and disorders | 415 | Day | NHS reference costs 2016–7[91] | NEL Tab |
| | 272 | Excess day | | NEL_XS Tab |
| Subchapter LB: urological and male reproductive system procedures and disorders | 505 | Day | NHS reference costs 2016–7[91] | NEL Tab |
| | 305 | Excess day | | NEL_XS Tab |
| Subchapter SA: haematological procedures and disorders | 550 | Day | NHS reference costs 2016–7[91] | NEL Tab |
| | 350 | Excess day | | NEL_XS Tab |
| Subchapter VC: rehabilitation | 362 | Day | NHS reference costs 2016–7[91] | REHAB tab |
| Subchapter WD: treatment of mental health patients by non-mental health service providers | 356 | Day | NHS reference costs 2016–7[91] | NEL Tab |
| | 264 | Excess day | | NEL_XS Tab |

**TABLE 5** Unit costs (*continued*)

| Variable name | Unit cost, 2016–7 (£) | Unit | Source | Notes/assumptions |
|---|---|---|---|---|
| Subchapter WH: poisoning, toxic effects, special examinations, screening and other healthcare contacts | 441 | Day | NHS reference costs 2016–7[91] | NEL Tab |
| | 274 | Excess day | | NEL_XS Tab |
| Subchapter WJ: infectious diseases and immune system disorders | 439 | Day | NHS reference costs 2016–7[91] | NEL Tab |
| | 287 | Excess day | | NEL_XS Tab |
| Subchapter YQ: vascular open procedures and disorders | 569 | Day | NHS reference costs 2016–7[91] | NEL Tab |
| | 294 | Excess day | | NEL_XS Tab |
| Inpatients, weighted average across specialities | 645 | Day | NHS reference costs 2016–7[91] | NEL Tab |
| | 299 | Excess day | | NEL_XS Tab |
| ***Day cases*** | | | | |
| Subchapter EY: interventional cardiology for acquired conditions | 1399 | Day | NHS reference costs 2016–7[91] | NEL Tab |
| | | | | NEL_XS Tab |
| Subchapter FE: digestive system endoscopic procedures | 539 | Day | NHS reference costs 2016–7[91] | DC tab |
| Subchapter HD: musculoskeletal and rheumatological disorders | 386 | Day | NHS reference costs 2016–7[91] | DC tab |
| Subchapter JA: breast procedures and disorders | 1418 | Day | NHS reference costs 2016–7[91] | DC tab |
| Subchapter JC: skin procedures | 745 | Day | NHS reference costs 2016–7[91] | DC tab |
| Subchapter LB: urological and male reproductive system procedures and disorders | 728 | Day | NHS reference costs 2016–7[91] | DC tab |
| Subchapter RD: diagnostic imaging procedures | 736 | Day | NHS reference costs 2016–7[91] | DC tab |
| Subchapter SA: haematological procedures and disorders | 423 | Day | NHS reference costs 2016–7[91] | DC tab |
| Subchapter WD: treatment of mental health patients by non-mental health service providers | 471 | Day | NHS reference costs 2016–7[91] | DC tab |
| Subchapter WH: poisoning, toxic effects, special examinations, screening and other healthcare contacts | 360 | Day | NHS reference costs 2016–7[91] | DC tab |
| Day cases, weighted average across specialties | 736 | Day | NHS reference costs 2016–7[91] | DC tab |

continued

**TABLE 5** Unit costs (*continued*)

| Variable name | Unit cost, 2016–7 (£) | Unit | Source | Notes/assumptions |
|---|---|---|---|---|
| ***Outpatients*** | | | | |
| Service code 100: general surgery | 130.78 | First attendance | NHS reference costs 2016–7[91] | Consultant and non-consultant-led first and follow-up face-to-face attendances, CL and NCL tabs |
| | 116.17 | Follow-up attendance | | |
| Service code 101: urology | 111.15 | First attendance | NHS reference costs 2016–7[91] | Consultant and non-consultant-led first and follow-up face-to-face attendances, CL and NCL tabs |
| | 102.88 | Follow-up attendance | | |
| Service code 103: breast surgery | 151.17 | First attendance | NHS reference costs 2016–7[91] | Consultant and non-consultant-led first and follow-up face-to-face attendances, CL and NCL tabs |
| | 130.51 | Follow-up attendance | | |
| Service code 104: colorectal surgery | 124.70 | First attendance | NHS reference costs 2016–7[91] | Consultant and non-consultant-led first and follow-up face-to-face attendances, CL and NCL tabs |
| | 109.83 | Follow-up attendance | | |
| Service code 110: trauma and orthopaedics | 119.83 | First attendance | NHS reference costs 2016–7[91] | Consultant and non-consultant-led first and follow-up face-to-face attendances, CL and NCL tabs |
| | 109.78 | Follow-up attendance | | |
| Service code 120: ear, nose and throat | 95.24 | First attendance | NHS reference costs 2016–7[91] | Consultant and non-consultant-led first and follow-up face-to-face attendances, CL and NCL tabs |
| | 87.94 | Follow-up attendance | | |
| Service code 130: ophthalmology | 91.26 | First attendance | NHS reference costs 2016–7[91] | Consultant and non-consultant-led first and follow-up face-to-face attendances, CL and NCL tabs |
| | 82.93 | Follow-up attendance | | |
| Service code 144: maxillofacial surgery | 126.68 | First attendance | NHS reference costs 2016–7[91] | Consultant and non-consultant-led first and follow-up face-to-face attendances, CL and NCL tabs |
| | 116.47 | Follow-up attendance | | |
| Service code 160: plastic surgery | 100.96 | Follow-up attendance | NHS reference costs 2016–7[91] | Consultant and non-consultant-led first and follow-up face-to-face attendances, CL and NCL tabs |
| | 94.52 | First attendance | | |
| Service code 191: pain management | 142.21 | Follow-up attendance | NHS reference costs 2016–7[91] | Consultant and non-consultant-led first and follow-up face-to-face attendances, CL and NCL tabs |
| | 127.87 | First attendance | | |
| Service code 300: general medicine | 158.15 | Follow-up attendance | NHS reference costs 2016–7[91] | Consultant and non-consultant-led first and follow-up face-to-face attendances, CL and NCL tabs |
| | 141.97 | First attendance | | |

**TABLE 5** Unit costs (*continued*)

| Variable name | Unit cost, 2016–7 (£) | Unit | Source | Notes/assumptions |
|---|---|---|---|---|
| Service code 301: gastroenterology | 150.57 | Follow-up attendance | NHS reference costs 2016–7[91] | Consultant and non-consultant-led first and follow-up face-to-face attendances, CL and NCL tabs |
| | 138.29 | First attendance | | |
| Service code 303: clinical haematology | 173.82 | Follow-up attendance | NHS reference costs 2016–7[91] | Consultant and non-consultant-led first and follow-up face-to-face attendances, CL and NCL tabs |
| | 164.74 | First attendance | | |
| Service code 304: clinical physiology | 73.72 | Follow-up attendance | NHS reference costs 2016–7[91] | Consultant and non-consultant-led first and follow-up face-to-face attendances, CL and NCL tabs |
| | 72.41 | First attendance | | |
| Service code 306: hepatology | 215.55 | Follow-up attendance | NHS reference costs 2016/17[91] | Consultant and non-consultant-led first and follow-up face-to-face attendances, CL and NCL tabs |
| | 214.57 | First attendance | | |
| Service code 307: diabetic medicine | 150.32 | Follow-up attendance | NHS reference costs 2016–7[91] | Consultant and non-consultant-led first and follow-up face-to-face attendances, CL and NCL tabs |
| | 141.00 | First attendance | | |
| Service code 320: cardiology | 130.24 | Follow-up attendance | NHS reference costs 2016–7[91] | Consultant and non-consultant-led first and follow-up face-to-face attendances, CL and NCL tabs |
| | 117.34 | First attendance | | |
| Service code 323: spinal injuries | 293.15 | Follow-up attendance | NHS reference costs 2016–7[91] | Consultant and non-consultant-led first and follow-up face-to-face attendances, CL and NCL tabs |
| | 283.62 | First attendance | | |
| Service code 324: anticoagulant service | 33.01 | Follow-up attendance | NHS reference costs 2016–7[91] | Consultant and non-consultant-led first and follow-up face-to-face attendances, CL and NCL tabs |
| | 30.04 | First attendance | | |
| Service code 330: dermatology | 103.56 | Follow-up attendance | NHS reference costs 2016–7[91] | Consultant and non-consultant-led first and follow-up face-to-face attendances, CL and NCL tabs |
| | 98.36 | First attendance | | |
| Service code 340: respiratory medicine | 161.63 | Follow-up attendance | NHS reference costs 2016–7[91] | Consultant and non-consultant-led first and follow-up face-to-face attendances, CL and NCL tabs |
| | 144.26 | First attendance | | |
| Service code 370: medical oncology | 169.36 | Follow-up attendance | NHS reference costs 2016–7[91] | Consultant and non-consultant-led first and follow-up face-to-face attendances, CL and NCL tabs |
| | 163.93 | First attendance | | |

continued

**TABLE 5** Unit costs (*continued*)

| Variable name | Unit cost, 2016–7 (£) | Unit | Source | Notes/assumptions |
|---|---|---|---|---|
| Service code 400: neurology | 169.73 | Follow-up attendance | NHS reference costs 2016–7[91] | Consultant and non-consultant-led first and follow-up face-to-face attendances, CL and NCL tabs |
| | 149.30 | First attendance | | |
| Service code 410: rheumatology | 150.25 | Follow-up attendance | NHS reference costs 2016–7[91] | Consultant and non-consultant-led first and follow-up face-to-face attendances, CL and NCL tabs |
| | 134.47 | First attendance | | |
| Service code 430: geriatric medicine | 231.84 | Follow-up attendance | NHS reference costs 2016–7[91] | Consultant and non-consultant-led first and follow-up face-to-face attendances, CL and NCL tabs |
| | 194.56 | First attendance | | |
| Service code 460: medical ophthalmology | 56.28 | Follow-up attendance | NHS reference costs 2016–7[91] | Consultant and non-consultant-led first and follow-up face-to-face attendances, CL and NCL tabs |
| | 57.42 | First attendance | | |
| Service code 502: gynaecology | 141.87 | Follow-up attendance | NHS reference costs 2016–7[91] | Consultant and non-consultant-led first and follow-up face-to-face attendances, CL and NCL tabs |
| | 130.36 | First attendance | | |
| Service code 650: physiotherapy | 48.94 | Follow-up attendance | NHS reference costs 2016–7[91] | Consultant and non-consultant-led first and follow-up face-to-face attendances, CL and NCL tabs |
| | 44.96 | First attendance | | |
| Service code 654: dietetics | 75.15 | Follow-up attendance | NHS reference costs 2016–7[91] | Consultant and non-consultant-led first and follow-up face-to-face attendances, CL and NCL tabs |
| | 68.75 | First attendance | | |
| Service code 658: orthotics | 119.16 | Follow-up attendance | NHS reference costs 2016–7[91] | Consultant and non-consultant-led first and follow-up face-to-face attendances, CL and NCL tabs |
| | 115.18 | First attendance | | |
| Service code 722: liaison psychiatry | 84.58 | Follow-up attendance | NHS reference costs 2016–7[91] | Consultant and non-consultant-led first and follow-up face-to-face attendances, CL and NCL tabs |
| | 61.57 | First attendance | | |
| Service code 812: diagnostic imaging | 47.79 | Follow-up attendance | NHS reference costs 2016–7[91] | Consultant and non-consultant-led first and follow-up face-to-face attendances, CL and NCL tabs |
| | 80.65 | First attendance | | |

**TABLE 5** Unit costs (*continued*)

| Variable name | Unit cost, 2016–7 (£) | Unit | Source | Notes/assumptions |
|---|---|---|---|---|
| Service code 920: diabetic education service | 317.68 | Follow-up attendance | NHS reference costs 2016–7[91] | Consultant and non-consultant-led first and follow-up face-to-face attendances, CL and NCL tabs |
| | 179.80 | First attendance | | |
| Memory clinic | 406 | – | PSSRU unit costs 2014, table 1.10[93] | Uprated using HCHS Pay and Prices inflator |
| Weighted average of follow-up attendances across service codes | 116.48 | Follow-up attendance | NHS reference costs 2016–7[91] | Consultant and non-consultant-led first and follow-up face-to-face attendances, CL and NCL tabs |
| | 105.51 | First attendance | | |
| Fragility hip fracture bed-day | 645 | Per day | 2017–8 and 2018–29 national tariff[102] | HRG codes associated with best practice tariff: HT12A, HT12B, HT12C, HT12D, HT12E, HT13A, HT13B, HT13C, HT13D, HT13E, VA11A, VA11B, VA11C, VA11D, VA12A, VA12B, VA12C, VA12D (weighted average LOS: 12 days) |
| Fragility hip fracture bed-day | 299 | Per excess bed day | NHS reference costs 2016–7[91] | HRG codes associated with Best Practice Tariff: HT12A, HT12B, HT12C, HT12D, HT12E, HT13A, HT13B, HT13C, HT13D, HT13E, VA11A, VA11B, VA11C, VA11D, VA12A, VA12B, VA12C, VA12D |

A&E, accident and emergency department; AMB, ambulance; CHS, Community Health Services; EM, emergency medicine; HCHS, hospital and community health service; MHCC, Mental Health Care Clusters; PSSRU, Personal Social Services Research Unit.

period covered by SIR-derived costs and to enable assessment of agreement between the HRE and SIR data sets. Prescription medication costs were calculated by attaching costs per standard quantity unit from the NHS *Prescription Costs Analysis England*.[103] The proprietary name of each medication in the analysis was assigned an index number; the same index number was assigned to corresponding medication names in the participant data. A unit cost per medication was allocated by matching these data sets on index number, dosage and unit (e.g. micrograms, milligrams). Where dosages were missing, the average cost of each medication (across dosages) was allocated. No assumptions or averages were applied where information on duration taken was missing. The resultant costs per period were weighted by the proportion of time spent in the community, to avoid double-counting costs already assigned by allocating NHS reference costs to hospital activities. In line with the protocol, where costs were missing for each hospital use category in the SIR data, if costs from the hospital records were available, they were substituted (SIR+).

The costs of carer time were calculated following approaches described in Wimo and Reed,[104] Dodel and Belger.[105] The unit cost of lost working time was taken as the average wage (gross mean wage for all employee jobs; sourced from the Annual Survey of Hours and Earnings tables).[100] The value of lost leisure time was assigned 35% of that figure. The costs of unpaid care were calculated as the costs of hours of work lost, or the costs of hours of care provided, whichever was larger. The costs of care by other friends and relatives were valued similarly but we assumed that these carers were employed and applied the value of lost working time to their care hours. We also examined alternative valuations of carer time at replacement costs (at the hourly rate of a home care worker) in a sensitivity analysis.

Care home fees reported by suitable informants were used to calculate care and nursing home costs. Where these fees were not reported, a published cost of a private care or nursing home was used; in cases where no provider sector was given, the providers were assumed to be private.[92] The costs of care homes were assumed to fall to only one funder; care home cost questions did not cover top-up fees paid by participants with local authority funding.

Individual items of resource use were costed and these costs were aggregated to category level. Costs of each item in a cost category were summed, assuming that if there was at least one service cost, costs missing for other services in the category were zero (but if all items in the category were missing, the total cost was considered to be missing). For instance, the 'hospital costs' category consisted of inpatient overnight and day hospital days, ED and outpatient attendances. If outpatient costs were missing but other items were not, the total cost of the category would be calculated assuming there were no outpatient costs for that participant. However, the next step was to sum all cost categories so that if any one category was missing, total costs also would be missing. Also, in the case of the 1-month follow-up, hospital category costs were recoded to missing in any cases with a zero-cost total, as we could not assume the cost of the inpatient stay to be zero when all participants were recruited as inpatients. Resource use items used to calculate costs are listed in *Table 6*.

