Rehabilitation of older patients: day hospital compared with rehabilitation at home.

Clinical outcomes

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Abstract

Objectives: to test the hypothesis that older people and their informal carers are not disadvantaged by home-based rehabilitation (HBR) relative to day hospital rehabilitation (DHR).

Design: pragmatic randomised controlled trial.

Setting: four geriatric day hospitals and four home rehabilitation teams in England.

Participants: eighty-nine patients referred for multidisciplinary rehabilitation. The target sample size was 460.

Intervention: multidisciplinary rehabilitation either in the home or in the day hospital.

Measurements: the primary outcome measure was the Nottingham extended activities of daily living scale (NEADL). Secondary outcome measures included EQ-5D, hospital anxiety and depression scale, therapy outcome measures, hospital admissions and the General Health Questionnaire for carers.

Results: at the primary end point of 6 months NEADL scores were not significantly in favour of HBR cf. DHR; mean difference –2.139 (95% confidence interval –6.87 to 2.59, P = 0.37). A post hoc analysis suggested non-inferiority for HBR for NEADL but there was considerable statistical uncertainty.

Conclusion: taken together the statistical analyses and lack of power of the trial outcomes do not provide sufficient evidence to conclude that patients in receipt of HBR are disadvantaged compared with those receiving DHR.

Keywords: day hospital, community rehabilitation, rehabilitation

Introduction

Geriatric (medical) day hospitals have traditionally provided rehabilitation [1]. More recently, there has been an emphasis of rehabilitation being available in the patients homes with government policy encouraging community care to prevent admission to hospital and promote early discharge [2–4]. Recently, services for people with long-term conditions have been required to adhere to national quality standards including the provision of early and specialist rehabilitation in hospital or other specialist settings with additional community rehabilitation and support [5]. The relative effectiveness of rehabilitation services provided in the day hospital compared with that provided in the home is therefore a key issue in the UK at the interface between hospital and community-based services for older people with long-term conditions.
While there are a number of previous randomised controlled trials of day hospital services, only two have compared day hospital rehabilitation (DHR) directly with home-based rehabilitation (HBR) [6, 7] and the nature of both services have changed substantially over the intervening period.

We have undertaken a multi-centre randomised controlled trial of DHR versus HBR for patients referred for multidisciplinary rehabilitation to test the hypothesis that older people and their informal carers are not disadvantaged by multidisciplinary rehabilitation delivered in the home as compared with that delivered in day hospitals.

Methods

The trial protocol was informed by interviews and discussion with staff and patient advisory groups [8].

A national survey of 400 service providers resulted in information about 19 sites which provided both types of service (DHR and HBR), who were then directly contacted to recruit the four sites that participated in the trial.

Multi-centre ethical approval was granted by the NHS South West Research Ethics Committee (MREC/04/6/14) and local research governance approval was obtained for all participating sites (ISRCTN71801032). The trial was funded in the Health Technology Assessment programme of the National Institute for Health Research (HTA 97/26/01).

On each site, clinical staff reviewed consecutive referrals to identify subjects who were referred to the service for multidisciplinary rehabilitation and had a permanent address within the defined catchment area of the service.

Subjects were of any age and able to provide informed consent, if necessary with the help of a carer or advocate. There were no over-arching exclusion criteria, but each site had some specific services (for example services for Parkinson’s disease or falls) which were provided in only one setting. Local exclusion criteria ensured that patients were excluded from randomisation if they had a specific clinical need that could only be addressed in one setting.

A web-based system was used to randomise to DHR or HBR. Random permuted blocks of size 10 were used and randomisation was stratified by centre, AMT score, gender and by the presence of a carer.

The primary endpoint was the overall score on the Nottingham extended activities of daily living scale (NEADL) [9] at 6-month follow-up (range 0–66). Secondary outcome measures included the NEADL total scores at 3 and 12 months and the NEADL sub-scale scores, the hospital anxiety and depression scale (HADS) [10] and Euroqol EQ-5D [11, 12] at 3, 6 and 12 months and the therapy outcome measures (TOMs) rating scale [13] at the end of therapist rehabilitation.

The General Health Questionnaire 30 (GHQ-30) [14, 15] was used with carers at 3, 6 and 12 months.

Data collectors were trained in the use of the assessment interview schedules and clinical staff received training in the use of TOMs. Patients completed interviews in their own homes with baseline data being collected after consent, but before randomisation. Questionnaires were completed in the patients’ homes by researchers, who were not aware of treatment allocation.

