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FAmily-Led RehabiliTaTion aftEr stroke in INDia

STATISTICAL ANALYSIS PLAN

Version 1.0 (final)

8 August 2016

STATISTICAL ANALYSIS PLAN APPROVAL SHEET

Study: ATTEND

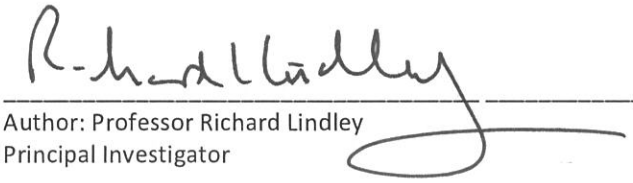
Title: Family-led rehabilitation after stroke in India

Principal Author of Analysis Plan: Laurent Billot
Version: 1.0 (final)
Version date: 8 August 2016

The undersigned have reviewed this plan and find it to be consistent with the requirements of the protocol as it applies to their respective areas. The principal author also finds this plan to be in compliance with ICH-E9 as well as The George Institute's SOP ST-SOP-04

11/8/16

Author: Associate Professor Laurent Billot — Date
Study statistician



11/8/16

Author: Professor Richard Lindley — Date
Principal Investigator

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1 Study design

1.1 Overview

ATTEND is a multicentre, randomised, blinded outcome assessor, controlled trial (PROBE design) of early supported discharge with a trained family-led caregiver-delivered, home-based stroke rehabilitation compared to usual care in 1250 patients with mild-moderate disability recruited from 14 sites in India.

1.2 Aims and hypotheses

To determine whether a family-led caregiver-delivered home-based rehabilitation intervention versus usual care is an effective, affordable Early Supported Discharge strategy for those with disabling stroke in India.

1.3 Patient population

1.3.1 Inclusion criteria:

- Adults (≥18 years);
- Recent (<1 month) acute ischaemic/haemorrhagic/unspecified stroke;
- Residual disability (requiring help from another person for everyday activities).
- Expected to survive to discharge from hospital with a reasonable expectation of 6 month survival (i.e. not palliative, no evidence of widespread cancer etc.);
- Able (or by proxy) to provide informed consent.

1.3.2 Exclusion criteria:

- Unable to identify a suitable family-nominated caregiver for training and subsequent delivery of care;
- Those unwilling/unable to adhere to follow-up.

1.4 Randomisation and blinding

Eligible patients were randomised within 7 days of hospital admission, using a secure, central, password protected, internet-based computerised system, stratified by centre and stroke severity. Outcomes were assessed by a trained research officer (blinded assessor) by home visit in-person interviews conducted at 3 and 6 months, whilst being kept blind to the treatment allocation of the patient

1.5 Intervention

Patients allocated to early supported discharge and family rehabilitation had their family-nominated caregiver trained by a specially trained stroke trial care coordinator health professional (i.e. physiotherapist) using a designed structured assessment (cognition, language, function and mobility) and recommended rehabilitation package. The 'package' included a structured check-list and culturally

appropriate manual covering the key activities relevant to daily living (e.g. positioning, transfers, mobilisation, feeding, dressing, activity and motor practice, and monitoring of mood etc). Training began in hospital with a planned ~60 mins per day training for about 3 days, with the intention of accelerating the patient's hospital discharge when it was safe to do so. The stroke trial care coordinator visited the patient and caregiver allocated Early Supported Discharge, up to 6 occasions to monitor progress post-discharge and was available by telephone for support and guidance as the patient progressed over the 2 months post randomisation.

1.5.1 Intervention package

Information about the intervention is presented in the trial protocol. In summary, the following components were added to routine care:

- Information on stroke recovery trajectory, risk, identification and management of low mood, importance of repeated practice of specific activities
- Positioning, transfers and mobility
- Discharge planning
- Joint goal setting with patient, nominated family caregiver and therapist (reviewed with coordinator as patient progresses and new goals set)
- Task orientated training (particularly walking, upper-limb and self-care tasks) with personalised copy of culturally appropriate manual

1.5.2 Control arm

These patients received usual hospital care in terms of access to rehabilitation, timeliness of discharge and follow-up, without any explicit provision of accelerated discharge or caregiver training.

1.6 Outcomes

1.6.1 Primary outcome

The primary outcome will be the proportion of patients who are dead or dependent at 6 months post-randomisation. Death or dependency is defined as a score of 3-6 on the modified Rankin Scale (mRS 0-2 versus 3-6).

1.6.2 Secondary outcomes

- Death or dependency at Month 3
- mRS analysed as an ordinal outcome with 7 levels at Month 3 and at Month 6
- The simple validated recovery ("Have you made a complete recovery from your stroke?") and dependency ("Do you need help from another person for everyday activities") questions
- Hospital length of stay
- Place of residence (same as prior stroke, Yes/No)
- Scores on the Barthel Index
- Health-related quality of life (WHOQOL-BREF and EQ-5D)

- Patient mood (Hospital Anxiety and Depression Scale)
- Extended activities of daily living (Nottingham Extended ADL Scale)

For the caregiver

- Caregiver Strain Index
- Caregiver mood (Hospital Anxiety and Depression Scale)

1.6.3 Safety outcomes

Safety outcomes will consist of the following expected serious events collected at hospital discharge, 3 and 6 month follow-up:

- Deaths (categorized as due to initial stroke, myocardial infarction, pneumonia, other vascular, non-vascular)
- Non-fatal events (recurrent stroke, myocardial infarction, bony fracture, infection, other)
- Re-hospitalisation after initial discharge (Yes/No)

Depending on the number of deaths, deaths coded as "other vascular" and "non-vascular" may be split into additional sub-categories. Similarly, non-fatal-events coded as "other" may be split further. The process of classifying deaths and events in additional subcategories will be done blinded to the treatment allocation.

1.6.4 Resource and cost outcomes

A detailed health economic analysis will be published after the main efficacy results due to the time required for the analysis of qualitative and quantitative data. It will include the following outcomes:

- Health care resource use (visits to health professionals, hospitalisation, and medication use) and direct (e.g. payment to the caregiver to act as carer for this patient, total direct costs of healthcare paid by the family since time of stroke)
- Indirect cost (e.g. family member giving up paid employment to act as caregiver) on the family. While most of the scales have been validated in India, additional independent qualitative process evaluations of the intervention on staff, patients, and caregivers are planned.
- Direct medical costs (e.g. total expenditure during hospital admission which includes first place where patient was taken, general or private admission, length of hospital stay, admission charges, investigation charges and drug treatment)
- Non-medical direct cost (e.g. travelling costs)

1.7 Sample size

In the meta-analysis of Early Supported Discharge trials, the rate of death or dependency at the end of follow-up was 50% and the likely beneficial effect of Early Supported Discharge treatment was 21% (95% CI 3-26%). Therefore, the proposed minimum sample size of 1200 (600 per group) provides at least 90% power (α 0.05) to detect likely plausible modest 20% reduction in death/dependency in the intervention

group with 20% drop out. The lower than expected loss to follow-up, and the final sample size of 1,250 will provide adequate power to detect a smaller treatment effect.

