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Synopsis

Home-based extended rehabilitation for older people with frailty (HERO): a multicentre randomised controlled trial with health economic analysis and process evaluation

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Abstract

Background: Half of older people in hospital have frailty and are at increased risk of re-admission or death following discharge. Although short-term rehabilitation can reduce early re-admissions, benefits are attenuated over time. It is unknown whether extended rehabilitation for older people with frailty can improve outcomes.

Trial design: Pragmatic, multicentre, individually randomised controlled parallel-group superiority trial with economic evaluation and embedded process evaluation.

Methods:

Participants: Eligible participants were 65 years or older with mild/moderate/severe frailty (score of 5–7 on Clinical Frailty Scale) admitted to hospital with acute illness or injury, then discharged home directly or from intermediate care (post-acute care) rehabilitation services. People with significant cognitive impairment and care home residents were among those ineligible. Recruitment took place from December 2017 to August 2021, with follow-up till August 2022.

Interventions: Participants were randomly assigned (1.28 : 1) to the Home-based Older People's Exercise programme – a 24-week home-based manualised, progressive exercise intervention delivered by National Health Service therapists as extended rehabilitation, or usual care (control). Randomisation occurred after the participant had been discharged from hospital or intermediate care. Participants were not masked to allocation.

Main outcome measures: The primary outcome was physical health-related quality of life, measured using the physical component score of the modified Short Form 36-item health questionnaire at 12 months. Secondary outcomes at 6 and 12 months included physical and mental health-related quality of life, functional independence, death, hospitalisations and care home admissions. Researchers involved in data collection were masked to allocation.

Data sources: Primary and secondary outcomes were obtained via self-report questionnaire at 6 and 12 months. Hospitalisations and deaths were collected from routine healthcare data.

Results: We randomised 740 participants (410 Home-based Older People's Exercise, 330 control) across 15 sites. Four hundred and seventy-nine (64.7%) participants completed 12-month follow-up. One hundred and eighty-eight Home-based Older People's Exercise participants (45.9%) completed 24 weeks of intervention delivery. Over half of participants completed more than 75% of prescribed exercises.

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Intention-to-treat analyses (258 Home-based Older People's Exercise participants, 208 control participants for primary outcome) showed no evidence that Home-based Older People's Exercise was superior to control for 12-month physical component score (adjusted mean difference −0.22, 95% confidence interval −1.47 to 1.03; $p = 0.73$). There was some evidence of a higher rate of all-cause hospitalisations in the control arm (incidence rate ratio 1.12, 95% confidence interval 1.00 to 1.25; $p = 0.05$), but no evidence of differences in other outcomes. The process evaluation found the intervention was largely delivered as intended and proved acceptable to most participants. The economic analysis showed incremental costs of Home-based Older People's Exercise plus usual care of GB£1401 (mean per participant), compared with usual care alone. There was a 0.024 quality-adjusted life-year improvement in Home-based Older People's Exercise compared to control. The incremental cost-effectiveness ratio was £58,375.

Limitations: This trial was delivered during especially challenging circumstances that included the COVID-19 pandemic. We examined outcomes taking account of this but detected no difference in primary or secondary outcomes, providing reassurance that COVID-19 was unlikely to have influenced trial results.

Conclusions: Based on our findings, we do not recommend routine commissioning of extended rehabilitation for older people with frailty after discharge home from hospital or intermediate care, following an acute admission with illness or injury.

Future work: Future work should consider how existing core intermediate care and community rehabilitation services should be best organised and delivered to ensure that older people with frailty feel ready for discharge from rehabilitation, and are enabled to maintain their independence.

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A plain language summary of this synopsis is available on the NIHR Journals Library Website https://doi.org/10.3310/GJAC1602.

Synopsis introduction

This report details the work undertaken in the Home-based Extended Rehabilitation for Older people with frailty (HERO) trial. The HERO trial was funded through a commissioned call from the National Institute for Health and Care Research (NIHR) Health Technology Assessment (HTA) programme (HTA 15/43). The call highlighted that older people with frailty admitted to hospital with an acute illness or injury and subsequently discharged back to their own home are likely to require considerably longer than 6 weeks for recovery and rehabilitation. The commissioned call sought to generate robust evidence on the clinical and cost-effectiveness of extended rehabilitation for older people with frailty discharged home after hospitalisation with acute illness or injury.

The overarching research question of the HERO trial was:

- What is the clinical and cost-effectiveness of extended community-based rehabilitation for older people with frailty after acute illness or injury?

The Home-based Older People's Exercise (HOPE) programme was proposed as a candidate intervention for extended rehabilitation in the community. The HOPE programme had been tested in an earlier pilot trial demonstrating evidence for feasibility, acceptability and potential for a positive, clinically important intervention effect on mobility.[1]

Introduction

Background

Population ageing is accelerating worldwide, with the number of those aged over 65 expected to be more than quadruple to 2 billion people by 2050. Frailty is an especially problematic expression of population ageing, with profound implications for planning and delivery of health and social care services. Frailty is characterised by reduced biological reserves and increased vulnerability to adverse outcomes, including falls, disability, hospitalisation, care home admission and death.[3,4] It develops through age-related decline in several physiological systems, which collectively result in vulnerability to sudden health status change triggered by relatively minor stressor events.

The majority of older people (≥ 65 years) in hospital have frailty and are at increased risk of re-admission or death following discharge home.[5,6] Sarcopenia is a core component of frailty[7] and is exacerbated by periods of

immobility in older age, such as those experienced in acute illness, injury and hospitalisation.[8] Skeletal muscle function can be further impacted by an inflammatory response associated with acute illness or injury.[3] This is problematic in frailty because accelerated loss of skeletal muscle function can compromise physical function and jeopardise a person's independence in their home environment. This loss of independence may result in increased support from an informal carer such as a spouse or wider family member, reliance on formal homecare services or care home admission.

Frailty negatively impacts on quality of life, caregiver burden and health and social care use.[3] It accounts for £6B of annual UK NHS expenditure[9] and is the strongest predictor of social care costs.[10] There has been a long-standing national prioritisation of care closer to home for older people, and a push for more widespread 'Hospital at Home' and 'Virtual Ward' services. In the UK, following acute NHS hospitalisation, around one-third of older people with frailty are likely to return home after a brief period of rehabilitation on a hospital ward. A further third will likely require and receive a longer period of rehabilitation. This NHS rehabilitation is termed 'intermediate care' (IC) and comprises of a range of community rehabilitation services to promote recovery of independence and reduce the premature need for long-term care. IC services are predominantly delivered to older people with frailty and are typically provided in bed-based rehabilitation units or in an older person's own home via home-based rehabilitation services.[11] NHS IC services are similar to related international rehabilitation models, such as 'post-acute' care.

National guidelines recommend only a brief contact (2–6 weeks) with these IC services,[12] with the average length of stay being around 30 days, and 80% of service users are discharged from IC within 6 weeks.[11] Findings from the 2017 UK National Audit of IC indicate people discharged from bed-based IC services are being discharged with higher levels of dependency than measured in previous audits and continues to highlight that many recipients of IC do not feel ready to leave rehabilitation services on discharge, which suggests possible incomplete recovery. Although reduced early re-admission to hospital (< 30 days) has been reported in a meta-analysis of IC trials,[13] this benefit appears to attenuate, with no benefit for re-admissions to hospital between 60 days and 6 months post discharge.[14,15]

A key challenge is, therefore, how to successfully reduce the loss of independence that often affects older people with frailty following discharge from hospital and any associated rehabilitation provision. A simple, generalisable intervention that can directly address the abnormal health state of frailty and extend the usual rehabilitation provided to older people following acute hospitalisation may improve longer-term outcomes. A programme of progressive physical exercise with integrated behaviour change techniques is a candidate intervention.[16]

Exercise has positive physiological effects on skeletal muscle, brain and endocrine systems.[3] There is also an inverse dose–response relationship between physical activity and inflammation,[17] which may be especially relevant following acute illness or injury. Older people at greatest risk of disability and loss of independence show the largest effect of exercise in down-regulating inflammation.[18]

There is preliminary evidence from systematic reviews indicating that exercise interventions can improve mobility and function for older people with frailty and slow progression to disability. However, few trials have used validated instruments to identify frailty or reported health-related quality of life (HRQoL).[16,19–22] Exercise programmes based on progressive strength training were important for functional improvement. This evidence for positive physiological and functional benefits of exercise in frailty supports our proposal for a home-based exercise intervention to extend the rehabilitation period for older people following acute hospitalisation.

Successful exercise programmes often incorporate strategies to promote behaviour change. Strategies demonstrating a positive effect include goal-setting, self-monitoring, demonstration of behaviour, provision of feedback, use of materials such as exercise logs and manuals, enablement through social support, and extended periods of contact/support from a healthcare provider.[23,24] It is difficult to draw causal links between individual behaviour change strategies due to the nuanced nature of many health interventions and associated interactions between the care provider and recipient. It is likely, though, that a successful exercise programme will likely need to include many of these behaviour change strategies.

We previously developed and tested in a pilot randomised controlled trial (RCT), the HOPE programme, which may be a suitable intervention to provide extended rehabilitation for older adults with frailty following acute hospitalisation.[1] The HOPE programme is aimed at improving strength, endurance and balance and is presented to participants in an exercise manual, delivered by community-based physiotherapy teams. The manualised nature of the programme, delivered face to face and with telephone support, is consistent with evidence-based strategies

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to promote physical activity behaviour change and intervention adherence. The HOPE programme pilot trial provided evidence for feasibility, acceptability and potential for a positive, clinically important, intervention effect on mobility. Informed by previously effective behaviour change programmes, the HOPE programme has been extended by a further 12 weeks of telephone-based support for intervention sustainability for the HERO trial.[25]

Protocol

The HERO trial protocol has been published.[2] The detailed statistical analysis plan (SAP), and health economic analysis plan (HEAP) are reported separately.[26,27] Protocol amendments after the internal pilot stage included provision of an unconditional gift voucher at 6 months, addition of a participant card to prompt questionnaire completion and inclusion of a final postal contact to collect Short Form questionnaire-36 items (SF-36) only.

Objectives

The primary objective in this individually RCT was to evaluate the impact of the HOPE programme on HRQoL at 12 months post randomisation, measured using the physical component score (PCS) of the SF-36.[28] Secondary objectives were to evaluate the impact of the HOPE programme on:

- Physical health at 6 months post randomisation, as measure by the PCS of the SF-36.
- Mental health at 6 and 12 months post randomisation, as measured by the mental component score (MCS) of the SF-36.[28]
- Functional independence at 6 and 12 months post randomisation, as measured by the Nottingham Extended Activities of Daily Living (NEADL)[29] and Barthel Index.[30]
- Hospital re-admission rates, care home admission rates, all-cause hospitalisation, hospitalisation due to falls or fractures, mortality and overall health and social care resource use (RU) at 12 months post randomisation.
- Cost-effectiveness, as measured by the difference in cost of service use between arms and the incremental cost-effectiveness ratios (ICERs) using quality-adjusted life-years (QALYs) derived from the EuroQol-5 Dimensions, five-level version (EQ-5D-5L)[31] at 6 and 12 months post randomisation.

A process evaluation was undertaken to:

- Understand how the HOPE intervention is understood and experienced by providers and recipients.
- Explore organisational implications of embedding and sustaining the intervention in preparation for possible wider implementation in NHS should the intervention prove to be effective.

Trial design

A pragmatic, multicentre, individually randomised controlled parallel-group superiority trial with embedded process and health economic evaluations. The trial included an internal pilot with clear progression criteria for: recruitment rates; timely intervention delivery; intervention acceptability and completeness of follow-up data (see *Appendix 1*).

Detailed descriptions of the methods for participant recruitment, intervention delivery, data collection and analysis are described in the published trial protocol,[2] the SAP,[26] HEAP[27] and the process evaluation results publication.[32] *Figure 1* shows how the elements of the trial were integrated.

Sites

The trial aimed to recruit older people with frailty on discharge from acute hospital wards or linked IC services after an acute admission to hospital in 15 NHS hospital trusts within two geographical areas (Yorkshire and South West England). Discharge was defined as returning home, and the cessation of rehabilitation following the acute admission. Eligible sites included acute hospital sites with elderly medicine/trauma and orthopaedics services, and

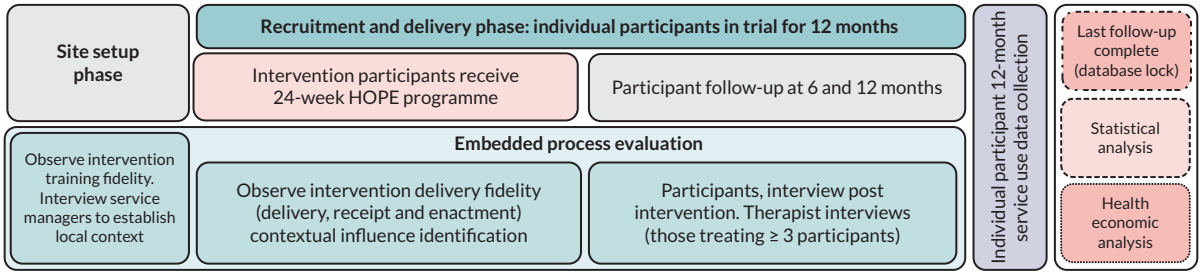

FIGURE 1 Integration of elements of the HERO with frailty trial.

linked IC services routinely accepting the trial population from the acute hospital setting. Sites required agreement from therapy services that intervention delivery was feasible and acceptable. Study sites are listed in the *Acknowledgements*.

Participants

Older people (aged ≥ 65 years) were screened and tracked through acute admission and rehabilitation pathways towards final discharge from hospital/rehabilitation.

Eligibility criteria:

- Admitted to general medicine/elderly medicine or trauma and orthopaedics care following acute illness or injury, then discharged home from hospital or from IC.
- Have mild, moderate or severe frailty, defined as a score of five to seven on the nine-item Clinical Frailty Scale (CFS).[33]
- Ability to complete the Timed Up and Go Test (TUGT) without additional external support.[34]
- Ability to give informed consent to participate in the study.

People were excluded if they were:

- Permanent care home residents.
- Those with significant cognitive impairment at baseline (defined as a score of < 20 on the Montreal Cognitive Assessment (MoCA) test).[35]
- Recent (< 3 months pre randomisation) myocardial infarction, or unstable angina.
- Very severe frailty (defined as a score of eight on the CFS).
- Terminally ill (defined as a score of nine on the CFS).
- Receiving palliative care.
- Referred at discharge for condition-specific rehabilitation (e.g. pulmonary rehabilitation, stroke rehabilitation, falls prevention programme).
- Another household member in the study.
- Currently participating in the HERO trial or another contraindicated study.

