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Occupational therapy pre-discharge HOme VIsits for patients with a Stroke (HOVIS): results of a randomised controlled trial.

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No competing interests declared.

Contributions of authors

AD contributed to the conception and design of the protocol, conducted follow ups, performed analysis, interpreted data and drafted the final paper. **PW** contributed to the design, patient recruitment, conducted follow ups, analysis, interpretation of data and drafted sections of the paper. **KF** contributed to the design, recruited patients, designed and conducted interventions, interpretation of data and commented on drafts of the paper. **NS** contributed to the design, interpretation of data and commented on drafts of the paper. **CS** led and conducted analysis and interpretation of health economic data and drafted sections of the paper. **CE** conducted data entry, analysis, interpretation of data and commented on drafts of the paper.**NL** contributed to the conception and design, interpretation of data and commented on drafts of the paper.

ABSTRACT

Objective To conduct a randomised controlled trial (RCT) of occupational therapy pre-discharge home visits for people after stroke in order to assess the feasibility of a definitive trial.

Design Two studies; a randomised controlled trial and a cohort study. We randomised eligible patients for whom there was clinical uncertainty about the need to conduct a home visit in to an RCT; patients for whom a visit was deemed 'essential', were enrolled into a cohort study.

Setting Stroke rehabilitation unit of teaching hospital

Participants 126 participants hospitalised following recent stroke.

Interventions Pre-discharge home visit with an occupational therapist or structured hospital based interview with occupational therapist.

Main outcome measures The primary objective was to collect information on the feasibility of an RCT, including eligibility criteria, consent procedures, control intervention, and outcome assessments. The primary outcome measure was the Nottingham Extended Activities of Daily Living scale (NEADL) at one month after discharge from hospital. Secondary outcomes were measures of activities of daily living, mood, quality of life and costs at one week and one month following discharge.

Results Ninety- three people were allocated to the RCT. Of these 47 were randomised to intervention and 46 to the control. Thirty-three patients were enrolled into the cohort study and received a home visit. Forty-one (87%) participants in the RCT intervention group and 29 (88%) participants in the cohort study received the intervention.

There were no significant differences in outcome between the groups in the RCT for the primary outcome measure (performance in extended activities of daily living) at one month. The average cost of a home visit was £208 (£183 for those in the RCT and £243 for those in the cohort study). The average cost of the interview for the control group was £75.

Conclusion Our main finding was that recruitment to the trial was feasible and no safety issues were raised. A trial is warranted given the resource implications of pre- discharge occupational therapy home visits.

Trial Registration Number Current Controlled Trials ISRCTN 62250268

Sponsor University of Nottingham

Introduction

People who have had a stroke and who are admitted to hospital may be offered a pre-discharge home visit by an occupational therapist. A home visit to evaluate patients in their usual environment is believed to increase the ability to cope at home and in the wider community [1] as well as enabling any issues about safety to be addressed [2]. In addition to assessing for potential problems, the visit provides the patient with the opportunity to practise the techniques they have learnt in hospital in their own home. This may be particularly important for people after stroke who may have hemiparesis, impaired cognition or aphasia. The 2006 National Sentinel Stroke Audit [3] reported that 73% of patients admitted to a stroke unit had a home visit before discharge but there is no evidence on whether they actually improve patient outcome.

Performing home visits constitutes a significant element of practice for NHS occupational therapists; a recent survey of the total time spent on home visits (including preparation, travel, visit, administration) with patients following a stroke was just under four hours per visit [4]. However there is little evidence to support the effectiveness of these visits. Barras[5] identified four RCTs of home visits, but these included both pre- and post-discharge assessments, focused on older people and concentrated particularly on falls prevention. The data were too limited and the follow up periods were too short to reach any meaningful conclusions and both the paucity of quality and quantity of the studies reviewed were highlighted. No RCT of home visits after stroke have been identified.

One of the reasons for the lack of evidence may be the concern that it would be unethical to withdraw such an established and accepted treatment [6]. A pilot study of home visits with older people in Australia [1] recruited only ten participants over three months despite admission records suggesting many more people should have been available. The authors believed that therapists were concerned about patients being allocated to the control group and consequently did not enrol them in the trial.

The aim of this study was to assess the feasibility of an RCT in order to test out and revise the design for a definitive trial. In order to address the potential ethical and recruitment issues, we set and agreed criteria for a 'home visit essential' cohort study to include those patients whom the clinical therapists would be unwilling to randomise due to safety concerns. The objective was to establish whether participants could be recruited to a RCT while acknowledging the clinical concerns of therapists.

