Clinical and cost-effectiveness of a home-based health promotion intervention for older people with mild frailty in England: a multicentre, parallel-group, randomised controlled trial

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Summary

Background Health promotion for people with mild frailty has the potential to improve health outcomes, but such services are scarce in practice. We developed a personalised, home-based, behaviour change, health promotion intervention (HomeHealth) and assessed its clinical effectiveness and cost-effectiveness in maintaining independent functioning in activities of daily living in older adults with mild frailty.

Methods This trial was an individual, multicentre, parallel-group, randomised controlled trial done in England. Participants were mainly recruited from general practices in three different areas of England (the London north Thames region, east and north Hertfordshire, and west Yorkshire). Participants were individuals residing in the community who were registered with a general practice, 65 years and older with mild frailty (scoring 5 on the CFS), with a life expectancy of more than 6 months, and with capacity to consent to participate. We excluded adults residing in nursing or care homes, those with moderate-to-severe frailty or with no frailty, those receiving palliative care, and those already case managed (eg, receiving a similar ongoing intervention from the voluntary sector or community service). Eligible participants were randomly assigned 1:1 to either the HomeHealth intervention or to treatment as usual. HomeHealth is a multidomain health promotion intervention delivered by the voluntary sector at home in six sessions over 6 months. The primary outcome was independent functioning (assessed using the modified Barthel Index [BI]) at 12 months. Outcome assessments were masked and were analysed by intention to treat using linear mixed models. Incremental costs and quality-adjusted life-years (QALYs) were calculated using seemingly unrelated regression and bootstrapping. The trial is registered on the ISRCTN registry (ISRCTN54268283).

Findings We recruited 388 participants between Jan 8, 2021 and July 2, 2022 (mean age 81 years, SD 6·5; 249 (64%) of 388 were women and 139 (36%) were men). 195 participants were randomly assigned to HomeHealth and 193 to treatment as usual. Median follow-up was 363 days (IQR 356–370) in the HomeHealth group and 362 days (IQR 355–373) in the treatment-as-usual group. HomeHealth did not improve BI scores at 12 months (mean difference 0·250, 95% CI –0·932 to 1·432). HomeHealth was superior to treatment as usual with a negative point estimate for incremental costs (–£796; 95% CI –2016 to 424) and positive point estimate for incremental QALYs (0·009, –0·021 to 0·039). There were 55 serious adverse events in the HomeHealth group and 85 in the treatment-as-usual group; none were intervention related.

Interpretation HomeHealth is a safe intervention with a high probability of cost-effectiveness, driven by a reduction in unplanned hospital admissions. HomeHealth should be considered as a health promotion intervention for older people with mild frailty.

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Introduction

Frailty is defined as a reduction in physiological reserves across several body systems with age, inhibiting recovery from stressor events such as infections or falls.[1] Frailty is present in approximately 12% of people older than 50 years worldwide,[2] and is consistently associated with adverse outcomes including poorer quality of life,[3] increased mortality,[4] and risk of hospital admission.[5] Health-care costs are higher in people who are more frail, mainly because of increased inpatient costs.[6] Guidelines for frailty recommend a range of interventions, including exercise programmes based on resistance training, social support,

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Research in context

Evidence before this study

We searched MEDLINE and Embase from inception to May 20, 2024 for systematic reviews and meta-analyses of interventions to promote health in older people with mild frailty or prefrailty, using the terms "mild frail*", "early frail*", "transitioning to frail*", "transitionally frail", "prefrail", "pre-frail", and "pre frail", combined with "intervention$", "meta-analysis", and "systematic review". As shown from 11 meta-analyses including 7–21 randomised controlled trials, the most effective intervention to improve functioning and reduce frailty is tailored, supervised, group-based exercise; additional benefits can potentially be gained from including a nutritional or cognitive component. Multidomain interventions appear to be more effective, although there is little clarity on whether social and psychological components are effective. Evidence was low-to-moderate quality. Few studies have evaluated the cost-effectiveness of interventions to support older people with mild frailty.

Added value of this study

HomeHealth is one of the few health promotion interventions for older adults with mild frailty delivered by non-specialist support workers based in the voluntary sector that have been evaluated and found cost-effective in a pragmatic trial. Furthermore, to our knowledge, it is the first of these services to show that a health promotion intervention can reduce unplanned hospital admissions in this population.

Implications of all the available evidence

Multidomain tailored interventions for older adults with mild frailty, such as HomeHealth, could reduce unplanned admissions and associated secondary care costs; however, the HomeHealth intervention showed little benefit for independent functioning. Enabling group-based exercise activities was limited by COVID-19 restrictions during trial delivery, which might have affected clinical effectiveness, given previous evidence suggesting that tailored group-based exercise is beneficial in improving independence. Strengthening the exercise component of HomeHealth might be necessary to achieve effects on independent functioning.

and comprehensive care plans addressing polypharmacy, sarcopenia, treatable causes of weight loss and fatigue, and protein or caloric supplementation for weight loss or malnutrition.[7] However, despite policy emphasis on prevention and ageing well through proactive identification of those who might benefit from targeted support to maintain independence, guidance on frailty prevention or upstream interventions is scarce.

Earlier stages of frailty, such as mild frailty, might be optimal to target because there is evidence that those in the earlier stages of frailty are more likely to become more robust over time than those who have more severe frailty.[8] Mild frailty represents an intermediate, early stage of frailty, defined on the Clinical Frailty Scale (CFS) as cases in which individuals experience some loss of physiological reserves but can recover from a stressor event, often feeling tasks take longer and they get easily tired, and requiring some assistance in instrumental activities of daily living such as cooking, shopping, and money management.[9] Around 13% of older people (aged 65 years and older) can be classified as having mild frailty.[9] Few interventions have targeted this population.[10]

Lifestyle and behaviour changes have an important role in frailty progression. Maintaining or increasing exercise and maintaining a stable bodyweight reduces the risk of worsening frailty.[11] There is evidence that resistance training improves frailty,[12,13] and that physical activity and multicomponent and nutrition interventions all reduce frailty compared with usual care in trials with older adults who are frail.[14] Community-based complex interventions with holistic assessment and personalised care planning and care coordination for older people have been shown to be associated with modest improvements in independent functioning, cognition, and mortality risk, but not quality of life.[15] Independent functioning encompasses a variety of skills that enable an individual to live autonomously. However, these multidomain interventions can vary greatly in content, and rarely report a clear underpinning theory of change, rigorous development process, or stakeholder input into intervention development. Furthermore, many interventions are resource-intensive, with concerns about delivery at scale and with scarce data on cost-effectiveness.[13] There is, therefore, still considerable uncertainty about optimal person-centred interventions to improve outcomes for older people who are frail, particularly those with mild frailty, that can be delivered in routine practice at scale.