Interventions

Study participants were randomised to receive the HOPE programme + usual care (UC), or UC alone. The original HOPE co-design has been previously described.[36] A detailed description of HOPE delivered during the trial is provided in the Template for Intervention Description and Replication checklist (see *Appendix 2*), with a concise overview provided below.

The HOPE, designed specifically for older people with frailty, is a home-based manualised, progressive exercise intervention, graded into three levels of increasing difficulty to account for the spectrum of frailty. The programme aims to improve strength, endurance and balance for basic mobility skills, including getting out of bed, standing up from a chair, walking a short distance and getting on/off the toilet. For this trial, the original HOPE programme was extended from 12 to 24 weeks to incorporate 12-week telephone-based support for intervention sustainability.

The HOPE was delivered by trained NHS community physiotherapy teams via scheduled weekly face-to-face or telephone contacts, with the first planned contact within 3 weeks of discharge home. Participants were provided with a tailored and manualised exercise programme from one of three HOPE programme-level manuals, based on their performance on the TUGT. Participants were encouraged to exercise three times daily (approximately 30 minutes in total) for 5 days per week as able, with flexibility to allow tailoring to individual needs. Therapists supported participants to appropriately progress their exercise programme through increased frequency, intensity, volume and number/type of different exercises. The therapists employed behaviour change strategies appropriate to each participant.

Usual care was not restricted in either arm and was expected to very dependent upon participant's level of health and social care need. UC service use was collected for 12 months post randomisation in both arms.

Outcomes

Participants completed baseline measures just prior to randomisation. The same outcomes were collected at 6 and 12 months via self-report postal questionnaires. Reminder letters were sent to non-responders at 3 weeks to prompt completion, followed by a telephone call to offer support and/or collect the data over the telephone or to arrange a face-to-face home visit. Outcome data were collected by blinded site researchers, independent of the study team.

The primary outcome was the PCS of the SF-36 as a measure of physical HRQoL,[28] measured at 12 months post randomisation. PCS was also measured at 6 months post randomisation. Other secondary outcomes, measured at 6 and 12 months post randomisation, included the SF-36 MCS score, activities of daily living (ADLs) (measured by the Barthel Index of ADL[30] and NEADL index[29]), HRQoL [measured by the EuroQol 5-Dimensions five-level version (EQ-5D-5L)[31]] and healthcare RU. Research staff recorded care home admission status. Hospital re-admission rates,

all-cause hospitalisation, and hospitalisation due to falls or fractures were recorded using routine Hospital Episode Statistics (HES) and mortality using linked Office for National Statistics (ONS) data. The primary and secondary outcomes are defined in full in *Report Supplementary Material 1*.

Usual care data were collected for 12 months post randomisation by site research teams from routine healthcare data (primary and secondary care electronic records). Adverse events, including death and hospitalisation rates due to falls and/or fracture, were collected by sites at 5 and 11 months post randomisation. These time points were selected to incorporate a status check of participants prior to contact for questionnaires at 6 and 12 months, reducing the risk of contacting participants who had died.

Capacity to consent to continued participation in the intervention was assessed on an individual basis by the therapists. Where there was non-return of postal questionnaire information at 6 and 12 months, an assessment of capacity to consent to continued participation in the trial was made by a researcher over the telephone, supported by a face-to-face follow-up visit if needed.

Randomisation

Eligible and consenting participants were individually randomised using a computer-generated minimisation programme, incorporating a random element, minimised by: site, discharge setting (hospital, bed-based IC, home-based IC), intended level of HOPE programme (level one, two or three) based upon TUGT, and reason for admission (acute illness or injury). Randomisation was performed and concealed using an automated 24-hour randomisation service, operated by the Clinical Trials Research Unit (CTRU) via web address and telephone, and accessible to trained researchers with an authorisation code and personal identification number.

Once a participant had consented, and baseline data were collected, the researcher accessed the 24-hour randomisation service. Following successful randomisation, the researcher and site principal investigator received notification of successful randomisation via automated e-mail, omitting details regarding allocation. Participants were contacted via letter to confirm their trial allocation, and the trial procedures that would follow. Therapy service managers were notified of participant recruitment and allocation to enable intervention initiation.

Blinding

Owing to the nature of the intervention, it was not possible to blind participants or those involved in the intervention delivery. General practices were notified of participants' enrolment on the study; however, they were not informed of their allocation status to prevent clinical behaviour change. Those responsible for data collection were blind to allocation. In the event a researcher became unblinded, this was reported to the CTRU and, where feasible, subsequent follow-up assessments were completed by an alternative researcher. Data analysts were not blinded, but the detailed SAP was finalised and agreed with the Trial Steering Committee (TSC) before any analysis was undertaken.

Statistical analysis

The sample size of 742 participants (417 HOPE, 325 control) provided 90% power to detect a minimum clinically important difference of three points in the PCS, at the two-sided 5% significance level, allowing for 35% loss to follow-up.[37] We assumed a mean PCS of 30 [standard deviation (SD) 9.47],[38] clustering in the HOPE arm only, an average cluster size of seven participants per therapist, an intraclass correlation coefficient of 0.03,[39,40] and a coefficient of variation in cluster size of 0.7 to account for a varying number of participants per therapist.

All analyses were conducted in SAS® version 9.4 (SAS Institute Inc., Cary, NC, USA) (SAS and all other SAS Institute Inc. product or service names are registered trademarks or trademarks of SAS Institute Inc. in the USA and other countries; ® indicates USA registration), for the intention-to-treat population, according to randomisation and regardless of compliance with, or withdrawal from, the trial. A single, final analysis of outcomes (including all internal pilot data) was conducted after data-lock at the end of the trial. With the exception of SF-36, participant-reported outcomes were scored according to user guides, with missing item-level data handled according to guidance, where available, or imputed using the half-rule.[41] SF-36 raw scores were scored and handled as per guidance using OPTUM PRO CoRE software (QualityMetric. Johnston, RI, USA).[42] All statistical testing were performed at the 5% significance level.

We analysed the primary outcome using a generalised linear mixed-effects regression model, adjusting for the minimisation factors, participant characteristics [age, gender, previous engagement or referral to community rehabilitation services, Charlson Comorbidity Index (CCI)] and PCS at baseline to test for differences in PCS between arms at 12 months. We planned to use a partially clustered model to account for clustering of outcomes

in the HOPE arm due to therapist effects;[43] however, this was not possible, as the average cluster size was too low. Missing data patterns were explored, and multiple imputation (MI) via pattern-mixture modelling with 40 imputations was used to impute missing values (including missing data due to death).[44] Treatment allocation, age, gender, ethnicity, discharge setting, reason for admission, intended level of HOPE programme, involvement in rehabilitation programme and baseline PCS were included in the imputation model. Rubin's rules were used to combine results of identical analyses performed on each of the imputed data sets.[45] Robustness of primary outcome analysis was tested via sensitivity analyses of participants with complete data, excluding participants who had died and including an additional covariate denoting the period of outcome measure completion (pre-/post-COVID-19 lockdown). Results were expressed as adjusted mean differences with 95% confidence intervals (CIs) and *p*-values.

Continuous secondary outcomes at months 6 and 12 were analysed as per the primary outcome and adjusted for minimisation factors, participant characteristics and respective baseline score. Sensitivity analyses of participants with complete data were compared with analyses using MIs for these outcomes. Binary secondary outcomes at 12 months were analysed similarly in logistic (care home admission, hospital re-admission, mortality) or Poisson (all-cause hospitalisations, hospitalisations due to falls) regression models, using available data without MI, expressing results as odds ratios (ORs) or incidence rate ratios (IRRs), where relevant, with 95% CIs. Time to death was analysed using Cox proportional hazards model, adjusting for the minimisation factors and participant characteristics. Assumptions were checked for all regression models using residual plots (linear, logistic and Poisson) or via assessment of proportional hazards (Cox). No adjustment for multiple comparisons was made.

Intervention delivery was summarised descriptively. A complier-average causal effect (CACE) analysis[46] was undertaken to understand the impact of participant and therapist compliance on the primary outcome using a two-stage instrumental variable regression approach, with randomised arm as the instrumental variable, adjusting for baseline PCS, age, gender and level of previous engagement with community rehabilitation services. Compliance was defined in four ways using combinations of the number of home visits and percentage completion of all exercises prescribed (see *Appendix 3*).

The number of participants withdrawing from trial elements was summarised by arm with reasons, where available. Safety data relating to deaths and hospitalisations resulting from falls and/or fractures were summarised descriptively by arm. The TSC and Trial Management Group reviewed accumulating safety data at agreed intervals throughout the trial.

Health economic analysis

The within-trial (WT) cost-effectiveness analysis compared the HOPE programme plus UC to UC alone, from the perspective of the UK's NHS and Personal Social Services. Participants were followed for 12 months: QALYs were derived from the EQ-5D-5L and survival data, and costs included intervention provision and participant-utilised resources (valued using national unit sources). Analysis was conducted with and without MI. A decision-analytic model (DAM) was developed to explore results over a longer time horizon of up to 15 years. The HEAP is available separately,[27] and further details, methods and specific model characteristics are in *Appendix 4*.

Results for both the WT analysis and the DAM are presented as ICERs and interpreted in context of NICE's (National Institute for Health and Care Excellence) willingness-to-pay (WTP) threshold of £20,000 per incremental QALY.[47]

Process evaluation

We undertook a qualitative mixed-methods process evaluation incorporating non-participant observations of intervention delivery, semistructured interviews and documentary analysis of the therapy record and participants' exercise diaries. Fidelity in intervention training and delivery and acceptability of its receipt and delivery were explored. Data analysis was based on thematic analysis and underpinned by Normalisation Process Theory. Further detail of the process evaluation is reported separately.[32]

Results

Main results

Between 1 December 2017 and 9 August 2021, 16,687 patients were screened; 5505 (33.0%) were deemed eligible for approach, of which 905 (16.4%) consented to further eligibility checks; and 775 (85.6% of consented) were eligible (*Figure 2*). We randomised 740 (95.5% of eligible) participants to receive HOPE (410) or control (330). Randomised participants were similar in age to those screened; however, some differences were noted for gender, ethnicity and reason for hospital admission (see *Appendix 4*). Recruitment paused during the COVID-19 pandemic between 16 March and 29 October 2020, in accordance with national guidance, and restarted on 30 October 2020. Follow-up ended on 1 September 2022,

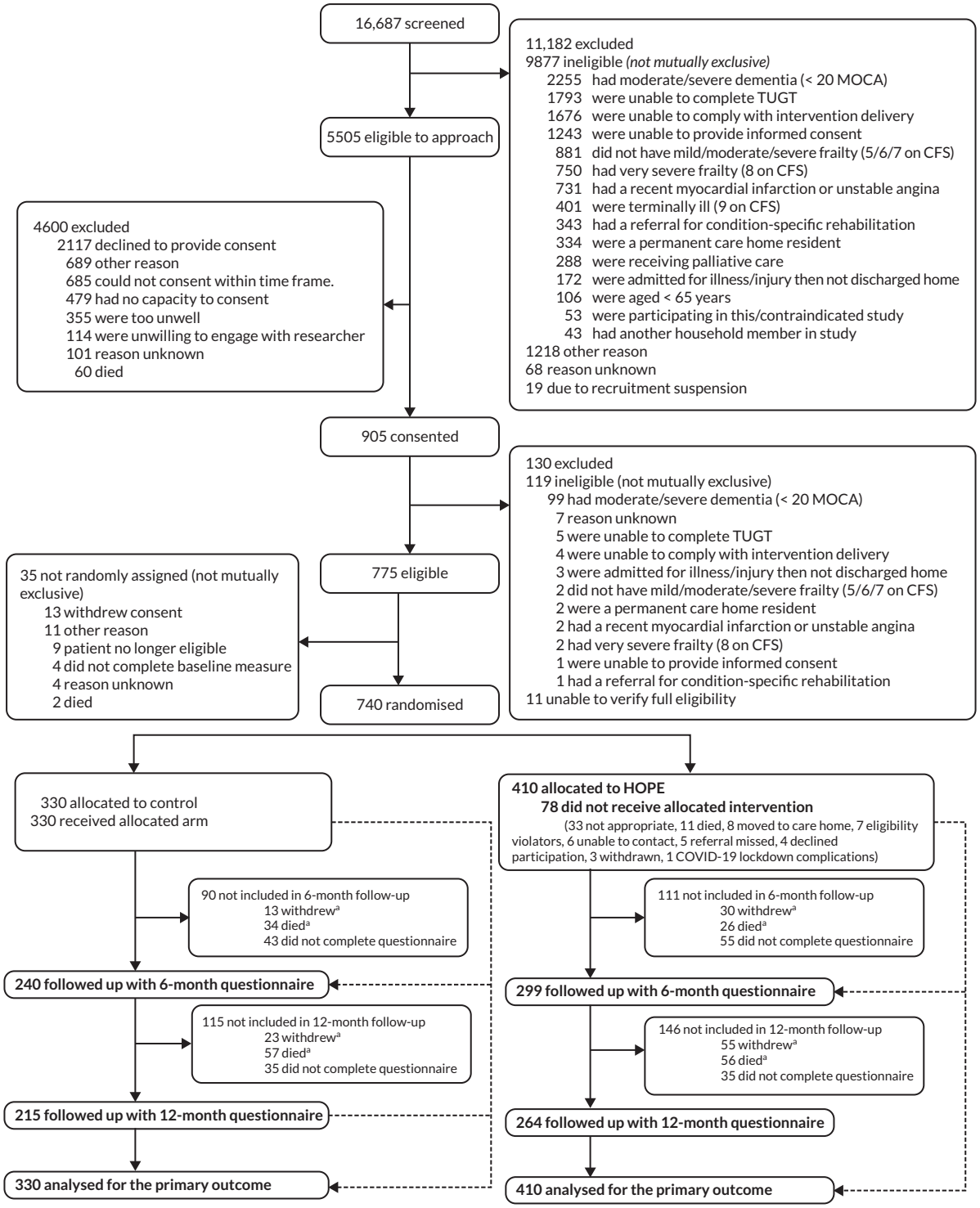

FIGURE 2 Trial flow. a, Withdrawals and deaths are cumulative.

with 539 (72.8%) participants completing a 6-month follow-up [299 (72.9%) of 410 in HOPE, 240 (72.7%) of 330 in control] and 479 (64.7%) participants completing a 12-month follow-up [264 (64.4%) of 410 in HOPE, 215 (65.2%) of 330 in control] (*Figure 2*). Summaries of eligibility violations and withdrawals are provided (see *Appendices 5* and *6*). All randomised participants were included in the intention-to-treat analysis.