2 Statistical analysis

2.1 Analysis principles

- Analyses will be conducted on an intention-to-treat (ITT) basis; that is, by analysing all patients according to the group they were randomised to and regardless of treatment compliance.
- All tests are two-sided and the nominal level of α will be 5%.
- The primary analysis of the treatment effects will be unadjusted.
- Subgroup analyses will be carried out irrespective of whether there is a significant treatment effect on the primary outcome. These analyses will be unadjusted.
- No formal adjustments for multiplicity will be applied. However, the outcomes are categorized by degree of importance (primary vs secondary) and a limited number of subgroup analyses will be pre-specified. Results will be interpreted in this context.
- Analyses will be conducted primarily using SAS software (version 9.3 or above).

2.2 Interim analyses

The Data Monitoring Committee (DMC) periodically reviewed unblinded data to ensure the safety of trial participants. In light of these analyses, the DMC could provide advice to the chair of the Steering Committee whether, in their view, the randomised comparisons have provided both (i) 'proof beyond reasonable doubt' that for all, or some, the treatment is clearly indicated or clearly contra-indicated and (ii) evidence that might reasonably be expected to materially influence future patient management. The DMC operated on the Haybittle-Peto principle that a difference of at least 3 standard deviations in an interim analysis of a major outcome event (e.g. death from all causes or independent survival at six months) may be needed to justify halting, or modifying, the study before the planned completed recruitment. The DMC allowed the trial to continue to full recruitment, and provided advice that it was safe to modestly over-recruit (50 more patients randomised than sample size) due to reaching target recruitment earlier than anticipated.

2.3 Data sets analysed

All analyses will be performed on the ITT population; that is, by analysing all patients according to the group they were randomised to and regardless of protocol compliance. This will be used to assess both efficacy and safety.

2.4 Trial profile

The flow of patients through the study will be displayed in a CONSORT diagram, shown in Appendix 2 (figure 1). The report will include: the number of screened patients who met study inclusion criteria and the number of patients who are included; and reasons for exclusion of non-included patients.

2.5 Patients characteristics and baseline comparisons

Description of the baseline characteristics will be presented by treatment group as outlined in Appendix 1 (Table 1). Discrete variables will be summarised by frequencies and percentages. Percentages will be calculated according to the number of patients in whom data are available. Continuous variables will be summarised by using mean and SD and median and interquartile range (Q1-Q3).

Baseline measures for all patients will be tabulated for the following variables:

1. Socio-demographic characteristics:
   - Sex
   - Age
   - Marital status
   - Carer details
   - Education
   - Work situation
   - Accommodation details (type and financial situation)
   - Household income
2. Stroke details
   - Time from stroke onset to randomization
   - Pathological type of stroke (ischaemic; haemorrhagic; unspecified)
   - OCSP classification (for known ischaemic strokes)
   - Presumed mechanism of ischemic stroke (ischaemic stroke patients only)
   - Symptoms and signs at stroke onset
   - NIHSS score
3. Risk factors
   - Hypertension
   - Diabetes mellitus
   - Dyslipidaemia
   - Atrial fibrillation
   - Coronary artery disease
   - Obesity
   - Smoking status
   - Alcohol use
   - Drug addiction
   - Carotid stenosis
   - Previous stroke/TIA

- Rheumatic heart disease
- Neoplastic disease
- Pregnancy

2.6 Analysis of the primary outcome

2.6.1 Main analysis

The primary endpoint is the proportion of patients dead or dependent as indicated by a modified Rankin score (mRS) of 3 to 6 at Month 6. The main analysis will be an unadjusted logistic regression model with the mRS dichotomized as poor outcome (mRS 3-6) vs favourable outcome (mRS 0-2). The effect of the intervention will be presented as the odds ratio of a poor outcome and its 95% confidence interval. The level of significance (p-value) will be obtained using a likelihood ratio test.

2.6.2 Adjusted analyses

The logistic regression will be run after adjustment for the following covariates: study site, stroke severity (NIHSS Score < 8 or ≥ 8), age (as a continuous variable), sex, income (<5000 INR/month, 5000-<15000, 15000-<30000, 30000 and more, no answer/missing) and education (college/university/postgraduate, high school, primary/secondary/less than primary school, no schooling/missing).

2.6.3 Subgroup analyses

The following subgroup analyses will be carried out for the primary outcome:

- Age (< 40, 40-<50, 50-<60, 60-<70, 70 or more)
- Stroke severity (NIHSS <5, 5-<10, 10-<15, 15 or more)
- Stroke type (ischaemic versus haemorrhagic)
- OCSP subtype (Lacunar, Posterior, Partial anterior, Total anterior)
- Carer type (spouse, daughter/daughter in law, son/son in law, other)
- Education level (college/university/postgraduate, high school, primary/secondary/less than primary school, no schooling)
- Household income (<5000, 5000-<15000, 15000-<30000, 30000 and more, no answer/missing)
- Type of accommodation (own house versus other)

The analysis for each subgroup analysis will be performed by adding the subgroup variable as well as its interaction with the intervention as fixed effects to the logistic regression model used for the primary analysis (see Section 2.6.1). Within each subgroup, summary measures will include raw counts and percentages within each treatment arm, as well as the OR for treatment effect with its 95%CI. The results will be displayed on a forest plot including the p-value for heterogeneity corresponding to the interaction term between the intervention and the subgroup variable.

In addition to the pre-specified subgroup analyses listed above, exploratory subgroup analyses may also be performed on the primary outcome.

2.6.4 Treatment of missing data

The primary analysis will use all available data with no imputation. As a sensitivity analysis, missing mRS values at 6 months will be imputed using the mRS value at 3 months if available.

In addition, if the primary endpoint (mRS at Month 6) is missing for more than 10% of patients, a sensitivity analysis will examine the treatment effect under all possible allocations (either a poor or a favourable outcome) for patients with a missing data endpoint [2]. Within each treatment arm, if we note m_k (k=0,1) the number of patients with a missing outcome, we will run m_k+1 possible scenarios from the most to the least favourable:

- Scenario 0: 0 patients have a poor outcome
- Scenario 1: 1 patient has a poor outcome
- Scenario 2: 2 patients have a poor outcome
- ...
- Scenario m_k: m_k patients have a poor outcome

For each of the resulting $(m_0+1)\times(m_1+1)$ combinations, we will calculate a contingency table and associated chi-square p-value and examine which combinations are consistent with the primary analysis. This will tell us how extreme the missing data assumption would need to be to provide a result that is different to our primary analysis.

2.7 Other analyses of mRS

2.7.1 Ordinal analysis of mRS

An ordinal analysis of the mRS at Month 6 using all seven categories (including 6 for death) will be conducted using ordinal logistic regression unadjusted and adjusted for the covariates listed in Section 2.6.2. In case of violation of the proportional odds assumption, the two treatment arms will still be compared using ordinal logistic regression to obtain an average treatment effect; however, the assumption-free permutation test proposed by Howard et al. [5] will be performed as a sensitivity analysis as well as to provide a more clinically interpretable summary.

2.7.2 Analyses at Month 3 and at time of discharge

The analysis of death or dependency (Sections 2.6.1 and 2.6.2) as well as the ordinal analysis (Section 2.7.1) will be replicated at Month 3. The mRS at time of discharge is not a blinded outcome measure and will only be analysed using a non-adjusted analysis of death or dependency. No subgroup analyses will be conducted at Month 3 or at the time of discharge.

2.7.3 "Leave one out" analysis

We will assess the robustness of the primary analysis (i.e. the unadjusted analysis of death or dependency at Month 6 described in Section 2.6.1) in a sensitivity analysis, whereby the effect on the primary outcome will be calculated with all participants from a single site deleted one at a time.