**TABLE 6** Use of health, social and unpaid care, intervention and control, for observations with economic data available at baseline, 1-, 2-, 3- and 6-month follow-up appointments (*N* = 282)

| | | Intervention | | Control | |
|---|---|---|---|---|---|
| **Service/item** | **Units** | **Users/valid observations (*n*/*n*)** | **Mean use (SE)** | **Users/valid observations (*n*/*n*)** | **Mean use (SE)** |
| ***Baseline – prior 3 months*** | | *N* = 132 | | *N* = 150 | |
| *Hospital services – medical records* | | | | | |
| ED | Attendances | 24/129 | 0.23 (0.05) | 22/145 | 0.17 (0.04) |
| Inpatient services | Admissions | 17/129 | 0.15 (0.03) | 17/145 | 0.17 (0.04) |
| Inpatients services | Days | 17/129 | 1.79 (0.61) | 17/145 | 1.21 (0.41) |
| Day hospital services | Days | 6/129 | 0.12 (0.05) | 7/145 | 0.10 (0.04) |
| Outpatients services | Visits | 27/129 | 0.54 (0.12) | 27/145 | 0.31 (0.05) |
| *Hospital services – CSRI* | | | | | |
| ED | Attendances | 33/127 | 0.81 (0.38) | 22/139 | 0.29 (0.08) |
| Inpatient services | Admissions | 15/127 | 0.11 (0.03) | 16/138 | 0.18 (0.05) |
| Inpatients services | Days | 15/127 | 1.13 (0.41) | 16/138 | 0.88 (0.32) |
| Day hospital services | Days | 5/126 | 0.14 (0.10) | 3/137 | 0.02 (0.01) |
| Outpatients services | Visits | 35/126 | 0.50 (0.11) | 33/137 | 0.38 (0.10) |
| *Primary and community health* | | | | | |
| GP | Visits | 83/127 | 1.53 (0.19) | 91/139 | 1.67 (0.22) |
| Practice nurse | Visits | 21/126 | 0.22 (0.05) | 25/139 | 0.41 (0.11) |
| Community/district nurse | Visits | 42/128 | 4.94 (2.30) | 40/138 | 5.96 (2.10) |
| Physiotherapist | Visits | 9/128 | 0.08 (0.03) | 8/139 | 0.13 (0.05) |
| Occupational therapist | Visits | 12/127 | 0.09 (0.03) | 10/140 | 0.10 (0.03) |
| Specialist nurse | Visits | 7/128 | 0.06 (0.03) | 11/140 | 0.15 (0.07) |
| Paramedic | Visits | 39/127 | 0.44 (0.07) | 45/139 | 0.46 (0.07) |
| Optician | Visits | 24/127 | 0.22 (0.04) | 31/140 | 0.27 (0.05) |
| Chiropodist | Visits | 54/127 | 0.62 (0.11) | 57/140 | 0.73 (0.13) |
| Dentist | Visits | 14/127 | 0.20 (0.06) | 26/137 | 0.23 (0.05) |

**TABLE 6** Use of health, social and unpaid care, intervention and control, for observations with economic data available at baseline, 1-, 2-, 3- and 6-month follow-up appointments (*N* = 282) (*continued*)

| Service/item | Units | Intervention | | Control | |
|---|---|---|---|---|---|
| | | Users/valid observations (*n*/*n*) | Mean use (SE) | Users/valid observations (*n*/*n*) | Mean use (SE) |
| *Community mental health* | | | | | |
| Mental health nurse | Visits | 5/126 | 0.09 (0.05) | 8/140 | 0.11 (0.04) |
| Psychiatrist | Visits | 3/128 | 0.03 (0.02) | 2/140 | 0.01 (0.01) |
| Psychologist | Visits | 0/128 | 0.00 (0.00) | 0/139 | 0.00 (0.00) |
| Mental health team | Visits | 2/128 | 0.02 (0.01) | 1/140 | 0.01 (0.01) |
| *Day services* | | | | | |
| Day centre | Attendances | 9/127 | 0.84 (0.30) | 10/137 | 0.76 (0.31) |
| Lunch club | Attendances | – | – | – | – |
| *Care in communal settings (permanent residence)* | | | | | |
| Residential home | Days | 22/128 | 14.45 (2.90) | 22/141 | 13.65 (2.75) |
| Nursing home | Days | 7/128 | 3.97 (1.61) | 14/141 | 8.43 (2.19) |
| NHS continuing care | Days | 0/128 | 0 | – | – |
| *Temporary care in communal settings* | | | | | |
| Respite – nursing home | Days | 0/127 | 0.00 (0.00) | 1/138 | 0.00 (0.00) |
| Respite – residential home | Days | 7/127 | 1.79 (0.89) | 2/138 | 0.18 (0.15) |
| NHS continuing care unit | Days | 2/127 | 0.70 (0.56) | 1/138 | 0.10 (0.10) |
| *Community-based social care* | | | | | |
| Social worker | Visits | 19/128 | 0.23 (0.06) | 17/140 | 0.24 (0.07) |
| Home care[a] | Hours | 28/128 | 25.76 (6.13) | 33/140 | 28.89 (7.10) |
| Cleaner | Visits | 16/128 | 2.09 (0.83) | 24/140 | 2.65 (0.95) |
| Meals on Wheels | Visits | 8/127 | 4.02 (1.58) | 4/140 | 0.14 (0.09) |
| Sitting service | Visits | 3/128 | 1.49 (1.45) | 4/140 | 0.34 (0.17) |
| Carer support worker | Visits | 2/128 | 2.65 (2.64) | 3/140 | 0.09 (0.09) |
| Medications | Units | 128/129 | 8.28 (0.39) | 139/146 | 7.22 (0.39) |
| *Equipment and adaptations* | | | | | |
| Equipment (health and social care providers) | Items | 32/128 | 0.77 (0.14) | 35/140 | 0.78 (0.14) |
| *Unpaid care and out of pocket* | | | | | |
| Equipment (bought privately) | Items | 20/128 | 0.30 (0.07) | 23/140 | 0.29 (0.06) |
| Travel to hospital | Trips | 23/99 | 2.83 (1.15) | 18/101 | 1.20 (0.46) |
| Travel to GP | Trips | 22/100 | 0.41 (0.11) | 17/102 | 0.27 (0.08) |
| Unpaid care SI | Hours | 96/98 | 484.45 (64.83) | 96/99 | 478.77 (64.04) |
| SI cut down work | Hours | 0/95 | 0.00 (0.00) | 2/97 | 0.25 (0.21) |

continued

**TABLE 6** Use of health, social and unpaid care, intervention and control, for observations with economic data available at baseline, 1-, 2-, 3- and 6-month follow-up appointments (*N* = 282) (*continued*)

| Service/item | Units | Intervention | | Control | |
|---|---|---|---|---|---|
| | | Users/valid observations (*n*/*n*) | Mean use (SE) | Users/valid observations (*n*/*n*) | Mean use (SE) |
| SI stopped work | Weeks | 2/97 | 0.08 (0.06) | 0/98 | 0.00 (0.00) |
| Unpaid leave | Hours | 7/102 | 2.39 (1.48) | 5/100 | 1.91 (1.27) |
| Unpaid care other relatives | Hours | 49/103 | 93.17 (18.59) | 64/104 | 147.78 (30.14) |
| Time off work other relatives | Days | 10/103 | 0.01 (0.00) | 10/104 | 0.02 (0.01) |
| ***1 month – prior month*** | | *N* = 109 | | *N* = 121 | |
| *Hospital services – medical records* | | | | | |
| ED | Attendances | 9/105 | 0.10 (0.03) | 5/112 | 0.04 (0.02) |
| Inpatient services | Admissions | 109/109 | 1.13 (0.05) | 121/121 | 1.18 (0.04) |
| Inpatients services | Days | 109/109 | 19.48 (0.75) | 121/121 | 18.43 (0.78) |
| Day hospital services | Days | 0/105 | 0.00 (0.00) | 2/112 | 0.04 (0.02) |
| Outpatients services | Visits | 4/104 | 0.04 (0.02) | 5/111 | 0.05 (0.03) |
| *Hospital services – CSRI* | | | | | |
| ED | Attendances | 11/106 | 0.11 (0.03) | 8/111 | 0.07 (0.02) |
| Inpatient services | Admissions | 109/109 | 1.03 (0.02) | 121/121 | 1.01 (0.01) |
| Inpatients services | Days | 109/109 | 20.52 (0.77) | 121/121 | 17.72 (0.83) |
| Day hospital services | Days | 0/105 | 0.00 (0.00) | 0/109 | 0.00 (0.00) |
| Outpatients services | Visits | 6/106 | 0.07 (0.03) | 7/110 | 0.08 (0.03) |
| *Primary and community health* | | | | | |
| GP | Visits | 34/105 | 0.42 (0.07) | 32/112 | 0.45 (0.08) |
| Practice nurse | Visits | 2/106 | 0.01 (0.01) | 5/111 | 0.05 (0.03) |
| Community/district nurse | Visits | 32/106 | 1.79 (0.48) | 38/111 | 2.50 (0.55) |
| Physiotherapist | Visits | 39/105 | 2.17 (0.59) | 34/111 | 1.07 (0.25) |
| Occupational therapist | Visits | 26/105 | 1.30 (0.51) | 14/110 | 0.32 (0.15) |
| Specialist nurse | Visits | 6/106 | 0.06 (0.02) | 4/111 | 0.43 (0.41) |
| Paramedic | Visits | 10/105 | 0.10 (0.03) | 5/111 | 0.04 (0.02) |
| Optician | Visits | 1/106 | 0.01 (0.01) | 1/111 | 0.01 (0.01) |
| Chiropodist | Visits | 5/106 | 0.06 (0.03) | 12/113 | 0.11 (0.03) |
| Dentist | Visits | 1/106 | 0.01 (0.01) | 1/111 | 0.02 (0.02) |
| *Community mental health* | | | | | |
| Mental health nurse | Visits | 0/105 | 0.00 (0.00) | 2/110 | 0.02 (0.01) |
| Psychiatrist | Visits | 1/105 | 0.14 (0.14) | 0/112 | 0.00 (0.00) |
| Psychologist | Visits | 1/106 | 0.00 (0.00) | 0/110 | 0.00 (0.00) |
| Mental health team | Visits | 0/106 | 0.00 (0.00) | 3/112 | 0.03 (0.02) |

**TABLE 6** Use of health, social and unpaid care, intervention and control, for observations with economic data available at baseline, 1-, 2-, 3- and 6-month follow-up appointments (*N* = 282) (*continued*)

| Service/item | Units | Intervention | | Control | |
|---|---|---|---|---|---|
| | | Users/valid observations (*n*/*n*) | Mean use (SE) | Users/valid observations (*n*/*n*) | Mean use (SE) |
| *Day services* | | | | | |
| Day centre | Attendances | 0/104 | 0.00 (0.00) | 1/109 | 0.01 (0.01) |
| Lunch club | Attendances | 1/105 | 0.03 (0.03) | 2/109 | 0.03 (0.02) |
| *Care in communal settings (permanent residence)* | | | | | |
| Residential home | Days | 19/106 | 5.45 (1.09) | 18/114 | 5.34 (1.06) |
| Nursing home | Days | 10/106 | 2.00 (0.67) | 13/114 | 3.11 (0.83) |
| NHS continuing care | Days | 13/106 | 2.51 (0.73) | 12/114 | 1.55 (0.51) |
| *Temporary care in communal settings* | | | | | |
| Respite – nursing home | Days | 2/106 | 0.12 (0.12) | 1/110 | 0.00 (0.00) |
| Respite – residential home | Days | 2/106 | 0.25 (0.15) | 5/110 | 0.46 (0.30) |
| NHS continuing care unit | Days | 32/105 | 4.51 (0.77) | 21/109 | 3.30 (0.71) |
| *Community-based social care* | | | | | |
| Social worker | Visits | 12/106 | 0.16 (0.05) | 5/111 | 0.05 (0.03) |
| Home care[a] | Hours | 17/100 | 5.51 (1.78) | 21/111 | 5.87 (1.87) |
| Cleaner | Visits | 7/100 | 0.31 (0.13) | 7/110 | 0.12 (0.05) |
| Meals on Wheels | Visits | 1/100 | 0.10 (0.10) | 4/111 | 0.42 (0.29) |
| Sitting service | Visits | 1/99 | 0.01 (0.01) | 0/111 | 0.00 (0.00) |
| Carer support worker | Visits | 3/100 | 0.84 (0.51) | 0/111 | 0.00 (0.00) |
| Medications | Units | 106/106 | 18.00 (0.81) | 113/114 | 10.60 (0.57) |
| *Equipment and adaptations* | | | | | |
| Equipment (health and social care providers) | Items | 37/99 | 0.85 (0.13) | 34/109 | 1.14 (0.19) |
| *Unpaid care and out of pocket* | | | | | |
| Equipment (bought privately) | Items | 6/99 | 0.12 (0.06) | 10/109 | 0.19 (0.07) |
| Travel to hospital | Trips | 72/89 | 16.20 (1.53) | 64/90 | 12.40 (1.46) |
| Travel to GP | Trips | 1/90 | 0.01 (0.01) | 0/96 | 0.00 (0.00) |
| Unpaid care SI | Hours | 87/87 | 116.25 (17.02) | 91/91 | 131.38 (18.01) |
| SI cut down work | Hours | 2/88 | 1.08 (0.92) | 1/91 | 0.33 (0.33) |
| SI stopped work | Weeks | 0/88 | 0.00 (0.00) | 1/91 | 0.04 (0.04) |
| Unpaid leave | Hours | 4/89 | 2.49 (1.59) | 6/97 | 1.56 (0.83) |
| Unpaid care other relatives | Hours | 53/90 | 27.34 (5.39) | 60/98 | 49.11 (11.05) |
| Time off work other relatives | Days | 10/90 | 0.03 (0.01) | 6/98 | 0.01 (0.00) |

continued

**TABLE 6** Use of health, social and unpaid care, intervention and control, for observations with economic data available at baseline, 1-, 2-, 3- and 6-month follow-up appointments (*N* = 282) (*continued*)

| Service/item | Units | Intervention | | Control | |
|---|---|---|---|---|---|
| | | Users/valid observations (*n*/*n*) | Mean use (SE) | Users/valid observations (*n*/*n*) | Mean use (SE) |
| ***3 months – prior 2 months*** | | *N* = 83 | | *N* = 102 | |
| *Hospital services – medical records* | | | | | |
| ED | Attendances | 16/81 | 0.23 (0.06) | 12/98 | 0.14 (0.04) |
| Inpatient services | Admissions | 23/81 | 0.32 (0.08) | 29/98 | 0.31 (0.06) |
| Inpatients services | Days | 23/81 | 4.57 (1.20) | 29/98 | 6.60 (1.64) |
| Day hospital services | Days | 2/81 | 0.05 (0.03) | 0/98 | 0.00 (0.00) |
| Outpatients services | Visits | 10/81 | 0.19 (0.06) | 19/98 | 0.22 (0.05) |
| *Hospital services – CSRI* | | | | | |
| ED | Attendances | 20/82 | 0.41 (0.15) | 14/96 | 0.17 (0.05) |
| Inpatient services | Admissions | 21/82 | 0.32 (0.07) | 22/97 | 0.23 (0.05) |
| Inpatients services | Days | 21/82 | 4.06 (1.02) | 22/97 | 3.95 (1.02) |
| Day hospital services | Days | 2/82 | 0.02 (0.02) | 1/96 | 0.01 (0.01) |
| Outpatients services | Visits | 17/82 | 0.27 (0.07) | 17/96 | 0.27 (0.06) |
| *Primary and community health* | | | | | |
| GP | Visits | 54/81 | 1.35 (0.24) | 59/95 | 1.19 (0.17) |
| Practice nurse | Visits | 7/81 | 0.10 (0.05) | 7/93 | 0.20 (0.10) |
| Community/district nurse | Visits | 35/82 | 1.72 (0.39) | 29/93 | 2.35 (0.82) |
| Physiotherapist | Visits | 27/81 | 2.25 (1.00) | 31/92 | 1.91 (0.48) |
| Occupational therapist | Visits | 19/81 | 1.79 (0.98) | 19/93 | 0.53 (0.20) |
| Specialist nurse | Visits | 7/81 | 0.21 (0.12) | 8/91 | 0.15 (0.06) |
| Paramedic | Visits | 24/81 | 0.37 (0.07) | 8/92 | 0.09 (0.03) |
| Optician | Visits | 3/81 | 0.04 (0.02) | 9/92 | 0.10 (0.03) |
| Chiropodist | Visits | 18/81 | 0.25 (0.06) | 34/93 | 0.44 (0.07) |
| Dentist | Visits | 3/80 | 0.04 (0.02) | 5/92 | 0.05 (0.02) |
| *Community mental health* | | | | | |
| Mental health nurse | Visits | 2/81 | 0.02 (0.02) | 5/93 | 0.08 (0.03) |
| Psychiatrist | Visits | 3/81 | 0.06 (0.04) | 4/89 | 0.18 (0.15) |
| Psychologist | Visits | 2/81 | 0.04 (0.03) | 1/90 | 0.01 (0.01) |
| Mental health team | Visits | 0/81 | 0.00 (0.00) | 4/92 | 0.04 (0.03) |
| *Day services* | | | | | |
| Day centre | Attendances | 3/82 | 0.29 (0.21) | 2/96 | 0.11 (0.09) |
| Lunch club | Attendances | 0/82 | 0.00 (0.00) | 1/95 | 0.17 (0.17) |