Baseline demographics and characteristics were broadly similar between the arms (*Table 1*). In the 740 randomised participants with available data, the mean age was 82.6 years (SD 7.1 years), 486 (65.7%) were female and 699 (97.6%) were White. Over two-thirds of participants [511 (69.1%)] were admitted to hospital due to acute illness, and 300 (40.5%) were discharged from home-based IC. The majority of participants had

TABLE 1 Baseline characteristics

	Hope (*n* = 410)	Control (*n* = 330)	Total (*n* = 740)
Age, years	82.4 (7.3)	82.9 (6.9)	82.6 (7.1)
Gender			
Male	134 (32.7%)	120 (36.4%)	254 (34.3%)
Female	276 (67.3%)	210 (63.6%)	486 (65.7%)
Ethnicity			
White	389 (97.7%)	310 (97.5%)	699 (97.6%)
Other[a]	9 (2.3%)	8 (2.5%)	17 (2.4%)
CFS score[b]	5.5 (0.6)	5.6 (0.6)	5.5 (0.6)
CFS (range 0–9)			
Vulnerable	1 (0.2%)	0 (0.0%)	1 (0.1%)
Mild frailty	215 (52.4%)	160 (48.8%)	375 (50.8%)
Moderate frailty	176 (42.9%)	148 (45.1%)	324 (43.9%)
Severe frailty	18 (4.4%)	20 (6.1%)	38 (5.1%)
MoCA score (range 0–30)	23.4 (2.9)	23.6 (2.9)	23.5 (2.9)
Reason for admission			
Acute illness	285 (69.5%)	226 (68.5%)	511 (69.1%)
Injury	125 (30.5%)	104 (31.5%)	229 (30.9%)
Setting discharged from			
Hospital	142 (34.6%)	116 (35.2%)	258 (34.9%)
Bed-based IC	101 (24.6%)	81 (24.5%)	182 (24.6%)
Home-based IC	167 (40.7%)	133 (40.3%)	300 (40.5%)
TUGT score	46.0 (37.0)	47.3 (39.1)	46.6 (37.9)
HOPE level			
Level 1	259 (63.2%)	207 (62.7%)	466 (63.0%)
Level 2	103 (25.1%)	84 (25.5%)	187 (25.3%)
Level 3	48 (11.7%)	39 (11.8%)	87 (11.8%)
Involved in previous rehabilitation programme	22 (5.6%)	18 (5.7%)	40 (5.6%)
Number of comorbidities			
None	123 (30.2%)	77 (23.8%)	200 (27.4%)
≥ 1	284 (69.7%)	247 (76.2%)	531 (72.6%)
Type of comorbidity[c]			
Diabetes mellitus	96 (34.7%)	84 (34.7%)	180 (34.7%)
Chronic obstructive pulmonary disease	74 (26.9%)	73 (30.8%)	147 (28.7%)
Congestive heart failure	59 (21.6%)	60 (25.2%)	119 (23.3%)
Moderate to severe chronic kidney disease	63 (22.8%)	55 (23.3%)	118 (23.0%)

continued

TABLE 1 Baseline characteristics (*continued*)

	Hope (*n* = 410)	Control (*n* = 330)	Total (*n* = 740)
Connective tissue disease	59 (21.8%)	39 (16.5%)	98 (19.3%)
Cerebrovascular disease	38 (14.0%)	35 (14.7%)	73 (14.3%)
Solid tumour (localised)	45 (16.4%)	31 (13.1%)	76 (14.8%)
Solid tumour (metastatic)	1 (2.3%)	6 (20.7%)	7 (9.7%)
Myocardial infarction	32 (11.7%)	39 (16.4%)	71 (13.9%)
Peripheral vascular disease	21 (7.7%)	23 (9.8%)	44 (8.7%)
Malignant lymphoma	10 (3.7%)	2 (0.8%)	12 (2.4%)
Dementia	9 (3.3%)	3 (1.3%)	12 (2.3%)
Peptic ulcer disease	4 (1.5%)	4 (1.7%)	8 (1.6%)
Leukaemia	2 (0.7%)	6 (2.5%)	8 (1.6%)
Hemiplegia	4 (1.5%)	2 (0.9%)	6 (1.2%)
Liver disease	6 (2.2%)	0 (0.0%)	6 (1.2%)
CCI	5.2 (1.7)	5.4 (1.7)	5.3 (1.7)

a Data have been grouped into Other to preserve anonymity.
b Lower scores better.
c Higher scores are better.
d Self-reported, not mutually exclusive.

Note
Data are mean (SD) or *n* (%).

either mild frailty [375 (50.8%)] or moderate frailty [324 (43.9%)] and were allocated to HOPE level 1 (466 [63.0%]). Participant-reported measures were balanced between the arms.

Of the 410 participants allocated to HOPE, 332 (81.0%) started the intervention and had an initial home visit, 223 (54.4%) had at least five home visits and 188 (45.9%) completed 24 weeks of intervention delivery (*Figure 3*). Over half of participants completed more than 75% of prescribed exercises. For a summary of intervention delivery, see *Appendix 7*.

Unadjusted and adjusted mean scores for the primary outcome, PCS, were stable over time and similar between arms at both 6 and 12 months (*Tables 2* and *3*, *Figure 4*). There was no evidence that HOPE was superior to control for PCS at 12 months (primary end point, adjusted mean difference −0.22, 95% CI −1.47 to 1.03; $p = 0.73$) or at 6 months (adjusted mean difference −1.10, 95% CI −2.32 to 0.12; $p = 0.08$, *Table 3*). All sensitivity analyses provided conclusions consistent with the primary analysis.

Measured by adjusted SF-36 PCS SF-36 PCS = SF-36 PCS, range 0–100. Estimated from a linear regression, adjusted for the stratification factors, age, previous engagement or referral to community rehabilitation services, CCI and baseline PCS. Error bars depict 95% CIs.

On average, unadjusted and adjusted scores for MCS (mental health, vitality and social functioning), NEADL and Barthel Index (ADL) and EQ-5D-5L (HRQoL) decreased over time in both arms, with the largest reductions noted for the NEADL; there was no evidence of a significant difference in these scores between arms at 6 or 12 months (*Tables 2* and *3*).

There was no evidence of a significant difference in care home admissions, hospital re-admission rates, hospitalisations due to falls, mortality or time to death at 12 months (*Table 2*). There was some evidence that the rate of all-cause hospitalisations was lower in the HOPE arm than in the control arm (IRR 1.12, 95% CI 1.00 to 1.26; $p = 0.05$) (*Table 3*). The proportion of deaths was similar across both arms (see *Appendix 8*). UC services accessed over the 12-month follow-up were broadly similar between the arms (see *Appendix 9*). No related and unexpected serious adverse events were reported.

The CACE analysis found no difference in PCS at 12 months when considering varying adherence to home visits and exercises (see *Appendix 3*).

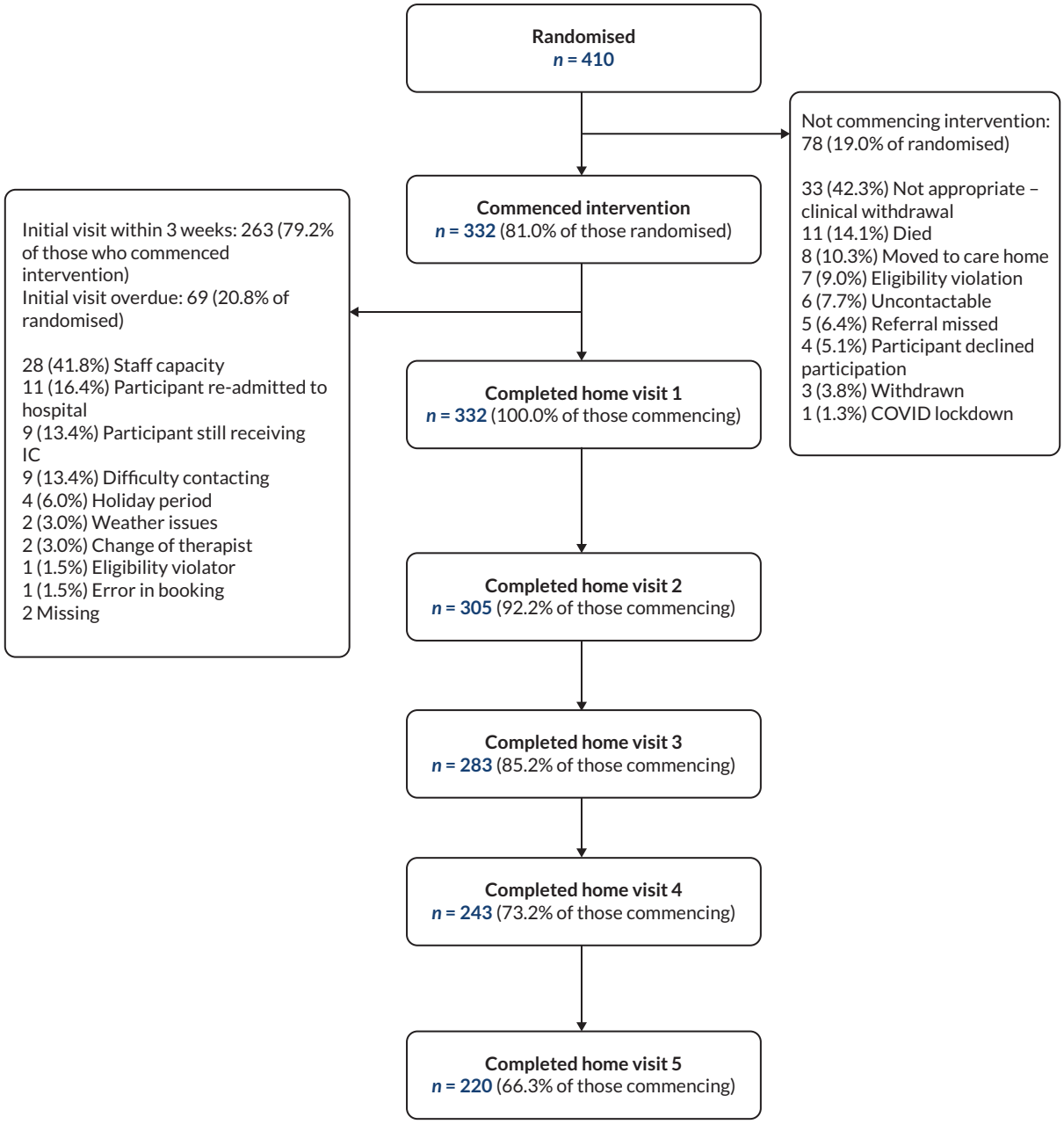

FIGURE 3 Intervention delivery.

Health economic analysis

At 12 months, the mean estimated QALYs and costs were higher for the HOPE arm compared to the control arm (incremental difference 0.024 QALYs and £1401 costs; ICER £58,375). The WT MI analysis similarly gave an ICER of £49,711 (incremental difference 0.03 QALYs and GB£1469 costs). Both ICERs are above the NICE £20,000/QALY threshold,[47] and it is unlikely the HOPE programme plus UC is cost-effective. The DAM model also estimated a low probability of cost-effectiveness over 5-, 10- and 15-year time horizons. Detailed results, including DAM ICERs, stranded by cohort baseline frailty status, are in *Appendix 4*.

Process evaluation

The process evaluation was successfully completed and is reported in full separately.[32] Key findings were that HOPE was broadly delivered as planned, with no significant variation between site/regions. Therapists and intervention participants perceived HOPE to be an acceptable rehabilitation intervention for use in this post-acute context. Some therapists felt that greater flexibility in intervention delivery was needed, to account for variation in individual circumstances. With appropriate resource allocation, it was feasible for HOPE to be delivered by therapists and appropriately trained and supervised therapy assistants in community-based rehabilitation settings.

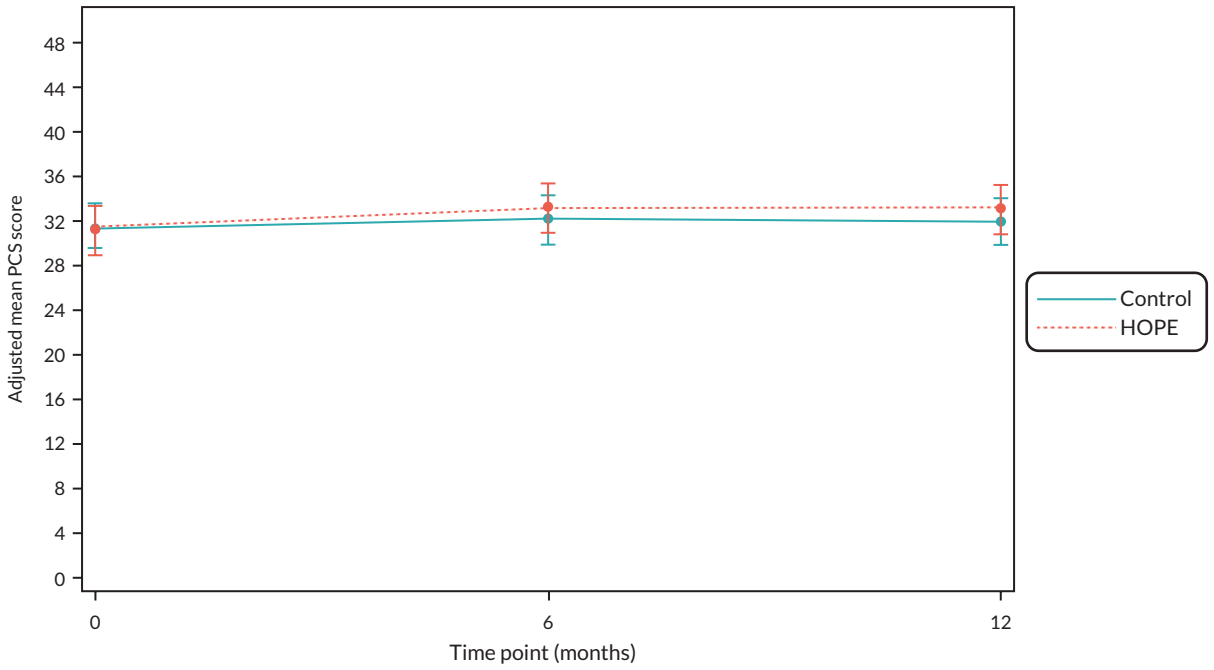

FIGURE 4 Health-related quality of life during follow-up.

