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The research reported in this issue of the journal was commissioned by the HTA programme as project number 97/26/01. The contractual start date was in September 2002. The draft report began editorial review in December 2007 and was accepted for publication in January 2009. As the funder, by devising a commissioning brief, the HTA programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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Abstract

Rehabilitation of older patients: day hospital compared with rehabilitation at home. A randomised controlled trial

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Objectives: To test the hypotheses that older people and their informal carers are not disadvantaged by home-based rehabilitation (HBR) relative to day hospital rehabilitation (DHR) and that HBR is less costly.
Design: Two-arm randomised controlled trial.
Setting: Four trusts in England providing both HBR and DHR.
Participants: Clinical staff reviewed consecutive referrals to identify subjects who were potentially suitable for randomisation according to the defined inclusion criteria.
Interventions: Patients were randomised to receive either HBR or DHR.
Main outcome measures: The primary outcome measure was the Nottingham Extended Activities of Daily Living (NEADL) scale. Secondary outcome measures included the EuroQol 5 dimensions (EQ-5D), Hospital Anxiety and Depression Scale (HADS), Therapy Outcome Measures (TOMs), hospital admissions and the General Health Questionnaire (GHQ-30) for carers.
Results: Overall, 89 subjects were randomised and 42 received rehabilitation in each arm of the trial. At the primary end point of 6 months there were 32 and 33 patients in the HBR and DHR arms respectively. Estimated mean scores on the NEADL scale at 6 months, after adjustment for baseline, were not significantly in favour of either HBR or DHR [DHR 30.78 (SD 15.01), HBR 32.11 (SD 16.89), p = 0.37; mean difference –2.139 (95% CI –6.870 to 2.592)]. Analysis of the non-inferiority of HBR over DHR using a 'non-inferiority' limit (10%) applied to the confidence interval estimates for the different outcome measures at 6 months' follow-up demonstrated non-inferiority for the NEADL scale, EQ-5D and HADS anxiety scale and some advantage for HBR on the HADS depression scale, of borderline statistical significance. Similar results were seen at 3 and 12 months' follow-up, with a statistically significant difference in the mean $EQ\text{-}5D_{index}$ score in favour of DHR at 3 months (p = 0.047). At the end of rehabilitation, a greater proportion of the DHR group showed a positive direction of change from their initial assessment with respect to therapist-rated clinical outcomes; however, a lower proportion of HBR patients showed a negative direction of change and, overall, median scores on the TOMs scales did not differ between the two groups. Fewer patients in the HBR group were admitted to hospital on any occasion over the 12-month observation period [18 (43%) versus 22 (52%)]; however, this difference was not statistically significant. The psychological well-being of patients' carers, measured at 3, 6 and 12 months, was unaffected by whether rehabilitation took place at day hospital or at

home. As the primary outcome measure and EQ-5D$_{index}$ scores at 6 months showed no significant differences between the two arms of the trial, a cost-minimisation analysis was undertaken. Neither the public costs nor the total costs at the 6-month follow-up point (an average of 213 days' total follow-up) or the 12-month follow-up point (an average of 395 days' total follow-up) were significantly different between the groups.
Conclusions: Compared with DHR, providing rehabilitation in patients' own homes confers no particular disadvantage for patients and carers. The cost of providing HBR does not appear to be significantly different from that of providing DHR. Rehabilitation providers and purchasers need to consider the place of care in the light of local needs, to provide the benefits of both kinds of services. Caution is required when interpreting the results of the RCT because a large proportion of potentially eligible subjects were not recruited to the trial, the required sample size was not achieved and there was a relatively large loss to follow-up.
Trial registration: Current Controlled Trials ISRCTN71801032.

Contents

List of abbreviations

AMT	Abbreviated Mental Test
ANCOVA	analysis of covariance
ANOVA	analysis of variance
CI	confidence interval
DHR	day hospital rehabilitation
EQ-5D	EuroQol 5 dimensions
GHQ	General Health Questionnaire
GQLQ	Geriatric Quality of Life Questionnaire
HADS	Hospital Anxiety and Depression Scale
HBR	home-based rehabilitation
HRQoL	health-related quality of life
IQR	interquartile range
ISRCTN	International Standard Randomised Controlled Trial Number
ITT	intention to treat
LOCF	last observation carried forward
MMRM	mixed models for repeated measures
NEADL	Nottingham Extended Activities of Daily Living scale
NETSCC	NIHR Evaluation, Trials and Studies Coordinating Centre
PCT	primary care trust
RCT	randomised controlled trial
SD	standard deviation
TIA	transient ischaemic attack
TOMs	Therapy Outcome Measures
UCHSC	Unit Costs of Health and Social Care
VAS	visual analogue scale

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices, in which case the abbreviation is defined in the figure legend or in the notes at the end of the table.

Executive summary

There is evidence from previous studies that day hospitals are an effective setting in which to provide comprehensive services for older people. Day hospitals provide rehabilitation for older people. In recent years there has been increased interest in the provision of services closer to the patient's home, resulting in the development of home-based rehabilitation services for older people. Most previous randomised controlled trials (RCTs) have not compared day hospital rehabilitation with rehabilitation delivered in the home and evidence has been lacking about the relative costs of these different settings and their influence on psychosocial functioning for patients and carers. This report describes the development and conduct of an RCT comparing home-based with day hospital rehabilitation.

Hypothesis

This study was designed to test the following hypotheses:

1. older people and their informal carers are not disadvantaged by home-based rehabilitation relative to day hospital rehabilitation
2. home-based rehabilitation is less costly.

Research activities

The research comprised a systematic literature review, a national survey of NHS trusts' rehabilitation services and a four-centre, two-arm RCT in which patients were randomised to receive either home-based rehabilitation or rehabilitation at a day hospital, and were followed up for a period of up to 12 months with outcome collection taking place at 3 months, 6 months and 12 months.

Literature review

The literature review was based upon a previous review of place of clinical care for older people (Parker et al., 2000) that had identified randomised and quasi-randomised trials from 1988 to 1999 across a range of care settings and including home-based and day hospital rehabilitation. We updated this review to 2007, repeating the searches and selection processes for home-based and day hospital rehabilitation, searching specifically for direct comparisons. We found no new reports of RCTs published since 1999 and therefore no reason to alter the conclusions of that review, which were as follows:

- overall, the day hospital has not yet been adequately evaluated as a setting for rehabilitation
- it is unlikely that the day hospital offers significant advantages over alternative settings for the delivery of comprehensive care with respect to mortality, hospital bed use or physical disability
- it is possible that the day hospital carries significant advantages or disadvantages over alternative settings for the delivery of comprehensive care with reference to quality of life, carer strain or health-care provider costs
- costs for patients, carers and social care providers have not been adequately ascertained
- patient and carer preferences for day hospital or alternative settings for the delivery of comprehensive care have not been evaluated.

These conclusions provide justification for a further RCT, with analysis of quality of life, carer strain and costs.

A national survey of NHS trusts

A national survey of NHS trusts' rehabilitation services in England was carried out in part to examine the current status of the research question and in part to develop a sampling frame for the development of a multicentre RCT.

Out of 480 possible replies, 372 (76%) completed an initial questionnaire. Of these, 324 (87%) trusts reported providing rehabilitation services, 184 (46%) reported the provision of both home-based rehabilitation and day hospital rehabilitation, 80 (20%) provided home-based rehabilitation but not day hospital rehabilitation and 60 (15%) day hospital rehabilitation but not home-based rehabilitation.

The survey confirmed that both day hospital and home-based rehabilitation services were currently being provided. Comparison with a previous survey conducted in 1998 suggested a recent increase in home-based rehabilitation teams.

It was clear from the survey results that both settings for rehabilitation represented current choices for service providers and clinicians recommending service developments and care settings to providers and clients. This provided further justification for an RCT with health economic analysis, to inform these decisions.

A randomised controlled trial

Trusts that were found to provide both home-based and day hospital rehabilitation were contacted to ascertain interest in participating in the trial. A total of 19 sites expressed initial interest and eventually four sites were recruited to carry out a pragmatic RCT in which patients were randomised between home-based and day hospital rehabilitation.

The primary outcome measure was change on the Nottingham Extended Activities of Daily Living (NEADL) scale at 6 months. Secondary outcome measures included the EuroQol 5 dimensions (EQ-5D), Hospital Anxiety and Depression Scale (HADS), Therapy Outcome Measures (TOMs), hospital admissions and the General Health Questionnaire (GHQ-30) for carers.

Originally a sample size of 460 subjects was proposed. However, as well as time-consuming difficulties in recruiting participating sites and implementing research processes, we experienced lower than anticipated rates of recruiting subjects into the trial in participating sites. We developed an exit strategy and stopped recruiting after 89 subjects had been randomised between the services. Overall, 42 subjects received rehabilitation in each arm of the trial.

At the primary end point of 6 months there were 32 patients in the home-based rehabilitation arm and 33 patients in the day hospital rehabilitation arm. In analyses conducted on this group of patients (the observed case data set), estimated mean scores on the primary outcome (the NEADL scale) at 6 months, after adjustment for baseline, were not significantly in favour of either home-based or day hospital rehabilitation [mean (SD) NEADL: total 30.78 (15.01) for day hospital rehabilitation versus 32.11 (16.89) for home-based rehabilitation ($p = 0.37$); mean difference after adjustment for baseline characteristics was –2.139 (95% CI –6.870 to 2.592)].

The trial hypothesis was expressed in terms of the non-inferiority of home-based rehabilitation over day hospital rehabilitation. To examine this directly, a 'non-inferiority' limit (10%) was applied to the confidence interval estimates for the primary and the secondary outcome measures at the 6-month follow-up. This analysis demonstrated non-inferiority for the NEADL scale, EQ-5D and HADS anxiety scale. The HADS depression scale suggested some advantage for home-based rehabilitation in some of the analyses, which was of borderline statistical significance.

A similar pattern of results was seen at the 3-month and 12-month follow-up points, although a statistically significant difference in the mean EQ-$5D_{index}$ score was seen in favour of day hospital care at 3 months ($p = 0.047$).

Following the end of rehabilitation, a greater proportion of patients in the day hospital group showed a positive direction of change from their initial assessment with respect to therapist-rated clinical outcomes. Conversely, however, a lower proportion of home-based care patients showed a negative direction of change and, overall, median scores on the TOMs scales did not differ between the two groups.

Hospital admission rates over the 12-month follow-up period were available for all 84 patients who were randomised and received treatment. Although fewer patients in the home-based care group were admitted to hospital on any occasion over the observation period [18 (43%) versus 22 (52%)], this difference was not statistically significant.

The psychological well-being of patients' carers, as measured by the GHQ-30 at 3, 6 and 12 months, was unaffected by whether rehabilitation took place at day hospital or at home.

As the primary outcome measure and EQ-$5D_{index}$ scores at 6 months showed no significant differences between the two arms of the trial, a cost-minimisation analysis was undertaken. Costs at the 6- and 12-month follow-up points were used when both a rehabilitation log and the appropriate number of economic questionnaires had been received. Neither the public costs nor the total costs

at the 6-month follow-up point (an average of 213 days' total follow-up) or the 12-month follow-up point (an average of 395 days' total follow-up) were significantly different between the groups.

Conclusions

Implications for practice

- Compared with day hospital rehabilitation, providing rehabilitation in patients' own homes confers no particular disadvantage for patients and carers.
- Our results are consistent with the non-inferiority of home-based rehabilitation compared with day hospital rehabilitation.
- The cost of providing home-based rehabilitation does not appear to be significantly different from that of providing rehabilitation in a day hospital.
- Rehabilitation providers and purchasers need to consider the place of care in the light of local needs, to provide the benefits of both kinds of services.

The results suggest that home-based rehabilitation produces outcomes in respect of the primary measure (NEADL) and all secondary measures at 3 months (with the possible exception of the $EQ\text{-}5D_{index}$) and at 6 months (with the possible exception of the HADS depression scale) that are at least as good as those expected if rehabilitation had taken place at the day hospital.

We have to be cautious in interpreting the results of the RCT because a large proportion of potentially eligible subjects were not recruited to the trial, the required sample size was not achieved and there was a relatively large loss to follow-up. Further, there were only four randomising sites and the majority of randomisations came from two centres.

However, considered together, the statistical analyses of the trial outcomes do not provide sufficient evidence to conclude that patients in receipt of home-based rehabilitation were disadvantaged compared with those receiving day hospital rehabilitation.

The finding that patients receiving rehabilitation in their own homes are not disadvantaged is complemented by the observation that the cost of providing home-based rehabilitation is not markedly different from that of providing rehabilitation in the day hospital.

Therefore, neither the new evidence provided by this RCT nor the existing evidence from previous trials suggests any advantage or disadvantage of providing rehabilitation in the day hospital or providing it in the patient's own home.

Although the results of the literature review, national survey of NHS trusts and this small RCT taken together can be informative for local providers, purchasers, commissioners and other stakeholders in relation to rehabilitation for older people, local decisions will need to be made in the context of local service delivery infrastructure and development needs. Therefore, in deciding about the settings in which to provide rehabilitation services, stakeholders will need to consider the benefits of home-based rehabilitation and ambulatory support provided in day hospitals in the light of local need and services to take advantage of (for example) local geography, existing infrastructure and stakeholder preferences.

Implications for research

- Future research in this area should examine syndrome- or condition-specific approaches to providing for the needs of older people in ambulatory care.
- Further attempts to address issues of cost-effectiveness and place of care in elderly rehabilitation research should focus more on the cost-effective use of specific day hospital services, rather than whether they compete with community care settings.
- The development and assessment of approaches and instruments for measuring outcomes for older people in receipt of rehabilitation in ambulatory care remains a justifiable focus for future research and development.
- Rather than comparing these settings for efficacy, future research might focus on identifying those services that are better provided in one or other setting, taking account of the current commissioning environment that explicitly supports choice in the provision of health services for patients.

Trial registration

This trial is registered as ISRCTN71801032

Chapter 1
Introduction

An ageing population

Population demography is an important driving factor in changing the emphasis of health service delivery from acute care in hospitals to community care for long-term conditions. Over the last 35 years the UK population aged over 65 years has grown by 31%, from 7.4 million to 9.7 million, whilst the population aged under 16 years has declined by 19%, from 14.2 million to 11.5 million. More recently, population ageing is reflected in the growth of the oldest old. The largest percentage growth in population in the year to mid-2006 was at ages 85 years and over (5.9%). The number of people aged 85 years and over grew by 69,000 in the year to 2006, reaching a record 1.2 million. Current population projections suggest that the number of centenarians in England and Wales will increase at an annual average rate of 6% a year to four times the current number, reaching almost 40,000 by mid-2031.[1] These projections, sometimes referred to as the 'demographic imperative', imply a need to respond by adapting existing services, introducing new ones and perhaps abandoning old ones to meet the evolving health and social care needs of an ageing population.

Assessment and rehabilitation

One of the key concepts in quality care for older people is the need for comprehensive assessment and a rehabilitative approach to care management. Traditionally this approach to care has been available in day hospitals, but it is increasingly being made available in the community (or at least elements of it are) – closer to or actually in the recipient's own home. In this context the day hospital may be regarded as an outpatient service, which is provided in a clinical setting and which does not require residence in the clinical institution to receive the service. The day hospital building may be provided in a hospital setting (e.g. on a teaching or district general hospital site) or closer to the patient's home (e.g. on a community hospital or rehabilitation unit site).

The day hospital has long been regarded as a central resource in medicine for older people and identified as a totem of good practice in health care for older people. The so-called 'geriatric day hospital' evolved from modest beginnings in the 1950s in Oxfordshire and rapidly became an essential component for the emerging departments of geriatric medicine. Literature descriptions of the work of day hospitals emphasised the importance of rehabilitation as a core component of day hospital work. Further facets described included medical, nursing and remedial treatments and elements of social care within an ambulatory care setting. More recently, the role of the day hospital as a provider of specialised multidisciplinary clinical assessment, admission avoidance and subacute care and investigation has been proposed.[2] In the UK the activities of day hospitals are seen primarily as alternatives to community-based rehabilitation or hospital inpatient care.[3] A survey of health authorities and trusts in England and Wales[4] showed that, of 345 trusts in England, 209 (61%) provided day hospitals, 193 (56%) provided outpatient rehabilitation and 120 (36%) provided community-based rehabilitation teams. The vast majority of day hospitals (195, 96%) had been established before 1993. In contrast, the majority of community rehabilitation teams (52%) had been established since 1993.

Over 10 years ago the National Audit Office[5] encouraged NHS executives to 'review the availability of research on the cost-effectiveness of care provided by day hospitals and encourage further research if appropriate'. The Public Accounts Committee[6] of the House of Commons has also acknowledged the lack of 'research evidence indicating unequivocally that in terms of clinical effectiveness and cost-effectiveness there was a case for day hospitals against other services'.

Policy context

More recently a number of developments in the UK health and social care environment have highlighted the need for a more complete understanding of the influence of rehabilitation

setting on costs and outcomes of care. Policy responses to the demographic imperative, and other concerns about the nature, quality and value of national health-care provision, have underlined a shifting emphasis from acute, hospital-based care to ambulatory, preventive and community-based care.

For example, in the UK, recent policy initiatives have emphasised joined-up working between health and social care.[2,7] Primary care organisations, which are now responsible for commissioning health care, are encouraged to partner with social services. Joint working between health-care and local government organisations is encouraged and supported by financial flexibilities introduced in the Health Act 1999. In some areas this has led to the formation of care trusts, which manage both health and social care services in a locality.