**TABLE 6** Use of health, social and unpaid care, intervention and control, for observations with economic data available at baseline, 1-, 2-, 3- and 6-month follow-up appointments (*N* = 282) (*continued*)

| Service/item | Units | Intervention | | Control | |
|---|---|---|---|---|---|
| | | Users/valid observations (*n*/*n*) | Mean use (SE) | Users/valid observations (*n*/*n*) | Mean use (SE) |
| *Care in communal settings (permanent residence)* | | | | | |
| Residential home | Days | 18/82 | 11.88 (2.65) | 20/97 | 9.57 (2.14) |
| Nursing home | Days | 14/82 | 7.94 (2.07) | 22/97 | 11.57 (2.30) |
| NHS continuing care | Days | – | – | 0/97 | 0 |
| *Temporary care in communal settings* | | | | | |
| Respite – nursing home | Days | 1/82 | 0.00 (0.00) | 0/97 | 0.00 (0.00) |
| Respite – residential home | Days | 3/82 | 1.35 (0.81) | 2/97 | 0.33 (0.31) |
| NHS continuing care unit | Days | 17/81 | 7.36 (1.76) | 10/95 | 3.70 (1.27) |
| *Community-based social care* | | | | | |
| Social worker | Visits | 16/81 | 0.44 (0.16) | 10/91 | 0.18 (0.06) |
| Home care[a] | Hours | 20/81 | 25.65 (6.62) | 34/97 | 30.82 (6.59) |
| Cleaner | Visits | 9/81 | 1.59 (0.79) | 15/97 | 1.48 (0.66) |
| Meals on Wheels | Visits | 1/81 | 0.10 (0.10) | 4/97 | 1.29 (0.87) |
| Sitting service | Visits | 2/81 | 0.14 (0.11) | 2/97 | 0.56 (0.48) |
| Carer support worker | Visits | 6/80 | 11.61 (5.07) | 2/97 | 0.01 (0.01) |
| Medications | Units | 80/82 | 9.72 (0.63) | 97/98 | 8.60 (0.53) |
| *Equipment and adaptations* | | | | | |
| Equipment (health and social care providers) | Items | 25/80 | 0.88 (0.18) | 33/96 | 1.34 (0.22) |
| *Unpaid care and out of pocket* | | | | | |
| Equipment (bought privately) | Items | 7/80 | 0.13 (0.05) | 14/96 | 0.21 (0.06) |
| Travel to hospital | Trips | 35/71 | 5.46 (1.30) | 20/76 | 6.82 (1.91) |
| Travel to GP | Trips | 5/71 | 0.11 (0.05) | 4/76 | 0.05 (0.03) |
| Unpaid care SI | Hours | 69/69 | 316.20 (51.49) | 74/75 | 269.70 (43.77) |
| SI cut down work | Hours | 0/68 | 0.00 (0.00) | 0/73 | 0.00 (0.00) |
| SI stopped work | Weeks | 4/69 | 0.38 (0.19) | 0/75 | 0.00 (0.00) |
| Unpaid leave | Hours | 3/70 | 0.75 (0.56) | 5/86 | 0.89 (0.45) |
| Unpaid care other relatives | Hours | 42/71 | 50.48 (11.23) | 47/85 | 108.63 (28.85) |
| Time off work other relatives | Days | 3/71 | 0.00 (0.00) | 7/86 | 0.01 (0.01) |
| ***6 months – prior 3 months*** | | *N* = 64 | | *N* = 79 | |
| *Hospital services – medical records* | | | | | |
| ED | Attendances | 16/59 | 0.34 (0.09) | 8/70 | 0.13 (0.05) |
| Inpatient services | Admissions | 9/59 | 0.22 (0.08) | 10/70 | 0.14 (0.04) |

continued

**TABLE 6** Use of health, social and unpaid care, intervention and control, for observations with economic data available at baseline, 1-, 2-, 3- and 6-month follow-up appointments (*N* = 282) (*continued*)

| Service/item | Units | Intervention | | Control | |
|---|---|---|---|---|---|
| | | Users/valid observations (*n*/*n*) | Mean use (SE) | Users/valid observations (*n*/*n*) | Mean use (SE) |
| Inpatients services | Days | 9/59 | 1.22 (0.64) | 10/70 | 2.68 (1.41) |
| Day hospital services | Days | 0/59 | 0.00 (0.00) | 4/70 | 0.13 (0.06) |
| Outpatients services | Visits | 16/59 | 0.50 (0.15) | 12/70 | 0.26 (0.07) |
| *Hospital services – CSRI* | | | | | |
| ED | Attendances | 18/64 | 0.33 (0.08) | 16/75 | 0.37 (0.13) |
| Inpatient services | Admissions | 9/63 | 0.21 (0.07) | 7/71 | 0.13 (0.04) |
| Inpatients services | Days | 9/63 | 1.37 (0.63) | 7/71 | 0.94 (0.44) |
| Day hospital services | Days | 0/63 | 0.00 (0.00) | 2/75 | 0.03 (0.02) |
| Outpatients services | Visits | 17/64 | 0.48 (0.13) | 16/75 | 0.22 (0.06) |
| *Primary and community health* | | | | | |
| GP | Visits | 40/62 | 1.05 (0.16) | 50/75 | 1.38 (0.20) |
| Practice nurse | Visits | 3/63 | 0.02 (0.02) | 12/75 | 0.21 (0.06) |
| Community/district nurse | Visits | 30/64 | 2.63 (0.83) | 23/75 | 3.86 (2.43) |
| Physiotherapist | Visits | 11/62 | 0.48 (0.18) | 14/75 | 1.05 (0.52) |
| Occupational therapist | Visits | 8/62 | 0.33 (0.14) | 13/75 | 0.36 (0.13) |
| Specialist nurse | Visits | 4/61 | 0.05 (0.03) | 4/75 | 0.08 (0.04) |
| Paramedic | Visits | 16/62 | 0.44 (0.12) | 10/75 | 0.20 (0.08) |
| Optician | Visits | 7/62 | 0.11 (0.04) | 13/75 | 0.21 (0.06) |
| Chiropodist | Visits | 28/62 | 0.67 (0.12) | 27/75 | 0.51 (0.09) |
| Dentist | Visits | 2/62 | 0.08 (0.06) | 16/75 | 0.23 (0.05) |
| *Community mental health* | | | | | |
| Mental health nurse | Visits | 2/61 | 0.00 (0.00) | 4/75 | 0.09 (0.05) |
| Psychiatrist | Visits | 4/62 | 0.06 (0.04) | 2/75 | 0.03 (0.02) |
| Psychologist | Visits | 1/62 | 0.02 (0.02) | 2/75 | 0.03 (0.02) |
| Mental health team | Visits | 3/62 | 0.05 (0.04) | 2/75 | 0.03 (0.02) |
| *Day services* | | | | | |
| Day centre | Attendances | 3/64 | 0.75 (0.53) | 2/75 | 0.28 (0.20) |
| Lunch club | Attendances | 0/64 | 0.00 (0.00) | 2/75 | 0.32 (0.22) |
| *Care in communal settings (permanent residence)* | | | | | |
| Residential home | Days | 17/64 | 24.17 (5.06) | 14/76 | 14.33 (3.71) |
| Nursing home | Days | 9/64 | 8.56 (3.15) | 17/76 | 18.43 (4.18) |
| NHS continuing care | Days | 0/64 | 0.00 (0.00) | 0/76 | 0.00 (0.00) |

**TABLE 6** Use of health, social and unpaid care, intervention and control, for observations with economic data available at baseline, 1-, 2-, 3- and 6-month follow-up appointments (*N* = 282) (*continued*)

| Service/item | Units | Intervention | | Control | |
|---|---|---|---|---|---|
| | | Users/valid observations (*n*/*n*) | Mean use (SE) | Users/valid observations (*n*/*n*) | Mean use (SE) |
| *Temporary care in communal settings* | | | | | |
| Respite – nursing home | Days | 2/64 | 0.00 (0.00) | 1/76 | 0.00 (0.00) |
| Respite – residential home | Days | 2/64 | 1.41 (1.11) | 2/76 | 0.59 (0.44) |
| NHS continuing care unit | Days | 4/64 | 2.17 (1.27) | 0/76 | 0.00 (0.00) |
| *Community-based social care* | | | | | |
| Social worker | Visits | 8/62 | 0.13 (0.06) | 18/75 | 0.31 (0.07) |
| Home care[a] | Hours | 21/64 | 71.44 (15.61) | 23/76 | 40.95 (9.43) |
| Cleaner | Visits | 7/63 | 1.89 (0.78) | 10/76 | 2.15 (1.25) |
| Meals on Wheels | Visits | 0/62 | 0.00 (0.00) | 0/76 | 0.00 (0.00) |
| Sitting service | Visits | 1/62 | 0.39 (0.39) | 3/76 | 1.86 (1.29) |
| Carer support worker | Visits | 5/61 | 27.48 (12.25) | 0/76 | 0.00 (0.00) |
| Medications | Units | 58/59 | 8.64 (0.64) | 70/70 | 7.60 (0.52) |
| *Equipment and adaptations* | | | | | |
| Equipment (health and social care providers) | Items | 12/64 | 0.75 (0.23) | 19/74 | 1.04 (0.25) |
| *Unpaid care and out of pocket* | | | | | |
| Equipment (bought privately) | Items | 8/64 | 0.19 (0.07) | 11/74 | 0.27 (0.09) |
| Travel to hospital | Trips | 20/58 | 2.26 (0.84) | 10/63 | 2.48 (1.38) |
| Travel to GP | Trips | 8/58 | 0.26 (0.10) | 3/63 | 0.17 (0.11) |
| Unpaid care SI | Hours | 56/56 | 476.15 (90.90) | 61/62 | 487.05 (82.70) |
| SI cut down work | Hours | 0/55 | 0.00 (0.00) | 0/61 | 0.00 (0.00) |
| SI stopped work | Weeks | 1/56 | 0.07 (0.07) | 0/60 | 0.00 (0.00) |
| Unpaid leave | Hours | 1/56 | 0.54 (0.54) | 2/70 | 0.39 (0.30) |
| Unpaid care other relatives | Hours | 28/57 | 54.47 (11.03) | 38/71 | 145.71 (35.23) |
| Time off work other relatives | Days | 2/57 | 0.00 (0.00) | 7/71 | 0.00 (0.00) |

SI, suitable informant.
a Hours have been calculated assuming that home care visits last 30 minutes on average[88]

### *Intervention costs*

The costs of the intervention were assembled from time inputs of personnel providing PERFECT-ER, including time spent championing the enhanced recovery pathway in the run-up to the trial. Unit costs were sourced from Curtis and Burns.[92] The unit cost for SIL time included mean full-time equivalent salary costs for a nurse on Agenda for Change band 6; salary on-costs and costs of capital and management, administrative and estates overheads and the unit cost for PIL time include the same components costs for a medical consultant. Time inputs and total costs per site of each

role over the study period are listed in *Table 7*. The costs of inputs per site were calculated by dividing the costs of each role by the number of potentially affected patients on each study ward over the intervention period results are listed in *Table 8*. In each site, research nurses recorded the number of patients on the study ward who met entry criteria over the recruitment period. These counts were used as the denominators in the cost-per-site calculations.

**TABLE 7** Per-site cost of 3 months start-up and 15 months of input from (a) PERFECT-ER SIL and (b) PPL

| (a) Per site SIL | % of year | Period FTE | Annual FTE |
|---|---|---|---|
| Champion ERP 1 August–31 October 2016 | 0.25 | 0.5 | 0.125 |
| First year: 1 November 2016–31 July 2017 | 0.75 | 0.2 | 0.15 |
| Second year: 1 August 2017–31 January 2018 | 0.5 | 0.2 | 0.1 |
| Total FTE @£70,017 per annum (2016–7 prices)[a] | £26,594 | | |

ERP, enhanced recovery pathway.
a Source: Schema 14: hospital nurses, Agenda for Change band 6.[92]

| (b) PPL | Hours |
|---|---|
| First year: 1 hour/week for 3 months | 13 |
| First year: 1 hour/month for 9 months | 9 |
| Second year: 1 hour/month for 6 months | 6 |
| Total hours PIL input | 28 |
| Total hours @£106 per hour (2016–17 prices)[b] | £2968 |

b Source: Schema 15: hospital-based doctors, medical consultant.[92]

**TABLE 8** Per-site costs over the study period (1 November 2016–31 January 2018)

| Site | Estimated potentially affected patients (*n*)[a] | SIL cost per case on study ward (£) | PPL cost per case on study ward (£) | Total costs per potentially affected patient (£) |
|---|---|---|---|---|
| 01 | 190 | 140 | 16 | 156 |
| 03 | 205 | 130 | 14 | 144 |
| 06 | 76 | 350 | 39 | 389 |
| 07 | 61 | 436 | 49 | 485 |
| 10 | 225 | 118 | 13 | 131 |

a Patients on study wards, ≥ 60 years, with confusion (Abbreviated Mental Test score ≤ 8/4AT ≥), hip fracture, surgery for hip fracture, ward stay of ≥ 5 days.

## Health economic results

**TABLE 9** Mean costs (standard errors): health and social care services for participant, unpaid carer (suitable informant) costs, out-of-pocket costs, total health and social care and societal costs over prior 3 months, at baseline, 2016–7 (£)

| | Intervention: clusters (*N* = 132), cases (*N* = 5) | | | Control: clusters (*N* = 150), cases (*N* = 6) | | | Intervention–control | |
|---|---|---|---|---|---|---|---|---|
| **Baseline** | ***n*** | **Mean** | **SE** | ***n*** | **Mean** | **SE** | **Mean difference** | **95% CI** |
| Hospital (SIR) | 126 | 664 | 150 | 134 | 433 | 146 | 232 | −242 to 705 |
| Hospital (HRE) | 129 | 837 | 198 | 145 | 612 | 187 | 225 | −392 to 841 |
| Hospital (HRE) inc. ambulance | 129 | 842 | 199 | 145 | 617 | 187 | 225 | −392 to 843 |
| Hospital (SIR+) | 130 | 645 | 147 | 145 | 472 | 139 | 173 | −285 to 630 |
| Primary and community health | 128 | 423 | 90 | 140 | 499 | 86 | −76 | −359 to 207 |
| Community mental health | 128 | 12 | 4 | 140 | 8 | 4 | 3 | −10 to 16 |
| Care/nursing home or NHS continuing care[a] | 128 | 1117 | 393 | 141 | 1298 | 375 | −181 | −1410 to 1048 |
| Respite residential/nursing | 127 | 220 | 138 | 138 | 143 | 134 | 77 | −358 to 512 |
| Community care | 128 | 603 | 142 | 141 | 457 | 135 | 146 | −298 to 590 |
| Day care (any provider) | 127 | 79 | 25 | 138 | 35 | 24 | 44 | −34 to 121 |
| Medications | 132 | 361 | 132 | 150 | 108 | 126 | 253 | −160 to 665 |
| Intervention | – | – | – | – | – | – | – | – |
| Equipment and adaptations[b] | 128 | 7 | 3 | 140 | 8 | 3 | −1 | −10 to 8 |
| Care/nursing home, self-funded | 128 | 757 | 294 | 141 | 1380 | 280 | −623 | −1542 to 296 |
| Equipment and adaptations[c] | 128 | 7 | 3 | 140 | 11 | 2 | −4 | −12 to 5 |
| Out of pocket[d] | 99 | 10 | 4 | 101 | 5 | 4 | 6 | −7 to 18 |
| Unpaid care[e] | 100 | 4875 | 958 | 103 | 5425 | 949 | −550 | −3600 to 2500 |
| Health and social care (HRE) | 125 | 3740 | 709 | 135 | 3196 | 691 | 544 | −1697 to 2784 |
| Health and social care (SIR) | 123 | 3458 | 653 | 130 | 3148 | 642 | 310 | −1761 to 2381 |
| Health and social care (SIR+) | 125 | 3544 | 663 | 135 | 3094 | 645 | 450 | −1642 to 2543 |
| Societal (HRE)[f] | 95 | 9661 | 949 | 100 | 9783 | 932 | −122 | −3131 to 2886 |
| Societal (SIR)[f] | 93 | 9249 | 946 | 97 | 9823 | 934 | −574 | −3581 to 2433 |
| Societal (SIR+)[f] | 95 | 9299 | 886 | 100 | 9635 | 867 | −336 | −3140 to 2469 |
| Intervention + health and social care (HRE) | 125 | 3740 | 709 | 135 | 3196 | 691 | 544 | −1697 to 2784 |
| Intervention + health and social care (SIR) | 123 | 3458 | 653 | 130 | 3148 | 642 | 310 | −1761 to 2381 |
| Intervention + health and social care (SIR+) | 125 | 3544 | 663 | 135 | 3094 | 645 | 450 | −1642 to 2543 |
| Intervention + societal (HRE)[f] | 95 | 9661 | 949 | 100 | 9783 | 932 | −122 | −3131 to 2886 |
| Intervention + societal (SIR)[f] | 93 | 9249 | 946 | 97 | 9823 | 934 | −574 | −3581 to 2433 |
| Intervention + societal (SIR+)[f] | 95 | 9299 | 886 | 100 | 9635 | 867 | −336 | −3140 to 2469 |

SIR+, corresponding hospital costs data from HRE used when costs were missing from the SIR data set.
a Funded by NHS or Social Services.
b Provided by NHS or Social Services.
c Expenditure by self or family on equipment purchases.
d Expenditure by self or family on travel to appointments.
e Unpaid carers' time in care and support to participant.
f Societal costs include: participant's health and social care costs; unpaid carers' time in care and support to participant; expenditure by self or family on travel to appointments, equipment purchases.

**TABLE 10** Mean costs (standard errors): health and social care services for participant, unpaid carer (suitable informant) costs, out-of-pocket costs, total health and social care and societal costs over prior 3 months, at 1 month, 2016–7 (£)

| | Intervention: clusters (*N* = 132), cases (*N* = 5) | | | Control: clusters (*N* = 150), cases (*N* = 6) | | | Intervention–control | |
|---|---|---|---|---|---|---|---|---|
| **1 month** | ***n*** | **Mean** | **SE** | ***n*** | **Mean** | **SE** | **Mean difference** | **95% CI** |
| Hospital (SIR) | 105 | 10,253 | 413 | 103 | 9076 | 413 | 1177 | −145 to 2499 |
| Hospital (HRE) | 103 | 9250 | 496 | 113 | 9099 | 472 | 151 | −1398 to 1699 |
| Hospital (HRE) inc. ambulance | 103 | 9250 | 497 | 113 | 9101 | 473 | 148 | −1403 to 1700 |
| Hospital (SIR+) | 107 | 10,213 | 398 | 113 | 9184 | 384 | 1029 | −223 to 2280 |
| Primary and community health | 106 | 335 | 67 | 113 | 251 | 65 | 84 | −127 to 296 |
| Community mental health | 106 | 33 | 25 | 112 | 2 | 25 | 31 | −49 to 111 |
| Care/nursing home or NHS continuing care[a] | 106 | 1618 | 616 | 114 | 1282 | 589 | 336 | −1592 to 2264 |
| Respite residential/ nursing | 106 | 1585 | 539 | 110 | 1199 | 521 | 386 | −1311 to 2083 |
| Community care | 106 | 120 | 40 | 113 | 83 | 38 | 37 | −88 to 161 |
| Day care (any provider) | 105 | 0 | 0 | 109 | 1 | 0 | 0 | −1 to 1 |
| Medications | 109 | 363 | 110 | 121 | 168 | 105 | 194 | −151 to 539 |
| Intervention | 132 | 41 | 8 | – | – | – | 41 | 1666 |
| Equipment and adaptations[b] | 99 | 1 | 1 | 109 | 3 | 1 | −2 | −6 to 2 |
| Care/nursing home, self-funded | 106 | 390 | 123 | 114 | 443 | 118 | −53 | −438 to 333 |
| Equipment and adaptations[c] | 99 | 1 | 1 | 109 | 2 | 1 | 0 | −3 to 2 |
| Out of pocket[d] | 89 | 36 | 12 | 90 | 39 | 12 | −3 | −42 to 36 |
| Unpaid care[e] | 89 | 1366 | 228 | 92 | 1711 | 224 | −345 | −1068 to 377 |
| Health and social care (HRE) | 89 | 12,819 | 527 | 99 | 11,636 | 505 | 1183 | −469 to 2834 |
| Health and social care (SIR) | 89 | 13,850 | 978 | 95 | 11,489 | 971 | 2361 | −757 to 5478 |
| Health and social care (SIR+) | 89 | 13,854 | 942 | 99 | 11,574 | 919 | 2280 | −697 to 5257 |
| Societal (HRE)[f] | 75 | 14,155 | 527 | 80 | 13,988 | 511 | 167 | −1495 to 1828 |
| Societal (SIR)[f] | 75 | 14,995 | 1023 | 76 | 14,123 | 1023 | 872 | −2402 to 4145 |
| Societal (SIR+)[f] | 75 | 15,000 | 1023 | 80 | 14,141 | 1001 | 859 | −2379 to 4097 |
| Intervention + health and social care (HRE) | 89 | 12,859 | 531 | 99 | 11,636 | 509 | 1223 | −441 to 2886 |
| Intervention + health and social care (SIR) | 89 | 13,890 | 980 | 95 | 11,489 | 974 | 2401 | −726 to 5527 |

**TABLE 10** Mean costs (standard errors): health and social care services for participant, unpaid carer (suitable informant) costs, out-of-pocket costs, total health and social care and societal costs over prior 3 months, at 1 month, 2016–7 (£) (*continued*)

| | Intervention: clusters (*N* = 132), cases (*N* = 5) | | | Control: clusters (*N* = 150), cases (*N* = 6) | | | Intervention–control | |
|---|---|---|---|---|---|---|---|---|
| **1 month** | ***n*** | **Mean** | **SE** | ***n*** | **Mean** | **SE** | **Mean difference** | **95% CI** |
| Intervention + health and social care (SIR+) | 89 | 13,894 | 945 | 99 | 11,574 | 922 | 2320 | −667 to 5306 |
| Intervention + societal (HRE)[f] | 75 | 14,191 | 526 | 80 | 13,988 | 511 | 203 | −1456 to 1862 |
| Intervention + societal (SIR)[f] | 75 | 15,032 | 1023 | 76 | 14,123 | 1023 | 908 | −2364 to 4180 |
| Intervention + societal (SIR+)[f] | 75 | 15,036 | 1023 | 80 | 14,141 | 1000 | 895 | −2341 to 4131 |

SIR+, corresponding hospital costs data from HRE used when costs were missing from the SIR data set.
a Funded by NHS or Social Services.
b Provided by NHS or Social Services.
c Expenditure by self or family on equipment purchases.
d Expenditure by self or family on travel to appointments.
e Unpaid carers' time in care and support to participant.
f Societal costs include: participant's health and social care costs; unpaid carers' time in care and support to participant; expenditure by self or family on travel to appointments, equipment purchases.