Method

Ethical Approval

All patients were approached for informed, written consent. In those who lacked capacity, consent was obtained in keeping with the research provisions of the Mental Capacity Act of England, and as approved by the Research Ethics Committee (Berkshire Research Ethics Committee ref 10/H0505/41). Participants were free to withdraw from the trial at any stage. Data were included in the analyses up to the point of withdrawal.

Design

The design consisted of two separate studies: a randomised controlled trial and a cohort study.

Eligible patients for randomisation were those for whom there was clinical uncertainty about whether or not a home visit was indicated. These patients were randomised to either an intervention (home visit) or control (no visit) group.

Patients included in the cohort study were those for whom ward clinicians believed a home visit was essential. The criteria were that these patients had new, significant functional impairment and/or environmental concerns which staff believed could not be assessed without a home visit. For example they were dependent in transferring or the home needed to be assessed for major equipment such as a hoist.

In conducting these studies, we were primarily interested in gathering and analysing information on eligibility criteria, consent procedures, intervention, collaboration with participating NHS staff and the completion rate of outcome assessments.

Participants

All patients transferred from the acute stroke unit to the stroke rehabilitation unit in Royal Derby Hospital between July 2010 and October 2011 with a confirmed diagnosis of stroke, were considered.

During their first 10 days on the stroke rehabilitation unit, the decision as to whether patients required a home visit (i.e. were eligible for cohort study) or were eligible for randomisation was made by the patient's named occupational therapist, in consultation with the multidisciplinary team.

Patients were excluded if they; did not speak English; would not normally be offered a home visit e.g. those with existing co-morbidities who needed to be transferred to other wards; were due for discharge out of the Derbyshire area; required an access visit only (a visit by the occupational therapist without the patient being present). Patients who were to be discharged to residential or nursing homes were eligible for inclusion. After obtaining informed consent, baseline data were collected on all participants in both the RCT and cohort studies.

Interventions

Patients recruited to the RCT were randomised using web based randomisation by Nottingham Clinical Trials Unit, who held a pre-prepared list in random varying block sizes.

Those allocated to the **intervention group** were offered a pre-discharge home assessment visit with an occupational therapist. Patients were assessed in their own

home and any potential problems were discussed and addressed **in the home environment.** The patient's relative or carer(s) were invited to be present during the visit. Referrals were made to other agencies where required. On the visit, patients were offered advice, given practise in transfers and activities of daily living (ADLs), and offered equipment or adaptations, such as grab rails.

Those allocated to the **control group** received a pre-discharge home assessment structured interview with an occupational therapist **in the hospital**. The patient's discharge and any potential problems were discussed in general terms. The patient's relative or carer(s) were invited to participate in the interview. Referrals on to other agencies were made as required and patients were given the opportunity to practise using equipment in hospital, if necessary.

Patients in the **cohort study** received a home visit using the same protocol as those in the RCT intervention group. A record was kept of the clinical team's reasons for deciding that a visit was essential.

Patients in all groups were treated by both ward occupational therapists and by the research occupational therapist who was based in the unit; visits were shared equally in order to control for the effect of individual therapists.

Outcome Measures

The primary outcome measure was the Nottingham Extended Activities of Daily Living (NEADL) [7] at one month after discharge from hospital.

Secondary outcomes were

- disability as measured by the Barthel Index[8]
- health related quality of life, measured using the EQ-5D[9] questionnaire

- mood using the GHQ 28[10] and the SADQ-H10[11]; those with communication problems had only the SADQ-H10 completed
- costs. For the home visit this included; costs of staff attending, travel time, time at home, administrative time associated with visit, cost of transport, cost of time taken to recommend actions, equipment and for referrals. For the interview this included; staff present, duration of interview, recommendations made, equipment tested, referrals made and any information supplied
- number of falls and readmissions.

For the outcome assessments the researcher was masked to the group allocation. All participants were followed up at one week and at one month following discharge from hospital.

Analysis

Data were analysed using SPSS version 16. The majority of the data were entered and analysed blind to group allocation; specific home visit data were entered last by an independent researcher.The analysis focused on determining feasibility, examining the primary outcome measure and on examining any differences between participants in the cohort and RCT studies. Analyses were carried out on the basis of intention to treat.