We developed a new personalised intervention to support independence and prevent frailty progression in older people with mild frailty (HomeHealth), on the basis of behaviour change theory, an asset-based approach, and Baltes' model of successful ageing.[16] We previously did a feasibility trial in 51 older people with mild frailty in two areas in England, which showed that the intervention was well received and the study was feasible and showed promising effects on independence in activities of daily living (ADLs), grip strength, and psychological distress.[16] We therefore aimed to test the clinical and cost-effectiveness of HomeHealth in maintaining independence in older people with mild frailty in a randomised controlled trial (RCT) in comparison to treatment as usual.

Methods

Study design and participants

We carried out a multicentre, parallel-group, RCT in three regions of England, with a published protocol[17] and within-trial cost–utility analysis. We did a parallel mixed-methods

process evaluation as described in our protocol,[17] and the results of this evaluation are reported separately.[18] Our protocol and the statistical analysis plan are available at the ISRCTN registry.

Recruitment was done in a period during which a range of national COVID-19 pandemic-related restrictions were in place in the UK. A UK national lockdown between January and March, 2021 precluded face-to-face trial and intervention visits during this period. Participants were mainly recruited from general practices in England, in three different areas (the London north Thames region, east and north Hertfordshire, and west Yorkshire; appendix p 4). Practices carried out list searches to identify potential participants, using the Electronic Frailty Index (eFI).[19] We initially identified people scoring as mild-to-moderate frailty on the eFI (ie, scoring 0·12 to 0·36 on the eFI) and these potential participants were screened by clinicians to identify those patients not eligible for participation (eg, those who did not have capacity). A study invitation pack was sent by practices to eligible patients inviting them to respond if they felt they might have frailty-related symptoms (eg, feeling slowed up or not having energy) and might be interested in participating. We additionally recruited through a range of community channels, including supported housing, day centres, voluntary sector organisations, and older people's organisations. Because of pandemic-related restrictions, we were mostly limited to reaching out through organisation mailing lists, with limited face-to-face outreach undertaken towards the end of recruitment.

Interested participants were then initially screened over the telephone by the research team using criteria based on the CFS to identify those likely to have mild frailty. Potentially eligible people were then invited to participate in a baseline assessment at their home with a research assistant (SK, MP, or GT). If participants did not speak English, a translation service or a research colleague who spoke the language was available to complete screening or assessment. Researchers completed written consent (if face to face), or audio-recorded verbal consent (if remote assessment) for all participants.

We included older people aged 65 years and older residing in the community, including those living in sheltered or extra-care housing (typically housing in which residents live independently, but with onsite support), who had mild frailty based on the CFS[9] (score 5). Participants needed to be registered with a general practice (family physician) in the participating site area, have a life expectancy of more than 6 months, and have capacity to consent to participate. We excluded adults residing in nursing or care homes, those with moderate-to-severe frailty (CFS score 6–9) or with no frailty (CFS score 1–4), those receiving palliative care, and those already case managed (eg, receiving a similar ongoing intervention from the voluntary sector or community service).

The study was reviewed and approved by the Health Research Authority Social Care Research Ethics Committee (20/IEC08/0013). Modifications caused by the COVID-19 pandemic were reviewed and approved by the Research Ethics Committee and by our independent Trial Steering Committee.

For more on the **ISRCTN registry** see https://www.isrctn.com/ISRCTN54268283

See **Online** for appendix

Randomisation and masking

Participants were randomly assigned 1:1 to receive the HomeHealth service or treatment as usual, stratified by site. Randomisation was carried out by unmasked staff members using the remote computerised web-based application Sealed Envelope, provided by the Priment CTU at University College London, London, UK, within 4 weeks of completion of a baseline assessment. The outcome assessors (research assistants SK, MP, and GT), Chief Investigator (KW), Trial Manager (RF), and Trial Management Group members (LM, SP, JH, BG, DAS, RLG, CC, VMD, KK, PL, and RH) who were not site Principal Investigators or involved in intervention delivery were all masked to participant allocation. Participants in the intervention group were allocated to a support worker, who commenced the intervention within 4 weeks of randomisation. We were unable to mask participants because of the nature of the intervention. To assess masking, we asked researchers at 12 months to report whether they were aware of or could guess group allocation.

Procedures

The HomeHealth intervention was developed through evidence reviews, qualitative research, and codesign workshops with stakeholders; further information about the development and structure of the intervention is reported in detail elsewhere,[16] and the TIDieR summary is in our protocol paper.[17] HomeHealth is a theory-based, manualised, multidomain tailored intervention, delivered over approximately six appointments over 6 months (minimum three appointments, with up to 12 appointments for complex needs such as several hospital admissions). Three voluntary-sector (non-governmental) organisations (Age UK Bradford & District, Age UK Camden, and Health and Independent Living Support) hosted between one and three part-time HomeHealth support workers (anticipated total 6–8 support workers seeing 24–33 clients each, actual total support workers n=7) and provided organisation-specific training, office space, information technology, and local supervision. HomeHealth workers were required to have experience working with older people, but not to have a specific health or social care qualification. HomeHealth workers followed a 1-week online training programme, including synchronous and asynchronous content on mild frailty, communication skills, strength and balance exercises, nutrition, psychological wellbeing, and behaviour change. A train-the-trainer approach was taken, with initial delivery by topic experts and subsequent delivery by a team leader (also involved in service delivery). HomeHealth workers were provided with an intervention manual and resources, supervised in fortnightly group supervisions by the team leader, with one-to-one supervision provided as needed, and top-up case-based training in behaviour change

approximately 3 months after the first training session. Topic experts could also be contacted for further support and information for complex cases.