2.8 Analysis of other secondary outcomes

Except for hospital length of stay, all secondary outcomes are collected at Month 3 and at Month 6. The analyses described below will be performed at Month 3 and at Month 6.

2.8.1 Simple validated recovery questions

The responses to the two questions "Have you made a complete recovery from your stroke?" and "Do you need help from another person for everyday activities?" will be summarized using counts and percentages and compared between treatment arms using a chi-square test.

2.8.2 Hospital length of stay

Duration of hospital stay will be summarized using the median and interquartile range. Differences between treatment arms will be assessed using a log-rank test of time to hospital discharge. Time to discharge will be censored at Month 6 or when the subject was last known to be alive, whichever occurs earlier.

2.8.3 Place of residence

Place of residence (same home as before stroke vs other) will be summarized using counts and percentages and compared using a chi-square test. Other will be classified further into: same hospital as admission for stroke; family or friend's home; other hospital; other dwelling. No formal test will be conducted on the distribution of the four "other" categories.

2.8.4 The Barthel Index

Each of the 10 questions (each with 3 categories) will be summarized using counts and percentages. The total score (0-100) will be summarized using the mean and standard deviation and compared between treatment arms using a t-test. No test will be conducted on the individual questions. The Barthel Index at time of discharge is not a blinded outcome measure and will only be analysed as the total score.

2.8.5 Caregiver burden scale

For each of the five factors (general strain, isolation, disappointment, emotional involvement and environment), we will calculate the score (sum of items) and summarise it using means and standard-deviations. The total score will also be summarized using means and standard-deviations and compared across treatments arms using a t-test. No test will be conducted on the individual factors.

2.8.6 Health-related quality of life (WHOQOL-BREF and EQ-5D)

- ***WHOQoL-BREF***

We will derive each of the four domain scores on a scale of 0 to 100 which will then be summarized using means and standard-deviations and compared across treatment arms using t-tests. In addition, the first two questions will be summarised using counts and percentages and compared across treatment arms using a chi-square test. Details on how to derive the domain scores are provided in the WHO scoring manual [3].

- ***EQ-5D***

Each of the five questions will be summarized using counts and percentages and compared across treatments arms using chi-square tests. The overall health state scale (0-100) will be summarized using means and standard deviations and compared using a t-test. A separate utility analysis will be included as part of the health economic analysis plan together with resource and cost outcomes (see Section 2.10).

2.8.7 Patient and caregiver mood (Hospital Anxiety and Depression Scale)

The anxiety and depression sub-scores as well as the overall score will be calculated and summarised using means and standard-deviations. In addition, the incidence of anxiety and depression will be defined as a corresponding subscore greater or equal to 8 and summarised using counts and percentages. A chi-square test will be used to compare the proportion of patients with anxiety and depression (separately) across treatment arms; however, no test will be performed on the continuous scores. This will be done for the patient and his/her caregiver.

2.8.8 Extended activities of daily living (Nottingham Extended ADL Scale)

The Nottingham Extended ADL Scale will be summarised by calculating the total score (0-66) as well as the score for each of the four domains (mobility, kitchen, domestic, leisure). Scores are obtained by coding the responses to each question from 0 (not at all) to 5 (on your own) and calculating the sum. The four domain scores are derived as the sum of the following questions:

- Mobility (0-18): questions 1 to 6
- Kitchen (0-15): questions 7 to 11
- Domestic (0-15): questions 12 to 16
- Leisure (0-18): questions 17 to 22

The five scores will be summarised using means and standard-deviations. Only the total score will be tested using a t-test.

2.9 Analysis of safety outcomes

Expected serious adverse events, deaths and hospitalisations will be summarised as the number and proportion of patients experiencing at least one event. This will be done by category of event and overall. For serious adverse events, in addition to the number of patients with at least one event, we will report the total number of events. Proportions of patients with SAEs, hospitalisations and deaths will be

compared between treatment arms using Fisher's exact test, both overall and by category. This will be done for the patient and his/her caregiver.

2.10 Analysis of activity logs and other stroke treatments

Trial interventions delivered during the hospital stay and at home will be summarised as follows, separately for interventions at the hospital and at home: overall cumulative time (hours) of training sessions, the total number of training sessions received (overall and by type of activity) and the percentage of patients receiving each of the different activities at least once.

Routine physiotherapy activities performed by non-trial hospital staff will be summarised in the same way as trial interventions but broken down by treatment arm. The average cumulative time (hours) of training sessions will be compared between the intervention and control arm using a t-test. For each activity, the proportion of patients with at least one session will be compared using Fisher's exact test.

Self-reported training time during the first 30 days after discharge for patients randomised to the rehabilitation arm will be summarised as the cumulative time of rehabilitation training (hours).

Other interventions and imaging studies (CT scan, MRI, etc.) will be summarised by treatment arm as the number and proportion of patients receiving at least one such test or intervention. Proportions between treatment arms will be compared using Fisher's exact test.

2.11 Analysis of resource and cost outcomes

Analysis of resource and cost outcomes will be specified in a separate health economic analysis plan.

3 References

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Appendix 1: Proposed main tables and figures