TABLE 2 Raw unadjusted summaries of patient-reported outcome measures by trial arm and time point

	HOPE			Control		
	N	Mean (SD)	Median (IQR)	*N*	Mean (SD)	Median (IQR)
SF-36 PCS						
Baseline	407	31.1 (8.09)	30.5 (25.8–36.2)	325	31.2 (7.93)	30.8 (25.6–36.0)
6 months	294	32.1 (9.66)	31.5 (25.0–38.4)	235	30.8 (8.43)	28.8 (25.3–36.5)
12 months	258	31.6 (9.19)	30.1 (25.5–37.3)	208	30.8 (8.75)	30.6 (24.3–35.6)
SF-36 MCS						
Baseline	407	48.3 (11.47)	50.0 (41.3–56.7)	326	48.6 (11.78)	50.9 (40.5–58.1)
6 months	294	47.3 (12.38)	49.4 (39.4–56.9)	235	46.8 (11.73)	46.9 (38.0–56.9)
12 months	258	46.3 (12.44)	48.5 (36.6–56.5)	210	45.0 (12.41)	46.0 (34.8–56.3)
NEADL (range 0–66)						
Baseline	408	41.6 (14.10)	43.0 (31.5–54.0)	328	40.3 (14.77)	40.0 (30.0–52.2)
6 months	292	35.3 (14.91)	36.0 (25.0–46.0)	229	35.8 (15.45)	36.0 (24.0–48.0)
12 months	253	32.4 (15.84)	33.5 (18.0–44.0)	204	33.7 (15.67)	33.0 (23.0–45.7)
Barthel Index						
Baseline	407	16.7 (2.70)	17.0 (15.0–19.0)	329	16.8 (2.70)	17.0 (15.0–19.0)
6 months	293	16.2 (3.53)	17.0 (15.0–18.0)	230	16.3 (3.25)	17.0 (15.0–18.0)
12 months	254	15.8 (3.71)	17.0 (14.0–18.8)	207	16.0 (3.50)	17.0 (15.0–18.0)

TABLE 2 Raw unadjusted summaries of patient-reported outcome measures by trial arm and time point (*continued*)

	HOPE			Control		
	N	Mean (SD)	Median (IQR)	*N*	Mean (SD)	Median (IQR)
EQ-5D-5L index						
Baseline	399	0.6 (0.24)	0.6 (0.4–0.7)	323	0.6 (0.26)	0.6 (0.4–0.7)
6 months	283	0.5 (0.29)	0.6 (0.4–0.7)	221	0.5 (0.2.7)	0.6 (0.4–0.7)
12 months	240	0.5 (0.27)	0.6 (0.3–0.7)	200	0.5 (0.27)	0.6 (0.3–0.7)
EQ-5D-5L VAS						
Baseline	381	58.1 (20.6)	60 (45.0–75.0)	312	57.5 (20.8)	60 (50.0–75.0)
6 months	251	57.3 (21.4)	60 (45.0–75.0)	198	55.7 (21.8)	60 (40.0–75.0)
12 months	211	58.3 (21.4)	60 (45.0–75.0)	179	56.4 (22.3)	50 (40.0–75.0)

SF-36 PCS, SF-36 physical component score, range 0–100; SF-36 MCS, SF-36 mental component score, range 0–100; Barthel Index, Barthel Index of ADL, range 0–20; EQ-5D-5L, EuroQol-5 Dimensions, five-level version, range −0.594 to 1; EQ-5D-5L VAS, EuroQol-5 Dimensions, five-level version visual analogue scale, range 0–100. Higher scores are better.

Note
Data are mean (SD) or median (IQR).

TABLE 3 Adjusted primary outcome at 12 months and secondary outcomes at 6 and 12 months

	6 months				12 months			
	HOPE (*n* = 410)	Control (*n* = 330)	Effect[a], 95% CI	*p*-value	HOPE (*n* = 410)	Control (*n* = 330)	Effect[a], 95% CI	*p*-value
Primary outcome								
Mean SF-36 PCS,[b] SD	32.5 (0.76)	31.4 (0.77)	−1.10 (−2.32 to 0.12)	0.08	31.3 (0.75)	31.1 (0.85)	−0.22 (−1.47 to 1.03)	0.73
Mean SF-36 PCS, Complete case	33.3 (1.09)	32.1 (1.11)	−1.19 (−2.56 to 0.18)	0.09	33.4 (1.04)	32.1 (1.07)	−1.24 (−2.77 to 0.29)	0.11
Sensitivity analysis, mean SF-36 PCS,[b] SD					31.5 (0.8)	31.4 (0.8)	−0.11 (−1.37 to 1.14)	0.86
Secondary outcomes								
Mean SF-36 MCS, SD	46.6 (1.08)	46.2 (1.05)	−0.38 (−2.06 to 1.31)	0.66	44.2 (1.06)	43.4 (1.13)	−0.88 (−2.66 to 0.90)	0.33
Mean NEADL (range 0–66), SD	35.5 (1.16)	35.9 (1.17)	0.44 (−1.36 to 2.24)	0.63	31.4 (1.08)	32.6 (1.08)	1.24 (−0.53 to 3.01)	0.17
Mean Barthel Index, SD	16.0 (0.27)	16.1 (0.29)	0.15 (−0.29 to 0.59)	0.51	15.2 (0.29)	15.3 (0.29)	0.10 (−0.32 to 0.52)	0.64
Mean EQ-5D-5L, SD	0.5 (0.03)	0.5 (0.03)	−0.02 (−0.06 to 0.03)	0.49	0.5 (0.03)	0.5 (0.03)	−0.03 (−0.07 to 0.02)	0.25
MEAN EQ-5D-5L VAS, SD	58.8 (2.30)	56.8 (2.28)	−1.95 (−5.69 to 1.80)	0.31	59.0 (2.26)	57.1 (2.28)	−1.87 (−5.70 to 1.94)	0.34
Care home admission	–	–	–	–	21/410 (5.1%)	9/330 (2.7%)	0.63 (0.28 to 1.46)	0.28
Hospital re-admission	165/410 (40.2%)	151/330 (45.8%)	1.26 (0.92 to 1.73)	0.15	245/410 (59.8%)	214/330 (64.8%)	1.27 (0.93 to 1.75)	0.14
All-cause hospitalisations	–	–	–	–	1.33 (0.16)	1.49 (0.18)	1.12 (1.00 to 1.26)	0.05
Hospitalisations due to falls/fractures[c]	–	–	–	–	0.00 (5.13)	0.00 (4.57)	1.12 (0.77 to 1.64)	0.55

continued

TABLE 3 Adjusted primary outcome at 12 months and secondary outcomes at 6 and 12 months (*continued*)

	6 months				12 months			
	HOPE (*n* = 410)	Control (*n* = 330)	Effect[a], 95% CI	*p*-value	HOPE (*n* = 410)	Control (*n* = 330)	Effect[a], 95% CI	*p*-value
Mortality	–	–	–	–	63/410 (15.4%)	62/330 (18.8%)	1.04 (0.68 to 1.60)	0.85
Time to death	–	–	–	–	–	–	1.08 (0.93 to 1.25)	0.34

SF-36 PCS, SF-36 physical component score, range 0–100; SF-36 MCS, SF-36 mental component score, range 0–100; Barthel Index, Barthel Index of ADL, range 0–20; EQ-5D-5L, EuroQol-5 Dimensions, five-level version −0.594 to 1; EQ-5D-5L VAS, EuroQol-5 Dimensions, five-level version visual analogue scale, range 0–100. Higher scores are better.

a Effect represents the mean difference between treatment arms for continuous outcomes (SF-36 PCS, SF-36 MCS, NEADL, Barthel Index, EQ-5D-5L), IRRs (all-cause hospitalisations, hospitalisations due to falls/fractures) ORs (care home admission, hospital re-admission, mortality) and hazard ratios (time to death) estimated using linear, Poisson, logistic or Cox proportional hazards regression, adjusted for the stratification factors, age, previous engagement or referral to community rehabilitation services, CCI and baseline score in linear regression. The proportional hazards assumptions were assessed by plotting the hazards over time (i.e. the log cumulative hazard plot) for each treatment group. For the randomised treatment term, there was no evidence that the proportional hazards assumption was violated ($p = 0.2740$, Kolmogorov-type supremum test based on 1000 simulations). Missing data were imputed via MI for all outcomes, with the exception of care home admission, hospital re-admission, all-cause hospitalisations, hospitalisations due to falls/fractures, mortality and time to death.

b Primary outcome at 12 months. No adjustment was made for multiple comparisons, therefore *p*-values for the secondary outcomes should be interpreted cautiously.

c There was a low number of hospitalisations due to falls/fractures reported, resulting in a mean number of 0.00 for both arms. The IRR indicates that participants in the control arm were 1.12 times more likely to be hospitalised due to falls/fractures than participants in the HOPE arm.

Research papers synthesised in this synopsis

	Reference/DOI
Trial protocol paper[2]	Prescott M, Lilley-Kelly A, Cundill B, Clarke D, Drake S, Farrin AJ, Forster A, Goodwin M, Goodwin VA, Hall A, Hartley S, Holland M, Hulme C, Nikolova S, Parker C, Wright P, Ziegler F, Clegg A. Home-based Extended Rehabilitation for Older people (HERO): study protocol for an individually randomised controlled multi-centre trial to determine the clinical and cost-effectiveness of a home-based exercise intervention for older people with frailty as extended rehabilitation following acute illness or injury, including embedded process evaluation. *Trials* 2021,**22**:783.
Main trial results paper[48]	Clegg A, Prescott M, Collinson M, Goodwin VA, Thompson E, Bestwick R, *et al*. Home-based extended rehabilitation for older people with frailty (HERO): a randomised controlled trial. *medRxiv* 2025. https://doi.org/10.1101/2025.06.17.25329580
Process evaluation analysis[32]	Hall A, Zeigler F, Prescott M, Goodwin VA, Hulme C, Farrin AJ, *et al*. Process evaluation exploring implementation and delivery of a home-based extended exercise intervention for older people with frailty: the Home-based Extended Rehabilitation of Older people (HERO) trial. [published online ahead of print 10 December 2025]. *Health Technol Assess* 2025. https://doi.org/10.3310/GJAC2501
SAP[27]	https://fundingawards.nihr.ac.uk/award/15/43/07
HEAP[28]	https://fundingawards.nihr.ac.uk/award/15/43/07

Discussion/interpretation

Principle finding

Our trial findings indicate no benefit of extended rehabilitation (via the HOPE programme) for older people with frailty on physical health, mental health or ADL. There was some evidence for a reduction in all-cause hospitalisations, but no effect on care home admissions or mortality. Overall, when considered collectively, the intervention was not cost-effective.

Contribution to existing knowledge

This is the first RCT to evaluate extended rehabilitation following discharge from acute hospitalisation in a population of older adults with well-characterised frailty. In contrast to studies, including a mixed population of older adults who are frail, pre-frail and those more robust, the HERO trial did not demonstrate effectiveness of extended rehabilitation for older people with frailty via the HOPE programme.

Strengths and weakness of the study – in relation to other studies

Our findings indicate that, overall, reported intervention adherence was reasonable, taking account of the frailty of the population and day-to-day health fluctuations, with over half of participants completing more than 75% of prescribed exercises. Reliable data on intervention adherence are challenging to collect, and it is possible that overall intervention adherence may have been lower than reported, thus reducing the potential for benefit.

Our HOPE intervention was designed to be tailored to individual needs, allowing flexibility in initial intervention intensity to engage participants who might have struggled with a higher intensity. Although intervention training was developed to account for this, our process evaluation findings included feedback from some therapists that greater flexibility in intervention intensity was required, suggesting a need for a stronger emphasis on this in initial training to support overall fidelity. Our CACE analysis, however, did not show any clear relationship between adherence and intervention effect, indicating that whatever the intervention adherence, it is challenging to generate intervention effect for this particular population. Related to this, some previous exercise interventions for older people have included more challenging components, such as using progressive weights or resistance bands, and it is possible that the resistance exercise training in the HOPE programme was not intensive enough to generate intervention effect.

Findings conflict with the robust evidence base for resistance exercise training to improve outcomes for older people with frailty. This evidence has typically been generated from the more stable population of community-dwelling older people outside of the unstable, unpredictable fluctuations that often accompany acute illness or after an injury. It is plausible that the adverse health trajectories of older people with frailty after acute illness or injury, and the accompanying challenges, including day-to-day health fluctuations, general fatigue and weakness, mean that it is more difficult to generate similar benefits in this group when compared with a more general population of community-dwelling older people.

Take-home messages

- The HOPE programme as extended rehabilitation for older people with frailty did not improve physical HRQoL after discharge home from hospital or IC following an acute admission with a medical illness or injury.
- Although there may be a reduction in hospitalisation rates for those receiving the HOPE programme as extended rehabilitation, overall it was not cost-effective.
- Based on this evidence, we do not recommend routine commissioning of extended rehabilitation via the HOPE programme for older people with frailty after discharge home from hospital or IC, following an acute admission with a medical illness or injury.

Reflections on the project and what could have been done differently

We delivered a highly complex trial, recruiting a historically underserved research group of older people with frailty, successfully recruiting to target. However, although recruitment across the internal pilot went well, subsequent recruitment was slower than anticipated which led to an initial 9-month costed extension. The trial paused to recruitment due to the COVID-19 pandemic, and, as a result, a second costed extension of 6 months was required (total extension time 15 months). We managed sites proactively, identifying where there were issues that could be rectified and closing sites where there was no realistic prospect of successful recruitment.

To support intervention delivery within the considerable NHS operational pressures, we could have initiated a 'bank' staff model at an earlier stage, which may have supported delivery across some sites. We made some minor changes to follow-up processes after the internal pilot (unconditional gift voucher at 6 months, participant card to prompt questionnaire completion and inclusion of a final postal contact to collect SF-36 only). Initiation of these measures from the start of the trial may have increased follow-up return rates.

Describe major/significant changes

None.

Challenges faced and limitations

We designed our trial using the best available data in our sample size calculation, and our assumption that 65% of participants would provide primary outcome data at 12 months post randomisation was correct. Using MIs, all trial participants were, however, included in the intention-to-treat analysis. The recruitment and follow-up rates observed in this trial will be of value to the wider research community when designing future trials involving older people with frailty.