During intervention sessions, the older person discussed what was important for them to live well, including in the domains of mobility, nutrition, psychological wellbeing, and socialising. Participants and support workers then agreed on an overall outcome goal, SMART goals (ie, specific, measurable, achievable, relevant, time-bound) to achieve this overall goal, and an action plan that assessed capability, motivation, and opportunity to achieve goals and included strategies to overcome any barriers. Action plans were tailored to individuals and included strength and balance exercises (via facilitated attendance at local group classes or selected exercises from the home-based Otago exercise programme for falls prevention[20] with hand grip exercises added), dietary changes, and increasing social contacts, among other components. Exercise equipment, such as resistance bands, ankle weights, and grip strengtheners, was provided for free where needed. HomeHealth workers also enabled access to relevant organisations and resources (eg, information about benefits and psychological therapy services). Progress towards goals was reviewed, with goals modified if needed or new goals added if previous goals were achieved. At the final appointment, progress was summarised, with further signposting as needed.

HomeHealth was originally planned to be delivered face to face in the homes of participants; however, during the earlier stages of intervention delivery, the service was provided entirely remotely (by video or telephone) because of COVID-19 pandemic-related restrictions. We offered participants the option to defer entry into the study until HomeHealth could be delivered in person, which was a popular option. We also offered study-funded, internet-enabled tablets to intervention participants to aid participation in the intervention via videoconferencing, but no participants took up this offer. When face-to-face intervention delivery was possible, participants were offered a choice of face-to-face or remote delivery; most participants chose the face-to-face option. All intervention sessions were audio-recorded with participant consent, and fidelity checklists were completed. Intervention fidelity and adherence are reported in our parallel-process evaluation paper, published separately.[18]

The treatment-as-usual control group received standard care that any patient aged 65 years and older would normally receive in primary care in England. No particular mild frailty intervention was widely available in the UK at the time of the trial; our feasibility study data suggested that treatment as usual consists of routine general practice, practice nurse, and outpatient appointments as needed.[16]

Public contributors were involved throughout study development and setup, and were crucial in helping to adapt the study to pandemic-related restrictions in ways that were acceptable to older people. Throughout the study, our patient and public involvement lead (JH) attended Trial Management Group meetings, and all public contributors provided feedback at key points, particularly regarding recruitment methods, designing participant newsletters, contributing to the process evaluation, and planning dissemination of results.

The HomeHealth RCT was overseen by an independent Trial Steering Committee (including three independent public contributors) and Data Monitoring and Ethics Committee (DMEC), which met on six occasions during the period of Nov 20, 2020 to Oct 24, 2023. A CTU statistician who did not do the final analysis completed the interim assessments for the DMEC. Masked research staff (the Chief Investigator KW, lead trial statistician LM, and Trial Manager RF) did not attend the unmasked section of the DMEC meetings.

Outcomes

Clinical outcomes were measured at baseline, at 6 months, and at 12 months by a researcher masked to intervention status. In the original protocol, all outcome assessments were to be done face to face, but this type of assessment was modified to allow for remote assessments (video-conferencing or telephone) according to government guidelines for prevention of COVID-19 infection and the preferences of the participants, because of COVID-19 pandemic restrictions on research activities at the time.

The primary outcome was the modified Barthel Index (BI)[21] at 12 months, a widely used, validated measure of perceived ability to undertake basic ADLs, a measure of independent functioning. The BI was interviewer-administered and scoring was based on discussions with participants about their self-reported ability to undertake basic ADLs. We also collected data on instrumental activities of daily living (IADLs; Nottingham Extended Activities of Daily Living [NEADL]),[22] wellbeing (Warwick-Edinburgh Mental Wellbeing Scale [WEMWBS]),[23] psychological distress (General Health Questionnaire-12 [GHQ-12]),[24] loneliness (University of California, Los Angeles [UCLA] 3-Item [UCLA-3] Loneliness Scale),[25] cognition (Montreal Cognitive Assessment [MoCA][26] or the telephone MoCA [t-MoCA; remote items only]),[27] falls (ProFANE consensus definition,[28] number of falls in the past 6 months), and mortality. The frailty outcome was assessed using the Fried phenotype.[1,29] Following protocol changes to allow for remote assessments, gait speed and grip strength were measured using both validated self-reported questions[30] (to remotely collect these data) and, when possible, objective face-to-face assessments. Physical activity was measured by the International Physical Activity Questionnaire-Elderly,[31] exhaustion by the two questions from the seven-item Centre for Epidemiological Studies Depression Scale,[29] and weight loss by the weight loss question from the Mini-Nutritional Assessment Short Form.[32] At baseline, we also collected data on alcohol intake using the Alcohol Use Disorders Identification Test–Consumption (AUDIT-C),[33] smoking status, socioeconomic deprivation by postcode, and demographic information, including self-identified gender.

Health economic outcomes of quality of life (EQ-5D-5L),[34] capability (ICECAP-O),[35] and carer burden (adapted from the Institute for Medical Technology Assessment Valuation of Informal Care Questionnaire),[36] and data regarding health care, social care, and community service use, and over-the-counter medications, vitamins, and food supplements were collected by a self-report modified client-services receipt inventory (CSRI)[37] measuring resource use at baseline, at 6 months, and at 12 months. Prescriptions and other health-service use, including unplanned hospital admissions, were collected from primary care medical records at 12 months for the health economic analysis. Our protocol gives full details on our outcome measurements.[17]

To optimise retention at follow-up, we offered a brief assessment if participants were unable to complete a full assessment (eg, because of time or fatigue). This assessment consisted of the BI, EQ-5D-5L, Fried phenotype, and ascertainment of adverse events collected by telephone, and the remaining assessments were posted to participants for self-completion. These assessments were administered in order of priority and participants were followed up if these were not returned. The MoCA was not used in these brief assessments because of the time required to complete and its lower priority compared to other assessments. Data on serious adverse events (SAEs) were collected at each research assessment by masked researchers, by ongoing self-reporting from participants, and from review of medical notes. Support workers additionally provided data on adverse events. Our clinical site Principal Investigators and our independent clinical safety lead assessed all adverse events and SAEs for severity and relatedness to the intervention. The masked SAEs were reviewed by the Chief Investigator and by the CTU safety officer.