During this period the concept of intermediate care was introduced in the NHS Plan[8] and National Service Framework for Older People.[9] The framework identifies the range of community-based services that should be used to prevent hospital admission where possible and to provide active rehabilitation in the community following discharge from hospital. The concept arose from concerns about the unnecessary use of acute hospital inpatient care to meet the needs of older people.[10]

Much of the policy focus has been around changing the delivery of acute care. This is illustrated in measures such as the time spent in the accident and emergency department becoming performance indicators and the introduction of the Community Care (Delayed Discharges etc.) Act,[11] which introduced a system of reimbursement for delayed transfers of care, to encourage coordination between acute health and community social care to reduce delayed transfers of care from hospital into the community.

The 'bed-blocking' older person, trapped in inpatient care and consuming precious health-care resources, continues to provide a powerful image to drive change in the way that acute care services are provided, and most importantly in their relationship to home-based services and in the development of services to provide recuperation and rehabilitation in the home.

More recently the National Service Framework for Long-term Conditions has defined a number of quality requirements for services for people with long-term conditions.[12] The framework focuses on neurological conditions, but the principles apply to other specific long-term conditions and to people of all ages, including older people. Older people have specific assessment and rehabilitation needs related to complex co-morbidity and age-related functional deficits and, as much as any other group with long-term conditions, respond to early and specialist rehabilitation (quality requirement 4) in hospital or other specialist settings to meet their continuing and changing needs, and community rehabilitation and support (quality requirement 5) to additionally increase their independence and help them live as they wish.

The 2006 White Paper Our Health, Our Care, Our Say[13] described a future in which resources will be shifted to provide more care outside hospital and in the home, which it is expected will be accompanied by a shift of resources into community health and social services and which emphasises preventive care and care 'closer to home'. This intention is accompanied by a clear commitment to shifting resources into preventive and community services and residential and home-based support for older people and people with long-term conditions. This agenda has a clear implication for the 'place of care' for services in health and social care in the future, which will be community- and home-based wherever possible.

The following extract from Hansard (Box 1) illustrates the current nature of the changes that are taking place in the health and social care system in the UK and provides a picture of the policy backdrop against which recent research into 'place of care' for rehabilitation (including the studies described in this document) is taking place. Clearly, the evolving policy and service landscape places value on appropriate and specialist rehabilitation services, together with community provision, close to the patient's own home when feasible and appropriate. When placed in this context, an RCT of day hospital compared with home-based rehabilitation is seen to address key policy issues at the interface between hospital and community-based services for older people.

Research challenges

Although the changing policy landscape provides an incentive to inform decision-making in this area, it provides for a rapidly changing background of provision, including a major shift in emphasis between hospital and community-based care, which

BOX 1 Extract from Hansard, 8 May 2007

NHS: Rehabilitation

Mr Dai Davies: To ask the Secretary of State for Health what recent assessment she has made of the adequacy of NHS rehabilitation and intermediate care services. [133626]

Mr Ivan Lewis: Rehabilitation should be part of any effective treatment and care package provided to meet an individual's needs, with a view to enabling them to return to as independent a life as soon as possible.

The national service framework for long-term conditions, published March 2005, addresses in detail the issue of rehabilitation. A range of quality requirements is identified covering early and specialist rehabilitation, community rehabilitation and support, and vocational rehabilitation.

As part of the intermediate care funding announced in the NHS Plan, £66 million capital funding was made available to strategic health authorities in 2002–03 and 2003–04 to expand capacity and to support the development of intermediate care services and in particular a growth in bed numbers.

As at 30 September 2006, there were almost 33,000 intermediate care beds and places. Compared to 1999–2000 the number of intermediate care beds has more than doubled, the number of intermediate care places in non-residential settings has trebled and almost three times as many people benefit from intermediate care.

has added considerably to the research challenges of developing useful comparative analyses between hospital-based and home-based services.

In addition to the general challenges to 'place of care' research occasioned by the rapidly changing policy and practice landscape referred to above, there are some specific challenges to developing meaningful comparative analyses of day hospital rehabilitation and home-based care:

- There is no systematic typology of day hospitals against which to compare the structure of individual units. Day hospitals provide a wide range of services, from social day care to medical assessment and treatment.[14,15] Different day hospitals provide different mixes of services[16] according to local needs, facilities and the availability of complementary services. Such variations in the level of structure of day hospitals reduce the potential for generalisation of studies of effectiveness/cost-effectiveness conducted in a single unit.
- There are a variety of objectives of care, ranging from active rehabilitation to social care, which leads to a broad case mix. For example, there is wide variation in physical and psychological disability among patients attending for each of the several objectives of care[17,18] and a range of professional perceptions of the reasons for attending.[19]
- Defining appropriate outcomes of day hospital care may also be problematic. Measurement at the levels of health and dependency[20,21] has not yet been shown to be appropriate or sensitive to change in this population. Measures of patients' and carers' satisfaction with the service may be useful,[22] as may approaches that measure the attainment of relevant goals.[23]
- The measurement of the costs of day hospital care is not straightforward.[22] Day hospitals are frequently not budget centres in their own right and transport (a significant component of day hospital costs) may not be costed separately or consistently between units.[24] Costs of community-based alternatives to day hospital care will fall upon a variety of agencies, all of which would have to be taken into account in comparative economic studies.

Research question

Against this background of rapidly changing service provision and the research and measurement challenges, we have attempted to perform a randomised controlled trial (RCT) of day hospital versus home-based rehabilitation with health economic analysis to test the following specific hypotheses:

1. older people and their informal carers are not disadvantaged by home-based rehabilitation relative to day hospital rehabilitation
2. home-based rehabilitation is less costly.

The research question was identified in the Health Technology Assessment programme's process

for identifying evidence gaps[25] and prioritising research.[26]

Review of previous studies of day hospital services for older people

Although there are already RCTs of day hospital services in the literature, few have provided detailed evidence of costs and outcomes to inform decision-making about the provision of rehabilitation services for older people with respect to place of care. A Cochrane review published in 1999[27] included 12 RCTs in which day hospital attendance was evaluated against comprehensive elderly care (five trials[28–32]), domiciliary care (four trials[33–36]) or no comprehensive care (three trials[37–39]). Overall, 2867 subjects were included and the review examined 22 individual day hospitals in both postacute and subacute care. The authors concluded that, compared with patients receiving neither comprehensive care nor domiciliary rehabilitation, patients attending day hospitals had less functional deterioration and institutional care and a small reduction in average hospital bed use. However, the studies that addressed the question of best place of care, by comparing the provision of active treatment in the community, showed that day hospitals offer little advantage for patient outcome over other forms of comprehensive medical services. The review included studies performed over a 35-year period and trials designed to answer questions about the setting for rehabilitation for stroke care, or alternative settings for care usually provided in inpatient units, outpatient units and nursing homes.

Review methods

We have brought our view of the literature up to date by developing a previous review of the best place of care for older people after acute and during subacute illness, which included papers published between 1988 and 1999 and included analysis of day hospital rehabilitation and community rehabilitation.[40] Guidelines from the NHS Centre for Reviews and Dissemination[41] were used as a methodological framework. Search strategies and methods have previously been described in detail[42] and results published in part elsewhere.[40]

We updated the review on day hospital rehabilitation by repeating the literature searches using the same strategies and databases as before, first in 2004 and subsequently in 2007. Study selection and data extraction used the same process of title and abstract review, selection of potentially relevant studies and review of selected studies against defined quality and relevance criteria. The update was carried out in two stages: for the update from 1999 to 2004 papers were included after a process of dual observer review, selecting papers on the basis of design (randomised and pseudo-randomised trials), the comparison being made (place of care) and the inclusion of subjects over 65 years; for the final update to June 2007 these processes were carried out by a single observer (SGP). Trials and quasi-randomised studies that compared day hospital care with an alternative setting for assessment and rehabilitation were eligible for inclusion.

Literature review results

Included studies

This review included five trials with data extracted from 11 papers. All of these studies had previously been identified.[40] The literature searches to update the review to 2007 identified no new published controlled or quasi-randomised trials that compared day hospital with home-based rehabilitation. Two of the trials were primarily concerned with stroke rehabilitation: day hospital-based comprehensive care versus conventional medical management for first stroke in one[37] and day hospital rehabilitation versus home physiotherapy for 'new' stroke in the other.[33] In the other three studies[31,32,35] the patients were not selected by diagnosis but by the presence of disability and referral to the service.[35]

Excluded studies

There are some significant differences between this review and the systematic review of Forster et al.[27] (Table 1), including the 1988 cut-off, which excludes the older studies, and the emphasis on place of care in this review, which has excluded trials in which the difference between treatments lay in the nature of the intervention rather than the setting. Two trials included in the Forster et al. review have been excluded from this review because of our emphasis on place of care. One of these studies[29] compared rehabilitation in the day hospital with no rehabilitation and was therefore a trial of a therapy rather than place of care. The Nottingham domiciliary rehabilitation trial[36] was also excluded. In this study 327 subjects were entered into an

RCT of domiciliary rehabilitation after stroke. Of these, 155 were recruited from the health care of the elderly stratum. Only patients in this stratum received day hospital care, 76 being randomised to hospital-based care in which the 'main option was a day hospital'. Of these, only 37 per cent (n = 28) received day hospital care, to which they were not randomised. This study therefore was a study of community-based rehabilitation against (potentially) hospital-based alternatives and does not qualify as a study of day hospital rehabilitation. The Bradford community stroke study[33] is the other study in which case mix was restricted to patients recovering after stroke; in this study day hospital rehabilitation was compared with community-based physiotherapy delivered in the patient's own home and so it is included.

Populations studied

Inclusion and exclusion criteria varied considerably between trials. All but one[35] used some minimum level of disability below which patients were not eligible for the trial – impaired function,[31] Barthel score below 20,[33,37] needing personal assistance for activities of daily living, bowel incontinence or significant cognitive impairment.[32] Most also had some upper level of disability or dependence which excluded patients from selection – needing 24-hour monitoring,[31] previous disability,[33] a previous stroke or dementia[37] in need of nursing care, medical procedures, drug monitoring, treatment more than twice a week, dysphasia or specific occupational therapy.[35] Being in residential care excluded patients in one trial[33] but not in others;[31,32] other trials[37,35] did not refer to this criterion. Three trials[33,35,37] restricted access to the trial to those living in the relevant catchment area and, in addition, all patients in one trial[33] had to be fit to travel to the day hospital. Three trials[31,33,37] had age criteria (60 or 65 years and over) for inclusion. Finally, one trial[31] was restricted to patients without concurrent acute illness and who had a positive long-term prognosis, and one[33] excluded those admitted for respite care.

The characteristics of the included studies are shown in Table 2.

Overall, 1276 subjects were included in the studies, with 636 patients randomised to receive day hospital care (Table 3). Follow-up was reported from 8 weeks[33] to 12 months with losses to follow-up of between 33% at 3 months and 89% at 1 year. One study randomised 826 patients between adult day health care and usual care alternatives[32] but also included subjects from an additional cohort who received the intervention but were not randomised. Losses from both trial and cohort were reported in aggregate making it difficult to calculate trial-specific follow-up rates.

There is variation between studies in the proportions of men and women recruited, some of which is explicable and some of which is surprising (Table 4). The preponderance of men in the Hedrick and Branch study[32] is to be expected because it was evaluating a Veterans Affairs-funded programme. All but one of the other studies have around two-thirds women and one-third men in their study populations. Given the average ages of the patients (Table 5), this might be expected. By contrast, however, the Bradford community stroke trial[33] actually includes more men than women, but with a similar average age.

Quality of studies

Study quality was assessed using the Jadad scale,[46] supplemented by an assessment of sources of bias,[47] the latter performed by a single observer (SGP) (Table 6). Losses to follow-up are shown in Table 3. Only two studies described processes to conceal treatment allocation and only one used blinded assessment of follow-up. These factors serve to illustrate some of the common problems of RCTs in the assessment of rehabilitation services, in which it is often not possible to conceal the treatment being received by trial participants.

Range of outcomes reported

All studies reported mortality, physical function, hospital admission/readmission and quality of life as outcomes. Reporting of other outcomes was variable (Table 7).

Mortality

The data from the studies seem to support the notion that day hospital patients are neither more nor less likely to die as a consequence of receiving their care in this setting. However, the data might also suggest a disadvantage for day hospital patients over time. Pooled data for 6-month (Figure 1) and 12-month (Figure 2) follow-up [odds ratio (OR) 1.33, 95% confidence interval (CI) 0.96 to 1.84] and for all final follow-up (Figure 3), regardless of when that was (OR 1.22, 95% CI 0.92 to 1.63), again suggest a slightly poorer outcome for day hospital patients, but the differences do not reach statistical significance.

TABLE 1 Comparison of studies included/excluded in the Cochrane review of day hospital care[27] and this review

Day hospital trials	Day hospital treatment	Comparison treatment	Included/ excluded	Comment
Woodford-Williams 1962,[38] Sunderland	Attendance once a week up to 1 year	Eligible, but not referred to usual services	Excluded	Pre-1988
Weissert 1980,[39] USA	New service. Average of 70 days attendance over 1 year	Eligible, but not referred to usual services	Excluded	Pre-1988
Tucker 1984,[28] Auckland	New service. Attendance 2/3 days per week for 6–8 weeks	Comprehensive elderly care (inpatient, outpatient follow-up with or without outpatient physiotherapy, domiciliary services, GP, day centre)	Excluded	Pre-1988
Cummings 1985,[30] New York	New service. Attendance 5 days a week. Mean attendance 69 days	Continuing rehabilitation in hospital	Excluded	Pre-1988
Vetter 1989,[34] Cardiff	Attendance for 8 weeks	New service: home rehabilitation by therapy team. Attempt to recognise amount of treatment given	Excluded	Pilot study. No outcome comparison between groups
Pitkala 1998,[29] Helsinki	New service. Attendance over 2 months for a total of 20 visits	Usual elderly care: home support + hospital care if necessary	Excluded	Subjects received day hospital-based rehabilitation, controls did not receive rehabilitation; therefore primarily evaluated efficacy of rehabilitation rather than place of care
Eagle 1991,[31] Ontario	Attendance 2 days a week	Usual elderly care (inpatient or outpatient clinic or community follow-up). Same staff treated both groups	Included	
Young 1992,[33] Bradford	Attendance 2 days a week for at least 8 weeks	Home physiotherapy to a maximum of 20 hours over the first 8 weeks	Included	Day hospital care compared with home-based physiotherapy after stroke
Hedrick 1993,[32] USA	Attendance 2/3 times a week. Average of 45 visits in 12 months	'Customary care' (nursing home, inpatient care, clinic visits, home care, etc.)	Included	Adult day health-care programme evaluated against nursing home, home-based or ambulatory clinic care
Gladman 1993,[36] Nottingham (health care of the elderly stratum only)	Routine hospital-based services if considered appropriate, outpatient physiotherapy, occupational therapy, day hospital attendance, etc.	New service. Domiciliary rehabilitation team: two half-time physiotherapists, one occupational therapist; 75% of allocated patients received treatment	Excluded	Trial of domiciliary rehabilitation after stroke. Subjects stratified by source of referral. Older patients in the health care of the elderly stratum could receive, but were not randomised to, day hospital care. Only 37% of the health care of the elderly stratum patients (n = 28) received day hospital care. Not primarily a day hospital evaluation
Hui 1995,[37] Hong Kong	Care under geriatrician-led team with day hospital follow-up after discharge	Same ward but care led by neurology team with medical outpatient follow-up	Included	Stroke management by neurology or care of the elderly team
Borland 1997,[43] Huntingdon	Multidisciplinary rehabilitation. Median of 16 attendances	Rehabilitation at a day centre provided by a physiotherapist and two support workers, available 2 days a week. Median of 10 attendances	Included	Included as Burch et al. 1999[35] (same study). Day hospital rehabilitation acted as control for experimental treatment, which was rehabilitation based in social services day centres

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TABLE 2 Characteristics of included studies

Study	Country	Model of care/compared with	Setting	Condition	Inclusions	Exclusions
Eagle 1991[31]	Canada	Geriatric day hospital vs comprehensive elderly services	Day hospital	Physically disabled older patients	65+ years, impaired function, no acute illness, positive long-term prognosis, living at home or in residential care	Life expectancy (6 months), illness/ disability requiring 24-hour monitoring
Hui 1995[37]	Hong Kong	Geriatric team using day hospital facility vs conventional medical management for stroke	Day hospital	Stroke	65+ years, first stroke, Barthel Index < 20, in catchment area	Previous stroke, dementia, Barthel Index 20, residence outside catchment area
Young 1991,[44] 1992,[33] 1993[45]	UK	Day hospital rehabilitation vs home physiotherapy treatment for stroke	Day hospital + patients' homes	Stroke	All discharges with new stroke, catchment area, > 60 years, fit to travel to day hospital, Barthel Index < 20	Prestroke disability, return to prestroke function, in residential care, respite
Hedrick 1993[32]	USA	Adult day health care vs care received in nursing home, ambulatory care clinic or home	VA-funded adult day health-care programmes	Physically disabled older patients	One of resident in a nursing home, dependent on personal assistance for activities of daily living, bowel incontinence, significant cognitive impairment	Not eligible, not appropriate, adult day health care rejects, refused consent
Burch 1999[35]	UK	Day hospital rehabilitation vs day centre rehabilitation	Day hospital and social services day centres in market towns	Physically disabled older patients	Referred to the day hospital from inpatient and outpatient assessment, living in day centre catchment area	Dysphasia, in need of nursing care, medical procedure, drug monitoring, > twice-weekly treatment, specific occupational therapy needs

VA, Veterans Affairs.

