

BMJ Open Effect of occupational therapy home visit discharge planning on participation after stroke: protocol for the HOME Rehab trial

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ABSTRACT

Introduction After first stroke, the transition from rehabilitation to home can be confronting and fraught with challenges. Although stroke clinical practice guidelines recommend pre-discharge occupational therapy home visits to ensure safe discharge and provision of appropriate equipment, there is currently limited evidence to support this recommendation.

Methods and analysis The HOME Rehab trial is a national, multicentre, phase III randomised controlled trial with concealed allocation, blinded assessment and intention-to-treat analysis being conducted in Australia. The trial aim is to determine the effect and potential cost-effectiveness of an enhanced occupational therapy discharge planning intervention that involves pre and post-discharge home visits, goal setting and occupational therapy in the home (the HOME programme) in comparison to an in-hospital pre-discharge planning intervention. Stroke survivors aged ≥ 45 years, admitted to a rehabilitation ward, expected to return to a community (private) dwelling after discharge, with no significant prestroke disability will be randomly allocated 1:1 to receive a standardised discharge planning intervention and the HOME programme or the standardised discharge planning intervention alone. The primary outcome is participation measured using the Nottingham Extended Activities of Daily Living. Secondary outcome areas include hospital readmission, disability, performance of instrumental activities of daily living, health-related quality of life, quality of care transition and carer burden. Resources used/costs will be collected for the cost-effectiveness analysis and hospital readmission. Recruitment commenced in 2019. Allowing for potential attrition, 360 participants will be recruited to detect a clinically important treatment difference with 80% power at a two-tailed significance level of 0.05.

Ethics and dissemination This study is approved by the Alfred Health Human Research Ethics Committee and site-specific ethics approval has been obtained at all participating sites. Results of the main trial and the secondary endpoint of cost-effectiveness will be submitted for publication in peer-reviewed journals

Trial registration number
ACTRN12618001360202

Strengths and limitations of this study

- The HOME Rehab trial will be conducted as a powered randomised controlled trial to measure the effect of adding an enhanced occupational therapy discharge planning intervention; it will provide clinicians and hospital administrators with important information about supporting people with stroke to transition from hospital to home.
- This is a phase III trial with concealed allocation, blinded assessment and intention-to-treat analysis and includes a process evaluation and economic evaluation.
- The trial will be adequately powered to detect a clinically important treatment difference in functional independence at 4-week post-discharge from hospital after first stroke.
- Owing to the type of interventions, blinding of the participants and treatment providers is not possible.

INTRODUCTION

Transitioning to home from hospital is a critical time for people poststroke.^{1–3} Hospital-community communication and coordination can be inadequate during the discharge phase,^{4–6} increasing the risk of poor return to community activity, low satisfaction, adverse events and unplanned readmission. The most effective method for supporting hospitalised people who have experienced stroke to transition from hospital to home is not yet known^{7,8} which has led to variability in practice within the rehabilitation context.^{9,10}

As a rehabilitation programme draws close to discharge, it is usual for people with stroke to be involved in discharge planning where they receive an occupational therapy pre-discharge home assessment. While it is recommended in national clinical guidelines that occupational therapy pre-discharge home

visits occur ‘to ensure safety and provision of appropriate aids, support and community services’,¹¹ research to date suggests that there may not be any difference in outcomes for people who do and do not receive pre-discharge occupational therapy home visits.^{12–16} What remains unknown is whether a comprehensive discharge support programme that crosses the boundaries between hospital inpatient and community outpatient services may be more beneficial than usual care, which may lack coordination and effective communication. Therefore, we have designed the HOME Rehab trial to address this research gap.

The aim of this phase III randomised trial is to determine the clinical effect (disability, participation, instrumental activities of daily living), change in the number of unplanned readmissions and the potential cost-effectiveness of an enhanced occupational therapy discharge planning intervention that involves pre and postdischarge home visits, goal setting and occupational therapy in the home (the HOME programme) in comparison to an in-hospital pre-discharge planning intervention. The specific research questions are:

1. In survivors of stroke, does the addition of the HOME programme to an in-hospital pre-discharge planning intervention improve activity participation at 4-week postdischarge (primary aim)?
2. Does it reduce unplanned hospital readmissions (secondary aim)?
3. Is it cost-effective (secondary aim)?

Primary end point is assessed at 4-weeks postdischarge; secondary aims, clinical outcomes and health economics are assessed at 6-month and 12-months postdischarge.