Figure 1: Consort flowchart

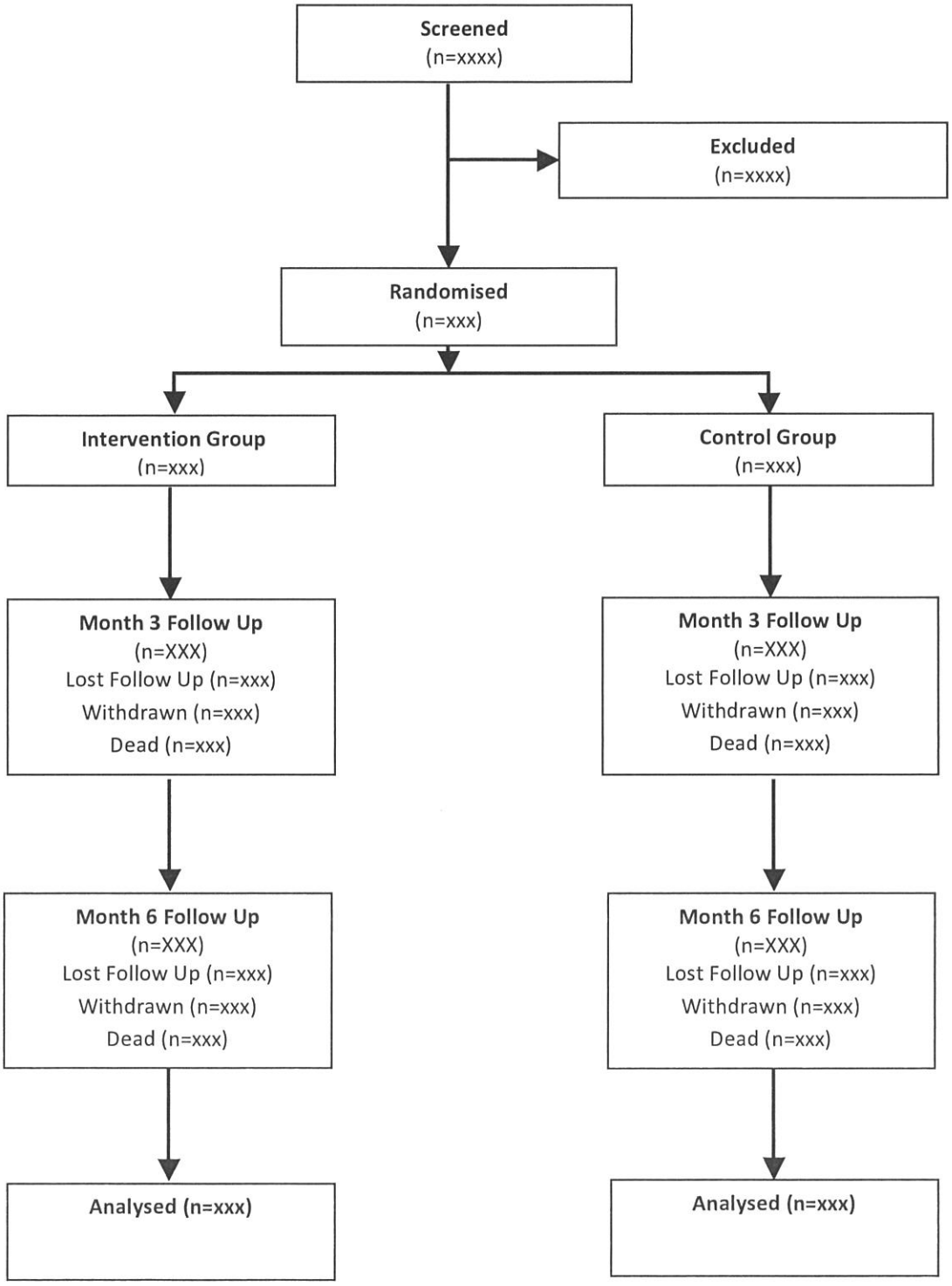


Table 1: Baseline characteristics

	Intervention (N=xxx)	Usual care (N=xxx)
Socio-demographic characteristics		
Sex	*n=xxx*	*n=xxx*
Male, n (%)	xxx (xx.x%)	xxx (xx.x%)
Female, n (%)	xxx (xx.x%)	xxx (xx.x%)
Age (years)	*n=xxx*	*n=xxx*
mean (SD)	xx.x (xx.x)	xx.x (xx.x)
median (Q1-Q3)	xx (xx-xx)	xx (xx-xx)
<40, n(%)	xxx (xx.x%)	xxx (xx.x%)
40-<50, n (%)	xxx (xx.x%)	xxx (xx.x%)
50-<60, n (%)	xxx (xx.x%)	xxx (xx.x%)
60-<70, n (%)	xxx (xx.x%)	xxx (xx.x%)
70-<80, n (%)	xxx (xx.x%)	xxx (xx.x%)
≥80, n (%)	xxx (xx.x%)	xxx (xx.x%)
Marital status	*n=xxx*	*n=xxx*
Married, n (%)	xxx (xx.x%)	xxx (xx.x%)
Separated/unmarried, n (%)	xxx (xx.x%)	xxx (xx.x%)
Widowed, n (%)	xxx (xx.x%)	xxx (xx.x%)
Main carer	*n=xxx*	*n=xxx*
Spouse, n (%)	xxx (xx.x%)	xxx (xx.x%)
Daughter/daughter in law, n (%)	xxx (xx.x%)	xxx (xx.x%)
Son/son in law, n (%)	xxx (xx.x%)	xxx (xx.x%)
Other, n (%)	xxx (xx.x%)	xxx (xx.x%)
Highest level of education completed	*n=xxx*	*n=xxx*
No schooling, n (%)	xxx (xx.x%)	xxx (xx.x%)
Less than primary school, n (%)	xxx (xx.x%)	xxx (xx.x%)
Primary school, n (%)	xxx (xx.x%)	xxx (xx.x%)
Secondary school, n (%)	xxx (xx.x%)	xxx (xx.x%)
High school, n (%)	xxx (xx.x%)	xxx (xx.x%)
College/university	xxx (xx.x%)	xxx (xx.x%)
Postgraduate degree	xxx (xx.x%)	xxx (xx.x%)

Unknown	xxx (xx.x%)	xxx (xx.x%)
Work situation	*n=xxx*	*n=xxx*
Full-time paid work, n (%)	xxx (xx.x%)	xxx (xx.x%)
Part-time paid work, n (%)	xxx (xx.x%)	xxx (xx.x%)
Retired, n (%)	xxx (xx.x%)	xxx (xx.x%)
Unemployed, n (%)	xxx (xx.x%)	xxx (xx.x%)
Home duties, n (%)	xxx (xx.x%)	xxx (xx.x%)
Student, n (%)	xxx (xx.x%)	xxx (xx.x%)
Others, n (%)	xxx (xx.x%)	xxx (xx.x%)
Accommodation details	*n=xxx*	*n=xxx*
Own house, n (%)	xxx (xx.x%)	xxx (xx.x%)
Own apartment/flat, n (%)	xxx (xx.x%)	xxx (xx.x%)
Rented flat, n (%)	xxx (xx.x%)	xxx (xx.x%)
Rented accommodation in a house, n (%)	xxx (xx.x%)	xxx (xx.x%)
Government/company provided house, n (%)	xxx (xx.x%)	xxx (xx.x%)
Jhuggi, n (%)	xxx (xx.x%)	xxx (xx.x%)
Other, n (%)	xxx (xx.x%)	xxx (xx.x%)
Living situation pre-stroke	*n=xxx*	*n=xxx*
Independent at home, n (%)	xxx (xx.x%)	xxx (xx.x%)
Dependent at home, n (%)	xxx (xx.x%)	xxx (xx.x%)
Other, n (%)	xxx (xx.x%)	xxx (xx.x%)
Household income (INR)	*n=xxx*	*n=xxx*
< 5000, n (%)	xxx (xx.x%)	xxx (xx.x%)
5000 - <15,000, n (%)	xxx (xx.x%)	xxx (xx.x%)
15,000 - <30,000, n (%)	xxx (xx.x%)	xxx (xx.x%)
30,000 - <60,000, n (%)	xxx (xx.x%)	xxx (xx.x%)
60,000 < 1,00,000, n (%)	xxx (xx.x%)	xxx (xx.x%)
>1,00,000, n (%)	xxx (xx.x%)	xxx (xx.x%)
No answer/ don't know	xxx	xxx
Stroke details		
Time from stroke onset to randomization (hrs:mins)	*n=xxx*	*n=xxx*
mean (SD)	xx.x (xx.x)	xx.x (xx.x)
median (Q1-Q3)	xxx (xx-xx)	xxx (xx-xx)
Stroke type	*n=xxx*	*n=xxx*
Ischaemic, n (%)	xxx (xx.x%)	xxx (xx.x%)