TABLE 3 Numbers of patients admitted, eligible for trial, randomised, included in analysis and lost to follow-up at various time points

Study	Number of patients assessed	Number of patients identified as eligible for trial	Number (%) of screened patients randomised	Number (%) of randomised patients included in analysis	Number (%) of randomised patients followed up at 8–12 weeks	Number (%) of randomised patients followed up at 6 months	Number (%) of randomised patients followed up at 12 months
Eagle 1991[31]	Not stated	128	113 (nk)	101 (89)	–	–	101 (89)
Hui 1995[37]	Not stated	Not stated	120	120 (100)	105 (87)	87 (72)	–
Young 1991[44]	516	139	124 (24)	123 (99)	112 (90)	108 (87)	–
Hedrick 1993[32]	1236	858	826 (67)	826 (100)	104 patients lost to follow-up at 12 months (see text)		
Burch 1999[35]	Not stated	163	105 (nk)	105 (100)	70 (67)	–	–

nk, not known.

TABLE 4 Gender of total sample

Study	Male patients (%)	Female patients (%)
Eagle 1991[31]	40	60
Hui 1995[37]	44	56
Young 1991[44]	56	44
Hedrick 1993[32]	96	4
Burch 1999[35]	36	64

TABLE 5 Mean ages of subjects and controls

Study	Mean age subjects (years)	Mean age controls (years)
Eagle 1991[31]	79.6	78.2
Hui 1995[37]	74.1	73.1
Young 1991,[44] 1992,[33] 1993[45]	72[a]	70[a]
Hedrick 1993[32]	72.3	Not stated separately
Burch 1999[35]	80.9	79.8

a Median.

TABLE 6 Quality and assessment of bias

Study	Model of care	Jadad score	Adequate sequence generation?	Allocation concealment?	Blinding?	Free of selective reporting?	Free of other bias?
Eagle 1991[31]	Geriatric day hospital vs usual care	3	Unclear	No	No	Unclear	Yes
Hui 1995[37]	Geriatric team using day hospital vs conventional medical management for stroke	1	Unclear	No	No	Yes	Yes
Young 1991[44]	Day hospital vs home-based physiotherapy	3	Unclear	Yes	No	Yes	Yes
Hedrick 1993[32]	Adult day health care vs care received in nursing home, ambulatory care clinic or home care	3	Yes	No	No	Yes	Yes
Burch 1999[35]	Day hospital vs day centre rehabilitation	3	Yes	Yes	Yes	Yes	Yes

Hospital admission/readmission

Although some of the studies reported a reduced use of hospital beds up to final follow-up, this outcome has not been consistently reported and only one study[37] recruited inpatients, the others providing little opportunity for the intervention to influence initial hospital stay (Table 8).

Total hospital days for the period up to final follow-up either is reported or can be calculated for two studies. Eagle et al.[31] report total hospital stay up to 12 months as 1388 days for subjects and 1351 days for controls. Hui et al.[37] recruited subjects as inpatients and include initial stay on acute or rehabilitation wards in the trial results. Total stay over 6 months can be calculated from the data

TABLE 7 Range of outcomes reported in studies

Outcome	Eagle 1991[31]	Hui 1995[37]	Young 1991,[44] 1992,[33] 1993[45]	Hedrick 1993[32]	Burch 1999[35]
Mortality	Yes	Yes	Yes	Yes	Yes
Length of stay	No	Yes	No	Yes	No
Change in physical function	Yes	Yes	Yes	Yes	Yes
Change in mental function	Yes	No	Yes	Yes	Yes
Costs to services	No	Yes	Yes	Yes	No
Costs to patients	No	No	No	Yes	No
Quality of life	Yes	No	Yes	Yes	Yes
Patient satisfaction	No	Yes	No	Yes	No
Impact on carers	Yes	No	Yes	Yes	Yes
Admission/readmission	Yes	Yes	Yes	Yes	Yes
Destination at final follow-up	Yes	Yes	No	No	Yes

			Statistics for each study					Dead/total		
Study name	Outcome	Time point	Odds ratio	Lower limit	Upper limit	z-value	p-value	Day hospital	Control	Odds ratio and 95% CI
Young 1992[33]	Mortality	6 months	1.208	0.409	3.562	0.342	0.733	8/61	7/63	
Hui 1995[37]	Mortality	6 months	1.038	0.315	3.421	0.061	0.951	6/59	6/61	
Hedrick 1993[32]	Mortality	6 months	1.297	0.889	1.935	1.272	0.203	62/411	60/415	
			1.261	0.881	1.804	1.270	0.204			

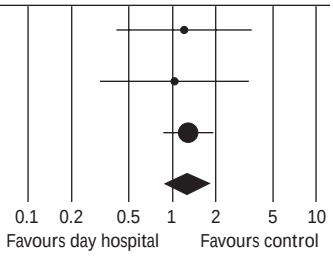

FIGURE 1 Mortality at 6 months.

			Statistics for each study					Dead/total		
Study name	Outcome		Odds ratio	Lower limit	Upper limit	z-value	p-value	Day hospital	Control	Odds ratio and 95% CI
Hedrick 1993[32]	Mortality	12 months	1.279	0.914	1.789	1.435	0.151	95/411	79/415	
Eagle 1991[31]	Mortality	12 months	2.298	0.650	8.120	1.292	0.196	8/55	4/58	
			1.329	0.961	1.838	1.719	0.086			

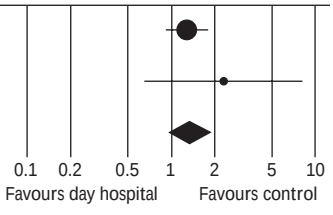

FIGURE 2 Mortality at 12 months.

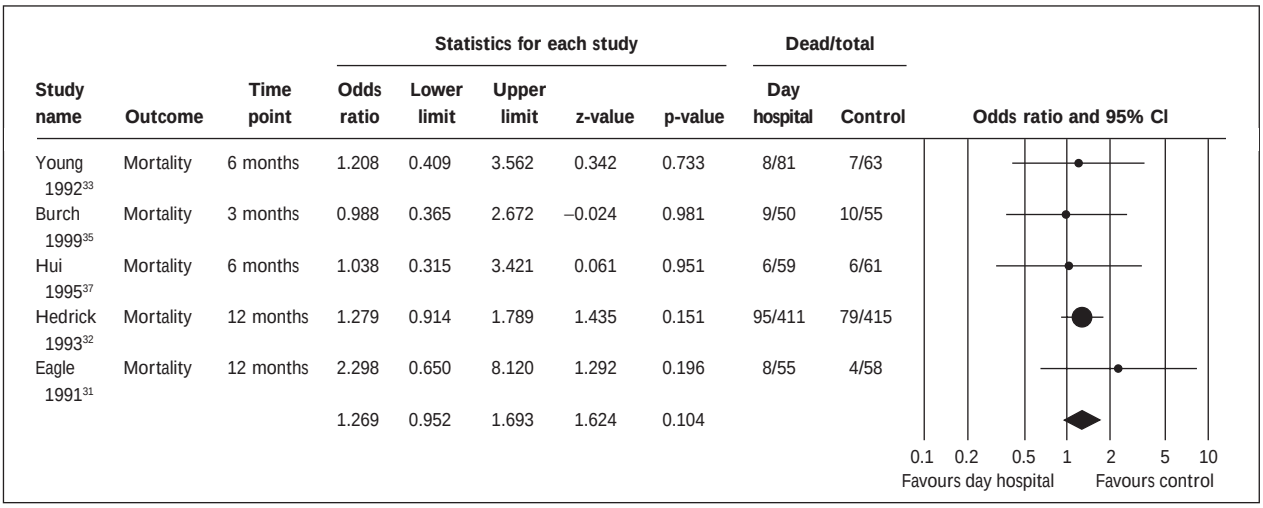

FIGURE 3 Mortality at final follow-up combined.

provided in the paper as 2046 days for subjects and 2292 days for controls.

Hedrick and Branch[32] report only readmissions, which can be calculated as 108 days for subjects and 93 days for controls. Finally, Young and Forster[33] report the rehabilitation of patients spending different periods of time attending day hospital or receiving home physiotherapy. This suggests only slight differences between subjects and controls. Similarly, there is no difference in readmissions up to 8 weeks of follow-up.

These trials thus provide no clear and consistent picture of the impact of the services on readmission and hospital stays.

Physical function

Four of the studies reported changes in physical function using the Barthel Index (Table 9). Other aspects of physical functioning (such as instrumental activities of daily living) were not reported consistently across the studies. Differences between assessments of core daily living activities were not readily apparent between the subjects and controls.

Change in cognitive function

Cognitive function was reported in all studies (Table 10). Hui et al.,[37] Young and Forster[33] and Burch et al.[35] all reported using the Abbreviated Mental Test (AMT), but none reported anything other than baseline measures. Eagle et al.[31] reported baseline scores of the mental status questionnaire. Hedrick and Branch[32] used the Mini-Mental State Examination at baseline, 6 and 12 months; there were no significant differences between groups.

Costs to health and social care providers

In general, the costs reported have been more or less crude estimates of service costs, calculated and presented in a variety of ways (Table 11). The studies have tended to report costs in terms of direct use of health care. Eagle et al.[31] report the number of hospital admissions and hospital days for the two groups after 12 months, but give no costs. Hui et al.[37] report mean costs per course of treatment at 3 and 6 months, the subjects having greater costs than controls, but not significantly so. Young and Forster[33] give direct costs for each group with subjects costing significantly more than controls. This cost difference is directly related to the rehabilitation received by each group, as there were no differences in home care or district nurse visits.

Hedrick and Branch[32] give figures for total costs and for total health-care costs. There were no differences between groups in total costs, but for the health-care element subjects again had significantly higher costs over the 12-month period. Interestingly, this difference in costs was incurred during the period from 7 to 12 months,

TABLE 8 Total length of hospital stay (including readmissions)

Study	Subjects[a]	Controls[a]	Statistical significance	Comment
Eagle 1991[31]	1388 hospital days (47 admissions)	1351 hospital days (38 admissions)	Not stated	Not clear
Hui 1995[37]	7.36 days (range 1–45)	9.7 days (range 2–47)	Not reported	DH shorter
Young 1991,[44] 1992,[33] 1993[45]	1/61 readmitted	1/63 readmitted	Not reported	At 8 weeks
	5/52 readmitted	3/43 readmitted	Not reported	At final FU
[b]Hedrick 1993[32]	18.06 days	18.60 days	p = 0.068, NS	DH shorter
Burch 1999[35]	Not reported	Not reported	–	–

DH, day hospital; FU, follow-up; LOS, length of stay; NS, not significant.
a As reported.
b Also reported nursing home LOS 21.24 vs 29.56 days (p = 0.055, NS).

TABLE 9 Change in physical function (Barthel Index scores)

Study	Time of follow-up	Mean Barthel Index score (SD/IQR)		Statistical significance	DH better/ worse than usual care
		Subjects	Controls		
Eagle 1991[31]	Baseline	83	81	p = 0.18	No difference
	3 months	79	82		
	6 months	76	80		
	12 months	74	77		
[a]Hui 1995[37]	Baseline	9.9 (4.9)	10.4 (5.3)	NS	No difference
	3 months	16.1 (3.9)	14.6 (5.8)	NS	
	6 months	17.1 (3.6)	15.6 (5.6)	NS	
[a]Young 1991,[44] 1992[33]	Baseline	14.5[b] (11 to 16)	16.0[b] (13 to 17)	0.35	Worse
	8 weeks	15.0[b] (12 to 18)	16.0[b] (15 to 18.5)	0.01	
	6 months	15.0[b] (12 to 18)	17.0[b] (15 to 19)		
[c]Hedrick 1993[32]		Not reported	Not reported		
Burch 1999[35]	Change baseline to 3 months	+1.5 (–0.66 to 2.34)	+1.5 (0.53 to 2.47)	NS	No difference

DH, day hospital; IQR, interquartile range; NS, not significant.
a Modified scale.
b Median score.
c Recorded activities of daily living using Katz Index but did not report use as outcome measure.

there being no significant difference between groups between baseline and 6 months.

Lastly, Burch et al.[35] reported figures for cost per attendance, the numbers of treatments received by each group and the numbers still being treated after 3 months. There were no significant differences between groups, although again subjects' costs were higher.

In all five studies the costs were higher for the day hospital patients than for control groups, significantly so in two.

TABLE 10 Mental function, quality of life and impact on carers

Study	Measure of QoL	When measured (first and final assessment)	Subjects[a]	Controls[a]	Statistical significance, how calculated, results
Eagle 1991[31]	GQLQ:				Treatment effect:
	Symptoms	Baseline	3.74	4.12	p = 0.17
		6 months	4	4.32	
		12 months	4.04	4.33	
	ADL	Baseline	4.38	4.71	p = 0.29
		6 months	4.43	4.63	
		12 months	4.01	4.43	
	Emotions	Baseline	4.58	5.03	p = 0.019
		6 months	4.6	5.24	
		12 months	4.4	5.22	
	GHQ	Baseline	4.08	4.35	p = 0.012
		6 months	3.75	4.49	
		12 months	3.85	4.33	
Hui 1995[37]	GDS	Baseline	Not reported	Not reported	No significant difference between groups
		3 months			
		6 months			
Young 1991,[44] 1992,[33] 1993[45]	NHP	Change from baseline to 8 weeks	–1.7 (–8.5 to 11.3)	+0.1 (–8.4 to 9.8)	p = 0.89, Mann–Whitney
		Change from baseline to 6 months	Not stated	Not stated	
	Frenchay Activities Index	Change from baseline to 6 months	3 (1 to 6)	4 (2 to 9.5)	p = 0.02, Mann–Whitney
Hedrick 1993[32]	MMSE	Baseline	23.8 (4.7)	23.3 (5.2)	NS
		6 months	23.8 (4.9)	23.7 (5.1)	NS
		12 months	23.7 (5.3)	24.3 (5.0	NS
Burch 1999[35]	PGCMS	Change from baseline to 3 months	+0.92 (–0.36 to 2.2)	+1.8 (0.46 to 3.14)	

ADL, activities of daily living; GDS, Geriatric Depression Scale; GHQ, General Health Questionnaire; GQLQ, Geriatric Quality of Life Questionnaire; MMSE, Mini-Mental State Examination; NHP, Nottingham Health Profile; NS, not significant; PGCMS, Philadelphia Geriatric Center Morale Scale; QoL, quality of life.
a As reported.

TABLE 11 Costs to health service providers

Study	How costs calculated to health service	Calculation period	Results for subjects	Results for controls	Statistical significance	Comments
Eagle 1991[31]	Number of hospital admissions; number of hospital days	12 months	Admissions 58; hospital days 1388	Admissions 51; hospital days 1351	Not stated	
Hui 1995[37]	Total costs: control subjects – total LOS (acute + rehab.) ± op. clinic ± hospital readmissions; GDH group – total LOS (acute + rehab.) ± GDH attendances ± op. clinic ± hospital readmissions; cost per course of treatment	6 months	HK$58,168 ± 25,898	HK$51,809 ± 30,480	p = 0.29, one-way ANOVA p = 0.055 (NS)	Costs derived from local data
		3 months	HK$53,891 ± 28,835	HK$44,960 ± 17,954		
Young 1993[45]	Direct rehabilitation + community care service = average cost per episode × n	8 weeks	£620 (550–730)[a]	£385 (240–510)[a]	p < 0.001, Mann–Whitney	
Hedrick 1993[32]	Total costs	12 months	US$28,709	US$26,204	NS	
		0–6 months	US$15,959	US$15,139	NS	
		7–12 months	US$12,749	US$11,011	NS	
Burch 1999[35]	Cost per attendance		£59.46	£77.93		

ANOVA, analysis of variance; GDH, geriatric day hospital; LOS, length of stay; NS, not significant.
a Median (interquartile range).

Impact on quality of life

Quality of life was measured in all five studies, although different measures were used and therefore results are difficult to compare. The Geriatric Quality of Life Questionnaire (GQLQ) was developed for one study, which also used the Global Health Question.[31] There is no mention of the validity of this new measure although the authors state that it was 'developed according to established principles'. The Geriatric Depression Scale was used by Hui et al.,[37] the Nottingham Heath Profile and the Frenchay Activities Index by Young and Forster,[33] the Sickness Impact Profile and the Psychological Distress Scale by Hedrick and Branch,[32] and the Philadelphia Geriatric Center Morale Scale by Burch et al.[35]

Quality of life was measured at various points including baseline, 8 weeks, 3 months, 6 months and 12 months, but no significant differences were found between subjects and controls at any of these time points in three trials. Young and Forster[33] found a significant difference between groups at 8 weeks in the Frenchay Activities Index, the controls scoring significantly higher. The difference was due to controls undertaking significantly more housework activities and walking outside. The Eagle et al.[31] study found that General Health Questionnaire (GHQ) ratings for controls were constant during the 12-month study period, but subject ratings decreased (p = 0.012). This study also found a significant treatment effect in favour of the control group on the emotions dimension of the GQLQ (p = 0.015) during the 12-month study period.