Statistical analysis

To provide 90% power at a two-sided 5% significance level in order to detect a minimum clinically important difference of 1·85 points[38] on the modified BI, with an SD of 5, 308 participants were required. Assuming 20% attrition over 12 months, we aimed to recruit 386 participants (193 per group). At the time of trial design, no trials in people with mild frailty had reported intraclass correlation coefficients (ICCs) for therapist clustering. Unpublished PhD thesis data examining therapist effects in a secondary analysis of a cluster group-based exercise trial in older people did not find significant clustering by therapist (ICC 0·01; p=0·54). We did not adjust for clustering by therapist in our sample size.

All analyses were done by modified intention to treat (defined as all those with data available for the given analysis) and by complete case, with no missing data imputation, and conducted by a masked statistician using Stata version 18. Participants' baseline characteristics were descriptively summarised by group. We analysed the primary outcome using linear mixed models with an identity covariance structure, including 6-month and 12-month data, controlling for baseline BI score and site (the stratification variable). Continuous secondary outcomes were analysed in the same way, with dichotomous outcomes (death, weight loss, and exhaustion) analysed using logistic regression. Falls were analysed using Poisson regression. The significance threshold was set to $p<0·05$. We did not make adjustments for multiplicity of outcomes. We examined baseline predictors of missingness for the primary outcome and included any significant predictors of missingness in a sensitivity analysis to restore the missing at random assumption using a similar model to the primary analysis. In a supplementary analysis, we accounted for clustering by therapist using random effects and calculated the ICC for our primary outcome (BI). Further supplementary analysis was done as part of our parallel process evaluation to explore fidelity, dose, and mechanisms, which will be reported separately.

For the health economic analysis, the same data-handling procedures were used as the main clinical effectiveness analysis. The economic analysis used the EQ-5D-5L to calculate the mean incremental cost per quality-adjusted life-year (QALY) gained of HomeHealth compared to treatment as usual at 12 months from a UK health and social care perspective. EQ-5D-5L scores were converted to utility scores using Devlin and colleagues' UK tariffs.[39] QALYs were calculated using the area-under-the-curve method[40] adjusting for baseline using patient-level utility scores. Resource use was costed in 2021–22 British pounds using published sources (appendix pp 1–3). The costs of training and intervention delivery were based on a budget-impact tool developed as part of the feasibility trial and assuming UK National Health Service (NHS) band-5 staff. Unplanned admissions, incremental costs, and QALYs were calculated using generalised linear models, with models chosen on the basis of the Akaike Information Criterion and Bayesian Information Criterion, with adjustment of baseline costs and utilities with fixed effects for site. Seemingly unrelated regression and bootstrapping of complete cases was used to calculate 95% CIs, cost-effectiveness acceptability curves, and cost-effectiveness planes. Years of full capability, the implications for service planning, and the budget impact will be published elsewhere. We conducted a sensitivity analysis to explore the effect of missing data for the CSRI.

This study is registered as an ISRCT number ISRCTN54268283. We developed a detailed statistical analysis plan before commencing analysis.

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, writing of the report, or the decision to submit for publication.

Results

We recruited 388 participants to the trial between Jan 8, 2021 and July 2, 2022, exceeding the recruitment target of 386 participants (figure). Of the 388 baseline assessments, 307 were done in person, 62 by telephone, and 19 by videoconferencing. At 6 months, 345 (89%) of 388 participants completed follow-up assessments;