Large artery atherosclerosis, n (%)	xxx (xx.x%)	xxx (xx.x%)
Cardio embolism, n (%)	xxx (xx.x%)	xxx (xx.x%)
Small artery occlusion, n (%)	xxx (xx.x%)	xxx (xx.x%)
Other etiology, n (%)	xxx (xx.x%)	xxx (xx.x%)
Undetermined, n (%)	xxx (xx.x%)	xxx (xx.x%)
Haemorrhagic, n (%)	xxx (xx.x%)	xxx (xx.x%)
Unspecified, n (%)	xxx (xx.x%)	xxx (xx.x%)
OCSP classification	*n=xxx*	*n=xxx*
Total anterior circulation infarct, n (%)	xxx (xx.x%)	xxx (xx.x%)
Partial anterior circulation infarct, n (%)	xxx (xx.x%)	xxx (xx.x%)
Posterior circulation infarct, n (%)	xxx (xx.x%)	xxx (xx.x%)
Lacunar infarct, n (%)	xxx (xx.x%)	xxx (xx.x%)
NIHSS score, mean (SD)	*n=xxx*	*n=xxx*
mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median (Q1-Q3)	xxx (xx-xx)	xxx (xx-xx)
<5, n (%)	xxx (xx.x%)	xxx (xx.x%)
5-<10, n (%)	xxx (xx.x%)	xxx (xx.x%)
10-<15, n (%)	xxx (xx.x%)	xxx (xx.x%)
≥15, n (%)	xxx (xx.x%)	xxx (xx.x%)
Medical history	*n=xxx*	*n=xxx*
Hypertension, n (%)	xxx (xx.x%)	xxx (xx.x%)
Diabetes Mellitus, n (%)	xxx (xx.x%)	xxx (xx.x%)
Dyslipidaemia, n (%)	xxx (xx.x%)	xxx (xx.x%)
Atrial fibrillation, n (%)	xxx (xx.x%)	xxx (xx.x%)
Coronary artery disease, n (%)	xxx (xx.x%)	xxx (xx.x%)
Obesity, n (%)	xxx (xx.x%)	xxx (xx.x%)
Current smoking, n (%)	xxx (xx.x%)	xxx (xx.x%)
Alcohol use, n (%)	xxx (xx.x%)	xxx (xx.x%)
Drug addiction, n (%)	xxx (xx.x%)	xxx (xx.x%)
Carotid stenosis, n (%)	xxx (xx.x%)	xxx (xx.x%)
Previous stroke/TIA, n (%)	xxx (xx.x%)	xxx (xx.x%)
Rheumatic heart disease, n (%)	xxx (xx.x%)	xxx (xx.x%)
Neoplastic disease, n (%)	xxx (xx.x%)	xxx (xx.x%)
Pregnancy, n (%)	xxx (xx.x%)	xxx (xx.x%)

Table 2: Analysis of mRS

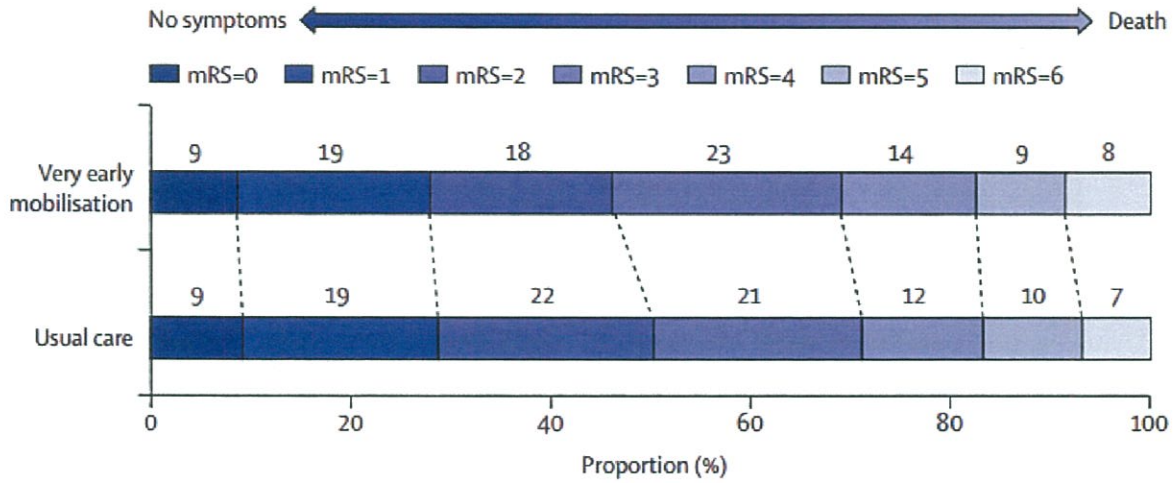
	Unadjusted analysis				Adjusted analysis [2]	
	Intervention (n=xxx)	Usual care (n=xxx)	Odds ratio (95% CI)	P-value [3]	Odds ratio (95% CI)	P-value [3]
Death or disability						
Month 3	xxx/xxx (xx.x%)	xxx/xxx (xx.x%)	x.xx (x.xx-x.xx)	0.xxx	x.xx (x.xx-x.xx)	0.xxx
Month 6 [1]	xxx/xxx (xx.x%)	xxx/xxx (xx.x%)	x.xx (x.xx-x.xx)	0.xxx	x.xx (x.xx-x.xx)	0.xxx
Ordinal analysis [4]						
Month 3			x.xx (x.xx-x.xx)	0.xxx	x.xx (x.xx-x.xx)	0.xxx
0	xxx (xx.x%)	xxx (xx.x%)				
1	xxx (xx.x%)	xxx (xx.x%)				
2	xxx (xx.x%)	xxx (xx.x%)				
3	xxx (xx.x%)	xxx (xx.x%)				
4	xxx (xx.x%)	xxx (xx.x%)				
5	xxx (xx.x%)	xxx (xx.x%)				
6	xxx (xx.x%)	xxx (xx.x%)				
Month 6			x.xx (x.xx-x.xx)	0.xxx	x.xx (x.xx-x.xx)	0.xxx
0	xxx (xx.x%)	xxx (xx.x%)				
1	xxx (xx.x%)	xxx (xx.x%)				
2	xxx (xx.x%)	xxx (xx.x%)				
3	xxx (xx.x%)	xxx (xx.x%)				
4	xxx (xx.x%)	xxx (xx.x%)				
5	xxx (xx.x%)	xxx (xx.x%)				
6	xxx (xx.x%)	xxx (xx.x%)				

1. *Primary endpoint*

2. *Adjusted analysis includes the following covariates: study site, stroke severity (NIHSS Score < 8 or ≥ 8), age (as a continuous variable), sex, income (<5000, 5000-<15000, 15000-<30000, 30000 and more, no answer/missing) and education (college/university/postgraduate, high school, primary/secondary/less than primary school, no schooling/missing)*
3. *P-value from the likelihood ratio test of the logistic regression.*
4. *Ordinal analysis performed using proportional odds logistic regression*

Programming note: the sensitivity analysis of mRS which replaces missing values at Month 6 with Month 3 values will not be included in the main table. It will only be mentioned in the text.

Figure 2: Distribution of mRS scores at Month 6



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Note: Figure legend to include the results of the method by Howard et al.