Other outcomes

No significant differences between groups were seen (when measured) in the costs to patients and informal carers and their families. Similarly, the impact on informal carers and family members, when measured, was not significantly different between groups. No differences were seen in patient satisfaction or changes in residence (including admission to institutional care).

Conclusion

Overall this review reveals a paucity of comparable studies in which the day hospital is evaluated as a setting for rehabilitation and compared with realistic alternatives for twenty-first century practice, such as community-based rehabilitation. Although the evidence base for day hospitals contains relatively large numbers of observations, these observations have been made over a period of five decades and with widely differing comparator interventions. None of the excluded trials compared day hospital rehabilitation with rehabilitation in the home, with the exception of the DOMINO study[36] in which patients were not randomised to day hospital care but to a 'care of the elderly stratum' in which they could receive day hospital care but mostly did not (about one-third of subjects in this stratum received day hospital care). Included trials have compared rehabilitation or some other intervention in the day hospital with comparator interventions such as inpatient hospital care, specialist neurological care, nursing home treatment or outpatient follow-up. In the Huntingdon community rehabilitation trial[35] patients received their rehabilitation in a day hospital or in a local authority day centre – a non-clinical institutional setting – rather than in their own homes. Given the significant methodological challenges that research into day hospitals presents, it is perhaps not surprising that the development of alternatives to the day hospital as settings for rehabilitation has proceeded in the absence of evidence of their relative costs or effectiveness, leaving day hospitals in service but increasingly unsure of their role.

Equally, the literature review has found evidence to support the view that home-based rehabilitation teams have not been systematically evaluated in comparison with day hospitals as a setting for rehabilitation in ambulatory care.

The hypotheses (older people and their informal carers are not disadvantaged by home-based rehabilitation relative to day hospital rehabilitation, and home-based rehabilitation is less costly) remain hypotheses that have not been fully evaluated in well-constructed RCTs, and in policy terms the research question – which is about cost-effective provision of rehabilitation services for older people and people with long-term conditions – remains one in which there is current interest for policy- and decision-makers in the NHS.

Chapter 2

A national survey of NHS trusts in England

Introduction

In preparation for an RCT of home-based rehabilitation versus day hospital rehabilitation we carried out a survey of NHS trusts in England.

Objectives

Our principal aim in conducting this survey was to establish the scope of provision of home-based and day hospital rehabilitation services to support the development and conduct of a pragmatic RCT, conducted in multiple centres in England and including health economic analysis (ISRCTN71801032),[48] with the aim of providing valuable information on which to base future decisions about day hospital and home-based rehabilitation services.

The objectives of the survey were to:

- discover the scope of service provision in home-based and day hospital rehabilitation for older people in England
- identify potential trial sites for an RCT.

Potential trial sites would already be running both home-based and day hospital rehabilitation services, would express interest in participating as a trial site in an RCT of these services and, ideally, would be able to predict a degree of stability in local service provision over the proposed duration of the trial.

Methods

We carried out a postal survey of NHS trusts in England during 2003. All trusts in England were identified by contacting each of the 28 strategic health authorities for a list of their primary care and hospital trusts. When this information was difficult to obtain, the Department of Health website was consulted. All trusts were sent an initial questionnaire that asked whether or not they provided home-based and/or day hospital rehabilitation for elderly patients. The trusts that replied then received a second questionnaire asking for more detail about type of service and staffing.

Results

Of the 534 potentially relevant trusts identified, 31 were found to no longer exist and 23 reported the survey as being irrelevant to their services (e.g. trusts dealing exclusively in the care of children or ambulance services). Of the remaining 489 trusts, 400 returned completed initial questionnaires and 372 (76%) contained complete and relevant responses (Table 12).

TABLE 12 Trusts providing home-based and/or day hospital rehabilitation

Service provided	Number	%
HBR and DHR	184	46
HBR, no DHR	80	20
DHR, no HBR	60	15
Neither	48	12
Incomplete	8	2
Irrelevant	20	5
Total	400	100

DHR, day hospital rehabilitation; HBR, home-based rehabilitation.

Of these, 324 (87%) trusts reported providing rehabilitation services, 184 (46%) reported the provision of both home-based rehabilitation and day hospital rehabilitation, 80 (20%) provided home-based rehabilitation but not day hospital rehabilitation and 61 (15%) day hospital rehabilitation but not home-based rehabilitation. Trusts providing rehabilitation services were sent a second questionnaire and 200 replies (62%) were received. The results of these replies for each service type are shown in Table 13, and a comparison of the results between trusts providing both day hospital and home-based rehabilitation services and those providing only one or the other setting for rehabilitation services is shown in Table 14.

TABLE 13 Analysis of service provision in day hospital and home-based rehabilitation services in England

	HBR		DHR		
Replies received	155		151		
	n	**%**	**n**	**%**	**p-value[a]**
Services					
Functional assessment	151	97.4	148	98.0	0.7280
Medical assessment	66	42.6	139	92.1	0.0000
Rehabilitation	136	87.7	135	89.4	0.6780
Respite and social care	58	37.4	44	29.1	0.0800
Specialist medical assessment	41	26.5	92	60.9	0.0000
Nursing procedures	112	72.3	139	92.1	0.0000
Specialised stroke care	83	53.5	100	66.2	0.0750
Specialised TIA care	47	30.3	77	51.0	0.0010
Parkinson's disease care	61	39.4	100	66.2	0.0000
Movement disorders	40	25.8	62	41.1	0.0110
Falls care	87	56.1	122	80.8	0.0000
Continence care	63	40.6	65	43.0	0.9800
Physical maintenance	43	27.7	53	35.1	0.2970
Time-limited service provision	99	63.9	73	48.3	0.0000
Staff					
Community nurse	89	57.4	25	16.6	0.0000
General practitioner	37	23.9	24	15.9	0.0700
Hospital nurse	14	9.0	86	57.0	0.0000
Hospital doctor	21	13.5	92	60.9	0.0000
Occupational therapist	137	88.4	135	89.4	0.4860
Physiotherapist	133	85.8	134	88.7	0.8340
Therapy assistant	121	78.1	113	74.8	0.2880
Administrative staff	86	55.5	107	70.9	0.0009
Speech and language therapist	24	15.5	22	14.6	0.7090
Dietician	9	5.8	16	10.6	0.1580
Social worker	24	15.5	2	1.3	0.0000

DHR, day hospital rehabilitation; HBR, home-based rehabilitation; TIA, transient ischaemic attack.
a p-value refers to the significance of the difference in provision between home-based and day hospital services (chi-squared test, one degree of freedom).

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TABLE 14 Survey responses reported for trusts providing either home-based rehabilitation or day hospital rehabilitation, and for trusts providing both day hospital and home-based rehabilitation services

	DHR only (n = 45)		HBR only (n = 49)			Both DHR and HBR (n = 106)				
	Day hospital		Home-based			Day hospital		Home-based		
	n	%	n	%	p-value	n	%	n	%	p-value
Services										
Functional assessment	43	95.6	49	100.0	0.136	104	98.1	102	96.2	0.407
Medical assessment	39	86.7	22	44.9	0.000	100	94.3	44	41.5	0.000
Rehabilitation	37	82.2	47	95.9	0.031	98	92.5	90	84.9	0.083
Respite and social care	38	84.4	21	42.9	0.000	39	36.8	37	34.9	0.775
Specialist medical assessment	25	55.6	16	32.7	0.025	67	63.2	25	23.6	0.000
Nursing procedures	37	82.2	38	77.6	0.573	102	96.2	74	69.8	0.000
Specialised stroke	29	64.4	29	59.2	0.600	71	67.0	54	50.9	0.018
Specialised TIA care	24	53.3	16	32.7	0.043	53	50.0	31	29.2	0.002
Parkinson's disease care	30	66.7	18	36.7	0.004	70	66.0	43	40.6	0.000
Movement disorders	15	33.3	14	28.6	0.618	47	44.3	26	24.5	0.002
Falls care	34	75.6	35	71.4	0.651	88	83.0	52	49.1	0.000
Continence care	14	31.1	27	55.1	0.019	51	48.1	36	34.0	0.036
Physical maintenance	11	24.4	13	26.5	0.817	42	39.6	30	28.3	0.082
Staff										
Community nurse	2	4.4	31	63.3	0.000	23	21.7	58	54.7	0.000
General practitioner	6	13.3	14	28.6	0.071	18	17.0	21	19.8	0.595
Hospital nurse	34	75.6	1	2.0	0.000	52	49.1	11	10.4	0.000
Hospital doctor	33	73.3	6	12.2	0.000	59	55.7	13	12.3	0.000
Occupational therapist	39	86.7	44	89.8	0.637	96	90.6	92	86.8	0.386
Physiotherapist	40	88.9	43	87.8	0.864	94	88.7	88	83.0	0.237
Therapy assistant	31	68.9	43	87.8	0.026	82	77.4	76	71.7	0.344
Administrative staff	29	64.4	26	53.1	0.263	78	73.6	58	54.7	0.004
Dietician	7	15.6	2	4.1	0.059	9	8.5	7	6.6	0.603
Speech and language therapist	9	20.0	9	18.4	0.841	13	12.3	15	14.2	0.685
Social worker	1	2.2	14	28.6	0.000	1	0.9	10	9.4	0.005

DHR, day hospital rehabilitation; HBR, home-based rehabilitation; TIA, transient ischaemic attack.

Discussion

This survey served the dual purpose of providing a snapshot of the scope of provision of home-based and day hospital rehabilitation services for older people and providing a sampling frame for the systematic identification of potential sites for an RCT.

In both settings trusts reported providing functional assessment and rehabilitation. Services in both settings were usually provided with physiotherapy, occupational therapy and nursing staff. Medical staffing was significantly less likely in the community-based services, and day hospitals were very much more likely to provide medical or specialised medical services [such as Parkinson's disease, falls, and transient ischaemic attack (TIA) clinics] and nursing procedures. Home-based services were more likely to be provided by community practitioners (GP and nurse) and be time limited in nature (i.e. restricted to a specific number of weeks' service provision) (see Table 13).

It was possible that trusts reporting only one or other type of service would provide more comprehensive services in a single setting than trusts in which services were provided in both settings. Accordingly the data were analysed by both service type and whether the responding trust provided only day hospital or rehabilitation services or both. This analysis (see Table 14) showed that the differences between home-based and day hospital-based services were broadly similar, whether or not the responding trust provided both types of service.

A project about the best place of care for older people (HTA project reference 96/43/01[4]) carried out a national survey of services for older people in England during 1988. This survey was more comprehensive in the range of services about which it gathered information than that reported here, but it included questions that may be directly comparable with the questions asked in the present questionnaire. The 1998 survey asked, 'Do you provide day hospital services for older people?', and in 2003 we asked, 'Does your trust provide day hospital rehabilitation services for elderly people?'. The 1998 survey asked, 'Do you provide community-based rehabilitation teams for older people?', and we asked, 'Does your trust provide a home-based rehabilitation service for older people?'.

A comparison of the results of these two survey questionnaires is summarised in Table 15. This suggests an increase in the provision of home-based rehabilitation services, which appear to have been provided in parallel with day hospital rehabilitation services – the proportion of trusts reporting day hospital rehabilitation services remained static during the period of comparison. Although the methods and the questions are not identical, and therefore this result could be explained by the slightly different emphases of the questions about home-based rehabilitation, it does suggest that NHS services managers, over the period of the two surveys, were actively taking the sort of decision about the provision of rehabilitation services for older people that our RCT was designed to inform. Further, the range of provision of day hospital and home-based rehabilitation services identified in this survey implies that, when the survey was performed, clinicians were making pragmatic decisions about the settings in which to provide rehabilitation for older people, which was being delivered by a variety of practitioners in different settings.

This sense of heterogeneity in provision, and in delivery of services, reveals that rehabilitation for older people is far from being a standardised service and may be taken to suggest ongoing uncertainty about the preferred setting for rehabilitation. It certainly implies that decisions

TABLE 15 Comparison of responses to 1988 and 2003 surveys of NHS trusts about day hospital and home-based rehabilitation services

	1988 survey		2003 survey	
Replies received	345		400	
Trusts providing	**n**	**%**	**n**	**%**
Day hospitals	209	61	244	61
Community-based rehabilitation	123	36	264	66

about the settings for rehabilitation were still current at the time of starting the RCT described later in this report.

Marked heterogeneity of services contains implications for the design of an RCT and led us to suggest that the number of sites involved in the RCT needed, if possible, to be higher than the three originally anticipated, to allow a broader representation of services.

Furthermore, heterogeneity and rapid service development and changes suggest that observational studies would be of value alongside an RCT to provide a clearer picture of the local and national context within which the trial was taking place.

In summary, when this research was commissioned, the research question was selected as being of national importance by the NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC). Survey work carried out before commencing the trial indicated that providers and commissioners were actively deciding to provide both types of service, and a systematic literature review indicated that the research question(s) had not already been answered.

Chapter 3

A randomised controlled trial of day hospital rehabilitation compared with rehabilitation at home

Introduction

This chapter has been written to follow the revised Consolidated Standards for Reporting Trials (CONSORT) framework[49] for reporting an RCT. The background and supporting literature review are presented in Chapter 1 of this report. A national survey of NHS trusts in England carried out to identify potential trial sites in 2003 is presented in Chapter 2.

Essential conclusions from the literature evidence and national survey data were that:

1. there is insufficient comparative evidence to inform choices on service development and the treatment of individual patients between day hospital and home-based rehabilitation
2. in the changing landscape of NHS provision both types of service are being provided by NHS managers (as evidenced by an increase in the proportion of trusts providing both service types between 1998 and 2003) and chosen between by NHS clinicians who are utilising the different service models for the benefits of their clients.

Objectives and hypotheses

We have designed and implemented a pragmatic RCT to compare home-based rehabilitation with day hospital rehabilitation. Rehabilitation itself, in a variety of forms and settings, is supported by evidence of effective practice,[50] suggesting that both day hospital and home-based rehabilitation are capable of providing benefit. However, a detailed comparison of costs between home-based and day hospital rehabilitation has not previously been available. This trial was conducted to test the following hypotheses:

1. older people and their informal carers are not disadvantaged by home-based rehabilitation relative to day hospital rehabilitation
2. home-based rehabilitation is less costly.

Trial design and methods

Preparatory work

In preparation for the RCT we developed and piloted research interviews to ensure their acceptability, maximise responses, minimise recall bias and inform coding procedures. Further, the developing trial protocol was disseminated at relevant professional conferences, where feedback on trial design and feasibility was sought. Staff and patient advisory groups were formed and consulted about the content of the interviews and conduct of the trial. Feedback and pilot results were used to modify the original trial protocol. A more detailed description of these processes and the outcomes, in terms of response rates, feedback and associated developmental changes in the trial protocol, are provided in Appendix 1.[51]

Study design

The study was conducted as a two-arm RCT in which patients were randomised to receive either home-based rehabilitation or rehabilitation at a day hospital and followed up for a period of 12 months with outcome collection taking place at 3 months, 6 months and 12 months. Alongside the trial a health economic study addressing the public budget and societal perspectives was carried out.

Participants

Participating sites

Our intention was to use the national survey data as a sampling frame for the recruitment of participating day hospitals and rehabilitation teams. Sites were identified that were providing both home-based and day hospital rehabilitation services, that had indicated interest in participating in the research and that were anticipating no major changes in their services over the next 3 years. This last criterion turned out to be limiting as the research was being carried out at a time of major change in the NHS, which included several policy imperatives to develop community-based services (including rehabilitation teams) to prevent

unnecessary hospital admissions and provide effective rehabilitation services to enable early discharge from hospital and to prevent premature or unnecessary admission to long-term residential care.

Eventually four sites were recruited into the trial and randomisation between day hospital and home-based rehabilitation services began in Chippenham, Wiltshire in April 2005, North Tyneside in August 2005, Newcastle upon Tyne in July 2006 and Barnsley in November 2006.

It should be noted that, despite the declared intention to recruit sites using a defined sampling frame against explicit, predefined criteria, and although the processes set in place for this objective sampling method were followed, the environment of rapid change meant that ultimately these methods proved not to be viable. In practice this meant that, although we identified and visited 17 potential sites that satisfied the rigorously defined criteria, those which proceeded to become recruiting and randomising sites were effectively a pragmatic sample of sites with a previous relationship with the investigators.

Participating subjects

On each site clinical staff reviewed consecutive referrals to identify subjects who were potentially suitable for randomisation according to the defined inclusion criteria. As this was a pragmatic trial our intention was to keep exclusion criteria to a minimum:

- participants were referred to the service for multidisciplinary rehabilitation
- they had a permanent address within the defined catchment area of the service
- they could be of any age (although in practice we expected 90% of subjects to be over 70 years of age)
- they were able to provide informed consent, if necessary with the help of a carer or advocate.

Patients were contacted by a member of the clinical team, who provided information about the trial and returned after a period of reflection of at least 48 hours. Potential subjects who indicated a willingness to be entered into the trial completed a consent form, the Oxford Handicap Scale and an AMT.

Although we recorded the presence of cognitive difficulties, we endeavoured not to exclude patients with such difficulties who expressed a desire to participate. We developed a procedure for subjects who scored less than 7 on the AMT, or when the clinical team had concerns about the capacity of a subject to consent for research. This procedure involved obtaining permission to contact a carer for assent and, when necessary, proxy information; however, in practice, this procedure was not required.