**TABLE 11** Mean costs (standard errors): health and social care services for participant, unpaid carer (suitable informant) costs, out-of-pocket costs, total health and social care and societal costs over prior 3 months, at 3 months, 2016–7 (£)

| | Intervention: clusters (*N* = 132), cases (*N* = 5) | | | Control: clusters (*N* = 150), cases (*N* = 6) | | | Intervention–control | |
|---|---|---|---|---|---|---|---|---|
| **3 months** | ***n*** | **Mean** | **SE** | ***n*** | **Mean** | **SE** | **Mean difference** | **95% CI** |
| Hospital (SIR) | 82 | 1200 | 327 | 95 | 603 | 304 | 596 | −413 to 1606 |
| Hospital (HRE) | 81 | 2010 | 1031 | 98 | 2398 | 979 | −388 | −3605 to 2830 |
| Hospital (HRE), including ambulance | 81 | 2013 | 1031 | 98 | 2405 | 979 | −392 | −3608 to 2823 |
| Hospital (SIR+) | 83 | 1194 | 378 | 99 | 1009 | 347 | 185 | −976 to 1346 |
| Primary and community health | 82 | 522 | 98 | 94 | 377 | 91 | 146 | −156 to 448 |
| Community mental health | 81 | 18 | 27 | 93 | 46 | 25 | −28 | −111 to 55 |
| Care/nursing home or NHS continuing care[a] | 82 | 2496 | 610 | 97 | 1184 | 569 | 1312 | −576 to 3200 |
| Respite residential/ nursing | 82 | 2704 | 726 | 97 | 1212 | 681 | 1491 | −760 to 3743 |
| Community care | 82 | 912 | 437 | 97 | 471 | 419 | 440 | −929 to 1810 |
| Day care (any provider) | 82 | 18 | 12 | 96 | 8 | 11 | 11 | −25 to 47 |
| Medications | 83 | 409 | 141 | 102 | 146 | 134 | 262 | −178 to 702 |

continued

**TABLE 11** Mean costs (standard errors): health and social care services for participant, unpaid carer (suitable informant) costs, out-of-pocket costs, total health and social care and societal costs over prior 3 months, at 3 months, 2016–7 (£) (*continued*)

| | Intervention: clusters (*N* = 132), cases (*N* = 5) | | | Control: clusters (*N* = 150), cases (*N* = 6) | | | Intervention–control | |
|---|---|---|---|---|---|---|---|---|
| 3 months | *n* | Mean | SE | *n* | Mean | SE | Mean difference | 95% CI |
| Intervention | 132 | 82 | 11 | – | – | – | 82 | 32 to 130 |
| Equipment and adaptations[b] | 80 | 6 | 3 | 96 | 6 | 2 | 0 | −8 to 8 |
| Care/nursing home, self-funded | 82 | 623 | 324 | 97 | 1535 | 301 | −912 | −1913 to 88 |
| Equipment and adaptations[c] | 80 | 2 | 2 | 96 | 6 | 2 | −4 | −11 to 4 |
| Out of pocket[d] | 71 | 15 | 6 | 76 | 15 | 6 | 0 | −18 to 18 |
| Unpaid care[e] | 71 | 2777 | 542 | 77 | 3679 | 521 | −902 | −2603 to 799 |
| Health and social care (HRE) | 75 | 9109 | 1721 | 88 | 5946 | 1684 | 3163 | −2284 to 8610 |
| Health and social care (SIR) | 75 | 8231 | 1258 | 87 | 4310 | 1226 | 3921 | −53 to 7894 |
| Health and social care (SIR+) | 75 | 8241 | 1274 | 88 | 4621 | 1236 | 3620 | −395 to 7635 |
| Societal (HRE)[f] | 64 | 12,717 | 1909 | 71 | 10,748 | 1847 | 1969 | −4040 to 7979 |
| Societal (SIR)[f] | 64 | 11,906 | 1341 | 70 | 8923 | 1297 | 2983 | −1239 to 7205 |
| Societal (SIR+)[f] | 64 | 11,917 | 1293 | 71 | 9243 | 1243 | 2674 | −1384 to 6732 |
| Intervention + health and social care (HRE) | 75 | 9193 | 1721 | 88 | 5946 | 1684 | 3247 | −2200 to 8695 |
| Intervention + health and social care (SIR) | 75 | 8315 | 1258 | 87 | 4310 | 1226 | 4004 | 30 to 7979 |
| Intervention + health and social care (SIR+) | 75 | 8325 | 1274 | 88 | 4621 | 1236 | 3704 | −311 to 7719 |
| Intervention + societal (HRE)[f] | 64 | 12,794 | 1909 | 71 | 10,748 | 1846 | 2047 | −3961 to 8054 |
| Intervention + societal (SIR)[f] | 64 | 11,983 | 1341 | 70 | 8923 | 1297 | 3060 | −1161 to 7281 |
| Intervention + societal (SIR+)[f] | 64 | 11,995 | 1293 | 71 | 9243 | 1243 | 2752 | −1305 to 6808 |

NHS CC, NHS continuing care; SIR+, corresponding hospital costs data from HRE used when costs were missing from the SIR data set.
a Funded by NHS or Social Services.
b Provided by NHS or Social Services.
c Expenditure by self or family on equipment purchases.
d Expenditure by self or family on travel to appointments.
e Unpaid carers' time in care and support to participant.
f Societal costs include: participant's health and social care costs; unpaid carers' time in care and support to participant; expenditure by self or family on travel to appointments, equipment purchases.

**TABLE 12** Mean costs (standard errors): health and social care services for participant, unpaid carer (suitable informant) costs, out-of-pocket costs, total health and social care and societal costs over prior 3 months, at 6 months, 2016–7 (£)

| | Intervention: clusters (*N* = 132), cases (*N* = 5) | | | Control: clusters (*N* = 150), cases (*N* = 6) | | | Intervention–control | |
|---|---|---|---|---|---|---|---|---|
| **6 months** | ***n*** | **Mean** | **SE** | ***n*** | **Mean** | **SE** | **Mean difference** | **95% CI** |
| Hospital (SIR) | 64 | 614 | 212 | 74 | 417 | 199 | 197 | −461 to 855 |
| Hospital (HRE) | 60 | 516 | 513 | 72 | 1005 | 492 | −489 | −2096 to 1118 |
| Hospital (HRE) including ambulance | 60 | 516 | 519 | 72 | 1015 | 499 | −499 | −2127 to 1129 |
| Hospital (SIR+) | 64 | 625 | 209 | 76 | 410 | 192 | 216 | −426 to 857 |
| Primary and community health | 63 | 338 | 105 | 75 | 426 | 96 | −88 | −410 to 233 |
| Community mental health | 62 | 18 | 8 | 75 | 13 | 8 | 5 | −21 to 30 |
| Care/nursing home or NHS continuing care[a] | 64 | 2479 | 784 | 76 | 2202 | 720 | 277 | −2130 to 2685 |
| Respite residential/ nursing | 64 | 998 | 342 | 76 | 81 | 316 | 916 | −137 to 1970 |
| Community care | 64 | 2161 | 780 | 76 | 678 | 778 | 1483 | −1008 to 3974 |
| Day care (any provider) | 64 | 47 | 33 | 75 | 15 | 33 | 32 | −74 to 138 |
| Medications | 64 | 371 | 184 | 79 | 168 | 180 | 203 | −380 to 787 |
| Intervention | 132 | 123 | 24 | – | – | – | 123 | 48,200 |
| Equipment and adaptations[a] | 64 | 10 | 5 | 74 | 5 | 5 | 4 | −11 to 20 |
| Permanent residential/ nursing self | 64 | 1573 | 557 | 76 | 1930 | 514 | −358 | −2072 to 1357 |
| Equipment and adaptations[a] | 64 | 6 | 5 | 74 | 9 | 5 | −3 | −20 to 14 |
| Out of pocket[b] | 58 | 52 | 31 | 63 | 7 | 29 | 45 | −51 to 141 |
| Unpaid care[e] | 58 | 3731 | 766 | 63 | 5877 | 735 | −2146 | −4548 to 257 |
| Health and social care (HRE) | 57 | 6679 | 1391 | 64 | 5146 | 1401 | 1533 | −2933 to 5999 |
| Health and social care (SIR) | 57 | 6699 | 983 | 64 | 4308 | 947 | 2391 | −698 to 5480 |
| Health and social care (SIR+) | 57 | 6712 | 989 | 64 | 4308 | 953 | 2404 | −703 to 5510 |
| Societal (HRE)[f] | 52 | 11,390 | 1450 | 54 | 12,478 | 1463 | −1088 | −5747 to 3570 |
| Societal (SIR)[f] | 52 | 11,393 | 1495 | 54 | 11,483 | 1523 | −91 | −4918 to 4737 |

continued

**TABLE 12** Mean costs (standard errors): health and social care services for participant, unpaid carer (suitable informant) costs, out-of-pocket costs, total health and social care and societal costs over prior 3 months, at 6 months, 2016–7 (£) (*continued*)

| | Intervention: clusters (*N* = 132), cases (*N* = 5) | | | Control: clusters (*N* = 150), cases (*N* = 6) | | | Intervention–control | |
|---|---|---|---|---|---|---|---|---|
| **6 months** | ***n*** | **Mean** | **SE** | ***n*** | **Mean** | **SE** | **Mean difference** | **95% CI** |
| Societal (SIR+)[f] | 52 | 11,407 | 1500 | 54 | 11,483 | 1528 | −77 | −4921 to 4767 |
| Intervention + health and social care (HRE) | 57 | 6807 | 1402 | 64 | 5146 | 1413 | 1661 | −2842 to 6164 |
| Intervention health and social care (SIR) | 57 | 6827 | 999 | 64 | 4308 | 965 | 2519 | −624 to 5661 |
| Intervention + health and social care (SIR+) | 57 | 6839 | 1004 | 64 | 4308 | 971 | 2531 | −629 to 5692 |
| Intervention + societal (HRE)[f] | 52 | 11,511 | 1462 | 54 | 12,478 | 1476 | −967 | −5666 to 3733 |
| Intervention + societal (SIR)[f] | 52 | 11,514 | 1506 | 54 | 11,483 | 1536 | 31 | −4836 to 4897 |
| Intervention + societal (SIR+)[f] | 52 | 11,528 | 1511 | 54 | 11,483 | 1541 | 44 | −4839 to 4928 |

SIR+, corresponding hospital costs data from HRE used when costs were missing from the SIR data set.
a Funded by NHS or Social Services.
b Provided by NHS or Social Services.
c Expenditure by self or family on equipment purchases.
d Expenditure by self or family on travel to appointments.
e Unpaid carers' time in care and support to participant.
f Societal costs include: participant's health and social care costs; unpaid carers' time in care and support to participant; expenditure by self or family on travel to appointments, equipment purchases.

**TABLE 13** Outcomes examined in cost-effectiveness analysis. Sample: cases where economic data were available[a]

| | Intervention | | | Control | | | Difference | |
|---|---|---|---|---|---|---|---|---|
| | ***N*** | **Mean** | **SE** | ***N*** | **Mean** | **SE** | **Intervention–control** | **CI** |
| ***Baseline – prior 3 months*** | | | | | | | | |
| *HSC–HRE data available* | | | | | | | | |
| Participant EQ-5D-5L-Proxy | 123 | −0.003 | 0.033 | 130 | 0.153 | 0.033 | −0.156 | −0.262 to −0.051 |
| SI EQ-5D-5L | 122 | 0.796 | 0.022 | 133 | 0.855 | 0.021 | −0.059 | −0.128 to 0.011 |
| Participant EQ-5D-5L | 90 | 0.24 | 0.083 | 82 | 0.31 | 0.084 | −0.069 | −0.336 to 0.197 |
| DEMQOL-U | 83 | 0.76 | 0.035 | 78 | 0.738 | 0.035 | 0.022 | −0.090 to 0.133 |
| DEMQOL-U | 125 | 0.656 | 0.02 | 132 | 0.655 | 0.019 | 0.001 | −0.061 to 0.063 |
| BADLS | 117 | 24.521 | 3.011 | 134 | 21.164 | 2.96 | 3.357 | −6.194 to 12.909 |
| *Societal (HRE) data available* | | | | | | | | |
| Participant EQ-5D-5L-Proxy | 93 | −0.014 | 0.045 | 97 | 0.121 | 0.046 | −0.135 | −0.280 to 0.011 |
| SI EQ-5D-5L | 92 | 0.796 | 0.028 | 99 | 0.838 | 0.028 | −0.042 | −0.132 to 0.047 |

**TABLE 13** Outcomes examined in cost-effectiveness analysis. Sample: cases where economic data were available (*continued*)

| | Intervention | | | Control | | | Difference | |
|---|---|---|---|---|---|---|---|---|
| | *N* | Mean | SE | *N* | Mean | SE | Intervention–control | CI |
| Participant EQ-5D-5L | 65 | 0.282 | 0.083 | 58 | 0.28 | 0.087 | 0.002 | −0.270 to 0.274 |
| DEMQOL-U | 60 | 0.723 | 0.036 | 54 | 0.715 | 0.038 | 0.008 | −0.110 to 0.126 |
| DEMQOL-U | 95 | 0.64 | 0.015 | 98 | 0.65 | 0.015 | −0.01 | −0.058 to 0.039 |
| BADLS | 88 | 25.67 | 3.337 | 99 | 19.96 | 3.362 | 5.711 | −5.004 to 16.426 |
| ***1 month – prior month*** | | | | | | | | |
| *HSC–HRE data available* | | | | | | | | |
| Participant EQ-5D-5L-Proxy | 88 | 0.214 | 0.043 | 98 | 0.277 | 0.042 | −0.063 | −0.198 to 0.072 |
| SI EQ-5D-5L | 89 | 0.812 | 0.024 | 95 | 0.859 | 0.023 | −0.046 | −0.120 to 0.028 |
| Participant EQ-5D-5L | 71 | 0.541 | 0.083 | 71 | 0.504 | 0.084 | 0.037 | −0.230 to 0.304 |
| DEMQOL-U | 64 | 0.807 | 0.02 | 71 | 0.819 | 0.019 | −0.012 | −0.075 to 0.052 |
| DEMQOL-U | 88 | 0.677 | 0.019 | 94 | 0.68 | 0.018 | −0.003 | −0.062 to 0.057 |
| BADLS | 86 | 26.186 | 3.163 | 96 | 23.927 | 3.163 | 2.259 | −7.861 to 12.378 |
| *Societal (HRE)* | | | | | | | | |
| Participant EQ-5D-5L-Proxy | 74 | 0.208 | 0.051 | 80 | 0.246 | 0.05 | −0.038 | −0.199 to 0.124 |
| SI EQ-5D-5L | 75 | 0.83 | 0.024 | 78 | 0.843 | 0.024 | −0.013 | −0.090 to 0.063 |
| Participant EQ-5D-5L | 57 | 0.593 | 0.076 | 58 | 0.458 | 0.077 | 0.135 | −0.109 to 0.379 |
| DEMQOL-U | 50 | 0.8 | 0.024 | 59 | 0.808 | 0.022 | −0.008 | −0.081 to 0.064 |
| DEMQOL-U | 74 | 0.662 | 0.018 | 78 | 0.663 | 0.017 | −0.001 | −0.057 to 0.055 |
| BADLS | 73 | 28.082 | 3.259 | 79 | 24.152 | 3.234 | 3.93 | −6.457 to 14.318 |
| ***3 months – prior 2 months*** | | | | | | | | |
| *HSC–HRE data available* | | | | | | | | |
| Participant EQ-5D-5L-Proxy | 75 | 0.309 | 0.043 | 88 | 0.362 | 0.041 | −0.053 | −0.187 to 0.081 |
| SI EQ-5D-5L | 74 | 0.838 | 0.027 | 88 | 0.88 | 0.026 | −0.042 | −0.128 to 0.044 |
| Participant EQ-5D-5L | 58 | 0.636 | 0.057 | 65 | 0.625 | 0.055 | 0.011 | −0.168 to 0.190 |
| DEMQOL-U | 58 | 0.835 | 0.033 | 62 | 0.82 | 0.033 | 0.016 | −0.090 to 0.121 |
| DEMQOL-U | 74 | 0.706 | 0.015 | 86 | 0.712 | 0.014 | −0.006 | −0.053 to 0.041 |
| BADLS | 74 | 24.392 | 2.293 | 86 | 21.302 | 2.218 | 3.09 | −4.126 to 10.305 |
| *Societal (HRE) data available* | | | | | | | | |
| Participant EQ-5D-5L-Proxy | 64 | 0.288 | 0.042 | 71 | 0.332 | 0.04 | −0.045 | −0.176 to 0.087 |
| SI EQ-5D-5L | 64 | 0.843 | 0.033 | 71 | 0.877 | 0.032 | −0.034 | −0.138 to 0.070 |
| Participant EQ-5D-5L | 47 | 0.666 | 0.049 | 52 | 0.593 | 0.046 | 0.073 | −0.079 to 0.226 |
| DEMQOL-U | 48 | 0.826 | 0.034 | 50 | 0.818 | 0.034 | 0.008 | −0.100 to 0.117 |
| DEMQOL-U | 63 | 0.704 | 0.016 | 69 | 0.694 | 0.016 | 0.009 | −0.042 to 0.061 |
| BADLS | 63 | 26.159 | 2.038 | 69 | 21.246 | 1.952 | 4.912 | −1.471 to 11.295 |