METHOD AND ANALYSIS

Design

The HOME Rehab trial is a multicentre, phase III randomised controlled trial being conducted in Australia with concealed allocation, blinded measurement and intention-to-treat analysis. Adults who have experienced stroke will be recruited from inpatient rehabilitation wards across multiple states in Australia; the list of sites is available on the trial registry. Participants will be randomly allocated to receive in-hospital pre-discharge planning and the HOME programme or in-hospital discharge planning alone. Clinical outcomes will be measured at baseline, 1-month (4-weeks) postdischarge (end of intervention) and 6 months postdischarge (beyond the intervention); health economic outcomes will be measured at 6 and 12 months postdischarge (figure 1). Measurements will be collected by assessors blind to group allocation. It is not possible to blind participants or therapists to group allocation. The protocol has been approved by the relevant Human Research Ethics Committees and is registered at www.ANZCTR.org.au (ACTRN12618001360202).

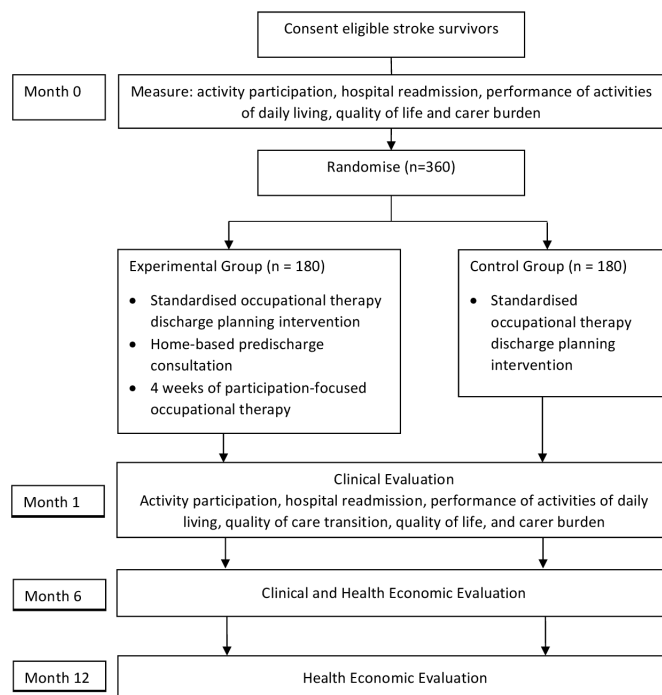


Figure 1 Design of the trial.

Participants, therapists, sites

People with stroke will be included if they are aged ≥ 45 years; admitted to a rehabilitation ward, which includes referral for occupational therapy; expected to return to live in a community (private) dwelling after discharge from hospital and have no significant prestroke disability (prestoke-modified Rankin Scale (mRS) score 0–2). Participants will be excluded if they need major home modifications or receive daily assistance with all care so as to enable discharge, have severe comorbid disease (as assessed by a score < 8 on the Charlson Comorbidity Index), have an illness likely to be associated with a life expectancy of < 12 months, have a significant cognitive impairment (> 5 adjusted errors on the Short Portable Mental Status Questionnaire), have a body mass index of 45 or higher, have moderate or severe aphasia or have a planned discharge to an address 2 hours or greater from a recruiting site.

Therapists will be eligible to deliver the intervention if they are occupational therapists with ≥ 3 years of experience and have completed training in the standardised delivery of the HOME programme.

Rehabilitation wards will be included if they have a stroke throughput of ≥ 20 /year.

Randomisation and blinding procedure

Assessors will be blinded to treatment allocation. Participants will be randomly allocated to one of the two groups using a fixed allocation ratio of 1:1 following consent and baseline assessment. We anticipate that the response to both discharge programmes may be associated with pretreatment motor ability and whether their inpatient occupational therapist conducts the postdischarge visits, and so participants will be stratified by baseline Functional

Independence Measure (FIM)¹⁷ motor score (≤ 38 vs >38) and mode of delivery of occupational therapy (inpatient therapist vs community therapist) to minimise group imbalances on these variables. To maintain sequential recruitment balance between groups throughout the trial, a permuted block randomisation process will be used within each strata using random block sizes. The randomisation creation process (including block sizes) and resulting schedule will be set, held and managed centrally external to the investigators (LCh, The University of Melbourne) and will be managed using Research Electronic Data Capture (REDCap).^{18 19}

Intervention

Participants in both groups (control and experimental) will undergo a standardised predischarge planning intervention led by an occupational therapist, and the experimental group will additionally receive the HOME programme.