It was found in the pilot study that many carers were present at the patient interviews. When this was the case carers were asked for consent for participation directly in the interviews. When this was not the case the researcher asked for permission to contact the carer to arrange a convenient interview appointment.

Although there were no overarching exclusion criteria, each of the sites had specific services that had been developed locally so as to be only provided in one of the settings. For some of these, local exclusion criteria were agreed so that patients would not be randomised to a setting that was unable to meet their rehabilitation needs. Examples include a Parkinson's disease service, a falls assessment service and a motor neurone disease-specific service. Each of these criteria was different between the participating sites.

Interventions

Home-based rehabilitation

Generally home-based rehabilitation services provide, as a minimum, physiotherapy and occupational therapy in the patient's own home. Services can be specialised (e.g. in stroke rehabilitation) or be provided for patients with a range of disabilities. The four participating home-based rehabilitation services all provided stroke rehabilitation, falls assessment and rehabilitation services, as well as a range of other services (Table 16).

Day hospital rehabilitation

Traditionally day hospitals have provided rehabilitation in addition to functional assessment, medical and nursing procedures, physical maintenance, social care and respite. Patients come to the day hospital where the rehabilitation service is provided for a full or half day. Usually ambulance transport is provided to bring patients into the service and return them home after a session.

The four day hospitals on the participating sites provided a range of assessment and rehabilitation services including stroke and TIA assessment and

TABLE 16 Services and staffing at the four randomising sites

	North Tyneside		Chippenham		Newcastle upon Tyne		Barnsley	
	Home team	**Day hospital**	**Home team**	**Day hospital**	**Home team**	**Day hospital**	**Home team**	**Day hospital**
Rehabilitation services								
Stroke	✓	✓	✓	✓	✓	✓	✓	✓
TIA		✓	✓	✓				✓
Parkinson's disease		✓		✓	✓	✓	✓	✓
Movement disorders		✓	✓	✓	✓	✓	✓	✓
Falls	✓	✓	✓	✓	✓	✓	✓	✓
Continence		✓				✓		✓
Physical maintenance	✓	✓	✓	✓	✓	✓		
Other	✓	✓		✓	✓	✓	✓	✓
Staffing								
Community nurse								
GP				✓				
Acute hospital nurse		✓		✓		✓		✓
Community hospital nurse				✓				
Other form of nurse		✓			✓	✓		
Hospital doctor		✓		✓	✓	✓		✓
Occupational therapist	✓	✓	✓	✓	✓	✓		✓
Physiotherapist	✓	✓	✓	✓	✓	✓	✓[a]	✓
Social worker	✓	✓			✓	✓		
Assistant(s)	✓	✓	✓	✓	✓	✓		
Administrative staff	✓	✓	✓		✓	✓		✓
Other	✓	✓			✓	✓		

TIA; transient ischaemic attack.
a Although this service is shown as having only one type of professional, in practice the physiotherapists work closely with colleagues from multiple disciplines to meet assessed needs for individual patients.

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rehabilitation for falls, Parkinson's disease and other movement disorders (Table 16).

Both types of rehabilitation service included therapy staff in their skill mix. The main difference in other staffing was the availability of specialist or community nursing and specialist or primary care medical input. The staffing in the services in the trial is outlined in Table 16.

Primary outcome

The primary end point was the overall score on the Nottingham Extended Activities of Daily Living (NEADL) scale at the 6-month follow-up.

The NEADL was designed by Nouri and Lincoln in 1987[52] for use with stroke patients. Bowling[53] found evidence for the reliability of the NEADL but found that few studies had evaluated its validity. Subsequent studies, though, have established the validity of the NEADL, for example Harwood and Ebrahim[54] concluded that the NEADL is valid for use with patients with arthritis of the hip, and Nicholl et al.[55] evaluated its usefulness with multiple sclerosis patients. Both of these studies support the reliability and validity of the method and suggest that it is a useful tool for a wider rehabilitation population than stroke patients. It has been used in studies of rehabilitation for older people[56] and a supported early hospital discharge scheme.[57]

The NEADL scale contains 22 items, each measured on a 4-point Likert scale. There are four dimensions: mobility, 6 items; kitchen, 5 items; domestic, 5 items; leisure, 6 items. These are summed producing a total score reflecting general functioning. Nouri and Lincoln[52] describe two principal scoring methods – one that involves collapsing the responses 'No' and 'Yes, with help' into one category (0) and the items 'On my own with difficulty' and 'On my own' into a second (1), and another that assigns each response a score from 0 to 3 respectively. The latter method was used as it was considered likely to be a more sensitive measure.

Using this method scores were created for the four dimensions plus an overall score. Additionally, the kitchen and domestic section scores were summed to create a household score.[58] Overall scores ranged from 0 to 66, with higher values indicating greater levels of independence.

Secondary outcome measures

NEADL total and subscale scores

In addition to using the NEADL scores at 6 months as the primary outcome measure, we used the NEADL total scores at 3 and 12 months and the NEADL subscale scores at 3, 6 and 12 months as secondary outcome measures.

Hospital Anxiety and Depression Scale at 3, 6 and 12 months' follow-up

The Hospital Anxiety and Depression Scale (HADS) was developed to identify anxiety disorders and depression among patients in non-psychiatric hospital clinics.[59] It contains an anxiety subscale and a depression subscale and is reported to have good reliability and validity and to be unaffected by the presence of physical illness.

Other studies since have confirmed its usefulness. It is easily understandable by and acceptable to patients and it is found to have good correlations with other well known scales.[53] Mykletun et al.[60] tested the psychometric properties of the HADS in a large population and found it to be good in terms of factor structure, intercorrelation, homogeneity and internal consistency. They also found that these properties were robust across a wide spectrum of subsamples, including age, gender and education. It has been used as a self-administered scale,[60] but it is generally recommend that it be interviewer administered.[53,59]

Its use in medical patients has been extensively reviewed[61] and it is concluded that the HADS is a reliable and valid instrument for assessing anxiety and depression in medical patients, with good internal consistency in the hospital population, and there is substantial evidence that it works well in general and in other populations.[61]

The HADS has been used extensively in studies of patients receiving rehabilitation, including elderly patients[62] and Parkinson's disease patients attending a day hospital for rehabilitation.[63]

It consists of 14 items on two subscales – seven pertaining to anxiety and seven to depression. Items within each subscale are summed to generate a score ranging from 0 (no problems) to 21 (lots of problems). When used as a clinical screening tool, most research indicates that a threshold score of 8 and over is associated with an increased likelihood of obtaining a clinical diagnosis.[64,65]

EuroQol 5 dimensions at 3, 6 and 12 months' follow-up

The EuroQol 5 dimensions (EQ-5D) was designed to provide a standardised non-disease-specific instrument for assessing health-related quality of life (HRQoL) and has been widely used in health economic evaluation. The EQ-5D has been widely used in rehabilitation studies, including an RCT of rehabilitation in patients with Parkinson's disease attending a day hospital.[63] The EQ-5D has been extensively validated and has been shown to be sensitive, internally consistent and reliable in the general population and other patient groups.[66]

The EQ-5D comprises two parts: a visual analogue scale (VAS) in which respondents are required to rate their health on a scale from 0 (worst health imaginable) to 100 (best imagined health), and five questionnaire items based on five dimensions of health (mobility, self-care, usual activities, pain or discomfort, and anxiety or depression). Each dimension has three possible response levels (ranging from 'no problems' to 'some problems' to 'cannot perform task'), giving a possible $3^5 = 243$ health states. To aid interpretation, each health state can be transformed into a weighted health state index score based on a UK sample to provide an index score ranging from –0.594 to 1.000 (where higher scores indicate better HRQoL). Thus, we have two measures of HRQoL from the trial: the VAS score ($EQ\text{-}5D_{vas}$) and the index score ($EQ\text{-}5D_{index}$). As a further aid to interpretation, following recommendations from the EQ-5D publishers, questionnaire items were recorded to indicate where patients experienced any difficulty in each of the five areas.

Therapy Outcome Measures rating at end of therapist rehabilitation

The Therapy Outcome Measures (TOMs) scale is a therapist-rated rehabilitation outcome measure that is psychometrically robust, with published data relating to its inter-rater reliability and validity.[67–69] It summarises the assessments and observations of the treating therapists in the areas of impairment, activity restriction, social participation and well-being. Thus, it is possible to identify whether an individual is improving in one area but not another. It has been suggested that home rehabilitation particularly promotes improvements in activities of daily living and psychosocial readjustment. These areas are thought not to do so well in hospital-based rehabilitation services. Rehabilitation is intended to have an impact on these dimensions and the research team felt that it was likely that the situation of rehabilitation, i.e. in the home or in the day hospital, could stimulate different patterns of benefit to the patients.

TOMs contains four dimensions – impairment (degree of severity of disorder), disability/activity (degree of limitation), social participation (degree of psychosocial engagement) and well-being (effect on emotion/level of distress) – with each dimension scored on an 11-point ordinal scale (0–5, including half-points). Lower scores indicate higher levels of impairment. Operational definitions of these ratings are given in Table 17.

Carer outcomes

The General Health Questionnaire 30 at 3, 6 and 12 months' follow-up

The GHQ is probably the most commonly used international scale of general psychiatric morbidity, across a wide range of patients.[53] Specifically, the 30-question version (GHQ-30) is the most popular, for its good psychometric properties and brevity. Bowling[53] stated that it has been extensively tested for reliability, validity and sensitivity to change with good results. It has also been used with elderly populations successfully, including when help has been needed to fill it in, and is acceptable for use with rehabilitation patients. It has recently been used in a study of mental health problems in older people in primary care,[70] and in a study of early supported discharge following acute stroke.[71]

The GHQ-30 was employed in the trial as a measure of carer psychological well-being and was administered at 3, 6 and 12 months. The GHQ-30 contains 30 items, each having four response options ranging from 'better/healthier than normal' through 'same as usual' and 'worse/

TABLE 17 Operational codes and descriptors for TOMs rating scale[69]

	Rating code					
	0.0–0.5	**1.0–1.5**	**2.0–2.5**	**3.0–3.5**	**4.0–4.5**	**5**
Description	Profound	Severe	Severe/ moderate	Moderate	Mild	Normal

more than usual' to 'much worse/more than usual'. A Likert scoring option was employed (0–3) and items were summed to create a single index score in which the higher the score, the more severe the condition. A brief review of the literature was conducted to investigate alternative methods of scoring the GHQ-30 with a view to extracting subscales. However, there appears to be no generally accepted method to achieve this and given that the publishers recommend the use of a single total score this was the only index used.

A summary of the questionnaire-based outcome measures used is given in Table 18.

Hospital admissions

The number of hospital admissions and the length of stay at each admission over the 12-month follow-up period were available from local hospital information systems for all those who were randomised and received rehabilitation (n = 84). Admission to hospital during the follow-up period was treated as a binary outcome variable (yes/no) for analysis purposes. Mean length of stay was also compared between the two care settings for those who experienced an admission.

Sample size and power

The intended sample size was based on the view that a difference of 2 points on the 22-point NEADL scale is clinically significant.[72] We therefore estimated that a sample of 460 patients (230 in each of the day hospital and home-based rehabilitation groups) would have 80% power to detect this difference using a significance level of 5%. Subsequently we used the 66-point NEADL scale and therefore a 7-point difference on this scale represents an equivalent clinically significant difference of 10% magnitude. Experience gained in day hospital audit and quality management[73] suggested about a 10% attrition rate over the course of the study, but we used the more conservative estimate of 15% in estimating sample size. We allowed for an initial non-response of 20% and attrition between times 1 and 2 of 15% and calculated that we needed to recruit 680 patients, probably from four to six participating clinical centres. The differences that we expected to detect with this actual sample size for different outcome measures are summarised in Table 19. As the number of patients completing the 6-month follow-up was only 65 it is noted that the study has 23% power to detect the same difference at a 5% significance level.

TABLE 18 Summary of questionnaire-based outcome measures

		Range of scores	
Measure	**Subscales**	**Worst**	**Best**
NEADL	Total (primary outcome)	0	66
	Mobility	0	24
	Kitchen	0	20
	Domestic	0	20
	Leisure	0	24
	Household	0	40
HADS	Anxiety	21	0
	Depression	21	0
$EQ\text{-}5D_{vas}$	n/a	0	100
$EQ\text{-}5D_{index}$	n/a	–0.594	1.000
TOMs	Impairment	0	5
	Disability/activity	0	5
	Social	0	5
	Well-being	0	5
GHQ-30	n/a	90	0

n/a, not available.

Data collection

Data collectors were appointed at each site and trained in the use of the assessment interview schedules by carrying out joint interviews with the trial manager (who in the first instance had been responsible for developing and piloting the questionnaires). Clinical staff in each of the participating sites received training in the use of TOMs before the start of the trial. Contact with the clinical and data collection staff was maintained through joint meetings and regular telephone contact. Staff in the trial office maintained records of recruitment and randomisation and sent reminders to data collectors when interviews were due. Patients were interviewed in their own homes, following prior arrangement by telephone or letter, by a data collector who was not told their treatment allocation. The interviews each took 30–60 minutes to perform.

Randomisation

Individuals were randomised to either home-based rehabilitation or day hospital rehabilitation using random permuted blocks of size 10. Randomisation was stratified by centre, AMT score and gender and by the presence of a carer. This procedure was undertaken using a web-based randomisation service provided by the Institute for Health and Society at Newcastle University.

Concealment of allocation

Baseline data were collected after consent was obtained but before randomisation. All of the interview questionnaires were completed in the patients' homes by local researchers, who were not aware of the treatment allocation. The nature of the treatments was such that it was not possible for the patients or their health-care professionals to be blinded to the treatment allocation, or to guarantee that the local researchers remained unaware of allocation for the duration of follow-up. The central research team, involved with data management, validation, analysis and interpretation of findings, remained blinded until after the first draft of the statistical and health economic analyses had been performed and discussed among the team.

Governance

The trial received multicentre ethical approval. Local research governance approval was sought and received at each of the participating sites. Progress of the research was reviewed approximately annually by an external steering group. Progress of the trial was monitored 6-monthly via reports to a NETSCC monitoring officer. We did not form a separate, independent data monitoring group as no interim analyses were planned and the trial was randomising between existing services, both of which were established and providing appropriate clinical care for trial subjects.

Statistical methods

General approach

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

Analysis methods

Continuous scale scores from primary and secondary outcomes were compared in the two

TABLE 19 Differences that can be detected with 80% power using a 5% significance level for a selection of outcome measures with a sample size of 230 in each group

					Difference between groups	
Outcome	**μ**	**Range**	**σ**	**ρ**	**Single point**	**Change score**
NEADL	9.0	0–22	6.6	0.70	2.0	1.6
HADS anxiety	5.9	0–21	4.3	0.78	1.3	0.9
HADS depression	6.3	0–21	4.2	0.77	1.3	0.9
GHQ-30	4.9	0–30	6.2	0.7	1.9	1.5

treatment arms at each follow-up period using analysis of covariance (ANCOVA) with baseline scores serving as the covariate. Dichotomous outcome data were analysed in a similar way using logistic regression.

Changes in outcome over the follow-up were assessed using repeated measures analysis of variance (ANOVA). To be consistent with previous studies, TOMs data were analysed using non-parametric methods (Mann–Whitney U test).

Hospital admission data were analysed using several approaches. In the first instance the outcome of interest was any admission to hospital during the 12-month follow-up period and was analysed using binary logistic regression. The effect of place of care on actual number of admissions was also analysed by fitting a Poisson regression model. The estimated treatment effect in such instances has a multiplicative impact on the outcome variable.

Additionally, continuous data were analysed using linear mixed models for repeated measures (MMRM) with interview follow-up point and patient treated as random effects. This method uses all available data, including data from patients who were lost to follow-up, taking advantage of the fact that measurements obtained from the same patients at different time points are correlated with each other. The MMRM method uses this information so that treatment effects are based on observations at the primary end point combined with contributions from all observations at other times.

Approach to missing data

Missing questionnaire items

For the statistical analyses of the questionnaire data, missing responses were replaced with the individual's mean relevant subscale score for the corresponding item, providing that the participant responded to at least half of the items within the subscale. In practice, only the NEADL scale had missing data – about 1% of data were missing for this scale, mainly because one of the questions was only partially relevant to some participants.

Data missing because of loss to follow-up

To conform to ITT principles, outcome scores missing because of loss to follow-up were imputed using the last observation carried forward (LOCF) method as prespecified in the analysis plan. Figure 4 illustrates this methodology.

All three methods (observed case, ITT with LOCF imputation and MMRM) were compared.

Health economic analysis

Study perspective and design

The study examined the effects on patient and carer outcomes, and on resource use, of the setting of rehabilitative care. A cost-effectiveness analysis was proposed if a significant difference in outcomes between day hospital and home-based rehabilitative patients was established. Cost-effectiveness analysis of EQ-$5D_{index}$ outcomes, or NEADL outcomes was feasible, but the latter would require conversion to a cardinal scale. In the absence of evidence of any significant difference in outcomes, analysis would revert to a cost-minimisation study. The perspective of the evaluation was societal:[74] alongside the costs falling on the patients and their carers, we included the costs to the NHS and local authorities.