For baseline and outcome measures where less than 10% of the total data were missing, mean values were imputed for individual missing items. Where 10% or more data were missing, the entire measure was coded as 'missing'. The exceptions were the ACE-R[12] (which was used only at baseline) and the EQ-5D [9]; no values were imputed for these measures and missing values were coded as '0'.

Results

Participants

The flow of participants through the study is shown in Fig 1. Out of 297 patients

admitted to the stroke rehabilitation unit, 216 met the eligibility criteria. Of the 81 not eligible; 36 were discharged before a decision about the need for a home visit was made, 10 were deemed to need access visits only, 9 were transferred (5 to other wards and 4 outside the catchment area) 7 died, 6 did not speak English, 5 were terminally ill, 4 were still on the ward when study was closed and 4 were 'other' reasons e.g. diagnosis of stroke unconfirmed, re-admission, planning not to return directly to own home, and missed.

Of the 216, 173 were suitable for the RCT and 93 were subsequently randomised (47 to the intervention; 46 to control). 33 people were enrolled into the cohort study. Baseline characteristics are shown in Table 1. The mean age at randomisation to the study was 72 years (SD 14.67, range 34-99). The RCT groups were well balanced at baseline for demographic characteristics and baseline measures.

By comparison with participants in the RCT, the participants in the cohort study were more likely to be female, live alone and have received a support package prior to admission. They were also more likely to have been consented by a consultee and have lower cognition scores as measured on the ACE-R[12]. The most common reasons for allocation to the cohort study were specific environmental concerns at home (e.g. stairs), cognitive issues including lack of insight or the patient living alone. Reasons were recorded for 24 of the cohort participants and for 23 of them, more than one reason was supplied.

Outcome measures

There were no significant differences between the groups in the RCT for any measure except mood (measured on the SADHQ 10[11] at one week) and readmissions to hospital at one month (Table 2). The former was in favour of the intervention group; the latter in favour of the control group). More participants in the intervention group (n=8) were readmitted to hospital by one month after discharge than in the control group

(n=2). This was statistically significant (p=0.04). More participants had one or more falls in the control group initially (6 compared to 2 in the intervention group); more participants had one or more falls in the intervention arm thereafter (n=13 compared to 9 in the control group). However these differences were not statistically significant.

Costs

The main costs associated with home visits related to the amount of staff time required. The average time spent by the primary member of staff on a home visit, (including organising, completing and writing-up visits) was 180 minutes for the RCT participants and 203 minutes for those in the cohort study. The average total cost of staff time in the RCT home visit was £158. The average cost of staff time in the cohort study was £215. Other costs related to home visits included travel costs, parking fees and the provision of milk for kitchen assessments. The total cost of a home visit for RCT participants was, on average, £183. For the cohort study group the average cost was £243, giving an average across all home visits of £208.

With regard to the RCT control group, the average time spent by the primary staff member on the hospital interview was 99 minutes, and the average total cost of a hospital interview was £75.

Feasibility

As the trial progressed, clinical staff allocated more patients to the RCT; in the first four months of recruiting the majority of patients were deemed to be 'essential' for a home visit and enrolled to the cohort study whereas in the last four months the situation was reversed (Figure 2).

With regard to consent, as Figure 1 shows, many people suitable for the RCT declined to participate (n=53; 31%) and even in the cohort group where people were already having a visit, 16% (n= 7) declined to participate in the study. However, follow up was good;

at one month there was 90% follow up (n=114). We were also able to follow up people as planned. The mean follow up time at one week across the groups was 7.42 days (SD 1.27; range 6-14 days) and 29.89 days at the one month assessment (SD 4.80; 24-56 days).

With reference to questionnaire completion, the majority of measures were fully completed. The main exception was GHQ 28[10] which had the most incomplete responses (see Table 2), even with an assessor available to help. Several questions were systematically missed by patients who felt they were intrusive such as questions related to suicidal thoughts.

In delivering the home visit intervention, 29 participants in the cohort study received the intervention although 2 of these had two home visits and 1 was discharged on the visit. Of the 4 people who did not subsequently have a visit, 1 went into a nursing home, 1 was for re-housing, 1 was transferred prior to having a visit and 1 was still in hospital when the study closed. In the RCT, 41 people had the intervention (1 person had two visits, 1 person had an access visit plus a home visit, 8 people were discharged on the visit and 3 people received the visit after discharge); 6 people did not (3 were transferred to other wards, 2 were discharged before intervention and 1 received the control interview). In the control group, 43 people had the hospital interview however of these 4 people also received an access visit and 2 people received a home visit (one of whom was discharged on the visit). 2 people did not receive the intervention (1 was discharged and 1 withdrew from the trial).