This standardised in-hospital predischarge planning intervention will include one 30 minute in-hospital discharge planning assessment using the Discharge Planning Assessment Tool (DPAT)²⁰ and a family-led home environment assessment. The DPAT is a client-centred assessment to prepare for discharge to a home environment; DPAT is to be completed by a client, significant other and occupational therapist and/or other team members early in hospitalisation and before discharge. The DPAT includes two rating scales of confidence (client and family member), and captures subscales related to returning home and managing care (including mobility in the home, mobility in the community, bathroom, bedroom, kitchen, household management, medication management, nutrition and diet, skin management and leisure). Results of the predischarge confidence and discharge plan evaluation (for participants in each group) will be shared with the inpatient rehabilitation team prior to discharge. The family-led home environment assessment is a standardised checklist that is completed by the family, who are also loaned a tablet computer or digital camera to take photos of areas of the home that the participant would need or wish to access on return home. Using digital photographs taken by family members, patient information and an equipment list has previously been shown to be an accurate method of collecting necessary information for occupational therapy home modifications/equipment prescriptions.^{21 22}

In addition, participants will receive written instructions outlining their recommended home modifications and education for use of prescribed equipment prior to discharge.

Participants in the experimental group will then receive the HOME programme immediately following the standardised discharge planning intervention. Previously tested in an older, acute population,^{15 23} and piloted in general rehabilitation,¹⁶ the HOME programme is centred in the occupational therapy understanding that the interactions between a person and their environment

Box 1 Clinical aims of the HOME occupational therapy programme

Prepare the person to return home and resume their desired lifestyle

- ▶ Assess the individual person's occupational needs respecting their personal beliefs, needs and goals and understand the older person's patterns of daily living.^{27 42}
- ▶ Recommend functional adaptations that will maximise the person's abilities as they reintegrate back to usual living.⁴³
- ▶ Optimise the person-environment fit.⁴⁴
- ▶ Recommend and implement environmental modifications.
- ▶ Prescribe adaptive equipment and observe its use in situ.⁴²
- ▶ Facilitate effective communication between the individual person and their General Practitioner (GP) / health partners to support the transfer of medical information from hospital to community.²⁸

Enhance self-efficacy beliefs and promote independence and sense of control through mastery of meaningful tasks

- ▶ Transfer altered skills to the home situation and assist in the adjustment to these changes.⁴⁵
- ▶ Habitual retraining in situ using strategies such as situational cues and targeting behaviours for change.
- ▶ Encourage one-on-one education about the safe performance of activities in and around their home and immediate community.
- ▶ Facilitate joint problem-solving and solution generation.^{42 45}
- ▶ Lessen a person's fear during the transition from hospital to home.⁴⁶

Use goal setting and motivational interviewing as therapeutic tools

- ▶ Develop client-centred goals that address individual occupational needs.^{27 42}
- ▶ Develop goals that aim to maximise the person's potential to participate in meaningful activities.⁴³
- ▶ Include goals that enable the person to participate in activities both in the home and in the community⁴² and incorporate primary health and physical activity goals.
- ▶ Plan for increasing independence/capacity postdischarge, setting goals for increasing activity.^{45 47}

drive meaningful participation in activity after hospitalisation.²⁴⁻²⁶ The HOME programme commences during hospitalisation and dovetails with the standardised discharge planning intervention, but unlike the control intervention, the HOME programme continues posthospitalisation (box 1). During hospitalisation, there is a focus on safety and transition from hospital, while posthospitalisation, the focus is on increasing a person's capacity to deal with demands from the environment and their newly acquired disability to maximise independence.

The experimental group will receive one predischarge (approximately 90 min) and two postdischarge visits by an occupational therapist, followed by two booster telephone support sessions. Although performance gaps addressed are participant-specific (tailored), the process to identify and address the issues limiting independence and return to activity will be systematic and reproducible across all participants in the experimental group. Thus, all participants will receive identical intervention components. While still in hospital, a predischarge home assessment is conducted to assess the person-environment fit as well as observe the use of prescribed equipment in situ.

Using the I-HOPE, activities that are valued but difficult to perform in the home environment will be identified and then prioritised, and the magnitude of the influence of the environment on performance of these activities will be assessed by the occupational therapist.²⁷ Participation goals will then be set and results were shared with the inpatient rehabilitation team. These same I-HOPE goals will then shape the two postdischarge occupational therapy sessions with the aim of enhancing self-efficacy beliefs and promoting independence and the sense of control through mastery of meaningful activities. The two booster telephone support sessions will reinforce goal performance, enhance intrinsic motivation to return to activity²⁸ and facilitate effective communication between the participant, family/carers and GP.²⁹

Participants in the control group will receive only the standardised discharge planning intervention. Contamination from the experimental intervention will be determined by examining the resource diary at the end of 4-week intervention period, specifically to identify occupational goals and interventions.