Elderly patients undergoing rehabilitative care are likely to consume considerable resources from both health and social care budgets. In addition, a large informal care burden may fall on the primary carer. The method of valuation of informal care is highly contentious. We valued it in monetary terms although we also reported separately the impact on the quality of life of carers.

The boundary between rehabilitation-related costs and the costs of unrelated co-morbidities is not always clear. There is the distinct possibility that the care setting for rehabilitation might determine patient resource use in other areas of health and social care; however, we were concerned that attempts to distinguish those costs arising from co-morbidities could introduce bias. We therefore took care to ensure that the overall health levels in the two groups were balanced at baseline, and then sought to measure all of the health and social care resource use for each patient.

In practice, the division of costs between NHS and local authority budgets, particularly with respect to the home-based rehabilitative teams, was an arbitrary product of local delivery structures. Consequently we have not attempted to delineate those costs falling on the NHS budget, but we do present costs falling on the public sector as a subanalysis of total costs.

Resource use data collection

The services provided by the rehabilitation teams to patients and the related use of resources were

Original data set

ID no.	EQ-5D$_{index}$ baseline	EQ-5D$_{index}$ 3 months	EQ-5D$_{index}$ 6 months
1	0.691	0.724	0.621
2	0.189	–	0.456
3	0.260	–	–
4	0.383	0.654	–
5	0.587	–	–
6	0.088	–0.056	–

After LOCF imputation

ID no.	EQ-5D$_{index}$ baseline	EQ-5D$_{index}$ 3 months	EQ-5D$_{index}$ 6 months
1	0.691	0.724	0.621
2	0.189	0.189	0.456
3	0.260	0.260	0.260
4	0.383	0.654	0.654
5	0.587	0.587	0.587
6	0.088	–0.056	–0.056

FIGURE 4 Example of the last observation carried forward method for EQ-5D$_{index}$ scores.

monitored using a log for each patient enrolled in the trial (see Appendix 1). Rehabilitation staff at each site were asked to record every task specific to the care of each patient. The log captured the date, duration and nature of each care episode and the grades of the health professionals involved. An economic questionnaire (see Appendix 1) was also administered to each patient 1 month after rehabilitation commenced. A second and third questionnaire followed at 3-month intervals, and some patients received a fourth economic questionnaire after a further 6 months. Each questionnaire asked about the period following the last questionnaire. The questionnaires aimed to capture the health and social care resources/costs that had not been captured in the rehabilitation logs. These included primary care, outpatient visits, home adaptations, medications and private health-care costs. They also included social care resource use such as residential and home care, which was likely to be provided, at least in part, in response to patients' rehabilitative care needs. In addition to the questionnaire, hospital stays were collated from hospital records for each patient.

Economic questionnaires were obtained for 79 patients and rehabilitation logs for 60 patients. Four of these logs were for patients without any questionnaires, hence there were 56 patients with a rehabilitation log and at least one questionnaire. Out of this subset 34 patients completed four questionnaires and 11 completed three questionnaires. The vast majority were from two of the four trial sites (Chippenham and North Tyneside).

Valuation of resources

The cost of an hour of direct patient contact time for each of the professionals listed on the rehabilitation logs was estimated using the Unit Costs of Health and Social Care 2006 (UCHSC)[75] adjusted by staff grade (Table 20). Costs for members of the home-based rehabilitation teams include an adjustment for the time and costs of travel. The hourly costs include training and on-costs but exclude overheads, which were calculated separately.

Outpatient appointments were costed at 10 minutes of a consultant's time (mid-band 8c–d, £15.84) unless the nature of the appointment suggested otherwise. Drug costs were obtained from the British National Formulary.[76] Test/investigation costs were estimated using NHS reference costs.[77] Rehabilitative equipment was valued at prices provided by Nottingham Rehab Supplies.[78] Equipment costs were annuitised[79] over 4 years at 3.5%. Home adaptations were costed using the data in the UCHSC 2006, which are annuitised over 10 years at 3.5%. Unit costs for most resource use such as inpatient stays and emergency transport were estimated using the UCHSC 2006.[75] No attempt was made to value loss of earnings for the patient or the effects of changes in benefits.

Day hospital overheads for each hospital were estimated using data from the hospital accounts. Attempts were made to exclude all inappropriate costs, but a large variation in overhead costs at the four trial sites remained. The reference cost submissions for each site indicate significant differences in overhead costs per patient. Nevertheless the possibility of omissions remains, particularly for Chippenham where only brief data were obtained. The cost of transport of the patient to and from the day hospital was estimated at £100 using data from the UCHSC 2006. Hence, in the base case, each hospital rehabilitation patient accumulated a cost equal to the overheads at that day hospital plus £100 for each day that they attended. The effect of these estimates was probed with a sensitivity analysis. The estimated

TABLE 20 Cost per hour of direct patient contact by professional according to staff grade

		Hourly cost	
Occupation	**Band**	**Community**	**Hospital**
Nurse	7	£62	£59
	6	£49	£50
	5	£41	£34
	4		£31
Clinical support worker	3	£16	£14
	2	£15	£16
Physiotherapist	6	£37	£33
	5	£31	£27
	4	£26	
	3		£19
Occupational therapist	6	£38	£38
	5	£32	£31
	4		£26
Occupational therapist (local authority)	Mid-point	£44	
Speech and language therapist	6	£38	
	5	£32	£31
Consultant	Mid-point	£300	£140
Radiographer	5		£32
Clinical psychologist	7	£53	£49
Social worker	Mid-point	£93	
Local authority home care worker		£16	

overheads are shown in Table 21, along with reference cost submissions for the year 2006/7 from each authority for comparison. The reference cost submissions may include more than one day hospital.

Overheads for the community rehabilitation teams are less clearly defined, with acute trusts, primary care trusts (PCTs) and local authorities sometimes providing resources to the same team. The home-based rehabilitation team in Barnsley is supported by Barnsley PCT and their accountant provided a breakdown of the team costs. The ratio of the total costs to the clinical staff costs of the team was calculated (1.44). This multiplier was applied to all staff costs for the community rehabilitation teams at each trial site to allow for overheads.

Informal care from partners, friends and relatives was valued at £8 per hour. Valuation of voluntary care is a contentious issue in the economic literature, and this valuation is explored in the

TABLE 21 Day hospital overheads

Day hospital	Estimated overheads	Reference cost submission
Chippenham	£63	£230
North Tyneside – Jubilee	£44	£110
Newcastle – Freeman	£31	£61
Barnsley	£136	£194
Mean	£69	

discussion. Given the large contribution of time by informal carers of these patients, a sensitivity analysis of this valuation was undertaken.

Data processing

Data collection

The interview schedule in Table 22 shows which interviews were conducted at which time points. [Interviews 2 and 3 (and 4 and 5) are grouped because they differ only in their wording: since the start of your rehabilitation versus since your last interview.]

Data entry

The data were entered into three SPSS (Statistical Package for the Social Sciences) files (recording interview 1, interviews 2/3 and interviews 4/5). Table 23 shows the number of forms entered at each time point for each interview and by site.

Data validation

Process

A checklist of the variables and the checks that needed to be performed on them was created. This list included dependencies (e.g. a field may have been required only if another field had a particular value) alongside any validation required.

The data were imported from SPSS into Excel to facilitate validation. Excel's AutoFilter was used to examine the data in reference to the checklist. Any data requiring further investigation based on the validation checklist criteria were recorded in a new worksheet (listing patient study number, form, field and the problem value).

Once the queries had been identified the values were checked against the information on the original forms and corrections made where necessary. During this process some additional input errors were found by chance and fixed (e.g. when an acceptable – but wrong – value had been recorded). Such errors could have been minimised through double data entry but this approach was decided against at an earlier stage because of practical constraints.

Queries raised

Table 24 summarises the numbers of queries raised at each time point and at each interview.

Altogether, 234 queries were raised across the 639 interview forms entered, giving a mean of 0.37 queries per form entered.

TABLE 22 Interview schedule

	Baseline	1 month	3 months	6 months	12 months
Interview 1	✓	–	✓	✓	✓
Interviews 2/3	–	✓	✓	✓	✓
Interviews 4/5	–	–	✓	✓	✓

TABLE 23 Number of forms entered at each time point for each interview

Time point	Interview 1	Interviews 2/3	Interviews 4/5	C	N	F	B	Total
Baseline	84	–	–	25	48	5	6	84
1 month	–	76	–	21	47	4	4	76
3 months	72	72	46	19	46	3	4	72
6 months	65	66	41	18	41	3	4	66
12 months	43	43	31	10	33			43
Total	264	257	118	93	215	15	18	341

B, Barnsley; C, Chippenham; F, Newcastle – Freeman; N, North Tyneside – Jubilee.

Three-quarters of the queries were discovered in the interview 2/3 forms. This was anticipated because there are substantially more questions in these forms than in the others.

Queries included those relating to potentially inaccurate, incongruous, invalid or missing values, and calculation error queries. A breakdown of these is shown in Table 25.

Missing forms

To ensure that all appropriate forms had been received and entered for each patient, a spreadsheet was maintained to log the date on which each appointment was due and whether the form had been completed.

Implications for statistical analysis

Numbers of erroneous and missing values were low for the key data included on the validation checklist. No errors that would obviously bias the data in a given direction were identified.

Management of health economic data

Data for the health economic analysis were collected at 1 month after randomisation and 3, 6 and 12 months later (the 3-, 6- and 12-month follow-up data). Accordingly the periods for the analysis were 7 and 13 months from randomisation and so analysis of the total costs and total public sector costs accumulated in the two arms was conducted at 7 and 13 months. For some observations there was a wide spread of dates for the observations. Many of the more significant costs (especially those for social care) were ongoing costs and rose throughout the follow-up period. As patients with later interview dates would be likely to accumulate higher costs, the costs for each patient were imputed to facilitate comparison – assuming a linear accumulation of costs since the last assessment. The data at the 6-month follow-up point were imputed at 213 days and the data at the 12-month follow-up point were imputed at 395 days.

Follow-up times were measured from the randomisation date for each patient. All costs recorded before the analysis point (213 or 395 days after randomisation) were summed. Costs recorded on the economic questionnaire following the analysis point were divided by the time interval between administration of that questionnaire and the previous questionnaire to calculate a 'cost per day'. The sum totals for costs recorded before the analysis point were then adjusted upwards for the appropriate number of days using the calculated cost per day (Box 2). When the final interview fell before the analysis point the costs accrued from the previous economic questionnaire were extrapolated to the analysis point using the same 'cost per day' calculation.

TABLE 24 Numbers of queries raised at each time point and at each interview

	Questions	Baseline	1 month	3 months	6 months	12 months	Total
Interview 1	53	12	–	9	14	7	42
Interviews 2/3	542	–	86	54	25	9	174
Interviews 4/5	72	–	–	8	5	5	18
Total	667	12	86	71	44	21	234

TABLE 25 Breakdown of queries

	Baseline	1 month	3 month	6 month	12 month	Total
Inaccurate	0	11	2	0	3	16
Incongruous	0	35	26	12	5	78
Invalid	2	5	4	1	0	12
Calculation error	2	0	3	4	1	10
Missing	8	34	35	27	12	116
Other	0	1	1	0	0	2
Total	12	86	71	44	21	234

Most but not all patients had completed their rehabilitation programme at 213 days. When rehabilitation was ongoing the total rehabilitation costs were divided by the programme duration to derive a cost per day. This was multiplied by 213 to estimate the costs at 213 days. The dates of hospital inpatient stays were used to assign costs at 213 and 395 days for hospital stays up to and including the 213th and 395th day after randomisation respectively.

Two patients did not receive their first interview until 4 months after randomisation. These patients were included as it was judged that the interview at 4 months would have captured resource use in the first month as well as the following 3 months.

Other assumptions/limitations

In comparing the mean and median costs of the two groups we are tacitly assuming that the identified costs can be saved if patients are transferred to care in the other setting. The closure of the day hospital at Chippenham supports this assumption but it seems likely that some of the overheads assigned to the day hospital would be reallocated to other departments rather than being simply eliminated. Similarly, as the community rehabilitation teams often provide other services apart from rehabilitation at home, some of the overheads identified with that team would not be saved if care was transferred to the day hospital.

Results

Research sites

A list of possible trial sites was initially drawn up using data from the national survey of NHS trusts in England. These sites all had both home-based rehabilitation and day hospital rehabilitation services, both of which provided functional and medical assessment and rehabilitation. Neither of the services on each site had indicated that they were expecting major change in the next 3 years, and they had not answered 'No' to the possibility of being involved in the trial. Of the 400 replies received to the first contact questionnaire, only 10 sites (the 'ideal sites') satisfied all of the necessary criteria. This proved inadequate to recruit sufficient sites for the trial and so the criteria were widened to include sites in the same geographical areas as ideal sites and sites in the geographical areas of the research teams.

This strategy resulted in 19 locations being assessed for participation in the trial as randomising sites. Of these, two did not proceed beyond expressions of interest. The remaining 17 sites were visited by the research team. At the first visit the nature and purpose of the study were explained to the staff and/or the service managers and detailed service and contact information was obtained. Five of the sites proved to be unsuitable for operational reasons (e.g. unsuitable service configuration or very small catchment population for randomisation). Five sites could not be recruited as the local clinical staff had concerns about participating in the research. These concerns often focused on the issue of the acceptability of randomisation as a research method in this context. Seven sites agreed to take part in the trial and we proceeded to obtain local ethical and research governance approval. Of these seven sites, four proceeded to become randomising trial sites. These services were located in Newcastle upon Tyne, North Tyneside, Chippenham and Barnsley. The remaining three sites dropped out of the process.

BOX 2 Calculation of costs

Example: Assume that the patient has accumulated £2500 of costs on the questionnaire at 45 days, £2000 at 125 days, £2400 at 205 days and £1200 at 405 days, and his rehabilitation log totals £3000 with 240 days of rehabilitation. Then the 213-day cost is calculated as follows:

£6900 (total cost on all questionnaires before the analysis point)

- between day 205 and day 405 the patient accrues £1200, which is £6 per day, hence £48 is the imputed cost from the last questionnaire up to 213 days (£6×8 days)
- as rehabilitation has not ended the imputed rehabilitation costs are £2662.50 (£3000×213/240)
- total 213-day cost is £9610.50 (£6900 + £48 + £2662.50)

Two withdrew after changes in site management arrangements and in one we encountered insurmountable logistical difficulties.

Flow of participants through the study: CONSORT diagram

Recruitment began at the first site in March 2005 and ended in October 2006, at which point four sites were randomising patients into the trial. Of the 907 participants assessed for eligibility, 89 were randomised and allocated to treatment, of whom 84 (42 in each treatment arm) received either home-based or day hospital rehabilitation (Figure 5).

Of the 472 patients who were considered ineligible to take part in the study, 272 (58%) were excluded as they were referred to the service for assessment by a single discipline. These subjects were therefore, by definition, not referred for multidisciplinary rehabilitation and were therefore not eligible for randomisation. Of the rest, the majority were excluded for local service-specific reasons. For example, 143 (30%) were excluded because of having a diagnosis of either motor neurone disease or Parkinson's disease at sites at which location-specific services had been established for these specific diagnoses.

The levels of ineligibility, exclusion and refusal led to lower than expected levels of recruitment into the trial, which eventually left us unable to meet recruitment targets resulting in closure of recruitment before the target sample size had been achieved.

We therefore developed and proposed an exit strategy that limited follow-up to 6 months for subjects already randomised before October 2006, so that data collection would finish by the end of April 2007. This meant that the 12-month follow-up was sacrificed for some subjects to achieve a timely end to the project. The strategy anticipated that about 90 subjects would be randomised and that 6-month follow-up data would be available on about 85% of randomised participants.