Discussion

This was a pragmatic trial undertaken in a clinical setting; the eligibility criteria were agreed beforehand and the use of a parallel cohort study meant that clinicians did not have to randomise patients for whom they felt a home visit was essential. We believe it was for this reason that we were able to recruit to this study,-in contrast to the problems

experienced by Australian colleagues [1]. We also think that giving control to the clinicians allowed them to be more confident in suggesting patients for randomisation, which increased over the study period.

However, although we have demonstrated that such a trial is feasible in terms of recruitment and follow up, we have identified some issues. There were problems with patient completion of one of the measures (GHQ 28)[10] and several questions were systematically not answered. This leads us to question the use of this measure in a subsequent trial. There was a need for stricter protocol adherence in the RCT; some people received a home visit or an access visit, when they should not, or received more than one visit or were discharged on the visit. All of these factors would need to be addressed in a definitive trial.

There were also important issues identified regarding the control group. It is likely that patients in this group received more intervention than is standard care in most centres; we know that in some hospitals patients are discharged from hospital following a stroke without any visit[4] and interviews are not routine practice. It may be that the control group received too much intervention - although it would have been difficult to give people nothing in a service where the majority of patients previously had a visit. It is also interesting, even allowing for the fact that the study was underpowered, that patients who had the interview seemed to have similar outcomes to those who had a home assessment. This may reflect that the in depth 'control' intervention attenuated any outcome differences between the two groups, or may reflect a genuine lack of efficacy of home visits. This clearly needs further investigation. Most importantly this trial shows that a larger definitive trial is possible and warranted given the cost of visits and the lack of evidence of efficacy.

- **Study question**

Is it feasible to conduct a RCT of pre-discharge occupational therapy home visits for patients after stroke?

- **What is already known and what this trial adds**

Pre-discharge home visits constitute a significant element of practice for NHS occupational therapists. However there is no clear rationale for patient selection, no evidence for efficacy and no information on costs. This research shows that a trial is both feasible and warranted. It also provides important data on the costs of undertaking home assessment visits.

- **Summary Answer**

This trial was feasible although the design of the control intervention needs further refinement and stricter protocol adherence would be essential in a definitive trial. A definitive trial is warranted given the resource implications of these assessment visits.