Table 3. Analysis of secondary outcomes at Month 3 and Month 6

	Month 3			Month 6		
	Intervention (n=xxx)	Usual care (n=xxx)	P-value	Intervention (n=xxx)	Usual care (n=xxx)	P-value [1]
Complete recovery from stroke, n (%)	xxx (xx.x%)	xxx (xx.x%)	0.xxx	xxx (xx.x%)	xxx (xx.x%)	0.xxx
Need help for everyday activities, n (%)	xxx (xx.x%)	xxx (xx.x%)	0.xxx	xxx (xx.x%)	xxx (xx.x%)	0.xxx
Place of residence, n (%)						
Same as before stroke	xxx (xx.x%)	xxx (xx.x%)	0.xxx	xxx (xx.x%)	xxx (xx.x%)	0.xxx [2]
Other	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)	xxx (xx.x%)	
Same hospital as admission for stroke	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)	xxx (xx.x%)	
Family or friend's home	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)	xxx (xx.x%)	
Other hospital	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)	xxx (xx.x%)	
Other dwelling	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)	xxx (xx.x%)	
Barthel Index total score, n mean (SD)	xxx xx.x (xx.x)	xxx xx.x (xx.x)	0.xx.x	xxx xx.x (xx.x)	xxx xx.x (xx.x)	0.xxx
Caregiver burden total score, n mean (SD)	xxx xx.x (xx.x)	xxx xx.x (xx.x)	0.xx.x	xxx xx.x (xx.x)	xxx xx.x (xx.x)	0.xxx

1. Chi-square or t-test

2. Chi-square test only performed on "same as before stroke" vs "other"

Table 4. Safety outcomes

	Intervention (n=xxx)		Usual Care (n=xxx)		p-value [3]
	# events [1]	n (%) [2]	# events [1]	n (%) [2]	
Deaths		xxx (xx.x%)		xxx (xx.x%)	0.xxx
Initial stroke		xxx (xx.x%)		xxx (xx.x%)	0.xxx
Myocardial infarction		xxx (xx.x%)		xxx (xx.x%)	0.xxx
Pneumonia		xxx (xx.x%)		xxx (xx.x%)	0.xxx
Other vascular		xxx (xx.x%)		xxx (xx.x%)	0.xxx
Non vascular		xxx (xx.x%)		xxx (xx.x%)	0.xxx
Other		xxx (xx.x%)		xxx (xx.x%)	0.xxx
Non-fatal events	# events	xxx (xx.x%)	# events	xxx (xx.x%)	0.xxx
Recurrent stroke	# events	xxx (xx.x%)	# events	xxx (xx.x%)	0.xxx
Myocardial infarction	# events	xxx (xx.x%)	# events	xxx (xx.x%)	0.xxx
Bony fracture	# events	xxx (xx.x%)	# events	xxx (xx.x%)	0.xxx
Infection	# events	xxx (xx.x%)	# events	xxx (xx.x%)	0.xxx
Other	# events	xxx (xx.x%)	# events	xxx (xx.x%)	0.xxx
Re-hospitalised after initial discharge		xxx (xx.x%)		xxx (xx.x%)	0.xxx

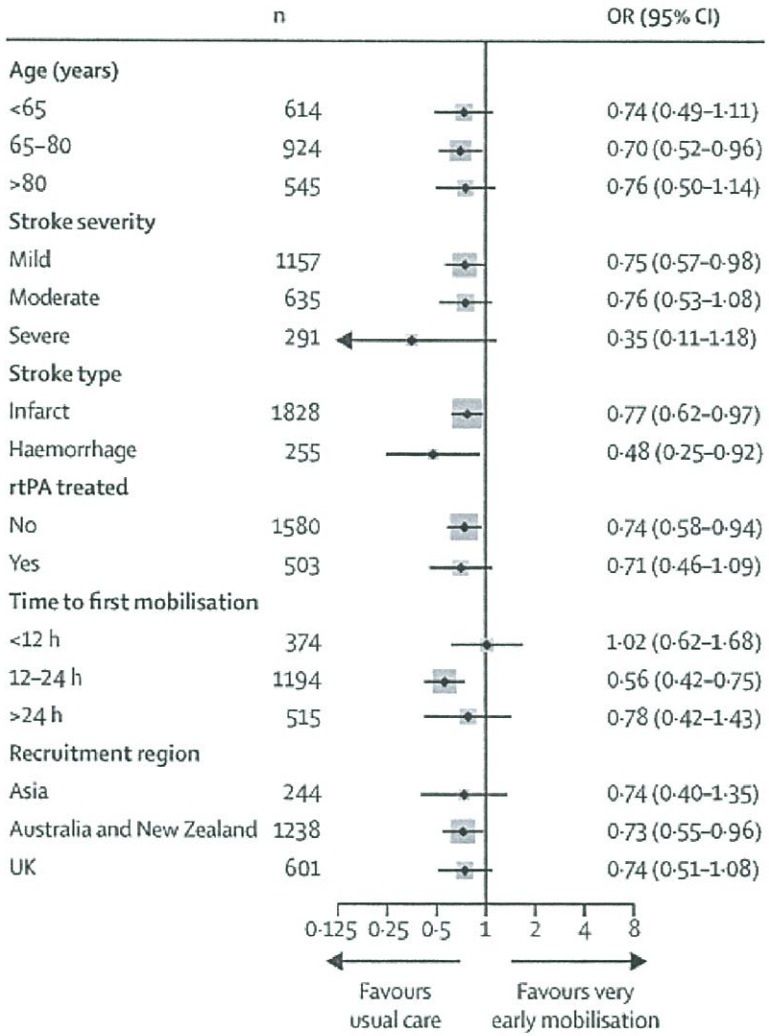
Notes:

1. Total number of events (one patient can contribute more than one event)

2. Number and proportion of patients with at least one event

3. Fisher's exact test comparing the proportion of patients with at least one event

Figure 3: Forest plot for subgroup analysis of mRS at Month 6



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Appendix 2: Extra tables and figures (for supplement or secondary papers)

Table 5. Stroke symptoms at stroke onset

	Intervention (n=xxx)	Usual care (n=xxx)
Side of the body affected		
Left	xxx (xx.x%)	xxx (xx.x%)
Right	xxx (xx.x%)	xxx (xx.x%)
Both	xxx (xx.x%)	xxx (xx.x%)
Limb weakness	xxx (xx.x%)	xxx (xx.x%)
Loss of sensation	xxx (xx.x%)	xxx (xx.x%)
Aphasia/dysphasia	xxx (xx.x%)	xxx (xx.x%)
	xxx (xx.x%)	xxx (xx.x%)
Etc.		
Impaired consciousness	xxx (xx.x%)	xxx (xx.x%)

Table 6. Hospital discharge information

	Intervention (n=xxx)	Usual Care (n=xxx)	P-value [1]
Hospital length of stay, n median (Q1-Q3)	xxx xxx (xxx-xxx)	xxx xxx (xxx-xxx)	0.xxx
Death or disability (mRS)	xxx (xx.x%)	xxx (xx.x%)	0.xxx
Barthel Index total score, n mean (SD)	xxx xx.x (xx.x)	xxx xx.x (xx.x)	0.xxx

1. *Log-rank test for analysis of time to discharge, chi-square test for death or disability, t-test for Barthel score*

Table 7. "Leave one out" sensitivity analysis of mRS at Month 6

Site omitted	Intervention (n=xxx)	Usual Care (n=xxx)	Odds ratio (95% CI)	P-value
Site xxx	xxx (xx)	xxx (xx)	xxx (xxx-xxx)	0.xxx
Site xxx	xxx (xx)	xxx (xx)	xxx (xxx-xxx)	0.xxx
Etc.				
Site xxx	xxx (xx)	xxx (xx)	xxx (xxx-xxx)	0.xxx