Primary outcome

Activity participation will be measured using the Nottingham Extended Activities of Daily Living (NEADL).³⁰ The NEADL is a self-reported measure of 22 activities representing four domains of daily living (mobility, kitchen, domestic and leisure) considered to be important to people with stroke who have been discharged home.

Secondary outcomes

- ▶ Quality of the care transition that is associated with hospitalisation will be assessed using the 3-item Care Transitions Measure,³¹ which is a validated measure reflecting the quality of a person's care transition that is associated with hospital utilisation.
- ▶ Disability will be assessed by administering the mRS.^{32 33}
- ▶ Functional ability will be assessed using the Functional Autonomy Measurement System,³⁴ which measures in five areas: activities of daily living, mobility, communication, mental functions and instrumental activities of daily living.
- ▶ Health-related quality of life will be assessed using the EQ-5D-5L³⁵ and will be used to also estimate quality-adjusted life years for the economic evaluation.
- ▶ Carer burden will be assessed using the Carer Experience Scale (CES).³⁶ The CES focuses on six domains: activities outside caring, support from family and friends, assistance from the government and other organisations, fulfilment from caring, control over caring and getting on with the care recipient; this measure is administered to the carer.

Descriptive information will include demographic and socioeconomic information, details of the index stroke and prior health-related resource use (including occupational therapy). Date and cause of death will be obtained

from linkages with the National Death Index held by the Australian Institute of Health and Welfare, including those who may be lost to follow-up at 6 months and 12 months.

Economic evaluation

Direct costs for delivering each intervention over and above standard care (staff time and transportation, consumables and equipment), participant-related direct and indirect costs (participant time and transportation, change in employment status and impact of the intervention on the activities of carers) and health system costs (ie, costs of health services used, readmissions) will be collected at each assessment time point and at 12 months. Hospital admissions (inclusive of emergency presentations and hospital admissions) will be collected from two sources at all timepoints, self-report by the participant and data obtained from hospital administrative data sets. Cost of each treatment pathway, resources used and their costs will be collected. Self-reported data related to health service utilisation and medications will be confirmed through person-level linkages of participant data with data held by state and commonwealth health departments. This will include the Pharmaceutical Benefits Scheme and Medicare Benefits Schedule for the 12 month period following discharge and a 12 month period prior to the index stroke event (to permit adjustment for prestroke utilisation trends that may be unrelated to the interventions being studied or unbalanced between the groups).

Data monitoring

Data safety and monitoring will be overseen by two health professionals and one statistician independent of the trial. The committee will review data related to safety and trial conduct within 3 months of enrolment of the first participant and then annually; an interim analysis will be undertaken at n=240. The committee will be responsible for stopping recruitment in the case of multiple serious, trial-related adverse events. For the purposes of this study, a serious adverse event will be defined as an event that (1) is fatal or life threatening, (2) results in persistent or significant disability or (3) results in hospitalisation. A nonserious adverse event would include such undesirable experiences such as noninjurious fall.

Patient and public involvement

Principles of the National Health and Medical Research Council Consumer and Community Involvement in Health and Medical Research statement³⁷ have informed our approach to consumer and public engagement, with collaborative engagement with people with stroke, clinicians and policymakers from trial inception and design, to conduct and dissemination. This trial is supported by an end-user advisory panel, inclusive of advisors living with stroke, carers, occupational therapists, health managers and policymakers, who meet on a regular basis throughout the study. We will consult this panel to voice

end-user concerns, review process evaluation data and to identify end-user-oriented solutions to any concerns; multiple opportunities for involvement and feedback will be made available during the analyses around emergent concepts and trial implications to ensure engagement through to dissemination. Trial results will be interpreted by the end-user advisory panel, before a summary will be shared with participants who have indicated this to be their preference. All advisory panel members are paid an honorarium and will be thanked in the contributorship statement of any publications.