continued

**TABLE 13** Outcomes examined in cost-effectiveness analysis. Sample: cases where economic data were available (*continued*)

| | Intervention | | | Control | | | Difference | |
|---|---|---|---|---|---|---|---|---|
| | *N* | Mean | SE | *N* | Mean | SE | Intervention–control | CI |
| ***6 months – prior 3 months*** | | | | | | | | |
| *HSC–HRE data available* | | | | | | | | |
| Participant EQ-5D-5L-Proxy | 41 | 0.367 | 0.056 | 55 | 0.349 | 0.049 | 0.018 | −0.150 to 0.185 |
| SI EQ-5D-5L | 45 | 0.845 | 0.034 | 55 | 0.871 | 0.033 | −0.026 | −0.132 to 0.080 |
| Participant EQ-5D-5L | 34 | 0.744 | 0.063 | 40 | 0.655 | 0.062 | 0.09 | −0.110 to 0.290 |
| DEMQOL-U | 41 | 0.867 | 0.032 | 42 | 0.864 | 0.034 | 0.003 | −0.103 to 0.109 |
| DEMQOL-U | 57 | 0.721 | 0.023 | 62 | 0.705 | 0.023 | 0.016 | −0.058 to 0.091 |
| BADLS | 54 | 26.333 | 2.459 | 64 | 19.313 | 2.475 | 7.021 | −0.871 to 14.913 |
| *Societal (HRE) data available* | | | | | | | | |
| Participant EQ-5D-5L-Proxy | 39 | 0.381 | 0.062 | 46 | 0.322 | 0.059 | 0.059 | −0.135 to 0.252 |
| SI EQ-5D-5L | 40 | 0.864 | 0.037 | 46 | 0.882 | 0.036 | −0.018 | −0.135 to 0.100 |
| Participant EQ-5D-5L | 29 | 0.774 | 0.058 | 35 | 0.62 | 0.053 | 0.154 | −0.024 to 0.332 |
| DEMQOL-U | 37 | 0.858 | 0.031 | 38 | 0.859 | 0.032 | −0.001 | −0.101 to 0.099 |
| DEMQOL-U | 52 | 0.717 | 0.021 | 52 | 0.699 | 0.021 | 0.018 | −0.048 to 0.084 |
| BADLS | 49 | 26.592 | 2.61 | 54 | 19 | 2.689 | 7.592 | −0.885 to 16.069 |

HSC, health and social care.
a Economic data included total HSC and societal costs including costs of hospital services calculated from HRE data.

**TABLE 14** Intraclass correlations of 6-month total health and social care and societal costs, 2016–7 (£) and QALYs over 6 months. Sample: cases where costs or outcomes data were available at all study period time points

| | Intervention: clusters (*N* = 132), cases (*N* = 5) | | | | Control: clusters (*N* = 150), cases (*N* = 6) | | | |
|---|---|---|---|---|---|---|---|---|
| | Clusters (*n*) | Cases (*n*) | Mean | 95% CI | Clusters (*n*) | Cases (*n*) | Mean | 95% CI |
| ***Costs*** | | | | | | | | |
| Health and social care (HRE) | 47 | 5 | −0.045 | −0.148 to 0.057 | 56 | 6 | 0.117 | −0.152 to 0.386 |
| Health and social care (SIR) | 47 | 5 | −0.051 | −0.147 to 0.045 | 53 | 6 | 0.034 | −0.165 to 0.232 |
| Health and social care (SIR+) | 47 | 5 | −0.050 | −0.147 to 0.048 | 56 | 6 | 0.028 | −0.154 to 0.210 |
| Societal (HRE) | 39 | 5 | −0.041 | −0.194 to 0.112 | 38 | 5 | 0.190 | −0.189 to 0.569 |
| Societal (SIR) | 39 | 5 | −0.057 | −0.194 to 0.079 | 36 | 5 | 0.214 | −0.201 to 0.628 |
| Societal (SIR+) | 39 | 5 | −0.055 | −0.194 to 0.084 | 38 | 5 | 0.240 | −0.169 to 0.649 |
| Intervention + health and social care (HRE) | 47 | 5 | −0.039 | −0.149 to 0.071 | 56 | 6 | 0.117 | −0.152 to 0.386 |

**TABLE 14** Intraclass correlations of 6-month total health and social care and societal costs, 2016–7 (£) and QALYs over 6 months. Sample: cases where costs or outcomes data were available at all study period time points (*continued*)

| | Intervention: clusters (*N* = 132), cases (*N* = 5) | | | | Control: clusters (*N* = 150), cases (*N* = 6) | | | |
|---|---|---|---|---|---|---|---|---|
| | Clusters (*n*) | Cases (*n*) | Mean | 95% CI | Clusters (*n*) | Cases (*n*) | Mean | 95% CI |
| Intervention + health and social care (SIR) | 47 | 5 | −0.044 | −0.148 to 0.059 | 53 | 6 | 0.033 | −0.165 to 0.232 |
| Intervention + health and social care (SIR+) | 47 | 5 | −0.043 | −0.148 to 0.061 | 56 | 6 | 0.028 | −0.154 to 0.210 |
| Intervention + societal (HRE) | 39 | 5 | −0.033 | −0.195 to 0.128 | 38 | 5 | 0.190 | −0.189 to 0.569 |
| Intervention + societal (SIR) | 39 | 5 | −0.049 | −0.194 to 0.096 | 36 | 5 | 0.214 | −0.201 to 0.628 |
| Intervention + societal (SIR+) | 39 | 5 | −0.047 | −0.194 to 0.101 | 38 | 5 | 0.240 | −0.169 to 0.649 |
| *QALY* | | | | | | | | |
| Participant 6-month QALY (EQ-5D-5L) | 30 | 5 | 0.268 | −0.173 to 0.710 | 31 | 4 | 0.263 | −0.236 to 0.762 |
| Participant 6-month QALY (EQ-5D-5L-Proxy) | 42 | 5 | 0.068 | −0.181 to 0.316 | 62 | 6 | 0.110 | −0.136 to 0.355 |
| Participant 6-month QALY (DEMQOL-U) | 34 | 5 | 0.236 | −0.190 to 0.662 | 34 | 5 | −0.001 | −0.255 to 0.253 |
| Participant 6-month QALY (DEMQOL-PROXY) | 60 | 5 | 0.004 | −0.121 to 0.129 | 67 | 6 | 0.037 | −0.125 to 0.198 |
| SI 6-month QALY (EQ-5D-5L) | 48 | 5 | 0.255 | −0.109 to 0.619 | 63 | 6 | −0.040 | −0.135 to 0.055 |

SIR+, hospital costs data from HRE used when these costs were missing from SIR data set.

**TABLE 15** Agreement between hospital-records and self-report hospital service use and costs

| Item | Period[a] | Mean, difference (SD) (HRE–SIR) | $\rho_c$ (95% CI) | 95% limits of agreement | Exact (none)[b] % (*n*) | Exact (some)[c] % (*N*) | Under,[d] % (*N*) | Over,[e] % (*N*) |
|---|---|---|---|---|---|---|---|---|
| A&E visits | Time 0 | −0.339 (2.945) | 0.099 (0.061 to 0.136) | −6.110 to 5.433 | 77 (198) | 9 (23) | 4 (10) | 10 (26) |
| | Time 1 | −0.015 (0.304) | 0.452 (0.343 to 0.561) | −0.611 to 0.581 | 90 (186) | 3 (7) | 2 (5) | 4 (8) |
| | Time 2 | −0.124 (0.908) | 0.308 (0.218 to 0.397) | −1.903 to 1.655 | 78 (132) | 8 (14) | 5 (8) | 9 (15) |
| | Time 3 | −0.143 (0.817) | 0.367 (0.249 to 0.485) | −1.744 to 1.458 | 75 (95) | 15 (19) | 2 (2) | 8 (10) |
| Admissions | Time 0 | 0.100 (0.630) | 0.620 (0.462 to 0.777) | −1.134 to 1.334 | 38 (23) | 27 (16) | 22 (13) | 13 (8) |
| | Time 1 | 0.108 (0.350) | 0.454 (0.350 to 0.557) | −0.577 to 0.794 | – | 90 (75) | 10 (8) | – |

continued

**TABLE 15** Agreement between hospital-records and self-report hospital service use and costs (*continued*)

| Item | Period[a] | Mean, difference (SD) (HRE–SIR) | $\rho_c$ (95% CI) | 95% limits of agreement | Exact (none)[b] % (*n*) | Exact (some)[c] % (*N*) | Under,[d] % (*N*) | Over,[e] % (*N*) |
|---|---|---|---|---|---|---|---|---|
| | Time 2 | 0.061 (0.493) | 0.617 (0.523 to 0.711) | −0.905 to 1.028 | 69 (112) | 9 (14) | 14 (23) | 9 (14) |
| | Time 3 | 0.033 (0.284) | 0.813 (0.753 to 0.873) | −0.525 to 0.590 | 83 (100) | 8 (10) | 6 (7) | 3 (3) |
| Inpatient days | Time 0 | 0.508 (5.513) | 0.449 (0.359 to 0.540) | −10.298 to 11.313 | 84 (103) | 8 (10) | 6 (7) | 2 (3) |
| | Time 1 | 0.000 (8.028) | 0.544 (0.445 to 0.643) | −15.735 to 15.735 | – | 41 (81) | 15 (29) | 44 (86) |
| | Time 2 | 1.093 (11.281) | 0.460 (0.342 to 0.579) | −21.017 to 23.203 | 66 (107) | 2 (3) | 15 (24) | 17 (27) |
| | Time 3 | 1.293 (9.211) | 0.197 (0.082 to 0.311) | −16.759 to 19.346 | 87 (100) | 1 (1) | 9 (10) | 3 (4) |
| Day hospital | Time 0 | 0.031 (0.902) | 0.037 (−0.075 to 0.149) | −1.736 to 1.799 | 94 (238) | – | 5 (12) | 2 (4) |
| | Time 1 | 0.025 (0.221) | – | −0.408 to 0.457 | 99 (161) | – | 1 (2) | – |
| | Time 2 | 0.006 (0.132) | 0.724 (0.670 to 0.777) | −0.254 to 0.265 | 98 (169) | – | 1 (2) | 1 (1) |
| | Time 3 | 0.056 (0.319) | 0.428 (0.369 to 0.487) | −0.569 to 0.681 | 97 (121) | – | 3 (4) | – |
| Outpatient | Time 0 | 0.008 (1.069) | 0.537 (0.448 to 0.625) | −2.087 to 2.103 | 67 (164) | 11 (28) | 11 (26) | 11 (28) |
| | Time 1 | −0.015 (0.272) | 0.417 (0.303 to 0.530) | −0.548 to 0.519 | 93 (188) | 3 (6) | 1 (3) | 3 (6) |
| | Time 2 | −0.047 (0.554) | 0.529 (0.420 to 0.637) | −1.134 to 1.039 | 77 (130) | 11 (18) | 4 (6) | 9 (15) |
| | Time 3 | 0.016 (0.589) | 0.764 (0.691 to 0.836) | −1.138 to 1.171 | 72 (88) | 10 (12) | 8 (10) | 10 (12) |
| Hospital costs (e) | Time 0 | 177.437 (1654.363) | 0.660 (0.597 to 0.723) | −3065 to 3420 | 50 (130) | 5 (12) | 24 (62) | 21 (55) |
| | Time 1 | −420.340 (3355.633) | 0.379 (0.262 to 0.496) | −6997 to 6157 | – | 27 (55) | 17 (34) | 56 (112) |
| | Time 2 | 1336.827 (4773.868) | 0.295 (0.182 to 0.409) | −8020 to 10,693 | 45 (78) | 2 (3) | 33 (57) | 21 (36) |
| | Time 3 | 342.110 (3151.993) | 0.261 (0.136 to 0.385) | −5836 to 6520 | 52 (66) | 3 (4) | 24 (31) | 21 (27) |

$\rho_c$, Lin's concordance correlation coefficient.
a Time 0, 3 months prior to baseline assessment; time 1, 1 month post fracture; time 2, 2 months prior to 3 months post fracture; time 3, 3 months prior to 6 months post fracture.
b Zero use/costs in both sources.
c The same frequency or cost in both sources.
d Under-reporting (lower frequency/cost in SIR than HRE).
e Over-reporting (higher frequency/use in SIR than HRE).

**TABLE 16** Completion times for workbook sections containing resource use questions and estimated time administering resource use questions (minutes)

| Baseline | Mean | SD | Minimum | Maximum | *N* |
|---|---|---|---|---|---|
| Section with hospital use and medications review[a] | 47.7 | 40.7 | 5.0 | 300.0 | 275 |
| Minutes per question | 3.0 | 2.5 | 0.3 | 18.8 | 275 |
| Minutes per hospital use and medications review | 14.9 | 12.7 | 1.6 | 93.8 | 275 |
| Section with CSRI[b] | 73.3 | 39.9 | 5.0 | 271.0 | 269 |
| Minutes per question | 0.4 | 0.2 | 0.0 | 1.3 | 269 |
| Minutes per CSRI | 16.6 | 9.0 | 1.1 | 61.4 | 269 |
| ***1 month*** | | | | | |
| Section with hospital use and medications review[a] | 45.1 | 70.3 | 2.0 | 862.0 | 221 |
| Minutes per question | 3.2 | 5.0 | 0.1 | 61.6 | 221 |
| Minutes per hospital use and medications review | 16.1 | 25.1 | 0.7 | 307.9 | 221 |
| Section with CSRI[b] | 47.8 | 31.1 | 10.0 | 300.0 | 216 |
| Minutes per question | 0.4 | 0.2 | 0.1 | 2.4 | 216 |
| Minutes per CSRI | 17.5 | 11.4 | 3.7 | 110.2 | 216 |
| ***3 months*** | | | | | |
| Section with hospital use and medications review[a] | 29.7 | 28.8 | 2.0 | 190.0 | 179 |
| Minutes per question | 2.1 | 2.1 | 0.1 | 13.6 | 179 |
| Minutes per hospital use and medications review | 10.6 | 10.3 | 0.7 | 67.9 | 179 |
| Section with CSRI[b] | 44.1 | 24.7 | 18.0 | 220.0 | 179 |
| Minutes per question | 0.3 | 0.2 | 0.1 | 1.7 | 179 |
| Minutes per CSRI | 16.3 | 9.1 | 6.7 | 81.4 | 179 |
| ***6 months*** | | | | | |
| Section with hospital use and medications review[a] | 28.1 | 25.0 | 2.0 | 160.0 | 135 |
| Minutes per question | 2.0 | 1.8 | 0.1 | 11.4 | 135 |
| Minutes per hospital use and medications review | 10.0 | 8.9 | 0.7 | 57.1 | 135 |
| Section with CSRI[b] | 59.0 | 80.5 | 15.0 | 970.0 | 141 |
| Minutes per question | 0.5 | 0.6 | 0.1 | 7.6 | 141 |
| Minutes per CSRI | 21.8 | 29.8 | 5.6 | 359.0 | 141 |

a Cases where the hospital use and medications review questions were not completed were excluded.
b Cases where the CSRI questions were not completed were excluded.

## *Cost-effectiveness*

Results of the cost-effectiveness analyses are shown in *Tables 19* and *20*.