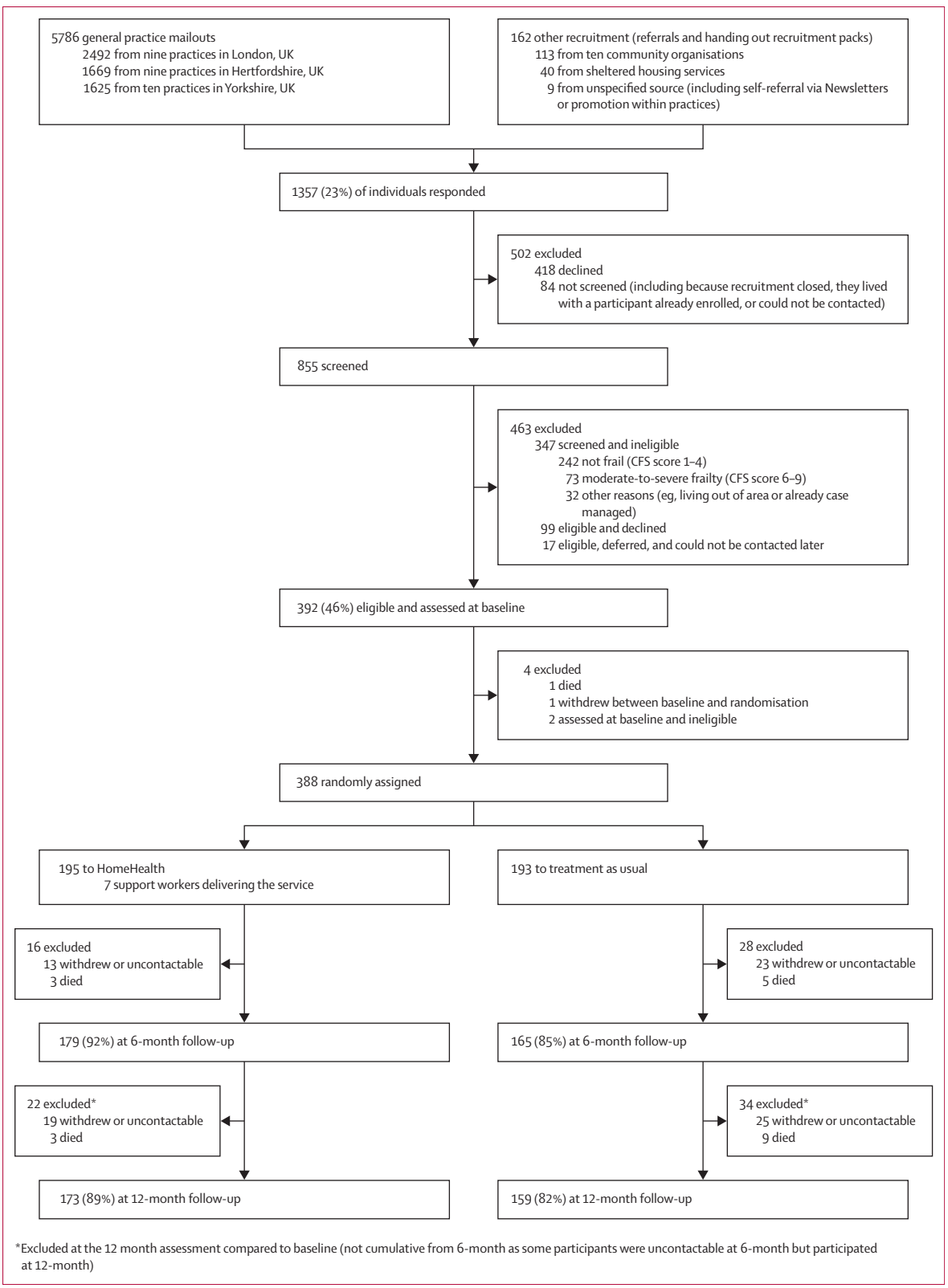

Figure: **CONSORT diagram recruitment and retention**
CFS=Clinical Frailty Scale.

253 assessments were carried out in person, 80 by telephone, and 12 by videoconferencing. At 12 months, 334 (86%) of 388 participants completed follow-up assessments; 252 assessments were carried out in person, 70 by telephone, and 12 by videoconferencing. Median follow-up was 363 days (IQR 356–370) in the HomeHealth group and 362 days (355–373) in the treatment-as-usual group. Follow-up rates were higher in the HomeHealth group (figure). Overall ten (5%) of 195 participants withdrew from the intervention; five participants withdrew before the intervention started and five withdrew during the intervention delivery period. Intervention sessions were well attended (mean attendance 5·33 appointments, SD 1·42, of the six intended), with 182 (93%) of 195 participants attending the minimum number of three or more appointments. Further detail on intervention fidelity and adherence is reported in our process evaluation paper.[18]

Participants had a mean age of 81 years (SD 6·5), and were mostly female and of White ethnicity (table 1). The sample was varied according to educational level, and most participants were retired and received a state pension. Participants had moderate alcohol intake (median AUDIT-C score 2), a mean of 5·26 (SD 2·22) long-term conditions, and few were current smokers. Demographics were similar between randomised groups.

At baseline, participants had a mean BI score of 96·0 (SD 5·59) and a NEADL score of 45·7 (SD 9·7), indicating little impairment in basic ADLs but some impairment in IADLs, as expected in a sample of adults with mild frailty. The mean score for the MoCA was 23·4 (SD 4·0), indicating mild cognitive impairment. At baseline, all participants scored 5 on the CFS and had a mean score of 1·88 (SD 1·22) on the Fried Phenotype Frailty Score.

We found no statistically significant effects of the HomeHealth intervention on our primary outcome of basic ADLs (BI). BI scores remained similar throughout the 12-month follow-up, with no difference between groups at 6 months or 12 months (table 2). The 95% CI did not include 1·85, the minimal clinically important difference for the BI. Similarly, there were no statistically significant differences between groups on IADLs (NEADL), cognition (t-MoCA), falls, loneliness (UCLA-3), quality of life (EQ-5D-5L), or capability (ICECAP-O) at 6 months or 12 months (table 2). At 6 months, we found small statistically significant effects on psychological distress (GHQ-12) and on frailty phenotype scores favouring the intervention group. However, these effects did not persist at 12 months, although we found a small statistically significant improvement in wellbeing (WEMWBS) in the intervention group, compared to the control group, at 12 months. There were no statistically significant differences between groups in any of the frailty phenotype model components (gait speed, grip strength, physical activity, weight loss, and exhaustion; appendix pp 5–6). Mortality was non-significantly lower in the HomeHealth group (three *vs* nine deaths; odds ratio 0·32, 95% CI 0·091–1·20; p=0·091).

	HomeHealth (n=195)	Treatment as usual (n=193)
Median age (years)	81·0 (76·0–86·0)	82·0 (76·0–86·0)
Gender		
Male	72 (37%)	67 (35%)
Female	123 (63%)	126 (65%)
Prefer not to say	0	0
Other (including transwoman/transfeminine, transman/transmasculine, non-binary, gender-queer or intersex)	0	0
Ethnicity		
White	181 (93%)	183 (95%)
Asian	7 (4%)	3 (2%)
Black	3 (2%)	3 (2%)
Any other or mixed ethnic group	4 (2%)	4 (2%)
Birth place		
UK	159 (81%)	167 (87%)
Another country	36 (18%)	26 (14%)
Sexuality		
Heterosexual or straight	189 (97%)	189 (98%)
LGB (plus other)	2 (1%)	4 (2%)
Prefer not to say	4 (2%)	0
Living arrangements		
Lives alone	111 (57%)	113 (59%)
Lives with spouse or partner	66 (34%)	62 (32%)
Lives with children	6 (3%)	6 (3%)
Lives with a friend or other	12 (6%)	12 (6%)
Marital status		
Single	18 (9%)	15 (8%)
Cohabiting, married, in a civil partnership	74 (38%)	68 (35%)
Separated or divorced	27 (14%)	30 (16%)
Widowed	76 (39%)	78 (41%)
Other	0	2 (1%)
Housing		
Owner occupied	139 (71%)	127 (66%)
Council rented, housing association rented, or social housing rented	29 (15%)	47 (24%)
Private rented	9 (5%)	4 (2%)
Sheltered housing	10 (5%)	9 (5%)
Other	8 (4%)	6 (3%)
Pension		
State pension	192 (99%)	193 (100%)
Employer pension	88 (45%)	89 (46%)
Private pension	76 (39%)	69 (36%)
Education level		
No formal qualifications	63 (32%)	63 (33%)
General certificate of education, O-level, or equivalent	37 (19%)	34 (18%)
A-level or equivalent	12 (6%)	17 (9%)
Higher national diploma or equivalent	27 (14%)	23 (12%)
Degree or higher degree	56 (29%)	56 (29%)
Mean Index of Multiple Deprivation score (deciles with 1 [most deprived] to 10 [least deprived])	5·8 (2·8)	6·1 (2·8)
Smoking status		
Current smoker	8 (4%)	6 (3%)
Never smoker	86 (44%)	74 (38%)
Ex-smoker	101 (52%)	113 (59%)