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Figure One: CONSORT Diagram

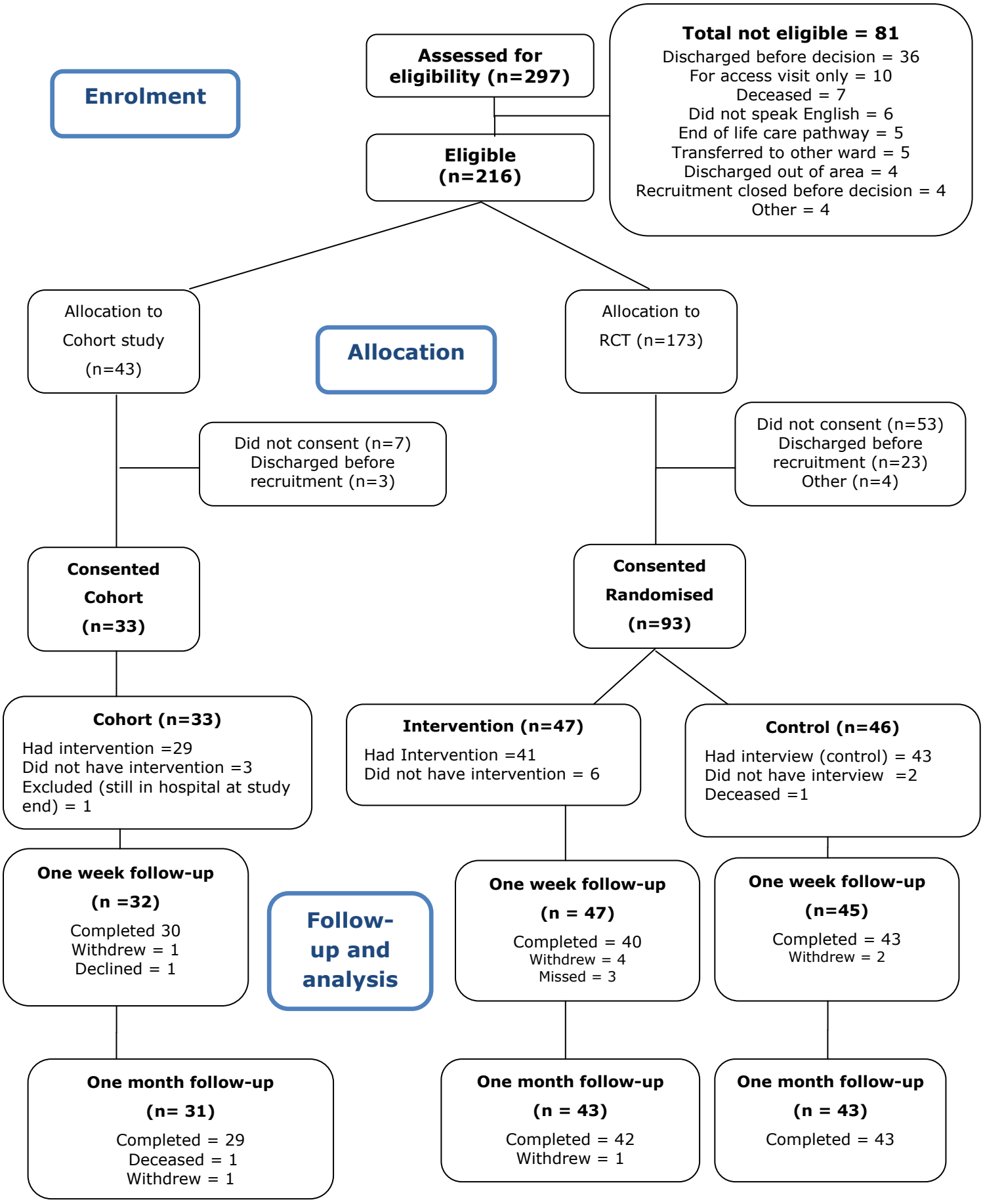

Figure 2 Recruitment during study.