The HERO trial was delivered during especially challenging circumstances that included the COVID-19 pandemic. During this time (March 2020–October 2020), the trial paused to recruitment and face-to-face intervention delivery. Participants who had been recruited/randomised

This synopsis should be referenced as follows:
Prescott M, Collinson M, Hall AJ, Bestwick R, Goodwin VA, Thompson E, *et al*. Home-based extended rehabilitation for older people with frailty (HERO): a multicentre randomised controlled trial with health economic analysis and process evaluation. *Health Technol Assess* 2026;**30**(4):1–40. https://doi.org/10.3310/GJAC1602

but who had not received ≥ 2 home visits to teach and check the intervention exercise performance were discontinued from the intervention (*n* = 8). Those who had started the intervention, having received ≥ 2 but < 5 home visits, had their remaining home visits switched to telephone contacts (*n* = 14). This limited the progression of exercise such that no new exercises were taught and only the dose of the previously taught exercises could be adjusted.

We remained mindful of the potential impact of COVID-19 restrictions on the physical activity and physical role components of the SF-36, which include engagement in outdoor activities. We explored this during analysis and adjusted for the timing of completion of a participant's 12-month outcome (pre lockdown or during/post lockdown) but detected no difference in any outcomes, providing reassurance that COVID-19 was unlikely to have influenced trial results.

We faced challenges relating to intervention delivery because of limited capacity to deliver the intervention in the face of considerable NHS operational pressures within therapy services, particularly during the immediate post-COVID period. We adapted the model of intervention delivery based on the capacity of individual sites; for example, at some sites, HERO therapists were employed within an NHS bank service to deliver the intervention on a case-by-case basis outside usual NHS therapy commitments. These staff were typically part of the existing NHS therapy team at the individual site and worked within existing governance frameworks.

We had good engagement from site research teams, although there were challenges relating to the allocation of site Clinical Research Network staff, who were generally allocated from other specialty recruitment teams (e.g. cardiology, neurology) rather than from within ageing specialty staff. This caused challenges in situations where staff were recruiting across multiple trials given the resource-intensive nature of screening and obtaining consent for HERO participants, who were characterised by frailty and therefore usually required additional time for research-based procedures.

Engagement with partners and stakeholders

We had excellent engagement with site therapy teams, co-ordinated through the therapy service directors, who were crucial to successful trial implementation. We also had excellent engagement with geriatric medicine teams, who provided site leadership alongside therapy leads and supported site-based identification of participants. We maintained good engagement with wider stakeholders, for example, specialist societies (British Geriatrics Society, Chartered Society for Physiotherapy) alongside policy-makers at NHS England and the Department of Health and Social Care through our NIHR Applied Research Collaboration and Older People & Frailty Policy Research Unit roles.

Individual training and capacity-strengthening activities

We sought to strengthen research capacity in historically under-represented disciplines of geriatric medicine and therapy services for older people. These are areas that have been prioritised by NIHR for capacity building, and our engagement with multiple sites increased exposure of practitioners to RCT and embedded process evaluation methods. Success of our capacity-strengthening activities is evidenced through Matthew Prescott, our Bradford Trial Manager and physiotherapist, who has secured a prestigious NIHR Pre-Doctoral Fellowship, building on his experiences gained through the HERO trial. One of our original HERO trial recruiting team has also secured a PhD studentship exploring recruitment of older adults with frailty to research trials.

Institutional capacity strengthening

Our institutions have demonstrated commitment to capacity building in this important area through the promotion of Chief Investigator Andrew Clegg to Professor of Geriatric Medicine in 2019, and South West Site Lead Vicki Goodwin promoted to Associate Professor in 2018 and to Professor of Ageing and Rehabilitation in 2022 and made a NIHR Senior Investigator in 2024. Statistical Guarantor Amanda Farrin became a NIHR Senior Investigator in 2021. Physiotherapist Abi Hall completed her PhD in 2019 alongside her role in the process evaluation, and in 2024, she was promoted to Senior Research Fellow.

Patient and public involvement

Aim

The aim of patient and public involvement (PPI) throughout this study was to ensure that the voices of older adults with frailty, and those of people involved in their care, were considered in intervention development, research process design/implementation, dissemination of the results and planning for future implementation of the intervention.

Methods

Patient and public representatives were involved in this research prior to it being commissioned. The HOPE programme intervention was co-designed in full partnership with older people and their carers.[1,36] We included Christine Smith as patient representative on the TSC, alongside representation from Age UK as the leading national charity representing the view of older people. We also had PPI representation on the Trial Management Group through Joyce Greenwood as patient representative, and Rifat Parveen and Julie Peacock from Carers Resource, a charity supporting the needs of informal carers. Additionally, service users, their carers and staff at Age UK Wakefield supported us in providing feedback and suggestions to refine participant-facing intervention materials. A group of physiotherapists supported refinement of the interventional therapy record. We convened a separate PPI group to work with us to refine our dissemination plan and associated materials.

Results of patient and public involvement input

Our PPI input throughout the original intervention co-design ensured that the intervention was designed and refined based on the needs of older people with frailty. Our PPI input throughout the trial ensured that all trial-based materials were aligned with the needs of older people. This included ensuring that we adhered to Royal National Institute for Blind People Clear Print guidelines.

Discussion of patient and public involvement input

An important challenge facing triallists in ageing research is retaining meaningful PPI in trial oversight procedures across an often extended trial time horizon, taking account of the fact that PPI representatives who have frailty at the outset of the trial may themselves face health-related fluctuations and changes in personal circumstances. We managed this carefully during the trial, aiming for a balance of lay representative input alongside the carer voice and voluntary sector organisation representation. At times, we arranged for our Trial Manager to visit PPI representatives at home, to discuss trial-related progress and challenges faced. Although this was successful, our collective experiences indicate that researchers should adopt a flexible approach to PPI input for trials of likely extended time horizon. The establishment of a core group of PPI representatives to provide input and steering across different frailty research studies has been implemented successfully within the Academic Unit for Ageing and Stroke Research, University of Leeds, and should be considered for replication. This model of PPI engagement has been published previously.[49]

Reflections and critical perspectives

The inclusion of PPI input into the TSC is an area that needs especially careful consideration. Our experiences across HERO and a range of other studies involving older people with frailty indicate that it can be especially challenging to co-ordinate this successfully. At times, and at the preference of PPI representatives, we have sought input into trial-related activity outside the main TSC, with trial team members providing feedback at the main committee meeting. Despite our best efforts, the unavoidably technical discussions that take place within TSC meetings can mean that, at times, PPI representatives can find active engagement challenging. Although this could be viewed as a failure of the trial team to articulate complex aspects of the trial in simple, lay language, our overall view is that triallists should take an especially careful approach to PPI representation of older adults with frailty for committees meetings which are, at times, likely to be lengthy and necessitate language and concepts that are technical in nature.

Equality, diversity and inclusion

The majority of HERO trial participants were female (67.3%). Although this is aligned to some extent with the older hospitalised demographic, and reflects the proportions of people who were eligible to approach after screening, there is a recognised under-representation of males in similar trials, for example, falls prevention trials. This is an area that requires careful attention, as gender imbalance (in either direction) in ageing research trials can generate evidence that may not be generalisable across the wider population.

Despite trial sites, including large metropolitan areas of ethnic diversity (e.g. Bradford, Leeds) the large majority of participants were of White ethnicity (97.6%). We tried to proactively mitigate against this through the inclusion of researchers with community language skills to facilitate recruitment of older people of south Asian ethnicity who did not speak English as their first language. However, the trial recruitment flow indicates this was less successful than planned, as 91.9% of those who were eligible to approach after screening were of White ethnicity, compared with 97.2% of those consented. We did not translate recruitment or intervention delivery materials because the main community dialect of our south Asian residents of Bradford is a spoken dialect with no equivalent written form. These considerations were also discussed in detail with our Therapy Service Managers as part of trial setup, and we were reassured that existing NHS services have the range of staff with community

language skills to support delivery. Methods to engage people of different ethnicities should be prioritised for all future ageing-related research. This should include consideration of 'opt-out' consent for research studies, which can be considered less burdensome for some older participants, and support engagement of people where their primary language does not have a written form and for those who do not read or write in their primary language.

Eleven out of 15 of our HERO trial authorship team are female. Six of the authors have a clinical background with one nurse, one medical doctor and four physiotherapists. Although our HERO trial senior academic leadership team did not include people of diverse ethnicity, 15% of the wider team at the Academic Unit for Ageing and Stroke Research are from ethnic minority groups. One of our original HERO trial recruiting team who is of south Asian ethnicity has since secured a PhD studentship, building much-needed research capacity among this under-represented group.

Across our trial sites, we encouraged members of the senior therapy and nursing teams to take on principal investigator roles. Twelve of the 15 trial sites had non-medical principal investigators or co-principal investigators.

We have included a range of experience and expertise across the research group, with opportunities provided for more junior members of the research team to actively contribute across the trial, including the leading of paper writing and preparation of abstract submissions for scientific conferences. Of the researcher coauthors of the trial report, four are pre-doctoral, two are in the early post-doctoral period and eight are senior academics.

Implications for decision-makers

Our trial findings provide important evidence for decision-makers. Based on our findings, we do not recommend routine commissioning of extended rehabilitation via the HOPE programme for older people with frailty after discharge home from hospital or IC, following an acute admission with a medical illness or injury. Instead, we recommend that available resources should be directed towards evidence-based core IC services to meet the needs of the growing population of older people in the UK and internationally, alongside resources for resistance exercise training targeted at the more stable population of community-dwelling older people with frailty.

Research recommendations

We feel that our trial provides robust evidence that our home-based exercise intervention as extended rehabilitation for older people with frailty does not improve key outcomes and is not cost-effective. Although different configurations of extended rehabilitation (e.g. ADL training, environmental assessment and home modification) could be trialled as alternative forms of home-based rehabilitation, our view is that future work should consider how existing core IC rehabilitation services should be best organised and delivered to ensure that older people with frailty feel ready to return home. We also recommend a research focus on proactive intervention for older people with frailty outside the context of an acute illness or injury, where there is existing aggregate evidence for effectiveness but uncertainty regarding how interventions should be best targeted to maximise clinical and cost-effectiveness. This could include new individual participant data meta-analysis, whereby original trial data sets are gathered together to support detailed analysis of how participant characteristics (e.g. age, gender, frailty, ethnicity) predict response to treatment, and examine the economic perspective to deliver best value for money.

Conclusions

Considered collectively, our trial findings provide important evidence for policy-makers and commissioners of rehabilitation services for older people globally. Based on our findings, we do not recommend routine commissioning of extended rehabilitation for older people with frailty after discharge home from hospital or IC, following an acute admission with a medical illness or injury. Instead, we recommend that available resources should be directed towards evidence-based rehabilitation and exercise programmes and core IC services to meet the needs of the growing population of community-dwelling older people living with frailty in the UK and internationally.

Additional information

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Sheffield Teaching Hospitals NHS Foundation Trust

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Cornwall Partnership Trust and the Royal Cornwall Hospitals NHS Trust

Hull University Teaching Hospitals NHS Trust

North Devon Healthcare NHS Trust

Mid Yorkshire Hospitals NHS Trust

Somerset Partnership NHS Foundation Trust

Dorset Healthcare University NHS Foundation Trust

Solent NHS Trust

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's 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 this citation here: https://understandingpatientdata.org.uk/data-citation.

Data-sharing statement

Data supporting this work are available on reasonable request. All requests will be reviewed by relevant stakeholders, based on the principles of a controlled access approach. All data requests would be subject to review by a subgroup of the trial team, which will include the chief investigator (Andrew Clegg) and data guarantor (Amanda J Farrin). Access to anonymised data could be granted following this review. All data-sharing activities would require a data-sharing agreement. Requests to access data should be made to Andrew Clegg in the first instance.

Ethics statement

The HERO trial was approved by the Yorkshire and Humber – Bradford Leeds Research Ethics Committee (17/YH/0097) on 22 June 2017.

Information governance statement

Bradford Teaching Hospitals NHS Foundation Trust; the University of Leeds; and the University of Exeter are 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. Under the Data Protection legislation, Bradford Teaching Hospitals NHS Foundation Trust and the University of Leeds are joint Data Controllers. The University of Leeds Clinical Trials Research Unit has established procedures for collecting and using personal data (available at https://ctru.leeds.ac.uk/privacy-cookies/how-we-use-personal-data/), including how personal data are handled and the individual right of participants. The contact details for our Data Protection Officer are also provided (email DPO@leeds.ac.uk).

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/GJAC1602.

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Abi J Hall reports NIHR, Alzheimer's Society and Chartered Society of Physiotherapy (CSP) funding. She is also a member of the CSP Scientific panel.

Rebecca Bestwick reports no conflict of interests.

Victoria A Goodwin reports NIHR, Dunhill Medical Trust and CSP funding, being a DMEC member, a member of NIHR grant funding and Fellowship panels, and a NIHR senior investigator.

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Chris Bojke reports no conflict of interests.

David Clarke reports no conflict of interests.

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Conference abstract presentation

Invited presentation of trial results at the British Geriatrics Society Spring Conference 2024

Conference posters

Prescott M, Goodwin V, Parker C, Cundill B, Hulme C, Thompson E, *et al*. Boosting recruitment rates in trials with complex recruitment pathways spanning acute and community healthcare: experiences from the HERO trial in older adults with frailty. In: Sydes M, Gillies K, Williamson P. ICTMC 2022: sixth International Clinical Trials Methodology Conference – book of abstracts. Zenodo (2023). https://doi.org/10.5281/zenodo.7741866

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List of supplementary material

Report Supplementary Material 1 HERO trial outcome definitions

Supplementary material can be found on the NIHR Journals Library report page (https://doi.org/10.3310/GJAC1602).

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.

The supplementary materials (which include but are not limited to related publications, patient information leaflets and questionnaires) are provided to support and contextualise the publication. Every effort has been made to obtain the necessary permissions for reproduction, to credit original sources appropriately, and to respect copyright requirements. However, despite our diligence, we acknowledge the possibility of unintentional omissions or errors and we welcome notifications of any concerns regarding copyright or permissions.