(Table 1 continues on next page)

	HomeHealth (n=195)	Treatment as usual (n=193)
(Continued from previous page)		
Median AUDIT-C (alcohol consumption) score (n=387)	2 (1–4)	2 (1–4)
Mean number of long-term conditions (n=345)	5·27 (2·20)	5·25 (2·24)
Site		
London region	71 (36%)	71 (37%)
Hertfordshire	68 (35%)	67 (35%)
Yorkshire	56 (29%)	55 (29%)

Data are mean (SD), median (IQR), or n (%).

Table 1: **Demographic characteristics of all randomly assigned participants by study group**

A sensitivity analysis of our primary outcome (BI) that included baseline predictors of missingness at 12 months (NEADL score, MOCA score, frailty exhaustion, and physical activity criteria) did not change the findings (difference 0·506, 95% CI –0·807 to 1·820; appendix p 15). In the supplementary analysis accounting for clustering by therapist as a random effect, the findings were similar to those in our main analysis, with no difference between groups at 6 months (mean difference –0·137, 95% CI –1·303 to 1·029) or 12 months (mean difference 0·250, –0·932 to 1·432). The ICC for the therapist for the BI was 0·079 (95% CI 0 to 0·207).

The mean total cost per participant of the HomeHealth intervention was £457 (SD 170), with a total cost of training, supervision, and consumables of £49 per participant. This cost includes time taken for trial-related administrative tasks (eg, completing fidelity checklists and uploading audio recordings). Using a caseload model based on each full-time HomeHealth support worker having a caseload of 120 people per year (typical caseload data provided by our voluntary-sector partners), and employed as NHS band-5 workers, the delivery cost including training and supervision would be £295 per participant. When intervention costs were added to other health and social care costs, total health and social care costs were lower in the HomeHealth intervention group than the treatment-as-usual group, although this difference was not statistically significant (adjusted mean £5064, SE 354, *vs* £5833, 535; mean difference –£769, 95% CI –2017 to 480; p=0·23).

There was a significant reduction in the number of unplanned admissions (predicted number of events 0·293 compared with 0·451; incident rate ratio 0·65, 95% CI 0·54 to 0·92; appendix p 7) and the cost of unplanned admissions in the HomeHealth group (£749 per person, 95% CI 378 to 1120) compared with treatment as usual (£1335 per person, 804 to 1866) at 12 months (difference –£586, 95% CI –£821 to –£351). There were no statistically significant differences in primary and community care and state-funded social care costs (appendix pp 8–9).

Adjusting for baseline differences and with site as a fixed effect, the intervention group had a mean of 0·699 QALYs (95% CI 0·680 to 0·718) compared with a mean of 0·685 (0·665 to 0·705) in the treatment-as-usual group, with a difference in QALYs of 0·014 (–0·014 to 0·041; p=0·34). As the intervention had a lower mean cost per person, but slightly higher QALYs, there is a high probability that the intervention is cost-effective at all decision thresholds, with a 92% probability of cost-effectiveness at a decision threshold of £20 000 per QALY gained (appendix pp 10–11). A sensitivity analysis to explore the effect of missing data for the CSRI did not alter the conclusions (appendix p 12).

The number of adverse events reported at research assessments and extracted from medical records were similar in both groups (211 events in the intervention group *vs* 209 in the control group) and were mostly non-injurious falls. There were fewer SAEs in the intervention group compared with the control group (38 patients and 55 events *vs* 51 patients and 85 events). All SAEs that could be assessed (139 of 140) were not related or unlikely to be related to the intervention, with similar numbers across groups. A small number of adverse events defined as definitely or probably related to the intervention (n=6) were mainly side-effects from exercises such as pain or fatigue (appendix p 13). Our efforts to maintain masking of outcome assessments were mostly successful at our primary endpoint, with researchers unable to guess group status for 284 (85%) of 333 participants at 12 months.

Discussion

This RCT found no effects of the HomeHealth intervention on our primary outcome of independence in ADLs and limited effects on other clinical outcomes compared with treatment as usual. There were small improvements in psychological distress and frailty at 6 months and wellbeing at 12 months in the intervention group, compared with the control group. Unplanned hospital admissions reduced by more than a third in participants receiving the HomeHealth intervention, with reduced associated hospital health-care costs. Because there was a lower overall cost for health care for the intervention, there is a high probability of cost-effectiveness for the intervention across a range of decision thresholds.