Patients, their health care professionals and local investigators could not be blinded to treatment allocation. The central research team, involved with data management, validation, analysis and interpretation of findings, remained blinded until after initial data analysis.

Hospital admission details over the 12-month follow-up period were obtained from hospital information systems.

Sample size calculation was performed using published characteristics of the Nottingham EADL [16] and we estimated that a sample of 460 patients (230 subjects and 230 controls) would have 80% power to detect a two-point difference using a significance level of 5%.

Continuous scale scores from primary and secondary outcomes were compared using analysis of covariance with baseline scores as the covariate. Dichotomous outcome data were analysed using logistic regression. TOMs data were analysed using non-parametric methods (Mann-Whitney U test). Hospital admission data were analysed using binary logistic regression.

The primary analysis was predefined as observed case analysis (an analysis in which data are analysed for every participant for whom data were obtained). An intention to treat analysis using missing value imputation was also conducted and the results of both of these were compared to assess potential attrition bias.

Continuous data were analysed using linear mixed models for repeated measures (MMRM) with interview follow-up point and patient treated as random effects. Outcome scores missing due to loss to follow-up were imputed using the last observation carried forward (LOCF) method [16]. All three methods were compared.

Additionally, a post hoc non-inferiority analysis was performed [17].

Results

Nineteen expressions of interest were received from 400 NHS Trusts. Seven agreed to participate in the trial and four sites were able to continue to randomisation. Services and staffing of participating sites are described elsewhere [8], and summarised in the table Appendix 1 available in Age and Ageing online.

Nine hundred and seven potential participants were assessed for eligibility, 89 were allocated to the trial and 84 randomised to either HBR or DHR (Figure 1). We assessed 472 patients who were ineligible including 272 (58%) who were not referred for multidisciplinary rehabilitation and 143 (30%) who were excluded because of site-specific service configuration, 235 patients declined to be enrolled in the trial and 111 were excluded for other reasons [see 8]. These levels of ineligibility, exclusion and refusal led to
lower than expected levels of recruitment into the trial and resulted in closure of recruitment before the target sample size had been achieved. Twelve-month follow-up was sacrificed for some subjects to achieve a timely end to the trial.

Demographic characteristics of the two groups of participants and their carers and baseline data were similar between the groups (Table 1). No participant scored <7 out of 10 on the abbreviated mental test (AMT) score.

Reasons for referral to the rehabilitation service (n = 134) included 30 (22%) for stroke rehabilitation, 36 (27%) for falls assessment, 29 (21%) for mobility assessment, 12 (9%) for orthopaedic rehabilitation and 27 (20%) for other reasons. Fifty-two (58%) were referred for a single reason, 37 for multiple reasons including 27 for 2 and 10 for 3 or more.

Mean (SD) total scores for the NEADL at 6 months were not significantly different between groups (HBR 30.78 (15.01) versus DHR 32.11 (16.89)) and this remained after adjustment for baseline score by analysis of covariance (mean difference −2.139, 95% confidence interval (CI) −6.87–2.59, P = 0.37) (Table 2). This is our best estimate of the effect, suggesting that HBR could be better by 2.1 points on the NEADL; however, it could be as high as 6.9 points better or as low as 2.6 points worse on the NEADL compared with DHR. No differences in NEADL sub-scale scores were observed. There were no significant differences in EQ5D or HADS scores for anxiety or depression between the groups at 6 months (Table 2). The EQ5D domain scores suggested a tendency for HBR patients to experience less difficulty with anxiety/depression than DHR (odds ratio (OR; 95% CI) 0.34, (CI 0.11–1.05) P = 0.06).

No statistically significant differences were seen in NEADL, EQ5D and HADS scores at 3 or 12 months. There was a tendency for differences in depression scores on the HADS at 3 months to be better for the HBR group.
Table 1. Baseline characteristics of patients and their carers