Process evaluation

The process evaluation plan was informed by the Medical Research Council Guidance on Process Evaluations of complex interventions³⁸ and will focus on the evaluation of fidelity and implementation context. Intervention fidelity will be monitored throughout the study through annual site review with participating therapists to ensure that key components of the intervention are delivered, adherence to the protocol, and completeness of outcome assessments is maintained throughout the trial. Implementation will be explored using the RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) framework³⁹ components of Reach (measures of participant participation and representativeness) with collection of both quantitative and qualitative data to provide insights into the acceptance and burden from the perspectives of both participants and their carers; effectiveness (success rate at an individual level); adoption (programme acceptance/uptake across the trial); implementation (fidelity of the programme to the protocolised intervention and factors which may potentially affect the trial outcome) and maintenance (long-term effects at the individual and organisational level) to both support explanation of trial findings and inform scale-up should the programme be effective.

Sample size estimates

Our pilot data demonstrated a mean change at 90 days postdischarge of 2.7 (SD 5.5) in activity participation measured by the NEADL in the home visit group and 0.8 (0.5) in the control group. For the purposes of power analysis, we have hypothesised a potentially smaller but still clinically important effect, where the control group would exhibit a change score of 1 and a common SD of 5.5. Recruitment of a total of $n=330$ (equally distributed between groups) would yield 80% power to detect such an effect using independent t-test with two-tailed alpha of 0.05. Allowing for potential attrition, the final total sample size of $n=360$ is adopted for this study. This sample size estimation is conservative, as in addition to the smaller hypothesised effect size, we would also expect an additional increase in power due to the inclusion of the baseline NEADL scores as a covariate in a corresponding analysis of covariance (ANCOVA) model prespecified for the primary analysis.

Once the outcomes for $n=240$ participants are obtained, an adaptive sample size estimation procedure will be undertaken as per the 'promising zone' methodology Mehta and Pocock⁴⁰ with a potential increase in the total sample size to the prespecified maximum of 360 participants.

Statistical analyses

All randomised participants will be included in the analyses following intention-to-treat principles. Treatment of missing data will be based on the satisfiability of missingness at random assumptions and will be based on the intention-to-treat strategy as per White *et al.*⁴¹ Outcomes will be analysed using appropriate analysis of covariance or logistic regression models, controlling for baseline values, and presented as mean between-group differences (95% CI). For the primary outcome analysis, differences in mean change in NEADL (baseline minus follow-up) will be compared between groups using ANCOVA model with change as an outcome, treatment group as a factor and baseline value of NEADL as a covariate. The outcome will be presented as mean between-group difference with respective 95% CI. Effect of participant characteristics on outcomes will be explored by including relevant interaction terms in regression models. The heterogeneity of effect across sites will be tested using respective mixed-effect models with individual centres as a random effect.

Similar adjusted analyses with appropriate regression models will be conducted for continuous secondary outcomes. Dichotomous secondary outcomes (ie, readmission) will be analysed using a logistic regression model with the readmission as the dependent variable and treatment group as independent variable, adjusted for relevant prespecified covariates. The outcomes will be presented as ORs with respective 95% CIs. Adjustment covariates will be prespecified in a separate Statistical Analysis Plan document that will provide the details of the analysis strategy prior to the lock of the trial data.

For the economic evaluation, there will be a cost description analysis of each treatment pathway and the incremental difference for costs and quality-adjusted life years determined. A full economic evaluation protocol will be published prior to study recruitment being completed.

Study sponsorship and funding

The study is funded by the National Health and Medical Research Council, Australia, grant ID 1141561). Trial organisation, data management and monitoring are supported by Monash University, Melbourne, Australia.

DISCUSSION

The HOME trial will provide information that will assist survivors of stroke returning home after rehabilitation and their families, rehabilitation clinicians and policy-makers make more informed decisions about the benefits of home assessments and postdischarge support for adults early after stroke. Findings will lead to evidence-based

clinical practise guideline recommendations, rather than expert opinion, allowing for clearer health policy, which in turn will improve outcomes for consumers and produce greater cost-efficiency in the rehabilitation sector.

The HOME Trial is the first prospective, randomised clinical trial to investigate the effect of adding an enhanced occupational therapy discharge planning intervention that involves pre and postdischarge home visits, goal setting and occupational therapy in the home to an in-hospital predischarge planning intervention within a rehabilitation setting. The trial has concealed allocation, blinded assessment and intention-to-treat analysis and includes a process evaluation and economic evaluation.

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Correction notice Figure 1 has been updated.

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Contributors NAL and LC conceived the study; NAL, LC, AD, MS, LCh, KL, SOK, IC, MC, TU, NA, LJ and DAC contributed to the design of the study. NAL, LC, AD, MS, LCh, KL, IC, MC, TU, NA and DAC procured the funding. NAL, DAC, SOK and LCh drafted the manuscript and all authors have read and approved the final manuscript.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not required.

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