There are several potential explanations for these findings which are explored in detail in our process evaluation reported separately.[18] The absence of intervention effects on basic ADLs might be because there was limited room for improvement (ie, ceiling effects). The mean BI scores at baseline were close to the maximum score (ie, no problems with ADLs) and did not decline over time as anticipated on the basis of our feasibility study data.[16] A measure of independent living that can record a greater range of functioning in more able populations might have captured meaningful changes that were missed through this ceiling effect. While a meta-analysis of trials of complex interventions to support older people found no effects on ADLs, but small effects on IADLs,[15] IADLs did not change in our trial. Our intervention with six home-based individualised sessions over 6 months was possibly not intensive or long enough to affect the functional ability of participants, and because of the COVID-19 pandemic we were unable to facilitate

	Baseline		6 months		Difference	12 months		Difference
	n	Mean (SD)	n	Mean (SD)		n	Mean (SD)	
Modified BI								
HomeHealth	195	96·1 (5·92)	179	95·5 (5·7)	−0·137 (−1·303 to 1·029)	173	95·3 (7·2)	0·250 (−0·932 to 1·432)
Treatment as usual	193	95·9 (5·24)	165	96·0 (5·4)		159	95·0 (8·1)	
NEADL								
HomeHealth	195	45·9 (9·8)	176	47·1 (10·3)	−0·221 (−1·783 to 1·340)	170	45·7 (11·6)	0·957 (−0·637 to 2·550)
Treatment as usual	193	45·6 (9·6)	163	46·9 (11·0)		153	44·4 (12·9)	
MoCA								
HomeHealth	151	23·3 (4·4)	123	23·6 (4·6)	−0·420 (−1·114 to 0·273)	116	24·0 (4·7)	0·015 (−0·695 to 0·725)
Treatment as usual	146	23·5 (3·7)	111	24 (3·6)		99	24·5 (4·0)	
t-MoCA								
HomeHealth	190	17·2 (3·3)	161	17·6 (3·4)	−0·409 (−0·880 to 0·061)	155	18·1 (3·4)	0·037 (−0·517 to 0·443)
Treatment as usual	187	17·5 (3·0)	149	18·3 (2·7)		139	18·3 (3·0)	
GHQ-12								
HomeHealth	195	13·2 (5·7)	179	11·6 (5·0)	−1·237 (−2·127 to −0·348)	173	12·1 (4·8)	−0·664 (−1·568 to 0·240)
Treatment as usual	193	13·5 (5·1)	162	13·0 (5·2)		156	12·8 (5·4)	
UCLA 3-item Loneliness Scale								
HomeHealth	193	4·9 (1·8)	176	4·7 (1·7)	−0·255 (−0·492 to 0·042)	170	4·7 (1·7)	−0·187 (−0·458 to 0·084)
Treatment as usual	193	5·0 (2·0)	161	5·0 (1·8)		154	4·8 (1·7)	
Frailty score (Fried phenotype)								
HomeHealth	195	1·94 (1·26)	176	1·60 (1·18)	−0·252 (−0·487 to −0·017)	175	1·82 (1·19)	−0·091 (−0·333 to 0·150)
Treatment as usual	192	1·81 (1·17)	164	1·76 (1·24)		154	1·81 (1·22)	
WEMWBS								
HomeHealth	193	47·3 (9·2)	176	48·1 (8·6)	0·392 (−0·911 to 1·695)	171	48·1 (8·5)	1·449 (0·124 to 2·775)
Treatment as usual	193	47·0 (9·4)	162	47·4 (9·0)		153	47·0 (9·6)	
Quality of life (EQ-5D-5L)*								
HomeHealth	195	0·688 (0·198)	182	0·694 (0·227)	0·020 (−0·019 to 0·058)	176	0·692 (0·225)	0·028 (−0·014 to 0·070)
Treatment as usual	192	0·702 (0·172)	170	0·689 (0·225)		167	0·679 (0·254)	
Capability (ICECAP-O)								
HomeHealth	192	0·772 (0·141)	171	0·768 (0·155)	0·114 (−0·017 to 0·044)	168	0·765 (0·158)	0·020 (−0·018 to 0·057)
Treatment as usual	189	0·759 (0·151)	166	0·740 (0·192)		158	0·739 (0·222)	
Falls								
HomeHealth	134	0·7 (1·1)	94	0·5 (1·0)	0·936 (0·764 to 1·147)†	98	0·6 (1·1)	0·905 (0·722 to 1·135)†
Treatment as usual	163	0·8 (1·9)	110	0·7 (1·6)		123	0·8 (2·2)	

*Includes people who died as 0. †Data are incident rate ratio (95% CI). ICECAP-O=ICEpop CAPability measure for Older people. BI=Barthel Index. NEADL=Nottingham Extended Activities of Daily Living. MoCA=Montreal Cognitive Assessment. T-MoCA=telephone Montreal Cognitive Assessment. GHQ-12=General Health Questionnaire-12. WEMWBS=Warwick-Edinburgh Mental Wellbeing Scale.

Table 2: **Outcomes at baseline, 6 months, and 12 months**

attendance at group-based activities as a component of the intervention. More intensive approaches have, however, not previously shown additional benefit; for example, a trial done in Taiwan showed that for participants including those with frailty (scoring 3–6 on the CFS) a more intensive approach of group exercise and problem-solving therapy showed little additional effects on frailty improvement compared to an education and exercise session at home.[41] The person-centred emphasis of our intervention might also have resulted in changes in different outcomes for different participants, which were not detected across the whole sample. There was a small but significant improvement in wellbeing at 12 months in the intervention group, which is an important outcome for older people.

Our trial showed a large, significant, and potentially important reduction in unplanned hospital admissions, with lower related health-care costs, which cannot be explained by any improvements in independent functioning. There is an associated high probability of cost-effectiveness across a range of decision thresholds, largely driven by the reduced costs from unplanned hospital admissions. Some other economic evaluations of health promotion interventions in frail populations have also found these interventions to have a high probability of cost-effectiveness,[42,43] although the evidence is mixed.[44,45] Economic evaluations in the area of frailty and falls are, however, often poor at reporting where in the health-care system the costs and benefits occur,[46] so identifying exactly what makes these interventions potentially cost-saving can be challenging. For economic evaluations done alongside trials in which data have been collected from clinical records, there is some evidence of reductions in inpatient admissions following randomisation to a frailty health

promotion intervention.[43,44] The small improvement in frailty score at 6 months observed in the current trial was largely driven by increases in physical activity in those who were most inactive at baseline. Although overall activity levels were not significantly higher in the intervention group, it is possible that improvements in those participants who were the least active at baseline led to fewer hospital admissions in a more vulnerable group. Similarly, we observed small improvements in psychological distress at 6 months in the intervention group, but it is possible that larger improvements in a subgroup of participants with higher baseline distress could have led to fewer hospital admissions in this group. Non-pharmacological trials with attainment of personalised goals as outcomes have identified significant improvements on these primary outcomes.[47] HomeHealth might have worked through attainment of participants' goals or improvement in self-management abilities decreasing the likelihood of unplanned admission, through mechanisms including improved access to planned care and support, greater health literacy, improved problem-solving skills, emotional wellbeing, or carer support.