List of abbreviations

ADL	activity of daily living
AfC	Agenda for Change
CACE	complier-average causal effect
CCI	Charlson Comorbidity Index
CFS	Clinical Frailty Scale
CTRU	Clinical Trials Research Unit
DAM	decision-analytic model

DMEC	Data Monitoring and Ethics Committee
EQ-5D-5L	EuroQol-5 Dimensions, five-level version
GP	general practitioner
HERO	Home-based Extended Rehabilitation for Older people with frailty
HEAP	health economic analysis plan
HES	Hospital Episode Statistics
HOPE	Home-based Older People's Exercise
HRQoL	health-related quality of life
HTA	Health Technology Assessment
IC	intermediate care
ICER	incremental cost-effectiveness ratio
IRR	incidence rate ratio
MCS	mental component score
MI	multiple imputation
MoCA	Montreal Cognitive Assessment
NEADL	Nottingham Extended Activities of Daily Living
NICE	National Institute for Health and Care Excellence
ONS	Office for National Statistics
OR	odds ratio
PCS	physical component score
PPI	patient and public involvement
PSA	probabilistic sensitivity analysis
PSSRU	Personal Social Services Research Unit
QALY	quality-adjusted life-year
RCT	randomised controlled trial
RR	risk ratio
RU	resource use
SAP	statistical analysis plan
SD	standard deviation
SF-36	Short Form questionnaire-36 items
TSC	Trial Steering Committee
TUGT	Timed Up and Go Test
UC	usual care
VAS	visual analogue scale
WPT	willingness to pay
WT	within trial

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Appendix 1 Internal pilot pre-specified progression criteria and results

Recruitment (assessed at 6 months after the start of recruitment – June 2018).

Green: ≥ 4 patients/month/site (measured in months 4–6 to allow time for recruitment to stabilise)

Amber: < 4 but ≥ 2 patients/month/site

Red: < 2patients/month/site

Intervention provision (assessed at 6 months after the start of recruitment – June 2018)

Green: ≥ 80% of intervention participants receiving their first home visit within 3 weeks

Amber: < 80% but ≥ 65% of intervention participants receiving their first home visit within 3 weeks

Red: < 65% of intervention participants receiving their first home visit within 3 weeks

Intervention acceptability (assessed at 9 months after the start of recruitment – September 2018)

Green: ≥ 80% retention of intervention participants

Amber: < 80% but ≥ 65% retention of intervention participants

Red: < 65% retention of intervention participants

6-month follow-up/completion of outcomes (assessed at 12 months after the start of recruitment – December 2018)

Green: ≥ 80% completion of the SF-36 PCS

Amber: < 80% but ≥ 65% completion of the SF-36 PCS

Red: < 65% completion of the SF-36 PCS

Recruitment and intervention provision, assessed at 6 months after trial opening, were rated as green and red, respectively. Overall recruitment during this period exceeded targets, and no revisions to the recruitment strategy were made. Protocol amendments to improve intervention provision included extension of the recruitment window to up to 7 days post discharge, addition of researcher guidance to assist conversations with potential participants, clarification of the process for commencing intervention delivery for those participants re-admitted to hospital and the addition of further checks to ensure eligibility criteria were met prior to randomisation.

Intervention acceptability and 6-month follow-up, assessed at 9 and 12 months after trial recruitment, were both rated as red. Protocol amendments at this stage included provision of an unconditional gift voucher at 6 months, addition of a participant card to prompt questionnaire completion and inclusion of a final postal contact to collect SF-36 only.

Progression to the main trial was approved by the TSC and HTA programme.

Appendix 2 Template for Intervention Description and Replication Checklist

Name: The Home-based Older People's Exercise (HOPE) programme
Why (rationale, theory, goal):
Around 50% of older people in hospital have frailty and are at higher risk of re-admission or death following discharge home, compared to robust older people. Although short-term rehabilitation reduces re-admission to hospital within a month of discharge, this benefit attenuates, with no reduction in re-admissions to hospital over the longer term.
A key challenge for healthcare systems internationally is how to sustain the benefit from short-term rehabilitation over a longer time horizon. Systematic review evidence indicates exercise interventions based on progressive strength training can improve mobility and function for older people with frailty and slow progression to disability. A programme of progressive exercise as extended rehabilitation, targeted at key muscle groups for functional mobility, with integrated behaviour change techniques (including information provision, goal-setting, self-monitoring and setting graded tasks), has potential for sustaining independence and HRQoL for older people with frailty following discharge from hospital or short-term rehabilitation.
The primary goal of the HOPE programme is to improve physical HRQoL for older people with frailty after acute illness or injury. Secondary goals include improvements in ADL, mental health and reduced hospitalisations and care home admission.

Name: The Home-based Older People's Exercise (HOPE) programme

What materials:

- The HOPE programme manual consists of five sections:
  1. Information: education around exercise in older age, likely benefits and an overview of the HOPE programme
  2. Safety tips: exercise environment considerations, general precautions for exercising
  3. Good posture: guidance for maximising a good seated or standing posture for exercising
  4. Exercises: level-specific exercises, each being named, information provided as to intended benefit of the exercise, bullet point text instructions for how to perform the exercise supported by photographs of a person performing the exercise.
  5. Staying on track: information provided here is aimed to help individuals remain engaged with the exercise programme in the long term; tips include seeking social support, making exercise fun perhaps by doing it with a friend or with music, setting goals, keeping an exercise diary, setting reminders and what to do on a 'bad day'.
- The manual is supplemented by a participant exercise diary, enabling the participant to monitor exercise sessions via a simple tick per session up to three times per day. The participant is also provided with a pen, to complete the diary and make notes, and a fridge magnet as a reminder to perform the exercise prescription. All materials are presented in a freestanding reusable bag, in which the items can be stored. The bag includes the HOPE programme logo as a further memory aid.
- The therapy record is provided for therapists to complete, based on a standard record used by therapy staff as part of clinical practice. It includes participant information (e.g. demographic detail, comorbidities and medications) and individual pages for the therapy staff to record a narrative description of each participant contact (home visit and telephone calls). The therapy record pages are structured to provide some prompting to guide content/discussion at therapy sessions. The therapy record also enables recording of information required to calculate costs for intervention delivery (including travel).

What procedures:

- The HOPE programme is a 24-week home-based manualised, graded, progressive exercise intervention aimed at improving strength, endurance and balance, required for basic mobility skills like getting out of bed, standing up from a chair, walking a short distance and getting off the toilet.
- The programme is graded into three levels to account for the spectrum of frailty. The functional exercises require no special equipment, and are taught by a HOPE programme-trained therapist, such that they can be performed without ongoing professional supervision.
- Participants were allocated to intervention level by:
  - HOPE level 1: participants completing the TUGT in ≥ 30 seconds, who are more likely to require assistance with walking, climbing the stairs and leaving the house.
  - HOPE level 2: participants completing the TUGT in 20–29 seconds, who demonstrate greater variability in mobility, balance and functional ability.
  - HOPE level 3: participants who complete the TUGT in < 20 seconds, who tend to be able to get in and out of a chair more easily and climb stairs.
- The programme was delivered as extended rehabilitation for trial participants allocated to receive it, upon discharge from their rehabilitation pathways following acute hospitalisation.

Who provided:

- Suitably trained and experienced community physiotherapists and therapy assistants, familiar with delivering community rehabilitation programmes to older people.
- Site physiotherapists and therapy assistants received detailed intervention training in interactive workshops delivered by trial physiotherapists experienced in HOPE programme and community rehabilitation delivery.
- Intervention training included: rationale, theory and goals of HOPE programme, description of intervention materials and procedures, along with strategies and practical delivery of the programme.
- Supervision of therapy staff was via usual NHS line management, with intervention delivery support/advice provided by the central trial team.
- Access to training materials was available to trained therapists, and regular updates and communication with trained therapists was maintained by the central trial teams.
- Communication between trial therapists for sharing of experiences and learning was facilitated by the central trial team, through regular therapist teleconferences, site update meetings and newsletters.

Name: The Home-based Older People's Exercise (HOPE) programme

- Therapists delivering the HOPE programme did not treat UC participants referred to community rehabilitation during the study period where feasible.

How and where: mechanism and location of delivery

- The HOPE programme was delivered by the trained therapists via one-to-one home visits and telephone contacts for ongoing support.
- Individual home visits and telephone calls were scheduled weekly, but in a flexible manner to fit participant availability.
- No specialist rehabilitation equipment was required.

When and how much:

- The exercise routines typically take < 15 minutes to complete, and participants were requested to complete the routine three times per day on 5 days of the week (as able).
- A graded approach was taken to build up the exercise prescription in line with participants' physical capacity.
- Progression of the programme included increased repetition of a given exercise prescription, introduction of additional exercises from the HOPE manual or progression to the next level within the programme.
- Review of exercise performance occurred at each weekly contact, and appropriate adjustment of the exercise prescription made.
- Participants documented exercise session completion in the exercise diary.

Tailoring:

- The initial HOPE programme level was tailored to an individual in line with TUGT at baseline.
- Physiotherapists further tailored the programme on an ongoing weekly basis in line with the physical capacity and health status of the individual participant.

Modifications:

- The HOPE programme was a 24-week programme, which included an additional 12 weeks of telephone support when compared to the originally piloted HOPE programme.
- The trial was impacted by a period of national lockdown due to the COVID-19 pandemic. During this time (March 2020–October 2020), the trial paused to recruitment and face-to-face intervention delivery. Some participants in receipt of the HOPE programme were impacted:
    - Those recruited/randomised and who had not received ≥ 2 home visits to teach and check the intervention exercise performance were discontinued from the intervention (n = 8).
    - Those who had started the intervention, having received ≥ 2 but < 5 home visits, had their remaining home visits switched to telephone contacts (n = 14). This limited the progression of exercise such that no new exercises were taught and only the dose of the previously taught exercises could be adjusted.

How well (planned):

- Exercise diary and therapy record captured data regarding the exercise prescription, exercise performance and exercise session completion.
- Therapy contact data were recorded, including the personnel performing, date and duration, mode of delivery, content of session.
- Process evaluation activity included review of intervention fidelity. This activity included non-participant observations and review of the training sessions completed, non-participant observations of implementation of the HOPE programme at home visits and telephone contacts, and participant, carer, therapist and therapy service manager interviews.

How well (actual):

- Of the 410 trial participants randomised to receive the intervention, 332 commenced the HOPE programme. The main reasons for not initiating the programme were:
    - Therapist deemed no longer appropriate (42.3%)
    - Participant had died (14.1%)
- Other key intervention delivery metrics are available in Table 8 and Figure 3.

The process evaluation concluded that the intervention had been delivered broadly as planned without significant variation between sites/regions.

Appendix 3 Complier-average causal effect analysis of primary outcome

Compliers were defined on two levels: participant 'compliance' with prescribed exercises with therapist fidelity assessed via session delivery. For the therapist delivery, the following were defined as 'compliant' in a staged approach:

1. Those who completed at least four home visits.
2. Those who completed at least two home visits.

Participant compliance was assessed by the exercises completed as a proportion of the exercises prescribed:

1. Those who completed 75% of all exercises prescribed (through the entire duration of the intervention).
2. Those who completed 50% of all exercises prescribed (through the entire duration of the intervention).

The CACE analysis took a staged approach and was repeated four times, considering the four different levels of participant/therapist compliers, taking account of both therapist and participant compliance:

1. Strictest compliance:

Those who had at least four home visits and completed at least 75% of all exercises prescribed.

2a. Relaxed definition of participant compliance:

Those who had at least four home visits and completed at least 50% of all exercises prescribed.

2b. Relaxed definition of therapist compliance:

Those who had at least two home visits and completed 75% of all exercises prescribed.

3. Most lenient compliance:

Those who had at least two home visits and completed at least 50% of all exercises prescribed.

Results for the HOPE programme effect according to the level of compliance through the CACE analysis are provided in *Table 4*.

TABLE 4 The CACE analysis results

	HOPE (*N* = 410)	Effect[a], 95% CI	*p*-value
Strictest compliance (1) *N* (%)	160 (39.0%)	−1.11 (−3.21 to 0.99)	0.30
Relaxed participant compliance (2A) *N* (%)	212 (51.7%)	−1.06 (−3.34 to 1.23)	0.36
Relaxed therapist compliance (2B) *N* (%)	173 (42.2%)	−1.35 (−3.99 to 1.29)	0.32
Most lenient compliance (3) *N* (%)	240 (58.5%)	−1.31 (−4.13 to 1.52)	0.36

a Effect represents the mean difference between treatment arms estimated using linear regression, adjusted for age, gender, previous engagement or referral to community rehabilitation services, and baseline PCS.

Appendix 4 Detailed health economics methods and results

Methods

Intervention

We identified HOPE provision costs arising from two areas: specific training of physiotherapists, and intervention delivery. The Agenda for Change (AfC) band of each therapist was used to identify their respective Personal Social Services Research Unit (PSSRU) unit cost.[50] This was used in conjunction with workshop duration to calculate person-time cost of training and delivering sessions. Delivery costs included time incurred through direct time with participant, travel time, associated admin time and equipment costs (provision of the exercise booklet, assumed to cost £2.50). Analysis was undertaken using an intention-to-treat approach.

Health and social care resource use

Participants were followed up for 12 months post randomisation. Data regarding RU were sourced from HES and participant self-reported questionnaires.

Secondary care data (from HES) included that relating to emergency attendances, outpatient appointments and inpatient admissions. HES data were run through the NHS Grouper Software to output the relevant Healthcare Resource Groups (HRGs).[51] The respective unit costs (from the National Cost Collection) were applied to the HRGs to attribute a cost to each relevant secondary care interaction which included 'unbundled' RU, such as MRI scans or high-cost drugs, excess bed-days and intensive care stays.[52] Complete HES data were also used as conditioning variable in the MI imputations.

Primary care and social care RU were predominantly collected from participant questionnaires completed at baseline, 6 months and 12 months. For the primary analysis, we include the primary care costs originating from appointments with general practitioners (GPs), practice nurses and district nurses. Social care costs considered were those arising from formal care at home, time spent in respite care, day centre visits and permanent moves to nursing homes. Permanent moves to a nursing home were captured through a change-of-address form. Unit costs for costed care elements were sourced from PSSRU.[50]

Utility

Participants' HRQoL was measured using the NICE-recommended EQ-5D-5 L questionnaire administered at baseline, 6 months and 12 months. In line with the NICE guidance, the questionnaire responses were first mapped to EuroQol-5 Dimensions, three-level version before then taking the corresponding HRQoL value from the UK value set.[53] If a participant died within the trial, their HRQoL was assumed to be zero at the next point of HRQoL reporting. Half-cycle corrections were not applied. Further detail of utility measurement is outlined in the HEAP.[27]

Modelling approach

We aimed to use a consistent approach for the regression modelling for the WT data and DAM. Considered patient characteristics included age (adjusted for cohort mean), gender, participant frailty at baseline, living status at baseline. By trial construction, there were multiple measures per individual, so, where possible, random effects were used to capture underlying heterogeneity. Across data sources, missing data were explored and, where required, was imputed using MI. We refer to analysis without imputed data as 'available case'.