Point incremental cost-effectiveness ratios (see *Table 17*) for QALY and HSC costs ranged from negative figures (DEMQOL-U, DEMQOL-PROXY, BADLS) resulting from between-group differences favouring the control to very large estimates (EQ-5D-5L and EQ-5D-5L Proxy QALY), far exceeding the £20,000–30,000/QALY threshold set by the National Institute for Health and Care Excellence for considering the adoption of the technology.[106]

**TABLE 17** Multilevel model estimates: outcomes and costs at 6 months from participants with cost and outcome data available

| | Intervention[a] | Control[a] | Intervention–control, mean difference | 95% CI[b] | *p*-value |
|---|---|---|---|---|---|
| ***Person with dementia*** | *n* = 22 (*N* = 5) | *n* = 28 (*N* = 4) | | | |
| QALY[c,d] (EQ-5D-5L) | 0.323 | 0.273 | 0.050 | −0.022 to 0.122 | 0.173 |
| Health and social care[e] | 24,365 | 18,259 | 6106 | −1997 to 14,209 | 0.138 |
| ***Person with dementia*** | Cases *n* = 12 (*N* = 4) | *n* = 13 (*N* = 3) | | | |
| QALY[c,d] (EQ-5D-5L) | 0.381 | 0.260 | 0.121 | 0.035 to 0.207 | 0.007 |
| Societal[e] | 32,052 | 43,127 | −11,074 | −24,801 to 2653 | 0.111 |
| ***Person with dementia*** | *n* = 32 (*N* = 5) | *n* = 48 (*N* = 6) | | | |
| QALY[c,e] (EQ-5D-5L-PROXY) | 0.153 | 0.127 | 0.026 | −0.036 to 0.088 | 0.412 |
| Health and social care[e] | 24,663 | 21,798 | 2865 | −3431 to 9162 | 0.372 |
| ***Person with dementia*** | *n* = 20 (*N* = 4) | *n* = 22 (*N* = 5) | | | |
| QALY[c,d] (EQ-5D-5L-PROXY) | 0.151 | 0.126 | 0.025 | −0.045 to 0.095 | 0.480 |
| Societal[e] | 34,816 | 36,802 | −1986 | −9721 to 5748 | 0.615 |
| ***Person with dementia*** | *n* = 26 (*N* = 5) | *n* = 30 (*N* = 5) | | | |
| QALY[c,d] (DEMQOL-U) | 0.419 | 0.428 | −0.009 | −0.036 to 0.017 | 0.496 |
| Health and social care[e] | 25,376 | 18,175 | 7200 | 29 to 14,372 | 0.049 |
| ***Person with dementia*** | *n* = 14 (*N* = 5) | *n* = 12 (*N* = 3) | | | |
| QALY[c,d] (DEMQOL-U) | 0.427 | 0.417 | 0.010 | −0.027 to 0.048 | 0.583 |
| Societal[e] | 33,467 | 40,278 | −6811 | −23,729 to 10,107 | 0.422 |
| ***Person with dementia*** | *n* = 47 (*N* = 5) | *n* = 52 (*N* = 6) | | | |
| QALY[c,d] (DEMQOL-PROXY) | 0.355 | 0.356 | −0.001 | −0.023 to 0.02 | 0.913 |
| Health and social care[e] | 25,708 | 21,242 | 4466 | −1702 to 10,634 | 0.156 |
| ***Person with dementia*** | *n* = 30 (*N* = 5) | *n* = 24 (*N* = 5) | | | |
| QALY[c,d] (DEMQOL-PROXY) | 0.349 | 0.347 | 0.002 | −0.025 to 0.028 | 0.886 |
| Societal[e] | 33,823 | 36,004 | −2180 | −10,436 to 6076 | 0.605 |
| ***Person with dementia*** | *n* = 42 (*N* = 5) | *n* = 54 (*N* = 6) | | | |
| BADLS[c] | 25.688 | 22.058 | 3.629 | 7.62 to −0.361 | 0.075 |
| Health and social care[e] | 25,550 | 21,158 | 4392 | −1555 to 10,339 | 0.148 |
| ***Person with dementia*** | *n* = 26 (*N* = 5) | *n* = 24 (*N* = 5) | | | |
| BADLS[c] | 27.000 | 26.777 | 0.223 | 5.532 to −5.086 | 0.934 |
| Societal[e] | 34,898 | 35,797 | −899 | −8396 to 6598 | 0.814 |

**TABLE 17** Multilevel model estimates: outcomes and costs at 6 months from participants with cost and outcome data available (*continued*)

| | Intervention[a] | Control[a] | Intervention–control, mean difference | 95% CI[b] | *p*-value |
|---|---|---|---|---|---|
| ***Suitable informant*** | *n* = 36 (*N* = 5) | *n* = 49 (*N* = 6) | | | |
| QALY[c,d] (EQ-5D-5L) | 0.435 | 0.424 | 0.011 | −0.01 to 0.032 | 0.298 |
| Health and social care[e] | 24,875 | 21,338 | 3537 | −2125 to 9200 | 0.221 |
| ***Suitable informant*** | *n* = 23 (*N* = 4) | *n* = 22 (*N* = 5) | | | |
| QALY[c,d] (EQ-5D-5L) | 0.444 | 0.433 | 0.011 | −0.028 to 0.051 | 0.567 |
| Societal[e] | 33,663 | 37,172 | −3509 | −12,894 to 5876 | 0.464 |

*N*, numbers of clusters; *n*, numbers of cases.
a Estimated marginal means.
b 95% CIs adjusting for cluster.
c Estimates from outcome equation: covariates are allocation to treatment and baseline outcome.
d QALY calculated using the area-under-the-curve method with linear interpolation between assessment points.
e Estimates from costs equation: covariates are allocation to treatment and costs over the 6-month study period.

**TABLE 18** Participant and suitable informant 6-month outcomes; point incremental cost-effectiveness ratio[a] (95% CI) for intervention over control, from health and social care and societal perspectives (*N* = 282)

| Participant (*n*) | BADLS[a] (*N* = 96) | QALY (DEMQOL-PROXY)[b] (*n* = 99) | QALY (EQ-5D-5L-PROXY)[b] (*n* = 80) | QALY (DEMQOL-U)[b] (*n* = 56) | QALY (EQ-5D-5L)[b] (*n* = 50) |
|---|---|---|---|---|---|
| Health and social care | 4392/−1.037 = −4235 (38,951, 1837) | 4466/−0.001 = −3,710,715 (unbounded, unbounded) | 2865/0.026 = 110,663 (unbounded, unbounded) | 7200/−0.009 = −789,155 (106,477, −24,607) | 6106/0.050 = 122,114 (−21,817, −471,936) |
| **Participant (*n*)** | **50** | **54** | **42** | **26** | **25** |
| Societal | −899/−0.064 = 14,086 (unbounded, unbounded) | −2180/0.002 = −1,128,672 (unbounded, unbounded) | −1986/0.025 = −79,153 (unbounded, unbounded) | −6811/0.01 = −659,324 (unbounded, unbounded) | −11,074/ 0.121 = −91,699 (−23,2300, 31,488) |
| **Suitable informant (*n*)** | | | | | **85** |
| Health and social care | – | – | – | – | 3537/0.011 = 316,131 (unbounded, unbounded) |
| **Suitable informant (*n*)** | | | | | **45** |
| Societal | – | – | – | – | −3509/0.011 = −306,000 (unbounded, unbounded) |

a Cost of achieving a 3.5-point difference between groups at 6 months; incremental effect is divided by 3.5 and reversed (so a higher score indicates higher function).
b Cost of achieving a QALY gain over 9 months; difference in QALY rounded to third decimal place.

Cost-effectiveness acceptability curves are shown in *Figures 4–7*.

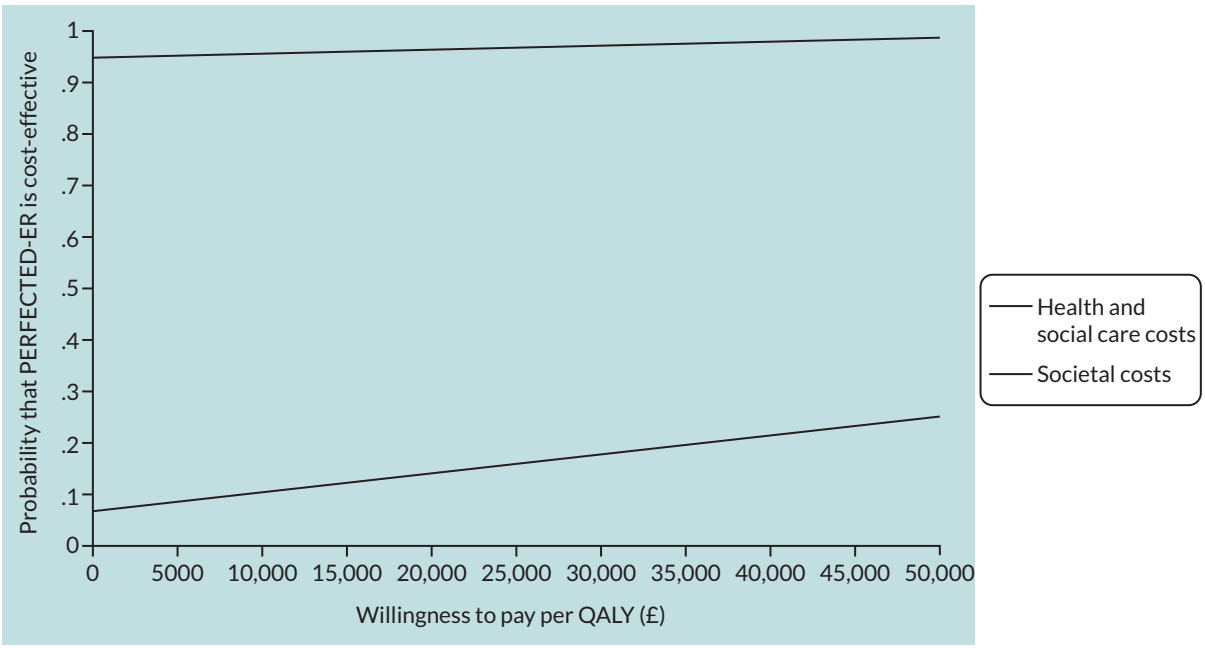


**FIGURE 4** Cost-effectiveness acceptability curve: participant QALY (EQ-5D-5L).

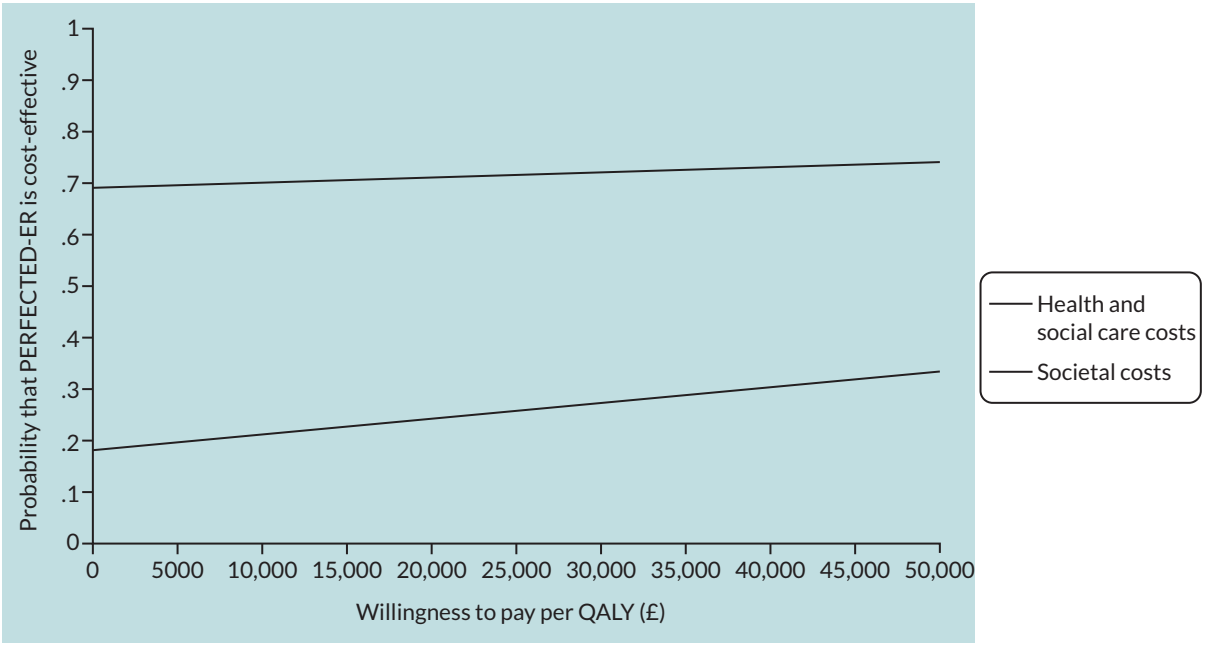


**FIGURE 5** Cost-effectiveness acceptability curve: participant QALY, EQ-5D-5L-PROXY.

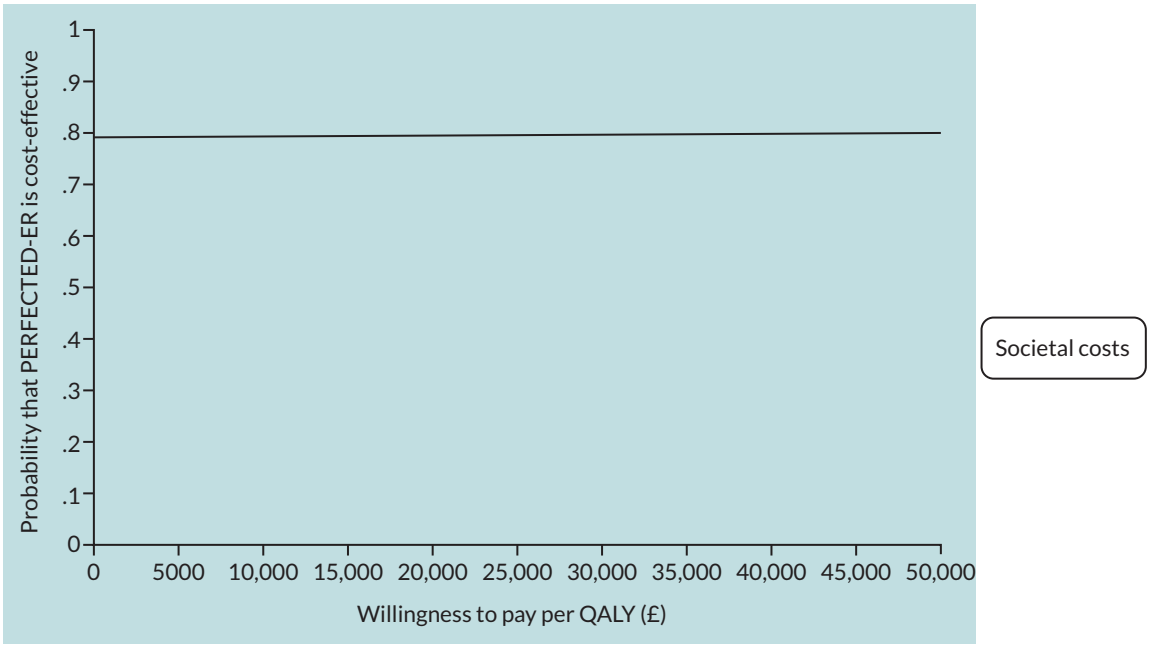


**FIGURE 6** Cost-effectiveness acceptability curve: participant QALY, DEMQOL-U.

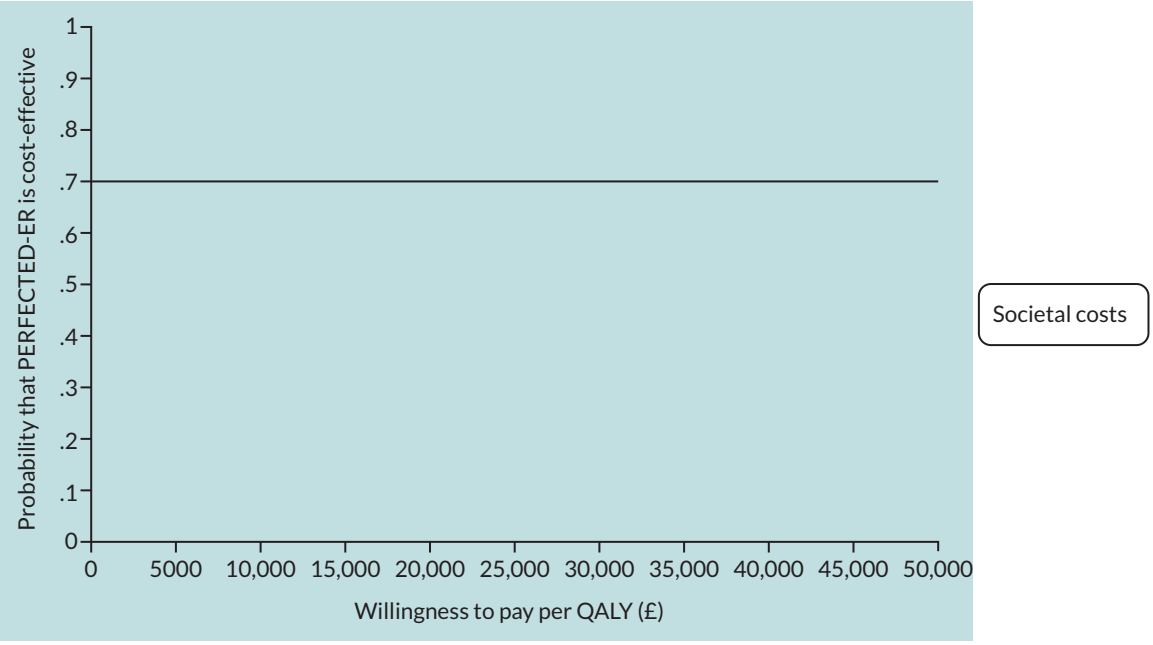


**FIGURE 7** Cost-effectiveness acceptability curve: participant QALY, DEMQOL-PROXY.

## Sensitivity analyses

Total societal costs (with and without intervention costs) were examined valuing unpaid carer time using replacement costs (the hourly cost of paid home care; *Table 21*).

Cost-effectiveness results of this sensitivity analysis are given in *Tables 22* and *23* (*Figures 9–14*), but taken together with incremental cost-effectiveness ratio confidence intervals (Table 24) should be read as indicating that there is no willingness to pay at which we could be confident that the intervention was cost-effective or not cost-effective compared with the control alternative. The exception was participant-reported EQ-5D-5L QALY but as this result was based on only 25 cases it is not further discussed.