The CONSORT diagram (Figure 5) shows that five patients were lost from the home-based

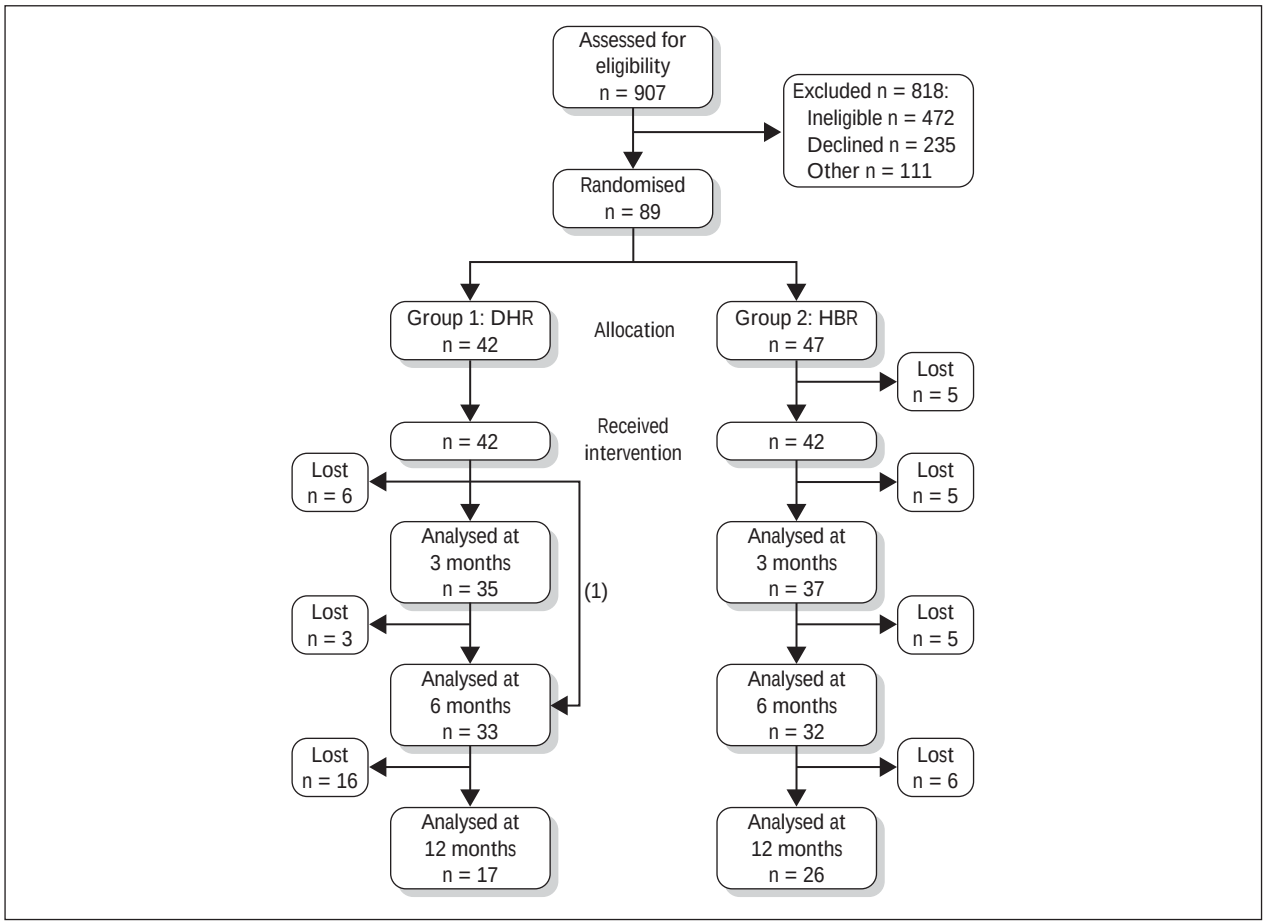

FIGURE 5 Flow of patients through the study.

rehabilitation group before the start of the intervention. Therefore, although 89 were randomised to the intervention (allocated), only 84 actually received an intervention. The reasons for loss to follow-up post treatment allocation are given in Table 26. At the 6-month follow-up, 33 patients in the home-based rehabilitation arm (79%) and 32 in the day hospital rehabilitation arm (76%) were available for analyses.

Comparison between completers and those lost to follow-up at 6 months

Demographic characteristics and baseline morbidity of patients (as measured by outcome scales) were compared between those who completed the study up to 6 months (n = 65) and those who received treatment but were lost to follow-up before this point (n = 19; Table 27). In a multiple logistic regression, the fact that a patient had a carer and higher EQ-5D$_{index}$ scores were both predictive of completing the study at 6 months, with odds ratios of 6.85 (95% CI 2.03 to 23.07) and 7.18 (95% CI 1.17 to 44.45) respectively.

Similar proportions of patients were lost to follow-up in both treatment arms at the 6-month follow-up (day hospital rehabilitation = 21.4%; home-based rehabilitation = 23.8; $\chi^2_{df=1} = 0.068$, p = 0.794). There were no differences in the baseline characteristics of the 19 patients who were lost to follow-up before the 6-month end point when compared by randomisation group (Table 28).

Characteristics of participants at baseline

Demographic characteristics of the two groups of participants and their carers are given in Table 29. Baseline/demographic data for the five participants who were allocated to but did not receive home-based rehabilitation are not available; therefore this analysis is reported for the patients who received the allocated intervention.

Reasons for referral for rehabilitation

Overall there were 134 reasons given for referral to the rehabilitation service (Table 30). A total of 52 subjects (58%) were referred for a single reason including stroke rehabilitation (n = 18), falls assessment (n = 12), mobility assessment (n = 8), orthopaedic rehabilitation (n = 5) and other reasons (n = 9). A total of 37 subjects were referred with multiple reasons for referral including 27 referred for two reasons, nine for three reasons and one for four reasons.

Questionnaire-based outcome data at baseline

Baseline outcome data for each group are given in Table 31.

Generally speaking there was little evidence of any chance imbalance between groups, with similar mean scores and proportions being observed. Although continuous scale scores on the HADS

TABLE 26 Reasons for loss to follow-up post treatment allocation

	Study arm	
Lost before	**Day hospital (n = 42)**	**Home (n = 47)**
Receiving intervention	Total (remaining): 0 (42)	Withdrew : 2; deceased: 1; unknown: 2 Total (remaining): 5 (42)
3-month follow-up	Withdrew: 4; too ill: 1; deceased: 1; interview missed but subject not lost to follow-up: 1 Total (remaining): 6 (36) (35 interviewed)	Withdrew: 3; deceased: 1; unable to locate patient: 1 Total (remaining): 5 (37)
6-month follow-up	Deceased: 3 Total (remaining): 3 (33)	Deceased: 1; withdrew: 2; unable to complete: 1; unknown: 1 Total (remaining): 5 (32)
12-month follow-up	Deceased: 2; withdrew: 2; unable to complete: 12 Total (remaining): 16 (17)	Unable to complete: 6 Total (remaining): 6 (26)

TABLE 27 Comparison between completers and non-completers at 6 months' follow-up

	Completed 6-month follow-up		
	Yes (n = 65)	**No (n = 19)**	**p-value**
Demographics			
Age (years), mean (SD)	74.15 (11.14)	78.83 (10.44)	0.106
Female (%)	52.3	63.2	0.403
With carer (%)	64.6	21.1	0.001
Baseline morbidity			
NEADL total score	31.39	25.23	0.121
$EQ\text{-}5D_{vas}$	56.09	53.00	0.499
$EQ\text{-}5D_{index}$	0.56	0.41	0.028
HADS anxiety	7.45	5.63	0.139
HADS depression	7.09	7.32	0.829

anxiety and depression scales were similar, it is noted that, using a threshold score of 8, the proportion of probable cases of clinical anxiety was higher in the day hospital group, whereas probable cases of clinical depression were more commonly seen in the home-based rehabilitation group. Frequency distributions for individual items from each questionnaire can be found in Appendix 2.

Therapist-rated outcome data

Baseline and discharge TOMs data were available for a subset of 46 patients (15 in day hospital rehabilitation and 31 in home-based rehabilitation) (Table 32). The difference in the sizes of these groups indicates that the usual safeguards imposed by random allocation may not apply and that these data should therefore be considered descriptive only. Median TOMs ratings at baseline ranged from 3.0, operationally defined as 'moderate' impairment, to 4.0 or 'mild' impairment.[67]

Summary of follow-up interview timings

A total of 65 interviews were conducted at the 6-month follow-up with a mean absolute difference between the actual and expected time of interview

TABLE 28 Group comparison of baseline characteristics for those lost to follow-up at 6 months

	Allocation		
	DHR (n = 9)	**HBR (n = 10)**	**p-value**
Demographics			
Age (years), mean (SD)	83.29 (6.30)	74.82 (12.05)	0.076
Female (%)	55.6	70.0	0.515
With carer (%)	33.3	10.0	0.213
Baseline morbidity			
NEADL total score (SD)	29.93 (19.31)	21.00 (14.20)	0.263
$EQ\text{-}5D_{vas}$ (SD)	57.78 (14.84)	48.70 (15.21)	0.206
$EQ\text{-}5D_{index}$ (SD)	0.50 (0.31)	0.33 (0.27)	0.220
HADS anxiety (SD)	5.33 (4.15)	5.9 (2.13)	0.709
HADS depression (SD)	7.67 (4.74)	7.00 (3.40)	0.727

DHR, day hospital rehabilitation; HBR, home-based rehabilitation.

TABLE 29 Demographic characteristics of patients and their carers

Variable	DHR (n = 42)	HBR (n = 42)
Patient demographics:	n = 42	n = 42
Mean age (years) at first interview (SD; min.–max.)	76 (11; 53–95)	74 (11; 43–88)
65 years or younger (%)	19.0	21.4
66–74 years (%)	14.3	19.0
75–84 years (%)	42.9	45.2
85 years or older (%)	23.8	14.3
Gender: % female	45.2	45.2
Details of carer:	n = 23	n = 23
Mean age (years) at first interview (SD; min.–max.)	64 (12.67; 39–93)	64 (10; 43–86)
Gender: % female	60.9	82.6
Relationship to patient (%):		
Spouse	61	48
Child	22	22
Friend	9	17
Other	9	13

DHR, day hospital rehabilitation; HBR, home-based rehabilitation.

of 16 days (SD 18 days; min. 0, max. 62). This was similar at 3 and 12 months' follow-up with little difference between randomisation groups at the primary 6-month end point.

To investigate the possibility that interview delays introduce bias, the relationship between interview delay and the primary outcome measure (NEADL at 6 months) was examined by simple linear regression. There was no evidence that delays in interview at 6 months affected mean NEADL total scores at 6 months' follow-up ($\beta = 0.09$, 95% CI –0.08 to 0.25, $p = 0.288$).

A detailed breakdown of these figures and the associated analysis can be found in Appendix 2.

TABLE 30 Reasons for referral for rehabilitation

Reason	Number (%)
Stroke rehabilitation	30 (22)
Orthopaedic rehabilitation	12 (9)
Movement disorder	1 (1)
Mobility assessment	29 (21)
Falls assessment	36 (27)
Other	26 (20)
Total	134

Interview-based outcomes

Analysis of outcomes using observed case data set

The following analyses were conducted on all patients for whom data were available at each follow-up point.

Primary outcome: NEADL total score at 6 months

Mean total NEADL scores for day hospital rehabilitation and home-based rehabilitation are given in Table 33, which suggests that home-based rehabilitation was slightly favoured on this outcome.

To assess this apparent difference between the two treatment arms, an ANCOVA was conducted providing a mean estimated difference between the two groups after adjusting for baseline scores on the same outcome (Table 34). This method allows preintervention differences in morbidity to be taken into account, increasing the statistical power of the comparison. Mean adjusted total NEADL scores at 6 months were estimated to be around two points lower in the home-based care group (a difference of 3%) but as the 95% confidence interval around this estimate includes zero, it is concluded that this difference is not statistically significant. The 'true' difference between home-based rehabilitation and day hospital rehabilitation in terms of the NEADL total score can therefore

TABLE 31 Baseline patient outcome data

	DHR (n = 42)	HBR (n = 42)
NEADL		
Mean mobility subscale score 0–24 (SD); median (IQR)	6.86 (4.66); 6.00 (8.25)	6.79 (5.12); 7.00 (8.00)
Mean domestic subscale score 0–20 (SD); median (IQR)	6.26 (4.48); 6.00 (7.00)	5.64 (4.85); 3.00 (9.25)
Mean kitchen subscale score 0–20 (SD); median (IQR)	10.43 (4.73); 12.00 (9.00)	8.83 (5.17); 10.00 (10.25)
Mean leisure subscale score 0–24 (SD); median (IQR)	7.89 (3.19); 7.10 (4.00)	7.30 (3.82); 7.00 (3.75)
Mean household derived score 0–40 (SD); median (IQR)	16.69 (8.52); 18.50 (15.25)	14.48 (9.22); 13.50 (17.50)
Mean total score 0–66 (SD); median (IQR)	31.43 (14.53); 32.60 (21.50)	28.56 (15.88); 28.50 (27.75)
EQ-5D		
EQ-5D weighted health state index ($EQ\text{-}5D_{index}$)		
Mean (SD); median (IQR)	0.51 (0.26); 0.59 (0.21)	0.55 (0.29); 0.60 (0.34)
Valuation of own health ($EQ\text{-}5D_{vas}$)		
Mean (SD); median (IQR)	56.74 (18.37); 55.00 (24.00)	54.05 (16.54); 50.00 (25.00)
Percentage of patients experiencing any HRQoL problem at baseline with respect to:		
Mobility	95.24	85.71
Self-care	61.90	59.50
Usual activities	88.10	83.33
Pain/discomfort	76.19	66.67
Anxiety/depression	47.62	38.10
HADS		
Mean anxiety score (SD); median (IQR)	7.79 (4.71); 8.00 (8.25)	6.29 (4.60); 5.00 (4.00)
Mean depression score (SD); median (IQR)	6.98 (3.74); 6.00 (6.00)	7.31 (4.12); 7.00 (7.25)
Probable clinical anxiety (%)	52.4	26.2
Probable clinical depression (%)	35.7	47.6

DHR, day hospital rehabilitation; HBR, home-based rehabilitation; IQR, interquartile range.

TABLE 32 Baseline TOMs ratings

Dimension	Statistic	DHR (n = 15)	HBR (n = 31)
Impairment[a]	Median (min.–max.)	3.0 (1.0–4.0)	3.0 (1.0–4.0)
Activity	Median (min.–max.)	3.5 (2.0–4.0)	3.0 (1.0–5.0)
Social participation	Median (min.–max.)	4.0 (1.0–5.0)	3.0 (0.0–4.0)
Well-being	Median (min.–max.)	4.0 (2.0–5.0)	4.0 (2.0–5.0)

DHR, day hospital rehabilitation; HBR, home-based rehabilitation.
a For the impairment scale there were two individuals from HBR for whom data were missing. Group sizes were thus 15 and 29 for DHR and HBR, respectively, for this variable.

be said (with 95% confidence) to lie between 6.9 points in favour of home-based care and 2.6 points in favour of day hospital care.

Secondary outcomes 1: NEADL subscales at 6 months

Mean scores from the four NEADL subscales plus the kitchen/domestic composite scale (household) were almost identical between the two treatment groups at 6 months, with a general tendency to be slightly worse in the day hospital group (Table 35). Mean estimated differences after adjusting for baseline scores are presented in Table 36.

Secondary outcomes 2: total NEADL scores at 3 and 12 months' follow-up

In addition to the primary end point of 6 months, group mean total NEADL scores for cases available at 3 months and at 12 months were also compared (Table 37). Estimated differences between each treatment group, after adjusting for baseline scores, favoured home-based care at 3 months but day hospital care at 12 months; however, neither result was statistically significant (3 months: estimate –2.79, 95% CI –7.84 to 1.90, p = 0.228; 12 months: estimate 1.39, 95% CI –6.11 to 8.88, p = 0.710).

Secondary outcomes 3: health-related quality of life and psychological well-being of patients at 6 months

Health-related quality of life, as measured by the EQ-5D, was similar in each group, in terms of both VAS ratings and the weighted health state index (Table 38). The proportions of patients who classified themselves as experiencing a problem in one of the five domains of HRQoL contained within the EQ-5D were also compared (Figure 6). In general, the results suggest that a smaller proportion of patients experienced HRQoL difficulties in the home-based rehabilitation group, particularly with respect to the anxiety/depression scale.

Statistical comparison of the proportions in Figure 6 was conducted using multiple logistic regression to take into account interindividual differences in HRQoL difficulties before the start of rehabilitation. The resulting statistic is the odds ratio, which in this instance provides a measure of how much more (or less) likely are patients in home-based care to have experienced HRQoL difficulties relative to patients who received rehabilitation at day hospital. An odds ratio of 1 indicates that patients are equally likely to experience difficulties in both groups. Health-related quality of life problems related to anxiety/depression appeared less common in the home-based rehabilitation group; however, as the 95% confidence intervals for the estimated odds ratios given in Table 38 all include 1, we conclude that there were no differences in HRQoL between the two groups at 6 months.

Mean scores on the HADS anxiety and depression scales were similar in each group at 6 months (Table 33) and did not differ significantly in analyses adjusted for baseline scores on these scales (Table 34). Using a clinical 'caseness' criteria threshold of 8, 39.4% and 31.3% of those in day hospital and home-based rehabilitation groups, respectively, were classified as having an increased likelihood of clinical anxiety. An increased likelihood of clinical depression was observed for 36.4% of day hospital cases and 37.5% of home-based care cases. Odds ratios for the likelihood of being considered a clinical case of anxiety or depression, adjusted for baseline proportions, are given in Table 39.

Summary of questionnaire-based outcomes at 6 months

Figure 7 provides a summary of the effect of place of care on the principal interview-based outcomes. Estimated differences between day hospital-based rehabilitation and home-based rehabilitation for each outcome (±95% confidence intervals), after

TABLE 33 Summary of patient outcomes at 6 months

Outcome	Possible range (worst to best)	DHR (n = 33), mean (SD)	HBR (n = 32), mean (SD)
NEADL total score	0 to 66	30.78 (15.01)	32.11 (16.89)
$EQ\text{-}5D_{index}$	–0.59 to 1.00	0.56 (0.23)	0.59 (0.32)
$EQ\text{-}5D_{vas}$	0 to 100	58.67 (16.08)	59.84 (19.48)
HADS anxiety	12 to 0	6.06 (4.67)	5.56 (4.15)
HADS depression	12 to 0	6.67 (3.05)	5.97 (4.16)

DHR, day hospital rehabilitation; HBR, home-based rehabilitation.