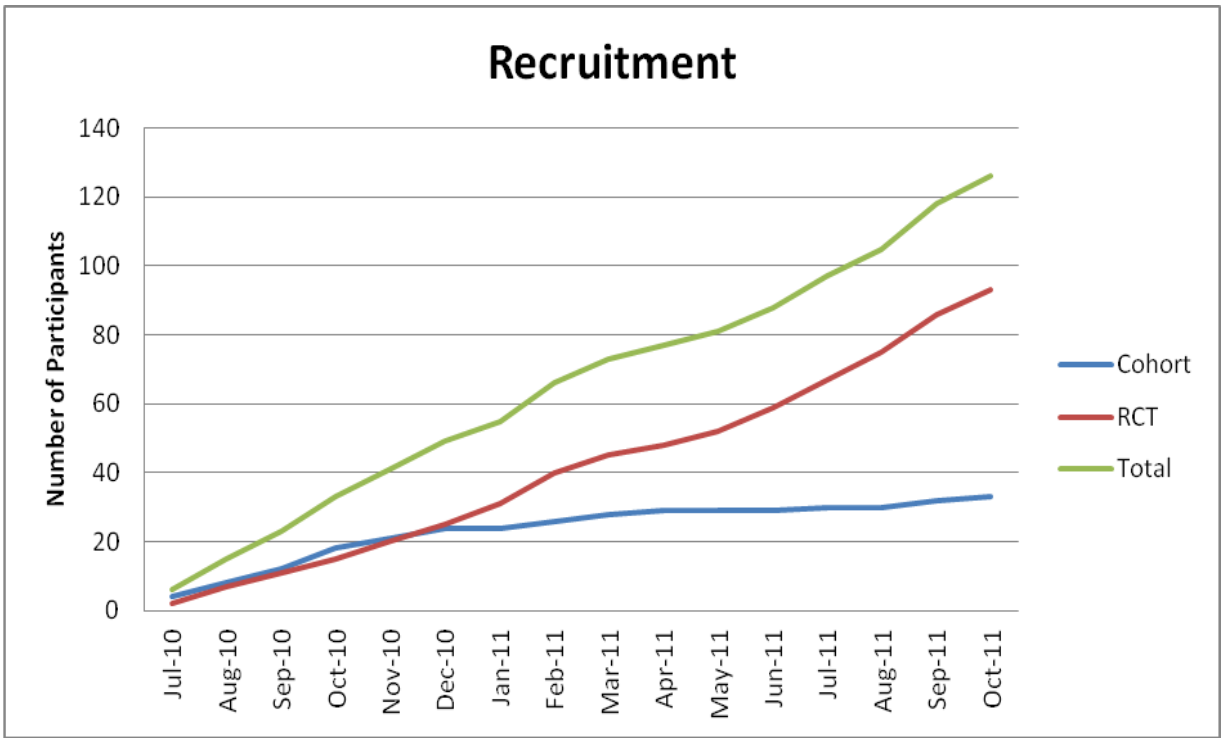

Table 1: Baseline Characteristics by Group

	RCT			Cohort
	Intervention Group (n=47)	**Control Group (n=46)**	**TOTAL for RCT (n=93)**	**Intervention (n=33)**
Age (sd) (Range)	70.64 (14.29) (34-88)	73.65 (15.06) (41-99)	72.13 14.67) (34-99)	71.73 (12.72) (44-88)
Male (%)	26 (55.3%)	24 (52.2%)	50 (53.8%)	15 (45.5%)
White British (%)	43 (91.5%)	41 (89.1%)	84 (90.3%)	30 (90.9%)
Living Alone (%)	15 (31.9%)	15 (32.6%)	30 (32.3%)	16 (48.5%)
Previous Support (%)	2 (4.3%)	3 (6.5%)	5 (5.4%)	6 (18.2%)
Consultee (%)	4 (8.5%)	2 (4.3%)	6 (6.5%)	5 (15.2%)
Modified Rankin*				
Moderate Disability (%)	6 (12.8%)	7 (15.6%)	13 (14.1%)	4 (12.1%)
Moderately Severe Disability (%)	22 (46.8%)	24 (53.3%)	46 (50.0%)	22 (66.7%)
Severe Disability (%)	19 (40.4%)	14 (31.1%) [1]	33 (35.9%) [1]	7 (21.2%)
Premorbid Barthel * median (IQR)	20 (20-20) [1]	20 (18-20)	20 (19-20) [1]	20 (20-20)
Recruitment Barthel * median (IQR)	9 (5.75-13.25) [1]	9 (5-14.25)	9 (5.25-13.75) [1]	10 (6.5-13)
+ GHQ-28 ** median (IQR)	14 (10-22) [2]	15 (10-19) [3]	15 (10.25-21) [5]	13.5 (9.75-21) [3]
ACE-R *** median (IQR)	72 (54-82.50) [2]	69.50 (53.75-80.50)	71 (54-82) [2]	64 (40.25-79.50) [1]
EQ-5D mean (SD)	0.394 (0.371) [2]	0.430 (0.316) [2]	0.411 (0.344) [4]	0.483 (0.321) [2]

+ lower score indicates a better outcome

[] missing values

Table 2: Outcome measures

	One Week				One Month			
	RCT			Cohort	RCT			Cohort
	Intervention Group (n=40) Median (IQR)	**Control Group (n=43)** Median (IQR)	**P value #**	**Intervention (n=30)** Median (IQR)	**Intervention Group (n=42)** Median (IQR)	**Control Group (n=43)** Median (IQR)	**P Value #**	**Intervention (n=29)** Median (IQR)
NEADL	10.5 (7-23.5)	13 (6-24.5) [1]	0.75	11 (6.75-19.75)	14.5 (3-37.25)	20 (9-36)	0.52	15 (7-30)
Barthel Index	14.5 (7.25-17.75)	16 (10-19)	0.29	16.5 (10-18.25)	15.5 (8-19)	17 (11-19)	0.41	16 (14-19)
Rivermead Mobility Index	6.5 (4-10)	7 (6-12)	0.26	7 4-9	N/A			
GHQ-28 +	18.5 (13.75-36.5) [6]	24 (15-32) [4]	0.35	19 (15-27.5) [6]	19 (12.25-23.75) [6]	23 (15.5-31.5) [6]	0.10	14.5 (12-24) [7]
SADQ-H10 +	4 (2.25-8) [8]	7 (4-11) [14]	**0.05**	5.5 (3-10.75) [10]	6 (3.25-9.75) [10]	7 (4-11) [16]	0.37	6 (3-12.25) [11]
Caregiver Strain Index +	5 (2.25-7) [19]	6 (3-7) [22]	0.49	3 (2.25-6.75)	5.5 (1.75-7)	6 5-8	0.11	3.5 (1.5-7)
EQ-5D		N/A			**Mean** 0.53 **SD** (0.33) [1]	**Mean**0.50 **SD** (0.35) [1]	0.74	**Mean** 0.57 **SD** (0.30) [2]

+ lower score indicates better outcome ; # p value from Mann Whitney U test; [] missing values