Data regarding secondary care use, nursing home admission and death were available in continuous time (from HES, ONS and change-of-address forms, respectively). In contrast, primary and community care data were collected through case report forms in discrete 3-monthly time intervals. To align with the DAM cycles, secondary care continuous data were also broken down into 3-month time spells. We conducted parametric survival modelling on WT data to enable survival estimate extrapolation beyond the trial period and incorporation within the DAM. A further regression model of EQ-5D-5L on patient characteristics and trial time points interacted with treatment arm facilitated modelling of HRQoL over WT time, adjusting for baseline differences. Detail on the structural development of the DAM is presented in the HEAP. We aimed to develop a model that adequately captured differences in the population (with and without the intervention) while also being concise and predominantly populated using WT data. DAM results are probabilistic and based on 10,000 random samples.

Secondary care costs and all regression analyses were performed using SAS 9.4. Intervention costs, primary/community RU and the DAM were analysed using R 4.2 (The R Foundation for Statistical Computing, Vienna, Austria).

Results

Home-based Older People's Exercise provision costs

About 410 participants were randomised to receive the intervention. 332 participants received at least one HOPE session, and in total, 4958 sessions were delivered. Per participant, the mean duration of all delivery time (including healthcare professional travel and admin time) was 8.9 hours, and mean delivery cost £924 (median £947). The total intervention provision (including training, delivery and equipment) cost £422,194. This equates to £1029 per participant randomised to the HOPE arm.

Resource use

Among the collected data, there was a wide range of 3-month primary/community care RU cost: median £140 (range £0–18,797). The highest costs in this category are from nursing home admissions. 76% of homecare questionnaires collected at 6 and 12 months reported zero formal homecare in the prior 3 months (864 returned questionnaires, between 527 distinct patients). In secondary care, inpatient admissions are notably more costly compared to outpatient or accident and emergency (A&E) attendances and also occurred less frequently. Inpatient stays, which were highly correlated with A&E attendances, were for a variety of reasons; the most common was pneumonia (87 admissions), followed by plasma exchange/blood transfusion (52 admissions). Across and within RU types (primary, community and

secondary care), there were lots of zero costs and bumps in distribution. To accommodate this, we adopted a classification system of ordered categories followed by two-part regression models. There were more missing data within the patient-reported primary care data compared with the systematic HES secondary care data. Around 30% of primary care data were missing at 12 months, although this was balanced across trial arms.

Survival analysis

During the trial, there were low levels of mortality, and there was non-significant better survival in the HOPE arm. From the parametric survival analysis, the exponential model with continuous hazard was the best fit according to both Akaike Information Criterion and Bayesian Information Criterion; increasing frailty is associated with greater risk of death ($p = 0.094$) and males die sooner ($p = 0.009$); there is no obvious impact of baseline living arrangements.

Health-related quality of life estimations

At baseline, there was substantial heterogeneity of HRQoL between participants, and this was broadly balanced between trial arms. Linear regression on the HRQoL data revealed that much of the variability between patients was explained by their frailty category; there was little impact of residence, and the treatment impact was small.

At 12 months, the mean estimated QALYs were slightly higher for the HOPE arm compared to UC (incremental difference 0.024 QALYs). When considering intervention costs alongside expected RU costs (after adjusting for survival), the incremental cost of the HOPE + UC arm is £1401. This gives an available-case base-case ICER of £58,375, and it is unlikely the intervention is cost-effective. The MI analysis also indicates that HOPE + UC is not cost-effective relative to UC (ICER of £49,711) from mean MI PSA (incremental costs £1469, incremental utility 0.03 QALY).

The WT cost-effectiveness acceptability curve is shown in *Figure 5*, and the cost-effectiveness plane is in *Figure 6*.

Decision-analytic model

The DAM facilitated extrapolation of result over the longer term, and a sketch of the model is outlined in *Figure 7*

The model's alive states (low, medium, high) are determined by patients' healthcare RU which can accrue from primary, community or secondary care. The cycle length in the model is 3 months. Within each cycle, patients can either stay in their current state, transition to a state of higher or lower RU or die. The starting cohort is 10,000 individuals aged 83 years, the mean age of the HERO trial cohort. We ran the model for three distinct groups, each representing a different level of cohort frailty: mild, moderate and severe. The model was also run over three separate time horizons: 5, 10 and 15 years. In line with NICE guidelines, future costs and QALYs were discounted at 3.5% per year. Transition D (probability of death within each cycle) is estimated through the parametric survival analysis of WT data and is independent of alive state. The remaining transition probabilities were estimated through regression analysis on the WT data.

Respective costs for the medium and high state were conditional from the regression model on WT data. The low RU state and dead state had a cost of zero. Conditional utility was similarly derived from regression analysis of WT data. The utility regression coefficients were applied as decrements to population estimates of EQ-5D utility.[54] Coefficient point estimates were used for deterministic analysis. For probabilistic analysis, we took 10,000 samples from a normal distribution using the point estimates and the regression–covariance matrix.

Model results

Using a 5-year time horizon, it is unlikely that HOPE + UC compared to UC alone is cost-effective.

The base-case ICERs for each frailty category (mild, moderate, severe) were £57,272, £78,362 and £139,215, respectively. At £20,000 WTP threshold, the probability that HOPE + UC is cost-effective compared to UC alone is 26.2% for a mild cohort, 19.4% for moderate and 16.7% for severe. *Figure 8* displays a cost-effectiveness acceptability curve for a 5-year time horizon, by the varying baseline frailty status. The corresponding cost-effectiveness plane is shown in *Figure 9*.

When extending to a 10-year or 15-year time horizon, the HOPE + UC is also unlikely to be cost-effective, with ICERs substantially over the NICE-accepted WTP.

Discussion

Costs

If the HOPE intervention were to be adopted into usual practice, the marginal cost of delivery may decrease, as training costs are dispersed among more participants. However, training costs contributed only 10% of total provision costs. Per-participant costs could also perhaps be decreased by delivery of fewer sessions, less specialist staff mix (lower AfC band) or delivery in a group setting. However, adjustments in these factors may also influence intervention effectiveness, acceptability and feasibility,

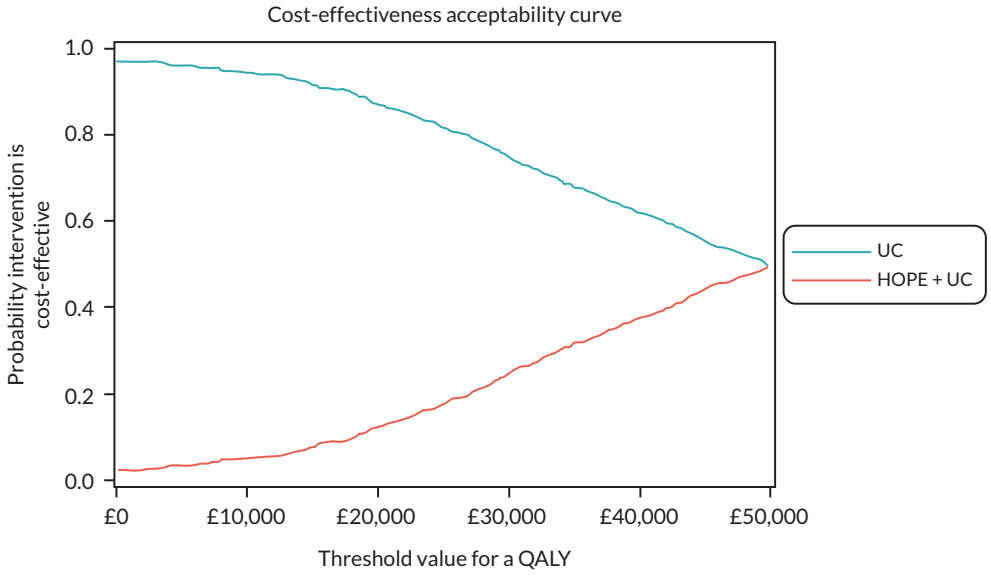

FIGURE 5 Cost-effectiveness acceptability curve: WT analysis, MI data set, PSA with 1000 simulations.

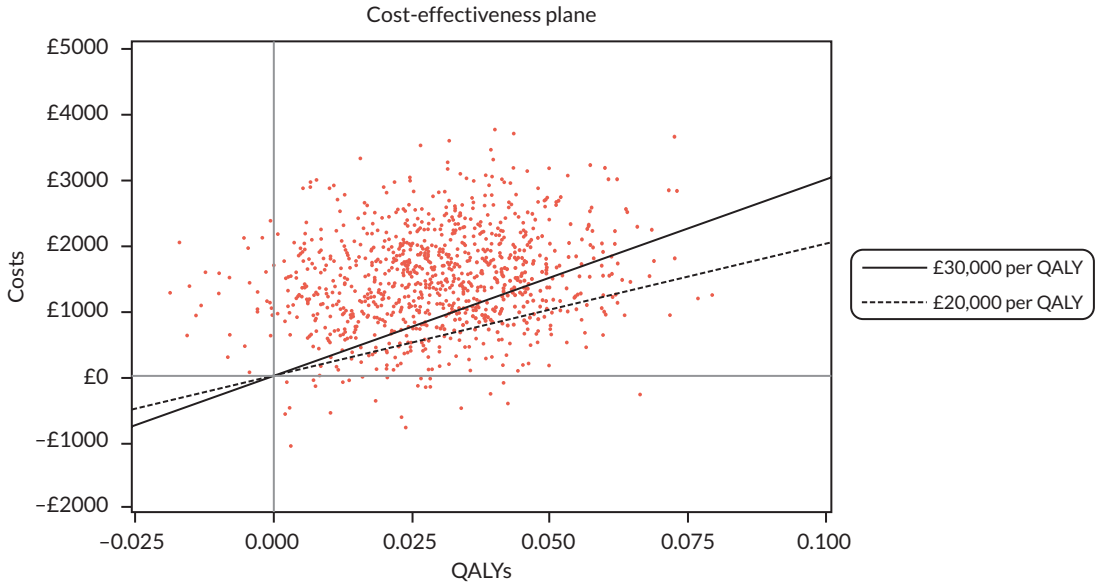

FIGURE 6 Cost-effectiveness plane: WT analysis, MI data set with 1000 simulations.

and, therefore, within this study, we cannot anticipate their impact on cost-effectiveness. Comparative to intervention costs, RU costs and participant QALYs are more uncertain. This is particularly apparent in the DAM, where the 95% CI for modelled incremental costs and QALYs are wide.

Survival analysis

Our survival analysis estimates an 83-year-old female with mild frailty and receiving UC lives 7.5 years before dying; this is similar to the ONS expectant life expectancy estimates for 83-year-old females (7.8 years).[55] Participants in the HOPE arm had non-significantly better survival compared to those in UC. The incremental increase in QALYs was small and associated with increased RU. When extrapolating over a greater time horizon, the incremental HOPE survival was predominantly in the DAM's medium RU state.

Resource use

Challenges of analysing and modelling a cohort of older adults include that there are many relevant health resources to consider each with varying and heterogeneous associations to age and frailty. Our economic analysis addresses some of these challenges through using composite RU states and subgrouping by frailty status. We further highlight that admission to nursing homes is an important and particular contributor to older cohorts' health care.

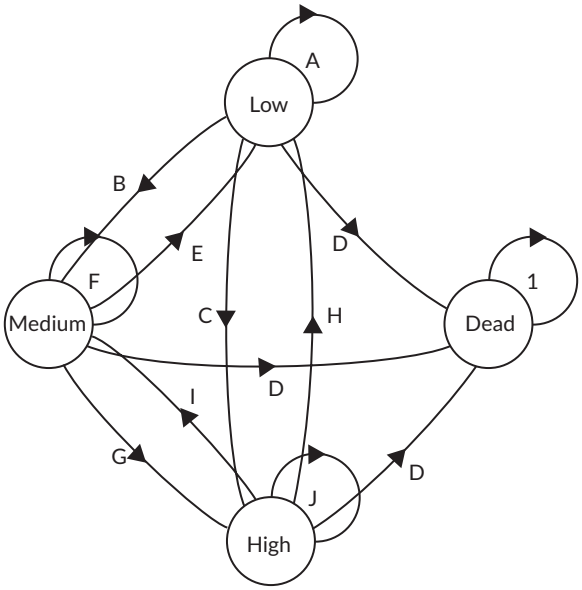

FIGURE 7 Decision-analytic model.

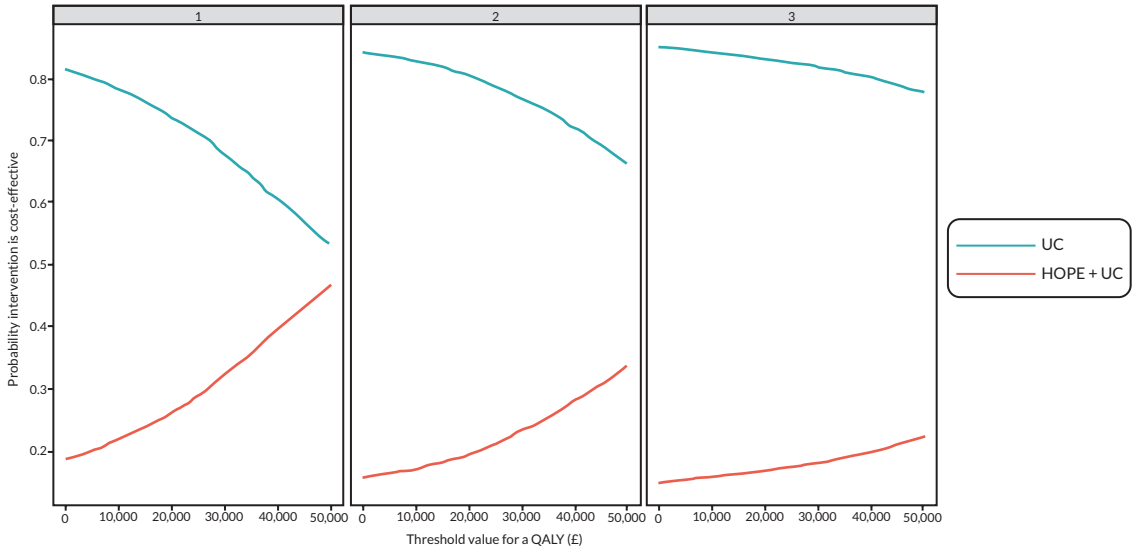

FIGURE 8 Cost-effectiveness acceptability curve. DAM with 5-year time horizon, stranded by frailty status. 1 = mild, 2 = moderate, 3 = severe. Results are from 10,000 samples from PSA. Cohort characteristic: female, aged 83 years, living alone at baseline.