Table 8. Quality of life

	Month 3			Month 6		
	Intervention (n=xxx)	Usual Care (n=xxx)	P-value	Intervention (n=xxx)	Usual Care (n=xxx)	P-value
WHOQoL-BREF						
Physical health	xxx xx.x (xx.x)	xxx xx.x (xx.x)	0.xxx	xxx xx.x (xx.x)	xxx xx.x (xx.x)	0.xxx
Psychological	xxx xx.x (xx.x)	xxx xx.x (xx.x)	0.xxx	xxx xx.x (xx.x)	xxx xx.x (xx.x)	0.xxx
Social relationship	xxx xx.x (xx.x)	xxx xx.x (xx.x)	0.xxx	xxx xx.x (xx.x)	xxx xx.x (xx.x)	0.xxx
Environment	xxx xx.x (xx.x)	xxx xx.x (xx.x)	0.xxx	xxx xx.x (xx.x)	xxx xx.x (xx.x)	0.xxx
Quality of life			0.xxx			0.xxx
Very poor	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)	xxx (xx.x%)	
Poor	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)	xxx (xx.x%)	
Neither poor or good	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)	xxx (xx.x%)	
Good	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)	xxx (xx.x%)	
Very good	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)	xxx (xx.x%)	
Satisfaction with health			0.xxx			0.xxx
Very dissatisfied	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)	xxx (xx.x%)	
Dissatisfied	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)	xxx (xx.x%)	
Neither satisfied or dissatisfied	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)	xxx (xx.x%)	
Satisfied	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)	xxx (xx.x%)	
Very satisfied	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)	xxx (xx.x%)	
EQ-5D						
Mobility			0.xxx			0.xxx
No problems in walking	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)	xxx (xx.x%)	
Some problems in walking	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)	xxx (xx.x%)	

Confined to bed	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)	xxx (xx.x%)	
Self-care			0.xxx			0.xxx
No problems	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)	xxx (xx.x%)	
Some problems	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)	xxx (xx.x%)	
Unable to bathe/dress	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)	xxx (xx.x%)	
Usual activities			0.xxx			0.xxx
No problems	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)	xxx (xx.x%)	
Some problems	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)	xxx (xx.x%)	
Unable	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)	xxx (xx.x%)	
Pain/discomfort			0.xxx			0.xxx
No pain/discomfort	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)	xxx (xx.x%)	
Moderate pain/discomfort	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)	xxx (xx.x%)	
Extreme pain/discomfort	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)	xxx (xx.x%)	
Anxiety/Depression			0.xxx			0.xxx
Not anxious/depressed	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)	xxx (xx.x%)	
Moderately anxious/depressed	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)	xxx (xx.x%)	
Extremely anxious/depressed	xxx (xx.x%)	xxx (xx.x%)		xxx (xx.x%)	xxx (xx.x%)	
Overall health state	xxx xx.x (xx.x)	xxx xx.x (xx.x)	0.xxx	xxx xx.x (xx.x)	xxx xx.x (xx.x)	0.xxx

Table 9. Patient and caregiver mood (Hospital Anxiety and Depression Scale)

	Month 3			Month 6		
	Usual care (n=xxx)	Intervention (n=xxx)	P-value	Usual care (n=xxx)	Intervention (n=xxx)	P-value
Patient						
HADS Total score						
N mean (SD)	xx xx.x (xx.x)	xx xx.x (xx.x)		xx xx.x (xx.x)	xx xx.x (xx.x)	
Median (Q1-Q3)	xx (xx-xx)	xx (xx-xx)		xx (xx-xx)	xx (xx-xx)	
HADS Anxiety score						
N mean (SD)	xx xx.x (xx.x)	xx xx.x (xx.x)		xx xx.x (xx.x)	xx xx.x (xx.x)	
Median (Q1-Q3)	xx (xx-xx)	xx (xx-xx)		xx (xx-xx)	xx (xx-xx)	
Score ≥ 8, n (%)	xx (xx.x%)	xx (xx.x%)	0.xxx	xx (xx.x%)	xx (xx.x%)	0.xxx
HADS Depression score						
N mean (SD)	xx xx.x (xx.x)	xx xx.x (xx.x)		xx xx.x (xx.x)	xx xx.x (xx.x)	
Median (Q1-Q3)	xx (xx-xx)	xx (xx-xx)		xx (xx-xx)	xx (xx-xx)	
Score ≥ 8, n (%)	xx (xx.x%)	xx (xx.x%)	0.xxx	xx (xx.x%)	xx (xx.x%)	0.xxx
Carer						
HADS Total score						
N mean (SD)	xx xx.x (xx.x)	xx xx.x (xx.x)		xx xx.x (xx.x)	xx xx.x (xx.x)	
Median (Q1-Q3)	xx (xx-xx)	xx (xx-xx)		xx (xx-xx)	xx (xx-xx)	
HADS Anxiety score						
N mean (SD)	xx xx.x (xx.x)	xx xx.x (xx.x)		xx xx.x (xx.x)	xx xx.x (xx.x)	
Median (Q1-Q3)	xx (xx-xx)	xx (xx-xx)		xx (xx-xx)	xx (xx-xx)	
Score ≥ 8, n (%)	xx (xx.x%)	xx (xx.x%)	0.xxx	xx (xx.x%)	xx (xx.x%)	0.xxx
HADS Depression score						

N mean (SD)	xx xx.x (xx.x)	xx xx.x (xx.x)		xx xx.x (xx.x)	xx xx.x (xx.x)	
Median (Q1-Q3)	xx (xx-xx)	xx (xx-xx)		xx (xx-xx)	xx (xx-xx)	
Score ≥ 8, n (%)	xx (xx.x%)	xx (xx.x%)	0.xxx	xx (xx.x%)	xx (xx.x%)	0.xxx

Table 10. Extended activities of daily living (Nottingham Extended ADL Scale)

	Month 3			Month 6		
	Usual care (n=xxx)	Intervention (n=xxx)	P-value	Usual care (n=xxx)	Intervention (n=xxx)	P-value
Total score						
N mean (SD)	xx xx.x (xx.x)	xx xx.x (xx.x)	0.xxx	xx xx.x (xx.x)	xx xx.x (xx.x)	0.xxx
Median (Q1-Q3)	xx (xx-xx)	xx (xx-xx)		xx (xx-xx)	xx (xx-xx)	
Mobility score						
N mean (SD)	xx xx.x (xx.x)	xx xx.x (xx.x)		xx xx.x (xx.x)	xx xx.x (xx.x)	
Median (Q1-Q3)	xx (xx-xx)	xx (xx-xx)		xx (xx-xx)	xx (xx-xx)	
Kitchen score						
N mean (SD)	xx xx.x (xx.x)	xx xx.x (xx.x)		xx xx.x (xx.x)	xx xx.x (xx.x)	
Median (Q1-Q3)	xx (xx-xx)	xx (xx-xx)		xx (xx-xx)	xx (xx-xx)	
Domestic score						
N mean (SD)	xx xx.x (xx.x)	xx xx.x (xx.x)		xx xx.x (xx.x)	xx xx.x (xx.x)	
Median (Q1-Q3)	xx (xx-xx)	xx (xx-xx)		xx (xx-xx)	xx (xx-xx)	
Leisure score						
N mean (SD)	xx xx.x (xx.x)	xx xx.x (xx.x)		xx xx.x (xx.x)	xx xx.x (xx.x)	
Median (Q1-Q3)	xx (xx-xx)	xx (xx-xx)		xx (xx-xx)	xx (xx-xx)	