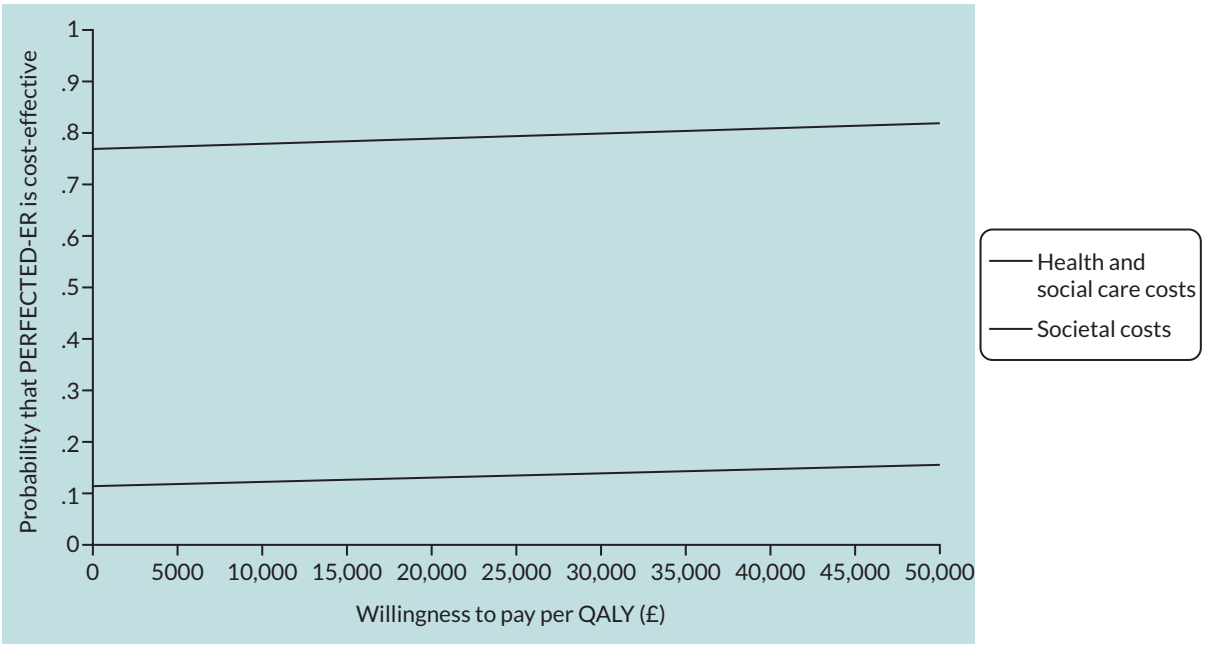


**FIGURE 8** Cost-effectiveness acceptability curve: suitable informant QALY (EQ-5D-5L).

**TABLE 19** Sensitivity analyses; mean costs over the study period of 6 months, 2016–7 prices (£). Sample: cases where total costs were available across follow-up assessments

| | Intervention | | | Control | | | Intervention–Control | |
|---|---|---|---|---|---|---|---|---|
| | *n* | Mean | SE | *n* | Mean | SE | Mean difference | 95% CI |
| Sensitivity: societal (HRE)[a] | 39 | 53,954 | 4579 | 38 | 58,481 | 4638 | −4527 | −19,557 to 10,502 |
| Sensitivity: societal (SIR)[a] | 39 | 54,595 | 4549 | 36 | 55,273 | 4734 | −678 | −15,817 to 14,462 |
| Sensitivity: societal (SIR+)[a] | 39 | 54,641 | 4530 | 38 | 55,481 | 4589 | −841 | −15,710 to 14,029 |
| Sensitivity: intervention + societal (HRE)[a] | 39 | 54,197 | 4583 | 38 | 58,481 | 4643 | −4284 | −19,329 to 10,762 |
| Sensitivity: intervention + societal (SIR)[a] | 39 | 54,838 | 4557 | 36 | 55,273 | 4744 | −434 | −15,602 to 14,734 |
| Sensitivity: intervention + societal (SIR+)[a] | 39 | 54,884 | 4534 | 38 | 55,481 | 4594 | −597 | −15,482 to 14,288 |

SIR+, corresponding hospital costs data from HRE used when costs were missing from the SIR data set.
a Societal costs include participant's health and social care costs, unpaid carers' time in care and support to participant, expenditure by self or family on travel to appointments, equipment purchases.

**TABLE 20** Sensitivity analysis: outcomes and costs at 6 months from multilevel model estimates. Sample: cases with cost and outcome data available over 6 months

| | Intervention | 95% CI[b] | Control[a] | 95% CI | Intervention–control, mean difference | 95% CI | *p*-value |
|---|---|---|---|---|---|---|---|
| ***Person with dementia*** | *n* = 24 *N* = 4 | | *n* = 26 *N* = 3 | | | | |
| QALY (EQ-5D-5L) | 0.383 | 0.383 to 0.332 | 0.260 | 0.209 to 0.311 | 0.123 | 0.049 to 0.198 | 0.002 |
| Societal | 47,025 | 30,649 to 63,400 | 68,322 | 52,589 to 84,056 | −21,298 | −44,649 to 2053 | 0.073 |

**TABLE 20** Sensitivity analysis: outcomes and costs at 6 months from multilevel model estimates. Sample: cases with cost and outcome data available over 6 months (*continued*)

| | Intervention | 95% CI[b] | Control[a] | 95% CI | Intervention–control, mean difference | 95% CI | *p*-value |
|---|---|---|---|---|---|---|---|
| ***Person with dementia*** | *n* = 32 *N* = 5 | | *n* = 48 *N* = 6 | | | | |
| QALY (EQ-5D-5L-PROXY) | 0.151 | 0.151 to 0.098 | 0.122 | 0.069 to 0.175 | 0.029 | −0.046 to 0.105 | 0.443 |
| Societal | 56,031 | 43,673 to 68,389 | 62,556 | 50,774 to 74,339 | −6525 | −23,600 to 10,549 | 0.454 |
| ***Person with dementia*** | *n* = 14 *N* = 5 | | *n* = 12 *N* = 3 | | | | |
| QALY (DEMQOL-U) | 0.427 | 0.427 to 0.404 | 0.422 | 0.395 to 0.449 | 0.005 | −0.032 to 0.041 | 0.791 |
| Societal | 44,619 | 30,011 to 59,228 | 65,137 | 49,190 to 81,084 | −20,518 | −42,728 to 1693 | 0.069 |
| ***Person with dementia*** | *n* = 30 *N* = 5 | | *n* = 24 *N* = 5 | | | | |
| QALY (DEMQOL-PROXY) | 0.349 | 0.349 to 0.329 | 0.347 | 0.323 to 0.37 | 0.003 | −0.029 to 0.034 | 0.861 |
| Societal | 51,845 | 42,038 to 61,652 | 60,234 | 49,257 to 71,212 | −8389 | −23,109 to 6331 | 0.264 |
| ***Person with dementia*** | *n* = 26 *N* = 5 | | *n* = 24 *N* = 5 | | | | |
| BADLS | 27.670 | 27.67 to 210.531 | 28.165 | 211.031 to −254.702 | −0.495 | 3086.54 to −3087.529 | 1.000 |
| Societal | 54,860 | 44,884 to 64,836 | 60,184 | 49,797 to 70,571 | −5323 | −19,725 to 9078 | 0.469 |
| ***Suitable informant*** | *n* = 23 *N* = 4 | | *n* = 22 *N* = 5 | | | | |
| QALY (EQ-5D-5L) | 0.444 | 0.444 to 0.422 | 0.436 | 0.413 to 0.459 | 0.008 | −0.024 to 0.041 | 0.608 |
| Societal | 52,689 | 38,783 to 66,594 | 64,915 | 50,795 to 79,036 | −12,227 | −32,045 to 7591 | 0.227 |

*n*, denotes number of cases, *N*, denotes number of clusters.

**TABLE 21** Sensitivity analysis: participant and suitable informant 6-month outcomes; point incremental cost-effectiveness ratio[a] (95% CIs) for intervention over control, from health and social care and societal perspectives (*N* = 282)

| | BADLS[a] (*n* = 96) | QALY (DEMQOL-PROXY)[b] (*n* = 54) | QALY (EQ-5D-5L-PROXY)[b] (*n* = 42) | QALY (DEMQOL-U)[b] (*n* = 26) | QALY (EQ-5D-5L)[b] (*n* = 25) |
|---|---|---|---|---|---|
| ***Participant (n)*** | | | | | |
| Societal | −5323/0.141 = −37,659 (unbounded, unbounded) | −8389/0.003 = −2991,226 (unbounded, unbounded) | −6525/0.029 = −221,878 (unbounded, unbounded) | −20,518/0.005 = −4,257,978 (unbounded, unbounded) | −21,298/ 0.123 = −172,988 (−411,793, 15,198) |
| | | | | | **45** |
| ***Suitable informant (n)*** | | | | | |
| Societal | NA | NA | NA | NA | −12,227/0.008 = −1,443,338 (unbounded, unbounded) |

a Cost of achieving a 3.5-point difference between groups at 6 months; incremental effect is divided by 3.5 and reversed (so a higher score indicates higher function).
b Cost of achieving a QALY gain over 9 months; difference in QALY rounded to third decimal place.

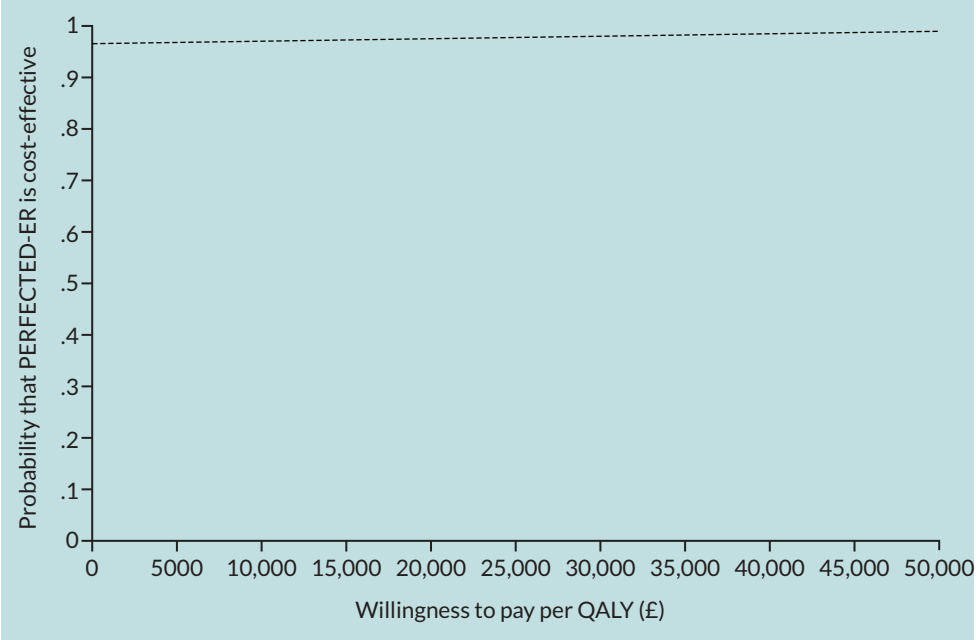


**FIGURE 9** Cost-effectiveness acceptability curve: participant QALY, EQ-5D-5L; replacement costs of unpaid care.

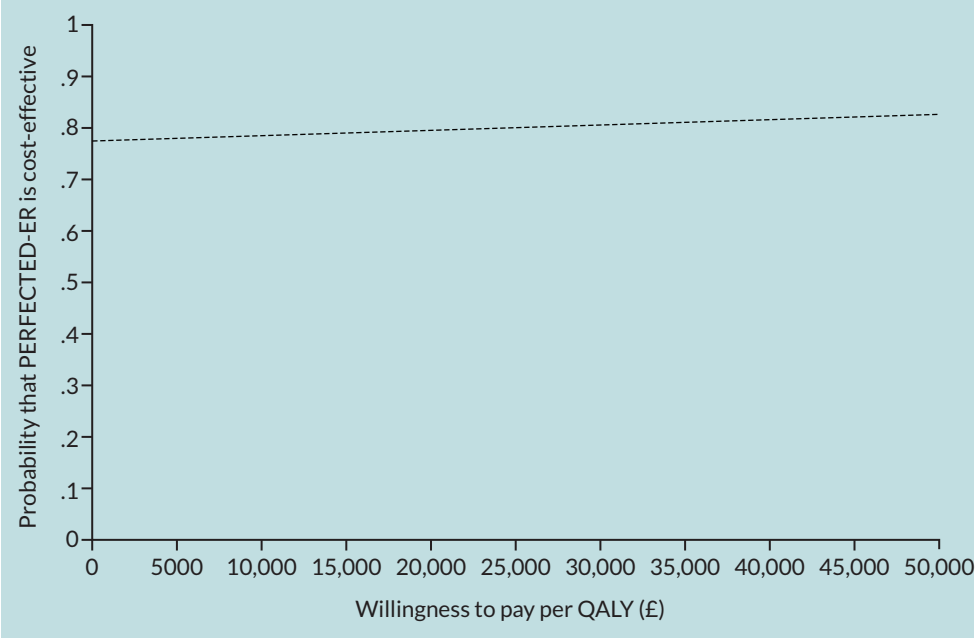


**FIGURE 10** Cost-effectiveness acceptability curve: participant QALY, EQ-5D-5L-PROXY; replacement costs of unpaid care.

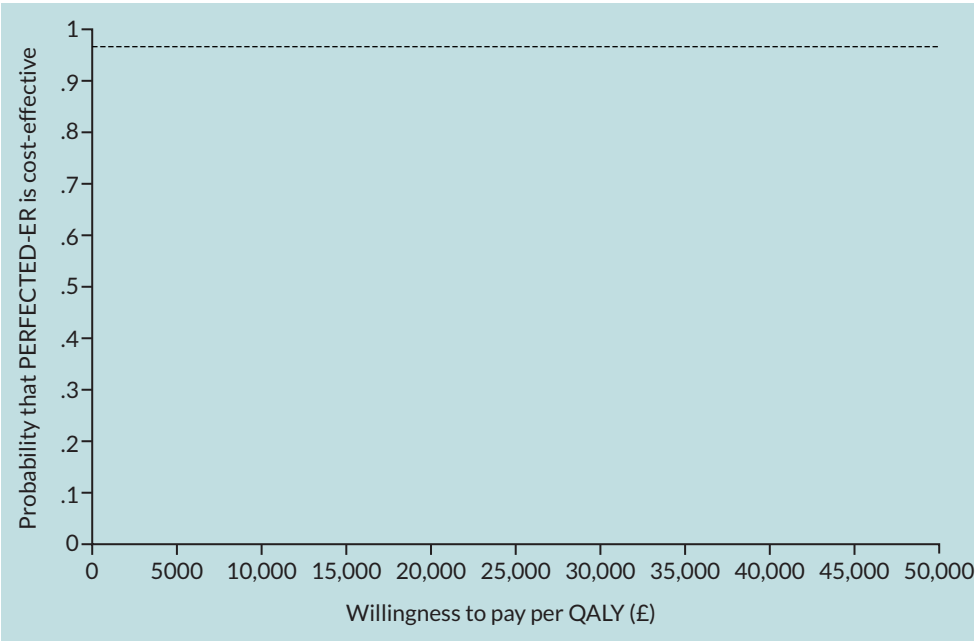


**FIGURE 11** Cost-effectiveness acceptability curve: participant QALY, DEMQOL-U; replacement costs of unpaid care.

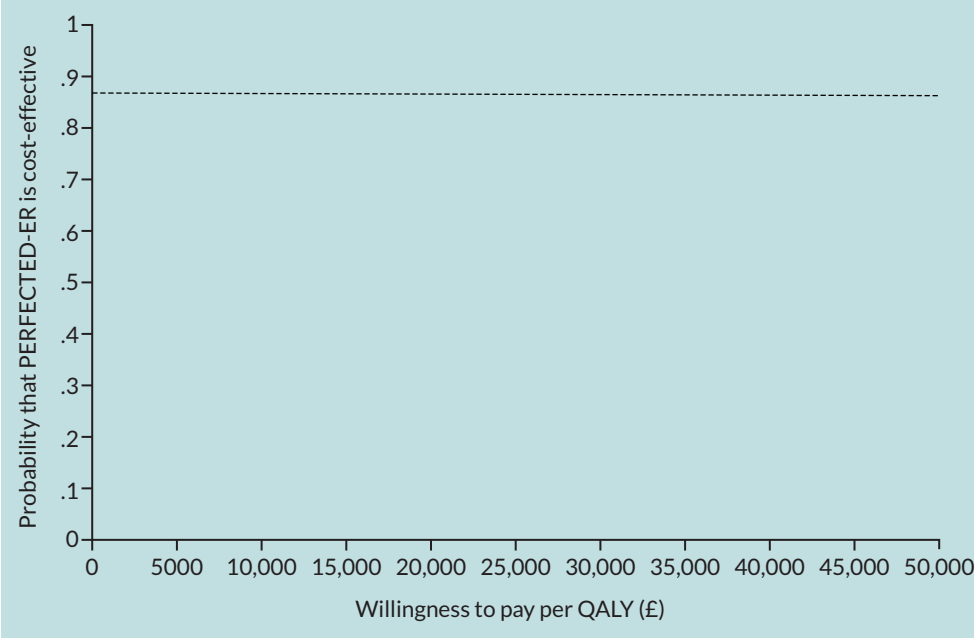


**FIGURE 12** Cost-effectiveness acceptability curve: participant QALY, DEMQOL-PROXY; replacement costs of unpaid care.

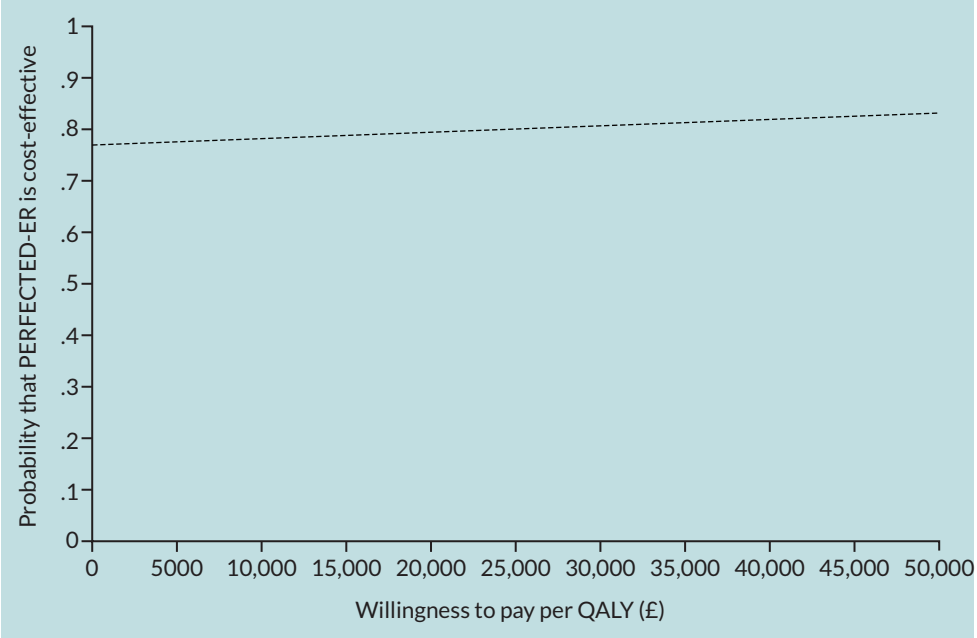


**FIGURE 13** Cost-effectiveness acceptability curve: suitable informant QALY, EQ-5D-5L; replacement costs of unpaid care.