The HomeHealth RCT evaluated a rigorously developed, evidence-based and theory-based health promotion service. Trial recruitment was successful despite the COVID-19 pandemic and associated restrictions, and there were high levels of retention, leading to a sufficiently powered study. We did the study in three diverse areas within England, with a pragmatic design in which the intervention was delivered by voluntary-sector partners. This approach might have led to more variability in delivery and made it more challenging to demonstrate effectiveness. However, the study was designed to be as close as possible to real-world implementation, which makes the results more strongly generalisable. Findings might not apply to other geographical settings with different health-care systems. The study was open label; because of the nature of the intervention it was not possible to mask participants to their intervention status. However, all outcome assessors and research trial staff were masked to intervention status. Potential adverse events were reported by intervention support workers, which probably led to bias in increased reporting of adverse events in the intervention group. Because of COVID-19 restrictions in face-to-face contacts, we were unable to collect objective measures at all timepoints for all participants, which required changing our measures of gait speed and grip strength to self-reported assessments. The characteristics of our study population were broadly representative of the eligible populations they were recruited from, although they might have under-represented older people from ethnic minority groups.

HomeHealth is unlikely to significantly increase independent functioning for older people with mild frailty in its current form, but it represents a safe intervention delivered by the voluntary sector at a modest cost, with a meaningful observed reduction in unplanned hospital admissions and associated costs, which is a policy imperative. HomeHealth was a rigorously developed and acceptable intervention, and exploring adaptations to the target population (eg, targeting those with an established need and desire for change or those at a clearer trajectory of worsening frailty rather than with long-term stable mild frailty) or maximising opportunities to optimise content (eg, enabling exercise classes attendance) could be worthwhile future steps. HomeHealth is one of the few health promotion interventions tailored for older people with mild frailty, delivered by the voluntary sector, and found to be cost-effective in a national pragmatic trial. It should be considered by policy makers as a potentially cost-saving intervention for the health system.

Contributors

KW was Chief Investigator and wrote the first draft of the report together with RF. KW, RF, CA, CG, AC, LM, JH, RE, BG, DAS, RLG, CC, VMD, PL, and RH contributed to conceptualisation and funding acquisition. All authors contributed to methodology and oversight. RF was the Trial Manager, SK was the Deputy Trial Manager. CA was the clinical safety lead and site Principal Investigator, CG, and AC were site Principal Investigators and supervised trial delivery at their site. JH, CJ, and RE were public contributors with lived experience. SK, FM, MP, and GT collected data. SP did the main statistical analysis, LM reviewed it as senior statistician, and RH did the health economic analysis. SP, LM, and RH directly accessed and verified the underlying data reported in the manuscript. FM, RF, BG, and RLG contributed to training. FM supervised intervention delivery. All authors had full access to all the data in the study, contributed to review and editing of the manuscript, and had final responsibility for the decision to submit for publication.

Declaration of interests

KW has received funding from National Institutes for Health Research (NIHR) programmes and is a member of the NIHR School of Public Health Research and NIHR Three Schools Prevention Advisory Boards. RF is Chair of the Study Steering Committee for the NIHR-funded CASCADE project and is Treasurer for the British Society of Gerontology (unpaid voluntary role). DAS is Director and holds shares in Later Life Training, a not-for-profit training organisation that delivers exercise delivery training to health and fitness professionals, which supported the exercise training programme for HomeHealth support workers included in the intervention. DAS has received funding as a Co-Investigator on grants funded by NIHR Applied Research Collaboration National Priority for Ageing, Dementia, and Frailty, Chief Scientists Office, UK Research and Innovation Public Health Intervention Development, European Commission (H2020-MSCA-ITN), Orthopaedic Research UK, and Singapore Physiotherapy Association. DAS is Chair of the British Geriatrics Society Rehabilitation Group, a member of the British Geriatrics Society Special Interest Group on Falls and Fractures, a member of the Scientific Advisory Board for the Older People and Frailty NIHR Policy Research Unit, is Chair of Academic Advisory Group, PACES Project, and the Medical Research Council funded project, University of Glasgow, and a member of the NIHR Advanced Fellowship Selection Committee. AC led the development and UK implementation of the electronic frailty index, which is licensed to suppliers of electronic health-record systems at no cost, on the basis a premium charge is not applied to the end UK National Health Service user. AC has received funding from NIHR, Dunhill Medical Trust, UK Research and Innovation, Geras Centre for Aging Research (2023 Centre Review), and Australia and New Zealand Society of Geriatric Medicine, and is Chair of global Ageing Research Trialists collaborative, member of National Institute for Health and Care Excellence Falls Prevention Guideline Development Group, and sits on Trial Steering Committee and Data Monitoring and Ethics Committee for NIHR trials. KK is a Trustee of Age UK Harrow, Hillingdon, and Brent (unpaid role). RE has received funding as Public Involvement Lead from Kings College London and is a member of the National Dignity Council. RH has received funding from AstraZeneca: advice on commissioning

cardiovascular disease management in primary care. All other authors declare no competing interests.

Data sharing

Data collected for the study, including the statistical analysis plan, de-identified participant data, and a data dictionary defining each field in the set, will be made available to others on receipt by Priment CTU (priment@ucl.ac.uk) of a reasonable request, at any date after publication of this Article. All requests will be reviewed by Priment CTU in line with Priment CTU guidance on sharing data and anonymising data. This process is to ensure that the request is reasonable and the dataset is suitably anonymised. The study protocol is available open access.

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