Table 11. Barthel index

	Month 3		Month 6	
	Usual care (n=xxx)	Intervention (n=xxx)	Usual care (n=xxx)	Intervention (n=xxx)
Feeding				
Unable	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Needs help	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Independent	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Bathing				
Dependent	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Independent	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Grooming				
Needs help	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Independent	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Dressing				
Dependent	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Needs help	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Independent	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Bowels				
Incontinent	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Occasional accident	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Continent	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Bladder				
Incontinent	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Occasional accident	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Continent	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)

Toilet use				
Dependent	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Needs help	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Independent	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Transfers				
Unable	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Major help	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Minor help	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Independent	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Mobility				
Immobile	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Wheelchair independent				
Walks with help	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Independent	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Stairs				
Unable	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Needs help	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)
Independent	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)

Table 12. Caregiver burden scale

	Month 3		Month 6	
	Usual care (n=xxx)	Intervention (n=xxx)	Usual care (n=xxx)	Intervention (n=xxx)
General strain				
N mean (SD)	xxx xx.x (xx.x)	xxx xx.x (xx.x)	xxx xx.x (xx.x)	xxx xx.x (xx.x)
Median (Q1-Q3)	xx (xx-xx)	xx (xx-xx)	xx (xx-xx)	xx (xx-xx)
Isolation				
N mean (SD)	xxx xx.x (xx.x)	xxx xx.x (xx.x)	xxx xx.x (xx.x)	xxx xx.x (xx.x)
Median (Q1-Q3)	xx (xx-xx)	xx (xx-xx)	xx (xx-xx)	xx (xx-xx)
Disappointment				
N mean (SD)	xxx xx.x (xx.x)	xxx xx.x (xx.x)	xxx xx.x (xx.x)	xxx xx.x (xx.x)
Median (Q1-Q3)	xx (xx-xx)	xx (xx-xx)	xx (xx-xx)	xx (xx-xx)
Emotional involvement				
N mean (SD)	xxx xx.x (xx.x)	xxx xx.x (xx.x)	xxx xx.x (xx.x)	xxx xx.x (xx.x)
Median (Q1-Q3)	xx (xx-xx)	xx (xx-xx)	xx (xx-xx)	xx (xx-xx)
Environment				
N mean (SD)	xxx xx.x (xx.x)	xxx xx.x (xx.x)	xxx xx.x (xx.x)	xxx xx.x (xx.x)
Median (Q1-Q3)	xx (xx-xx)	xx (xx-xx)	xx (xx-xx)	xx (xx-xx)
Total score				
N mean (SD)	xxx xx.x (xx.x)	xxx xx.x (xx.x)	xxx xx.x (xx.x)	xxx xx.x (xx.x)
Median (Q1-Q3)	xx (xx-xx)	xx (xx-xx)	xx (xx-xx)	xx (xx-xx)

Table 13. Hospital and home trial activities

	In hospital		At home	
Total activity time (hours)				
n mean (SD)	xxx xx.x (xx.x)		xxx xx.x (xx.x)	
median (Q1-Q3)	xx.x (xx.x – xx.x)		xx.x (xx.x – xx.x)	
min, max	xx.x, xx.x		xx.x, xx.x	
Types of activities performed				
Goal setting	# sessions	xxx (xx.x%)	# sessions	xxx (xx.x%)
Positioning	# sessions	xxx (xx.x%)	# sessions	xxx (xx.x%)
Mobility training	# sessions	xxx (xx.x%)	# sessions	xxx (xx.x%)
Functional task training	# sessions	xxx (xx.x%)	# sessions	xxx (xx.x%)
Communication practice	# sessions	xxx (xx.x%)	# sessions	xxx (xx.x%)
Other	# sessions	xxx (xx.x%)	# sessions	xxx (xx.x%)

Table 14. Self-reported rehabilitation training performed after hospital discharge

	Rehabilitation (N=xxx)
Total activity time (hours)	
n mean (SD)	xxx xxx.x (xxx.x)
median (Q1-Q3)	xxx.x (xxx.x – xxx.x)
min, max	xxx.x, xxx.x

Table 15. Hospital Routine Physiotherapy Activities Performed By Non-Trial Hospital Staff

	Usual care (n=xxx)		Intervention (n=xxx)		p-value [1]
Total activity time (hours)					
n mean (SD)	xxx xxx.x (xx.x)		xxx xxx.x (xx.x)		0.xxx
median (Q1-Q3)	xxx.x (xxx.x – xxx.x)		xxx.x (xxx.x – xxx.x)		
min, max	xxx.x, xxx.x		xxx.x, xxx.x		
Types of activities performed					
Goal setting	# sessions	xxx (xx.x%)	# sessions	xxx (xx.x%)	0.xxx
Positioning	# sessions	xxx (xx.x%)	# sessions	xxx (xx.x%)	0.xxx
Mobility training	# sessions	xxx (xx.x%)	# sessions	xxx (xx.x%)	0.xxx
Functional task training	# sessions	xxx (xx.x%)	# sessions	xxx (xx.x%)	0.xxx
Communication practice	# sessions	xxx (xx.x%)	# sessions	xxx (xx.x%)	0.xxx
Other	# sessions	xxx (xx.x%)	# sessions	xxx (xx.x%)	0.xxx

1. *T-test for the mean total activity time. Fisher's exact test for the proportion of patients with at least one activity.*

Table 16. Other intervention and imaging studies

	Usual care (n=xxx)	Intervention (n=xxx)	p-value [1]
CT brain	xxx (xx.x%)	xxx (xx.x%)	0.xxx
MRI brain	xxx (xx.x%)	xxx (xx.x%)	0.xxx
CT angiography	xxx (xx.x%)	xxx (xx.x%)	0.xxx
Thrombolytic Therapy	xxx (xx.x%)	xxx (xx.x%)	0.xxx
Intravenous tPA	xxx (xx.x%)	xxx (xx.x%)	0.xxx
Bridging therapy	xxx (xx.x%)	xxx (xx.x%)	0.xxx
Mechanical thrombectomy	xxx (xx.x%)	xxx (xx.x%)	0.xxx
MR angiography	xxx (xx.x%)	xxx (xx.x%)	0.xxx
Selective cerebral angiography	xxx (xx.x%)	xxx (xx.x%)	0.xxx
X-ray	xxx (xx.x%)	xxx (xx.x%)	0.xxx
Doppler ultrasound of carotids	xxx (xx.x%)	xxx (xx.x%)	0.xxx
Lumbar puncture	xxx (xx.x%)	xxx (xx.x%)	0.xxx
Transthoracic echocardiogram	xxx (xx.x%)	xxx (xx.x%)	0.xxx
Transesophageal echocardiogram	xxx (xx.x%)	xxx (xx.x%)	0.xxx
Transcranial Doppler ultrasound	xxx (xx.x%)	xxx (xx.x%)	0.xxx
Carotid endarterectomy	xxx (xx.x%)	xxx (xx.x%)	0.xxx
Carotid angioplasty	xxx (xx.x%)	xxx (xx.x%)	0.xxx
Cerebral angioplasty/stent	xxx (xx.x%)	xxx (xx.x%)	0.xxx
Vertebral angioplasty/stent	xxx (xx.x%)	xxx (xx.x%)	0.xxx

Numbers and percentages represent patients with at least one intervention.

Denominators are all randomised patients. P-value is from Fisher's exact test.