<table>
<thead>
<tr>
<th>Variable</th>
<th>DHR (n = 42)</th>
<th>HBR (n = 42)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient demographics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>42</td>
<td>42</td>
</tr>
<tr>
<td>Mean age in years at first interview (SD; min—max)</td>
<td>76 (11; 53–95)</td>
<td>74 (11; 43–88)</td>
</tr>
<tr>
<td>65 years or younger (%)</td>
<td>19.0</td>
<td>21.4</td>
</tr>
<tr>
<td>66–74 years (%)</td>
<td>14.3</td>
<td>19.0</td>
</tr>
<tr>
<td>75–84 years (%)</td>
<td>42.9</td>
<td>45.2</td>
</tr>
<tr>
<td>85 years or older (%)</td>
<td>23.8</td>
<td>14.3</td>
</tr>
<tr>
<td>Gender: % female</td>
<td>45.2%</td>
<td>45.2%</td>
</tr>
<tr>
<td>Nottingham extended ADL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean total score 0–66 (SD)</td>
<td>31.43 (14.53)</td>
<td>28.56 (15.88)</td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>32.60 (21.50)</td>
<td>28.50 (27.75)</td>
</tr>
<tr>
<td>EUROQOL EQ5D</td>
<td></td>
<td></td>
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<tr>
<td>EQ5D weighted health state index (EQ5Dindex)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>0.51 (0.26)</td>
<td>0.55 (0.29)</td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>0.59 (0.21)</td>
<td>0.60 (0.34)</td>
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<tr>
<td>Valuation of own health (EQ5Dv)</td>
<td></td>
<td></td>
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<tr>
<td>Mean (SD)</td>
<td>56.74 (18.37)</td>
<td>54.05 (16.54)</td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>55.00 (24.00)</td>
<td>50.00 (25.00)</td>
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<tr>
<td>HADS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean anxiety score (SD)</td>
<td>7.79 (4.71)</td>
<td>6.29 (4.60)</td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>8.00 (8.25)</td>
<td>5.00 (4.00)</td>
</tr>
<tr>
<td>Mean depression score (SD)</td>
<td>6.98 (3.74)</td>
<td>7.31 (4.12)</td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>7.00 (6.00)</td>
<td>7.00 (7.25)</td>
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<tr>
<td>Probable clinical anxiety (%)</td>
<td>52.4</td>
<td>26.2</td>
</tr>
<tr>
<td>Probable clinical depression (%)</td>
<td>35.7</td>
<td>47.6</td>
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<tr>
<td>Details of carer</td>
<td></td>
<td></td>
</tr>
<tr>
<td>n</td>
<td>23</td>
<td>23</td>
</tr>
<tr>
<td>Mean age at first interview (SD; min—max)</td>
<td>64 (12.67; 39–93)</td>
<td>64 (10; 43–86)</td>
</tr>
<tr>
<td>Gender: % female</td>
<td>60.9%</td>
<td>82.6%</td>
</tr>
<tr>
<td>Relationship to patient (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spouse</td>
<td>61</td>
<td>48</td>
</tr>
<tr>
<td>Child</td>
<td>22</td>
<td>22</td>
</tr>
<tr>
<td>Friend</td>
<td>9</td>
<td>17</td>
</tr>
<tr>
<td>Other</td>
<td>9</td>
<td>13</td>
</tr>
</tbody>
</table>

by 1.35 points (95% CI –0.039 to 2.768, P = 0.056) after adjustment for baseline.

The figure in Appendix 2 available in Age and Ageing online provides a summary of the effect of place of care on the principal outcomes. Estimated differences between DHR and HBR on each outcome (±95% CI intervals), after adjusting for baseline scores, were expressed as a percentage using respective scale ranges as denominators. The 5 and 10% inferiority limits are shown to guide interpretation.

Median therapist ratings for the four TOMs dimensions (impairment, activity, psychosocial and well-being) at the end of rehabilitation were 4.0 (*mild impairment*) or better with similar scores seen between groups. Differences between the two treatment groups on discharge (Mann–Whitney U) were not statistically significant.

There was no evidence of any differences between groups in the mean GHQ-30 scores of carers at 3, 6 or 12 months.

Eighteen (43%) HBR patients and 22 (52%) DHR patients were admitted to hospital over the observation period (OR = 0.75, 95% CI = 0.62–3.47, P = 0.383). Mean total length of stay was not significantly different between the groups (mean difference 95% CI 9.3 (–12.5 to 31.1) days).

Mean total NEADL scores at 6 months along with those for the other main patient outcomes were analysed after replacement of missing data due to loss to follow-up by the LOCF method. The only statistically significant difference in this analysis was for HADS depression, which was estimated to be 1.4 points better in the HBR group (95% CI 0.05–2.66, P = 0.042).

Estimated differences in 6-month patient outcomes obtained from the observed case and LOCF datasets were compared with estimates provided by the MMRM analysis. The general conclusions reached from the primary analysis dataset were supported in all three analyses.