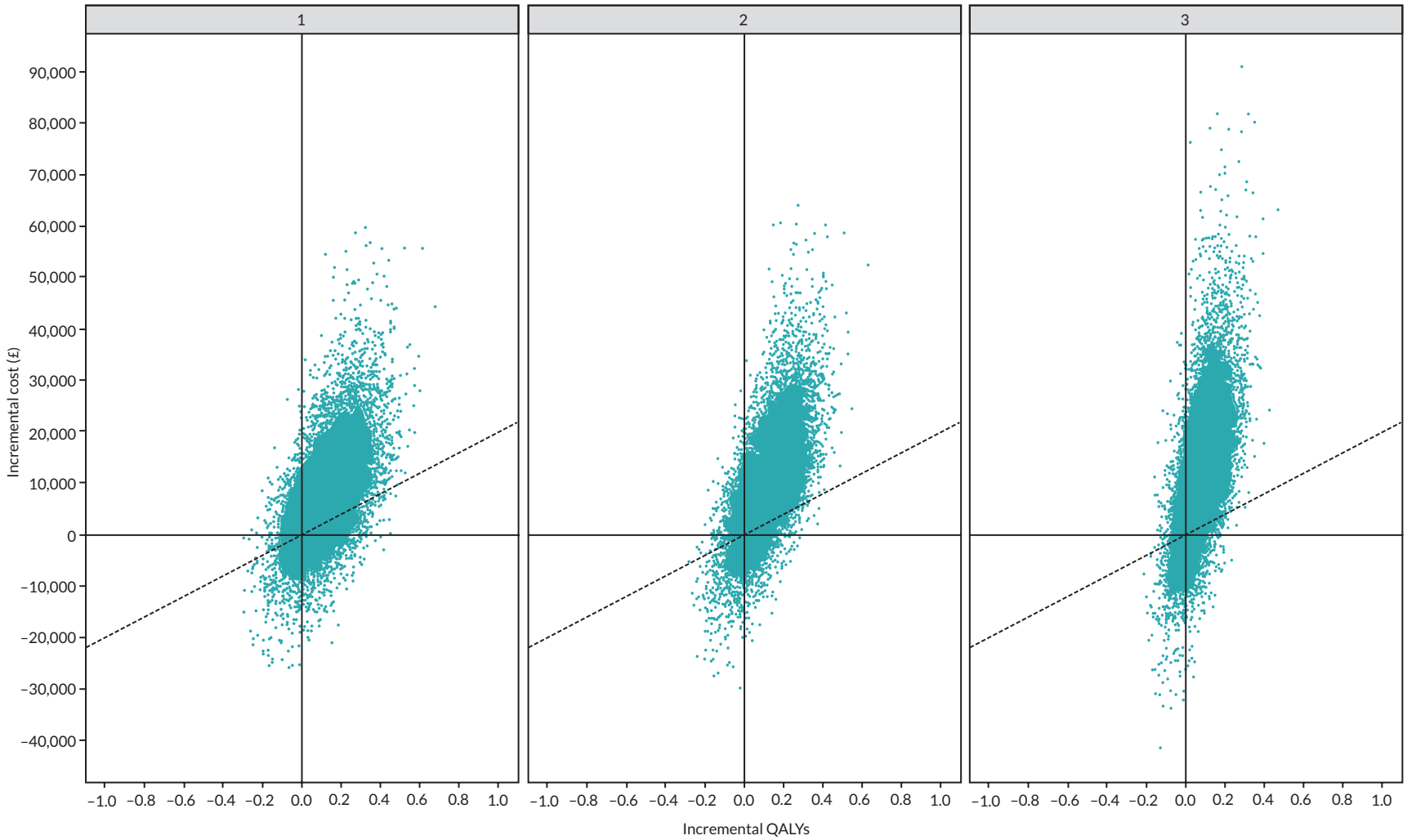

FIGURE 9 Cost-effectiveness plane. DAM 5-year time horizon, stranded by frailty status. 1 = mild, 2 = moderate, 3 = severe. Results are from 10,000 samples from PSA. Cohort characteristics: female, aged 83 years, living alone at baseline.

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Appendix 5

TABLE 5 Demographics of patients screened, eligible to approach, consented, eligible and randomised

	Screened (*n* = 16,687)	Eligible to approach (*n* = 5505)	Consented (*n* = 905)	Eligible (*n* = 775)	Randomised (*n* = 740)
Age					
Mean (SD)	83.7 (7.6)	83.9 (7.0)	83.0 (7.0)	82.7 (7.1)	82.7 (7.1)
Missing	312	210	9	7	0
Gender					
Male	6729 (40.6%)	2000 (36.6%)	318 (35.3%)	269 (34.8%)	254 (34.3%)
Female	9855 (59.4%)	3460 (63.4%)	584 (64.7%)	504 (65.2%)	486 (65.7%)
Missing	103	45	3	2	0
Ethnicity					
White	15011 (92.9%)	4779 (91.9%)	859 (97.2%)	739 (97.6%)	699 (97.6%)
Other[a]	1139 (7.1%)	422 (8.1%)	25 (2.8%)	18 (2.4%)	17 (2.4%)
Missing	537	304	21	18	24
Reason for hospital admission					
Acute illness	12461 (77.2%)	3674 (70.5%)	621 (69.5%)	527 (68.6%)	502 (68.5%)
Injury	3688 (22.8%)	1535 (29.5%)	273 (30.5%)	241 (31.4%)	231 (31.5%)
Missing	538	296	11	7	7

a Data have been grouped to Other to preserve anonymity.

Appendix 6

TABLE 6 Baseline characteristics according to 12-month follow-up status

	Successful (*n* = 479)	Unsuccessful (*n* = 261)	Total (*n* = 740)
Age, years	82.5 (7.2)	82.9 (7.0)	82.6 (7.1)
Gender			
Male	160 (33.4%)	94 (36.0%)	254 (34.3%)
Female	319 (66.6%)	167 (64.0%)	486 (65.7%)
Ethnicity			
White	454 (97.4%)	245 (98.0%)	699 (97.6%)
Other[a]	12 (2.6%)	5 (2.0%)	17 (2.4%)
SF-36 PCS[b]	31.5 (8.0)	30.6 (8.0)	31.2 (8.0)
SF-36 MCS score[b]	48.6 (12.0)	48.2 (10.9)	48.4 (11.6)
Barthel Index score[b]	17.0 (2.6)	16.4 (2.8)	16.8 (2.7)
NEADL (range 0–66) score[b]	42.4 (14.2)	38.5 (14.5)	41.0 (14.4)
CFS score[c]	5.5 (0.6)	5.6 (0.6)	5.5 (0.6)

TABLE 6 Baseline characteristics according to 12-month follow-up status (*continued*)

	Successful (*n* = 479)	Unsuccessful (*n* = 261)	Total (*n* = 740)
CFS score			
Vulnerable	1 (0.2%)	0 (0.0%)	1 (0.1%)
Mild frailty	260 (54.4%)	115 (44.2%)	375 (50.8%)
Moderate frailty	196 (41.0%)	128 (49.2%)	324 (43.9%)
Severe frailty	21 (4.4%)	17 (6.5%)	38 (5.1%)
MoCA score (range 0–30)[b]	23.7 (2.9)	23.1 (2.9)	23.5 (2.9)
Reason for admission			
Acute illness	318 (66.4%)	193 (73.9%)	511 (69.1%)
Injury	161 (33.6%)	68 (26.1%)	229 (30.9%)
Setting discharged from			
Hospital	166 (34.7%)	92 (35.2%)	258 (34.9%)
Bed-based IC	109 (22.8%)	73 (28.0%)	182 (24.6%)
Home-based IC	204 (42.6%)	96 (36.8%)	300 (40.5%)
TUGT score	46.0 (38.9)	47.6 (36.2)	46.6 (37.9)
HOPE level			
Level 1	287 (59.9%)	179 (68.6%)	466 (63.0%)
Level 2	128 (26.7%)	59 (22.6%)	187 (25.3%)
Level 3	64 (13.4%)	23 (8.8%)	87 (11.8%)
Involved in previous rehabilitation programme	31 (6.7%)	9 (3.7%)	40 (5.6%)
Number of comorbidities			
None	130 (27.4%)	70 (27.2%)	200 (27.4%)
≥ 1	344 (72.6%)	187 (72.8%)	531 (72.6%)
Type of comorbidity			
Diabetes mellitus	116 (34.6%)	64 (34.8%)	180 (34.7%)
Chronic obstructive pulmonary disease	91 (27.6%)	56 (30.8%)	147 (28.7%)
Congestive heart failure	69 (20.9%)	50 (27.6%)	119 (23.3%)
Moderate to severe chronic kidney disease	73 (22.1%)	45 (24.9%)	118 (23.0%)
Connective tissue disease	63 (19.3%)	35 (19.4%)	98 (19.3%)
Cerebrovascular disease	52 (15.9%)	21 (11.6%)	73 (14.3%)
Solid tumour (localised)	45 (13.6%)	31 (17.1%)	76 (14.8%)
Solid tumour (metastatic)	2 (4.7%)	5 (17.2%)	7 (9.7%)
Myocardial infarction	40 (12.1%)	31 (17.1%)	71 (13.9%)
Peripheral vascular disease	25 (7.6%)	19 (10.1%)	44 (8.7%)
Malignant lymphoma	6 (1.8%)	6 (3.3%)	12 (2.4%)
Dementia	6 (1.8%)	6 (3.3%)	12 (2.3%)
Peptic ulcer disease	5 (1.5%)	3 (1.7%)	8 (1.6%)

continued

TABLE 6 Baseline characteristics according to 12-month follow-up status (*continued*)

	Successful (*n* = 479)	Unsuccessful (*n* = 261)	Total (*n* = 740)
Leukaemia	8 (2.4%)	0 (0.0%)	8 (1.6%)
Hemiplegia	6 (1.8%)	0 (0.0%)	6 (1.2%)
Liver disease	2 (0.6%)	4 (2.2%)	6 (1.2%)

Barthel Index, Barthel Index of ADL, range 0–20; CFS, Clinical Frailty Scale, range 0–9; F-36 MCS, SF-36 mental component score, range 0–100; SF-36 PCS, SF-36 physical component score, range 0–100.
a Data have been grouped to Other to preserve anonymity.
b Higher scores are better.
c Lower scores better.
d Self-reported, not mutually exclusive.

Note
Data are mean (SD) or *n* (%).

Appendix 7

TABLE 7 Eligibility violations and withdrawals

	HOPE (*n* = 410)	Control (*n* = 330)	Total (*n* = 740)
Has an eligibility violation been noted for the participant?			
Yes	20 (4.9%)	3 (0.9%)	23 (3.1%)
No	390 (95.1%)	327 (99.1%)	717 (96.9%)
Has participant withdrawn from questionnaires, optional interviews or further data collection?			
Yes	77 (18.8%)	30 (9.1%)	107 (14.5%)
No	333 (81.2%)	300 (90.9%)	633 (85.5%)

Appendix 8

TABLE 8 Summary of intervention delivery and content

	Commenced intervention (*n* = 332)
Timing of first home visit	
Mean (SD)	20.9 (19.02)
Number of contacts	
Median (range)	18 (1, 26)
Number of home visits	
Median (range)	5 (1, 9)
Number of telephone contacts	
Median (range)	14 (1, 22)
Level of exercise prescribed	
Level 1	178 (53.6%)
Level 2	85 (25.6%)

TABLE 8 Summary of intervention delivery and content (*continued*)

	Commenced intervention (*n* = 332)
Level 3	52 (15.7%)
Level 1 and 2	1 (0.3%)
Not prescribed exercises	16 (4.8%)
Number of exercises completed per home visit	
Mean (SD)	6.0 (2.6)
Percentage of prescribed exercises completed	
< 50%	69 (21.5%)
Between 50% and 75%	76 (23.7%)
More than 75%	176 (54.8%)
Number who had goals set	292 (88.0%)
Number of goals set	
Mean (SD)	2.2 (1.5)
Number of goals achieved	
Median (range)	0.0 (0, 55)
Time taken to achieve goals (days)	
Median (range)	35.0 (0, 283)
Participant engaged with weekly diary entries	278 (83.7%)
Number of weekly exercise diaries completed	
Median (range)	17.5 (0, 37)
Length of engagement with weekly exercise diaries (weeks)	
Median (range)	22.9 (0, 129)

Appendix 9

TABLE 9 Summary of deaths and hospitalisations due to falls or fracture

	HOPE (*n* = 410)	Control (*n* = 330)	Total (*n* = 740)
Did participant die?			
Yes	63 (15.4%)	62 (18.8%)	125 (16.9%)
No	347 (84.6%)	268 (81.1%)	615 (83.1%)
Was participant hospitalised due to fall or fracture?			
Yes	50 (12.2%)	46 (13.9%)	96 (13.0%)
No	360 (87.8%)	284 (86.1%)	644 (87.0%)
Number of hospitalisations due to falls and fractures			
Mean (SD)	0.2 (0.50)	0.2 (0.48)	0.2 (0.49)

Appendix 10

TABLE 10 Summary of UC services accessed

	HOPE (*n* = 410)	Control (*n* = 330)	Total (*n* = 740)
Did researcher complete a 12-month UC ***review for participant?***			
Yes	204 (49.8%)	166 (50.3%)	370 (50.0%)
No	206 (50.2%)	164 (49.7%)	370 (50.0%)
UC service accessed			
Planned GP contact	111 (54.4%)	89 (53.6%)	200 (54.1%)
District nurse or health visitor	108 (52.9%)	90 (54.2%)	198 (53.5%)
Practice nurse	78 (38.2%)	53 (31.9%)	131 (35.4%)
Community matron	52 (25.5%)	47 (28.3%)	99 (26.8%)
Physiotherapist or occupational therapist	56 (27.5%)	42 (25.3%)	98 (26.5%)
Podiatrist/chiropodist	43 (21.1%)	31 (18.7%)	74 (20.0%)
Other rehabilitation/therapy team member	30 (14.7%)	25 (15.1%)	55 (14.9%)
Unplanned GP contact	20 (9.8%)	19 (11.4%)	39 (10.5%)
Advanced nurse practitioner	19 (9.3%)	15 (9.0%)	34 (9.2%)
Community pharmacist	17 (8.3%)	6 (3.6%)	23 (6.2%)
Speech and language therapist	14 (6.9%)	5 (3.0%)	19 (5.1%)
Community mental health team	4 (2.0%)	6 (3.6%)	10 (2.7%)
Social worker	6 (2.9%)	3 (1.8%)	9 (2.4%)