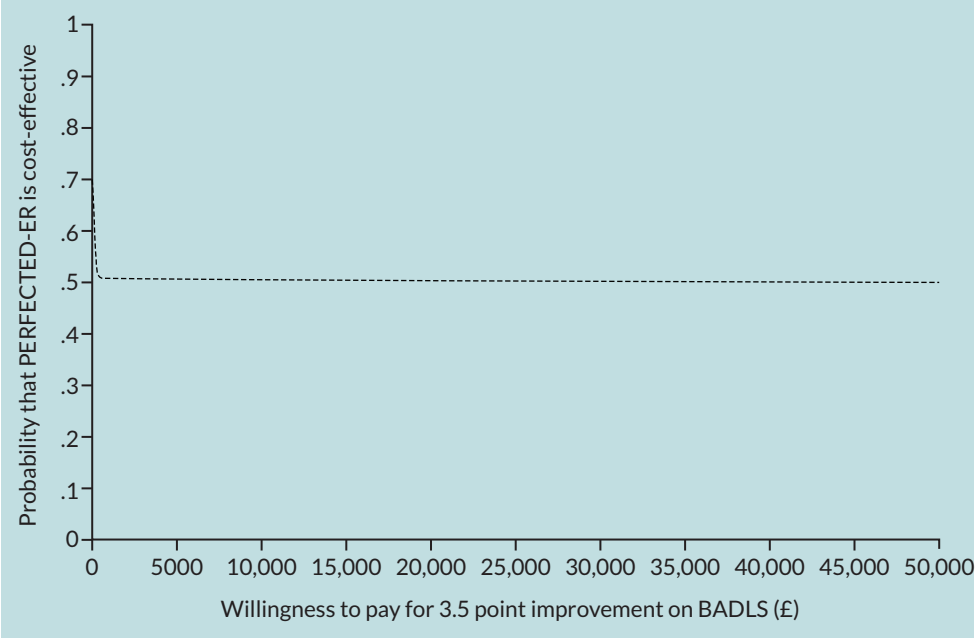


**FIGURE 14** Cost-effectiveness acceptability curve: participant BADLS; replacement costs of unpaid care.

**TABLE 22** Service improvement lead organisation profile scores

| | Pre-trial run period (2016) | | Trial period (November 2016–January 2018) | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Active SITE | −3 months BL August score *n*(%) | −2 months September score *n*(%) | Trial BL November 2016 score *n*(%) | 4 months February 2017 score *n*(%) | 7 months May 2017 score *n*(%) | 10 months August 2017 score *n*(%) | 13 months November 2017 score *n*(%) | 15 months January 2018 score *n*(%) | Change |
| 01 | 11(73) | 11(73) | 12(80) | 12(80) | 11(73) | 10(67) | 11(73) | 11(73) | 0 |
| 03 | 13(87) | 14(93) | 14(93) | 14(93) | 15(100) | 15(100) | 15(100) | 15(100) | + 2 |
| 06 | 10(67) | 12(80) | 11(73) | 11(73) | 12(80) | 12(80) | 12(80) | 12(80) | + 2 |
| 07 | 10(67) | 4(27) | 7(47) | 7(47) | 7(47) | 7(47) | 7(47) | 7(47) | 0 |
| 10 | 7(47) | 10(67) | 10(67) | 10(67) | 11(73) | 11(73) | 13(87) | 13(87) | + 6 |

BL Baseline.

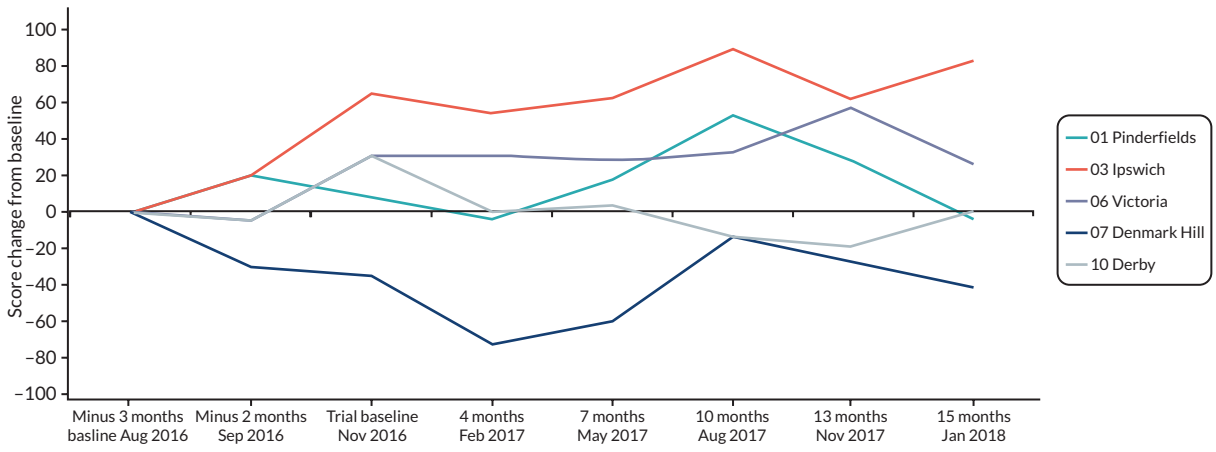


**FIGURE 15** Service improvement lead PERFECT-ER ward profile scores at intervention sites.

# Appendix 8 Patient and public involvement


Faculty of Medicine and Health Sciences

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Dear colleague

As detailed in our annual progress report of the Perioperative Enhanced Recovery hip FracturE Care of paTiEnts with Dementia 'PERFECTED' (Ref: DTC-RP-PG-0311-12004) research programme, we have experienced significant barriers in our efforts to implement public and patient involvement (PPI) in 'front-line' research activities. We write to provide an overview of these difficulties. In the context of NIHR aims to widen PPI participation across the research process, we seek to encourage critical reflection at a policy level regarding the effects of disproportionate and inappropriate clinical governance clearances requested of PPI members. We would recommend urgent review of these issues by NIHR to inform guidance for NHS trusts to adapt their procedures.

Patient and public involvement is designed to play a key role throughout the PERFECTED research programme. PERFECTED was developed in collaboration with PPI members and their active and continuing participation remains vital in a variety of roles and processes. Many of these roles represent more 'typical' advisory roles. These involve PPI members reviewing protocols and sitting on the programme's monitoring and advisory groups. However, we have also sought to widen the remit for volunteer PPI members to include them more (with support and clearly delimited roles and time commitment) in 'front-line' research activities. This has included recruiting and training PPI members as 'lay-observers' to assist the research team in the collection, analysis and dissemination of ethnographic qualitative data gained in WP1 phase 3.

We realise that innovative endeavours will challenge existing processes and that current procedures are geared towards academic/clinical researchers. Procedures are not, however, presently sensitive to the individual characteristic and potential contributions of PPI members. The challenge faced by the PERFECTED team and our PPI members has been two-fold: the research environment (acute hospital wards) and the research method (focused ethnographic observations of care delivery). Clearly, governance and procedural permissions are vital, but to operate effectively these must be proportionate and valid.

At present they are not. To undertake two 3-hour sessions of research observations of staff delivering care in an acute hospital setting, the research team needed to support PPI members in securing NHS research passports. This meant PPI members being required to: (1) undertake several hours of good clinical practice (GCP) training; (2) gain occupational health clearances (entailing up to date inoculations which meant going to their own GP and asking for their inoculation history); (3) provide a signed and dated curriculum vitae; (4) undergo a Disclosure and Barring Services (DBS) check; and (5) secure a temporary contract as University of East Anglia employee to be covered by indemnity insurance. The nature of the research activity meant PPI members were also required to undertake PERFECTED project-designed activity-specific training to enable them to work appropriately as PPI contributors to the research.

Meeting these requirements took far more time than the research activity itself. For academic/clinical researchers, a strong case can be made for such clearances. For PPI members not interacting with patients and spending less time on wards than an average visitor, the case is tenuous. Despite the research team's best efforts to support PPI members through each stage, half of our PPI members withdrew from these roles. All PPI members expressed their deep frustrations, many citing the 'highly disproportionate number of clearances' and the 'process-blindness' they had to endure.

If we are to achieve the long-term goal of achieving 'real' service-user led research and widen the PPI remit beyond more conventional advisory roles, there is an urgent need to revisit, reconsider, review and refine what are at present disproportionate obstacles.

We suggest the NIHR needs to examine the suitability of universal GCP training for PPI, according to the design of the research project and the nature of the PPI research roles to be undertaken. We acknowledge the importance of GCP training to academic/clinical researchers, but this must not act as a barrier. A universal insistence on PPI members undertaking unsuitable GCP training to gain NHS research passports is counter-productive and ultimately detrimental to the pursuit of service-user led research.

Yours sincerely

p.p Dr Chris Fox (Chief Investigator) and Dr Simon P Hammond (Programme Manager and Research Fellow)

Prof Fiona Poland (PPI lead)

Prof Cameron Swift (Chair of Programme Steering Committee)

Prof Cornelius Katona (Chair of Programme Advisory Group)

Mrs Lynne Chambers (PPI Rep, Programme Steering Committee)

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Dr Simon P Hammond
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01 September 2015

Dear Dr Hammond,

**Re: Peri-operative Enhanced Recovery hip FacturE Care of paTiEnts with Dementia, "PERFECTED", research programme (Ref: DTC-RP-PG-0311-12004)**

Thank you for alerting the Health Research Authority to the problems you have encountered in involving patients and the public in the 'PERFECTED' project. It is clear from the report prepared by the project team about these issues that disproportionate and inappropriate requirements have been made of the public contributors to the project by NHS organisations in which the research is being conducted.

It is important that patients and the public who get involved in research studies are considered and treated in the same way as other members of a research team. That should include a proportionate approach to the checks and balances needed for them to perform their role. In the PERFECTED project it is clear that the patients you are involving are working alongside professional members of the research team at all times and are never conducting any part of the research on participants in the study on their own. In other words they are supervised at all times. Therefore, there is no need for them to undergo the same level of training and meet the same research governance requirements as the members of the research team who are supervising them. That means that they will not need NHS research passports, undergo Good Clinical Practice training, be listed in Study Delegation Log or meet any of the other requirements that you have indicated they have been asked for. However, they will, of course, need full briefing and training to undertake the tasks they are doing as appropriate to those tasks, which is something that has been addressed.

The patients and public contributors to the project are acting as 'special advisers' to the work based on their lived experience of the health issues at the heart of the project. As such it is reasonable and fair to offer them payment for their time commitment to the project. While it is up to individual researchers to decide whether or not to offer payment to their public contributors, doing so is in line with widely recognised best practice in patient and public involvement in health and social care research, e.g. as recommended by NIHR INVOLVE. The Health Research Authority recognises the importance of paying public contributors for their time. It offers payment to the patients and members of the public it involves in its own work and encourages other organisations to do the same.

NHS
Health Research Authority

On behalf of the Health Research Authority I hope that the information above will assist you in ensuring that a measured and appropriate approach is taken to the continued involvement of patients and the public in the work by the NHS organisations in which you are conducting the PERFECTED study.

Yours sincerely

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# **Appendix 9** Additional outputs

## Dissemination event attendance

A total of 98 people registered for the event with a 62% turnout and a peak of 50 people spending 2.5 hours in attendance. It attracted a mainly UK-based audience (92%) with six international attendees (Spain: 2, Ireland: 1, Netherlands: 1, USA: 1, Denmark: 1) (A summary *Figure 16*; *Table 23*).

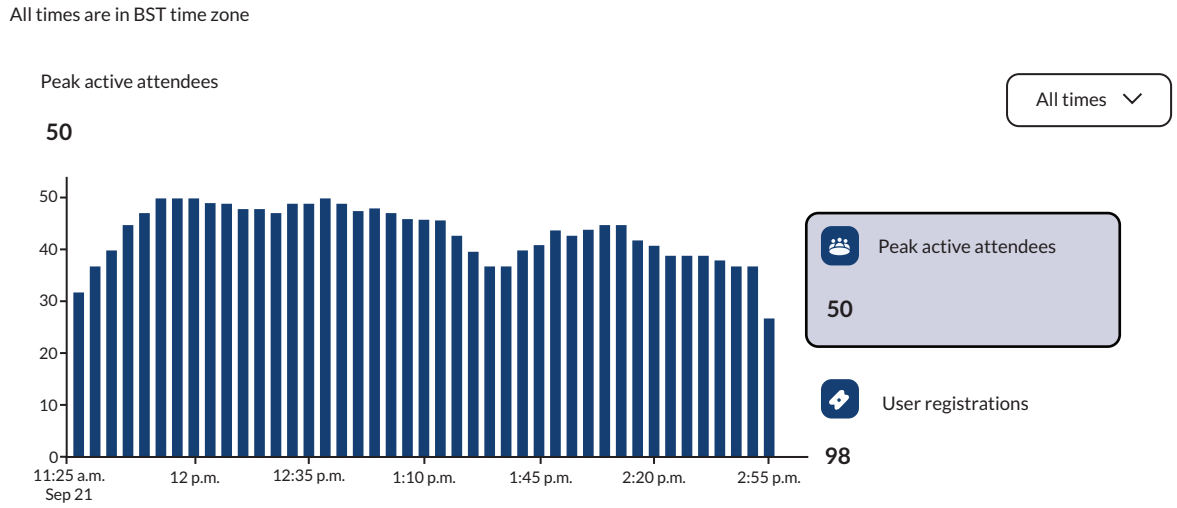


**FIGURE 16** Graphic showing attendance at impact review, 21 September 2021.

**TABLE 23** Summary tabulation of attendee interest and behaviour

| Attendee interest and behaviour | Number |
|---|---|
| Registered users | 98 |
| Turnout | 57 |
| Average time spent (minutes) | 151 |
| Stage visitors | 50 |
| Session visitors | 41 |
| Expo visitors | 10 |

Below is draft text from the ward leaflet based key learning from PERFECTED which we are using to advance education about dementia on acute wards.

### *Your stay in our ward*

#### Welcome to our ward

This ward is an orthopaedic ward. Our patients have problems with bones and joints. Sometimes patients come to us after a fall or accident. Others come in for planned treatment.

Many of our older patients have a broken hip after a fall. In these patients some were living with dementia before their fall and some will develop delirium because of the injury or the treatment. Delirium can be a very serious condition and can sometimes look like dementia, but the effect is not usually long-lasting.

You have been given this leaflet because you are sharing a ward with people who have dementia or delirium or are visiting someone who is.

### About patients with dementia and delirium

A hospital stay can be uncomfortable and unsettling for any patient but for patients with dementia or delirium and a serious injury, a hospital stay can be very frightening.

For patients with dementia or delirium everyday activities such as eating, drinking, taking medicines or going to the toilet in a new environment can feel strange. They may not always understand the care or treatment we offer and they may see or believe things that are not real. They may also be uncomfortable or in pain but unable to make us understand what they need. This can sometimes make them feel frustrated or upset and they may get angry.

Like many of our older patients, people with dementia or delirium can be incontinent. Incontinence is not usually difficult to manage in hospital but can be very difficult to manage in people with dementia or delirium. You may also notice some of our patients behaving in ways you might not expect. For example, some may take off their clothes or constantly try to get out of bed, or even try to leave the ward.

We cannot provide one-to-one care for all our patients but you may see dementia-specialist healthcare assistants caring one-to-one for our most vulnerable patients. We also welcome carers to our ward. They often understand the needs of the person they care for very well. It can be difficult for our nurses and healthcare assistants to understand and manage the needs of patients with dementia or delirium. We will listen to the people who care for them and to the advice of our dementia specialists to help us to provide the most suitable care.

### What this means for you

We want you to feel safe and comfortable in our care. We know many of you will recognise the difficulties that patients with dementia and delirium and the people that care for them face. At the same time we also understand that you may be feeling vulnerable and that sharing a ward with people with dementia or delirium may frighten or upset you.

If you are unsettled or frightened by anything you hear or see on the ward, please talk to our staff or volunteers. They will be happy to discuss your concerns and to talk with you about hospital stays for people with dementia or delirium.

Whatever the reason for your stay, we will do our best to meet your needs, to make your stay as comfortable as possible, and to treat you and other patients with equal kindness and respect.

We thank you for your patience and understanding.

EME
HSDR
HTA
**PGfAR**
PHR

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