**Discussion**

This RCT, comparing DHR to HBR, was stopped early following discussion with the HTA Programme Director, who commissioned the study and the Trial Steering Committee. The target sample size was not achieved due to difficulties recruiting centres and participants associated with continuous reconfiguration of services in many locations. These changes to day-hospital services and other community-based rehabilitation services would be a major challenge to any community-based research, and we had the experience that many willing and potential participating sites were unable to be involved in research because of uncertainty of stability in service provision. Before the start of the trial we carried out a national survey of Health Authorities and Trusts, which suggested continued validity of the research question, despite a changing service landscape [8].

Primary analyses were based upon the observed case dataset. In supplementary analyses data missing due to loss to follow-up were replaced using the LOCF method and using a mixed model for repeated measures analysis [17]. All of these analyses gave rise to the same interpretation.

We found little evidence of a difference in NEADL scores between the groups at 3, 6 and 12 months. Our best estimate of any effect is that HBR may be better by an
average of about 2.1 points on the NEADL scale. However, it could be as high as 6.9 points better than or as low as 2.6 points worse. No strong effects on secondary outcome measures were observed at any time point for either patients or carers.

Although the original study hypothesis was stated in terms of non-inferiority (‘older people and their informal carers are not disadvantaged by HBR relative to DHR’), the original sample size calculation was based on the power to detect a clinically significant difference between the two arms of the trial. A post hoc decision was taken by the analysis team to perform additional statistical analyses based on testing for non-inferiority. This is a controversial approach since the assessment of non-inferiority can only be made if it is part of the a priori analysis strategy with pre-defined non-inferiority limits defined with the involvement of independent experts. This study was not designed as a non-inferiority study and there was no discussion between the analysis team and independent experts about the setting of non-inferiority limits, which depend on an a priori definition of minimum clinically worthwhile difference. The NEADL has been used in studies in hospital and HBR in older people which have observed differences between treatments of 0 (the DOMINO study [18]), 3 points (or about 4% of scale range) in a trial of an early discharge rehabilitation service [19], 7.1 points (10% of scale range) 3 months after successful hip replacement [20] and about 12 points (18% of scale range) a year after stroke [21]. The test–re-test reliability of the NEADL has been found to be of the order of plus or minus four points [22].

This analysis could be said to have almost demonstrated the non-inferiority of HBR, depending on the definition of the non-inferiority limit, but there remains considerable statistical uncertainty. We therefore advise caution in generalising the study conclusion: considered together the statistical analyses of the trial outcomes do not provide sufficient evidence to conclude that participants in receipt of HBR are disadvantaged compared with those receiving DHR.

A systematic literature review has suggested that day hospital-based comprehensive services are advantageous to the recipients, producing shorter inpatient stays and improved functional outcomes [23]. These studies effectively compared treatment with no treatment and established a role for day hospital-based services and were undertaken when home-based rehabilitation was less usual. Studies that examined place of care have suggested little advantage or disadvantage of day hospitals over other settings for providing ‘comprehensive’ care [24]. A recent study that compared day hospital with home-based care favoured the home as a better site for post-hospital rehabilitation, and suggested that DHR encouraged higher levels of service use [7]. Place of care remains an important focus for research, because of the current policy imperative to shift care into the community.

While the results of this and other research can be informative for local stakeholders in rehabilitation for older people, local decisions will need to be made in the context of local service delivery infrastructure and development needs. While the configuration of community services remains important, trials of day hospital versus HBR services currently provide only limited evidence about optimising these services to meet patient’s needs. Therefore in deciding about the settings in which to provide rehabilitation services, stakeholders will need to consider the costs and benefits of HBR and ambulatory support provided in day hospitals in the light of local needs to provide the benefits of both kinds of service.

Key points
- Provision of rehabilitation services is a traditional function of day hospitals.
- Provision of rehabilitation in the home is a viable alternative.
- Similar clinical outcomes can be achieved in both settings.

Supplementary data
Supplementary data mentioned in the text is available to subscribers in Age and Ageing online.

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Conflicts of interest
None declared.

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References
Childhood intelligence and brain white matter hyperintensities predict fluid intelligence age 78–81 years: a 1921 Aberdeen birth cohort study

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Abstract

Objectives: to evaluate the role of childhood intelligence and white matter hyperintensities (WMH) in the prediction of the trajectory of fluid intelligence in healthy old people from age 78 to 81.

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