TABLE 34 Mean estimated difference in outcomes at 6 months adjusted for baseline scores by analysis of covariance

Outcome	Mean estimated difference adjusted for baseline	Lower 95% CI	Upper 95% CI	p-value
NEADL total score	–2.139	–6.870	2.592	0.370
$EQ\text{-}5D_{index}$	0.023	–0.114	0.161	0.735
$EQ\text{-}5D_{vas}$	–1.601	–8.809	5.607	0.659
HADS anxiety	–0.578	–2.409	1.253	0.530
HADS depression	1.033	–0.441	2.507	0.166

TABLE 35 NEADL subscale scores at 6 months

Subscale	Possible range (worst to best)	DHR (n = 33), mean (SD)	HBR (n = 32), mean (SD)
Mobility	0 to 24	7.30 (5.16)	8.19 (6.19)
Kitchen	0 to 20	10.76 (4.31)	10.34 (5.07)
Domestic	0 to 20	5.21 (4.52)	5.91 (5.04)
Leisure	0 to 24	7.51 (3.79)	7.68 (3.31)
Household (composite)	0 to 40	15.97 (7.94)	16.25 (9.28)

DHR, day hospital rehabilitation; HBR, home-based rehabilitation.

TABLE 36 Mean estimated difference in NEADL subscale scores at 6 months adjusted for baseline

Subscale	Mean estimated difference adjusted for baseline	Lower 95% CI	Upper 95% CI	p-value
Mobility	–0.58	–2.59	1.42	0.564
Kitchen	–0.40	–1.90	1.11	0.601
Domestic	–0.91	–2.31	0.49	0.198
Leisure	–0.11	–1.41	1.20	0.872
Household (composite)	–1.38	–3.88	1.12	0.273

TABLE 37 Mean NEADL total scores at 3 and 12 months' follow-up

		Group	
		DHR	HBR
3 months	Group size	35	37
	Mean score (SD)	31.69 (14.68)	31.05 (17.23)
12 months	Group size	17	26
	Mean score (SD)	31.61 (15.36)	28.06 (17.50)

DHR, day hospital rehabilitation; HBR, home-based rehabilitation.

TABLE 38 Odds ratios for the likelihood of experiencing an HRQoL difficulty at 6 months, adjusting for baseline proportions by multiple logistic regression

EQ-5D domain	Adjusted odds ratio[a]	95% CI for odds ratio		p-value
		Lower	Upper	
Mobility	1.16	0.24	5.51	0.852
Usual activities	0.33	0.09	1.23	0.100
Self-care	0.65	0.22	1.89	0.431
Pain/discomfort	2.18	0.64	7.41	0.212
Anxiety/depression	0.34	0.11	1.05	0.060

a General model: $\ln(p/(1-p)) = \chi + \beta_1$(randomisation group) + β_2(baseline proportion).

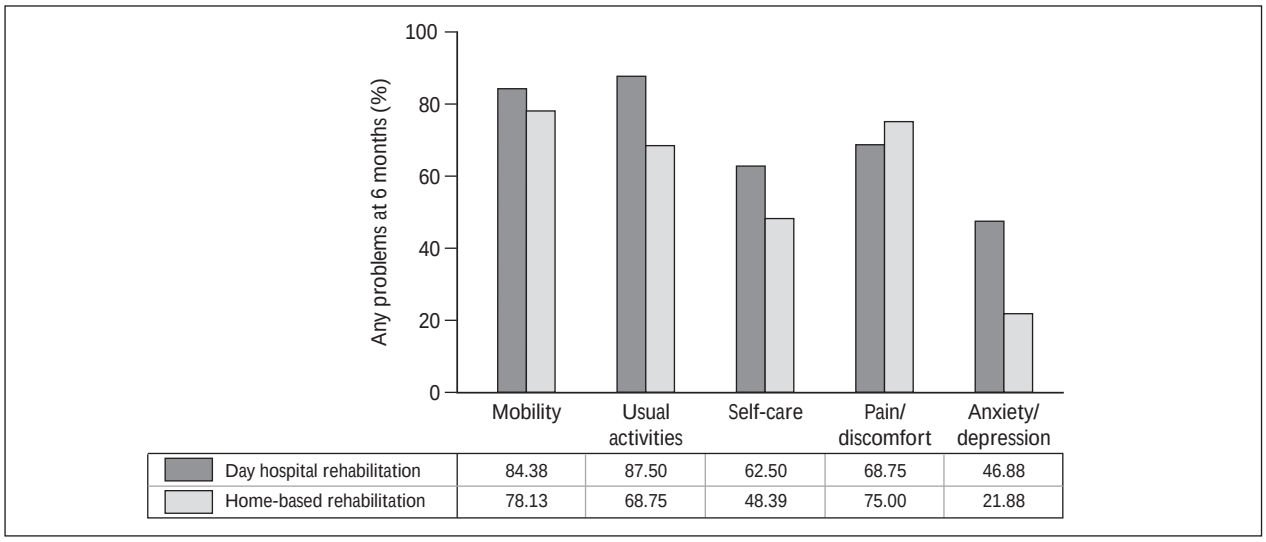

FIGURE 6 Percentages of patients experiencing problems in each of the EQ-5D domains at 6 months.

adjusting for baseline scores, were expressed as a percentage using respective scale ranges as denominators. The two shaded areas in Figure 7 provide 5% and 10% 'non-inferiority margins'. Non-inferiority for home-based care, for a given outcome, is inferred when the 95% confidence interval is contained within this shaded area. Thus, we may conclude that after 6 months' follow-up home-based care is not inferior to day hospital-based care in respect of all outcomes with the exception of HADS anxiety. There is insufficient evidence to reject the null hypothesis for this outcome as the estimated range of possible values falls outside of 10% in favour of hospital-based care. It is also noted, however, that the confidence intervals around the mean total NEADL and HADS depression scores include values higher than 10% in favour of home-based care.

Secondary outcomes 4: health-related quality of life and psychological well-being at 3 and 12 months

Mean EQ-5D$_{index}$ scores were better for day hospital patients than for home-based care patients at the 3-month follow-up (Table 40). The estimated difference between groups in this outcome, after adjustment for baseline scores, was 0.122 (95% CI 0.002 to 0.242) and was significant at the 5% level (Table 41). There were no other differences in outcomes at 3 months, although a marginally statistically significant difference in depression scores on the HADS was observed in favour of home-based care (p = 0.056).

Health-related quality of life and psychological well-being outcomes were both similar between the two groups of patients who were able to be

TABLE 39 Odds ratios for the likelihood of being classified as a clinical case of anxiety or depression at 6 months, adjusting for baseline proportions by multiple logistic regression

HADS domain	Adjusted odds ratio[a]	95% CI for odds ratio		p-value
		Lower	Upper	
Anxiety	1.22	0.376	3.97	0.739
Depression	0.86	0.29	2.60	0.793

a General model: $\ln(p/(1-p)) = \chi + \beta_1(\text{randomisation group}) + \beta_2(\text{baseline proportion})$.

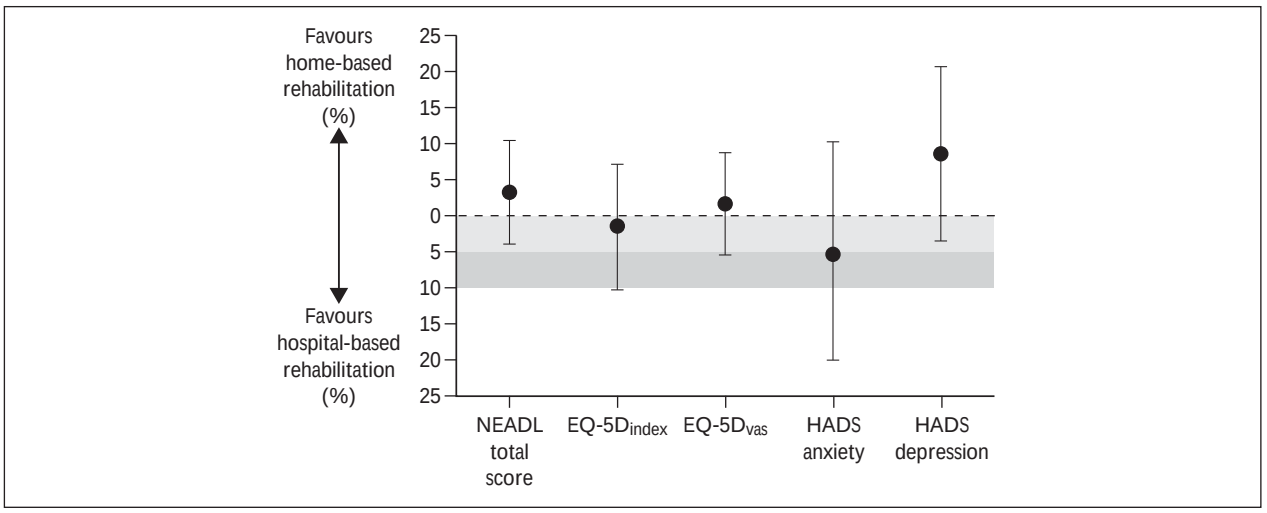

FIGURE 7 Effect of place of care on patient outcomes at 6 months.

followed up at 12 months (Table 42). The observed difference in HADS anxiety scores is probably explained by differences between the two groups at baseline and was not statistically significant following ANCOVA (Table 43).

Secondary outcomes 5: therapist-rated outcomes

Median ratings for the four TOMs dimensions at the end of rehabilitation were 4.0 ('mild impairment') or better with similar scores seen between groups on the four TOMs dimensions (Table 44). A formal test of the differences between the two treatment groups on discharge did not reveal any statistically significant findings (Table 45).

Changes in therapist-rated outcomes between treatment groups for the subset of patients for whom data were available are compared in Table 46. Focusing on patients who improved between initial and discharge assessment (Figure 8), there was a greater proportion of patients with a positive direction of change in the day hospital group on all aspects of the TOMs rating scale with the exception of social participation. However, if deterioration in TOMs rating is considered, a smaller proportion of patients in the home care group were seen to have a negative direction of change following rehabilitation.

Secondary outcomes 6: carer psychological health at 3, 6 and 12 months

In both treatment groups, 23 of the 42 (55%) patients who provided baseline data had carers (55%), the psychological well-being of whom was measured using the GHQ-30 at 3, 6 and 12 months. Mean GHQ-30 scores for the carers who completed this questionnaire at each follow-up point are given in Table 47. There was no evidence of any differences in the psychological health of carers of day hospital patients and home-based patients at any of the three follow-up points.

TABLE 40 Health-related quality of life and psychological well-being of patients at 3 months

Outcome	Possible range (worst to best)	DHR (n = 35), mean (SD)	HBR (n = 37), mean (SD)
$EQ\text{-}5D_{index}$	–0.59 to 1.00	0.61 (0.21)	0.51 (0.32)
$EQ\text{-}5D_{vas}$	0 to 100	56.54 (15.51)	57.70 (17.73)
HADS anxiety	12 to 0	6.83 (4.16)	5.65 (3.96)
HADS depression	12 to 0	6.83 (3.28)	5.81 (4.01)

DHR, day hospital rehabilitation; HBR, home-based rehabilitation.

TABLE 41 Mean estimated difference in outcomes at 3 months adjusted for baseline scores by analysis of covariance

Outcome	Mean estimated difference adjusted for baseline	Lower 95% CI	Upper 95% CI	p-value
$EQ\text{-}5D_{index}$	0.122	0.002	0.242	0.047
$EQ\text{-}5D_{vas}$	–2.559	–9.371	4.254	0.456
HADS anxiety	0.047	–1.466	1.559	0.951
HADS depression	1.374	–0.039	2.786	0.056

Secondary outcomes 7: hospital admissions during the 12-month follow-up period

The frequency of hospital admissions for both sets of patients over the 12-month follow-up period is shown in Table 48. Fewer patients in the home-based care group were admitted to hospital on any occasion over the observation period (43% versus 52%); however, this difference was not statistically significant (OR 0.75, 95% CI 0.62 to 3.47, p = 0.383). For those patients who had at least one hospital admission (22 in the day hospital rehabilitation group and 18 in the home-based rehabilitation group), the mean total length of stay was greater for the day hospital group (mean difference 9.3 days, 95% CI –12.5 to 31.1 days) but, as the confidence interval indicates, this difference was not statistically significant. The mean duration of stay per visit was similar (day hospital rehabilitation 15.8 days versus home-based rehabilitation 16.4 days, p = 0.936).

As hospital admission data were in the form of counts, a Poisson regression model was also fitted. The number of admissions over the 12-month follow-up period was not affected by place of care in this model ($\exp^{\beta} = 0.68$, 95% CI 0.41 to 1.12, p = 0.130).

Changes in principal outcomes during the 6 months' follow-up

In total, 32 patients in each arm of the study provided outcome data at all three follow-up points up to 6 months. To examine the extent to which outcomes changed over this period, and whether they did so in a different way depending upon which group is considered (an 'interaction effect'), a repeated measures ANOVA model was formed for the five main outcome variables. Means plots for the five outcomes are given in Figure 9 and the resulting p-values for these models are shown in Table 49. The p-values for the three effects may be interpreted as follows:

1. between-group effect – looks for a significant difference in mean outcome scores between the two groups, ignoring any changes over the course of the study
2. follow-up point effect (within-group effect) – looks for a significant difference in mean outcome over the 6-month follow-up period, ignoring any differences between the groups
3. group × follow-up point interaction (interaction effect) – examines whether any changes that occur over the 6-month follow-up period do so in a consistent manner across both groups.

There was no evidence of change in either NEADL total scores nor EQ-5D measures over the 6-month follow-up period; however, both HADS scales saw statistically significant improvements, with most of this seen between baseline and 3 months. Although there was clear evidence of an interaction for the $EQ\text{-}5D_{index}$ outcome, neither main effect reached statistical significance.

TABLE 42 Health-related quality of life and psychological well-being of patients at 12 months

Outcome	Possible range (worst to best)	DHR (n = 17), mean (SD)	HBR (n = 26), mean (SD)
$EQ\text{-}5D_{index}$	–0.59 to 1.00	0.55 (0.35)	0.51 (0.33)
$EQ\text{-}5D_{vas}$	0 to 100	58.71 (15.94)	53.08 (18.61)
HADS anxiety	12 to 0	7.24 (4.51)	5.27 (4.59)
HADS depression	12 to 0	6.76 (3.78)	7.27 (4.76)

DHR, day hospital rehabilitation; HBR, home-based rehabilitation.

TABLE 43 Mean estimated difference in outcomes at 12 months adjusted for baseline scores by analysis of covariance

Outcome	Mean estimated difference adjusted for baseline	Lower 95% CI	Upper 95% CI	p-value
$EQ\text{-}5D_{index}$	0.147	–0.051	0.345	0.141
$EQ\text{-}5D_{vas}$	6.315	–3.184	15.815	0.187
HADS anxiety	0.223	–1.906	2.351	0.834
HADS depression	–0.167	–2.423	2.089	0.882

TABLE 44 Discharge TOMs ratings

Dimension	Statistic	DHR (n = 15)	HBR (n = 31)
Impairment[a]	Median (min.–max.)	4.0 (1.0–4.5)	4.0 (1.0–5.0)
Activity	Median (min.–max.)	4.0 (0.0–5.0)	4.0 (1.0–5.0)
Social participation	Median (min.–max.)	4.5 (1.0–5.0)	4.0 (2.0–5.0)
Well-being	Median (min.–max.)	4.0 (2.0–5.0)	4.0 (3.0–5.0)

DHR, day hospital rehabilitation; HBR, home-based rehabilitation.
a For the impairment scale there were two individuals from the HBR group whose data were missing. Group sizes were thus 15 and 29 for the DHR and HBR groups respectively.

TABLE 45 Test of differences between groups on discharge TOMs scores

	Impairment	Activity	Social participation	Well-being
Mann–Whitney U test	188.50	211.50	199.00	218.00
p-value	0.455	0.613	0.421	0.718

TABLE 46 Changes in TOMs ratings between initial and discharge assessment

Dimension	Direction of change	DHR (n = 15)	HBR (n = 31)
Impairment[a]	Negative	1 (6.7%)	1 (3.4%)
	Sustained	6 (40%)	14 (48.3%)
	Positive	8 (53.3%)	14 (48.3%)
Activity	Negative	2 (13.3%)	0
	Sustained	4 (26.7%)	14 (45.2%)
	Positive	9 (60%)	17 (54.8%)
Social participation	Negative	2 (13.3%)	0
	Sustained	4 (26.7%)	11 (35.5%)
	Positive	9 (60%)	20 (64.5%)
Well-being	Negative	0	0
	Sustained	6 (40%)	17 (54.8%)
	Positive	9 (60%)	14 (45.2%)

DHR, day hospital rehabilitation; HBR, home-based rehabilitation.
a For the impairment scale there were two individuals from the HBR group whose data were missing. Group sizes were thus 15 and 29 for the DHR and HBR groups respectively.

TABLE 47 Mean carer GHQ-30 scores at each follow-up point

	Group size		GHQ-30 total score, mean (SD)					
Follow-up point	DHR	HBR	DHR	HBR	Mean difference	Lower 95% CI	Upper 95% CI	p-value
3 months	23	23	33.91 (16.40)	35.96 (13.21)	–2.04	–10.89	6.80	0.644
6 months	20	21	34.45 (14.08)	35.33 (16.92)	–0.883	–10.75	8.979	0.857
12 months	13	18	31.54 (9.95)	31.78 (4.60)	–0.239	–8.73	8.251	0.954

DHR, day hospital rehabilitation; HBR, home-based rehabilitation.

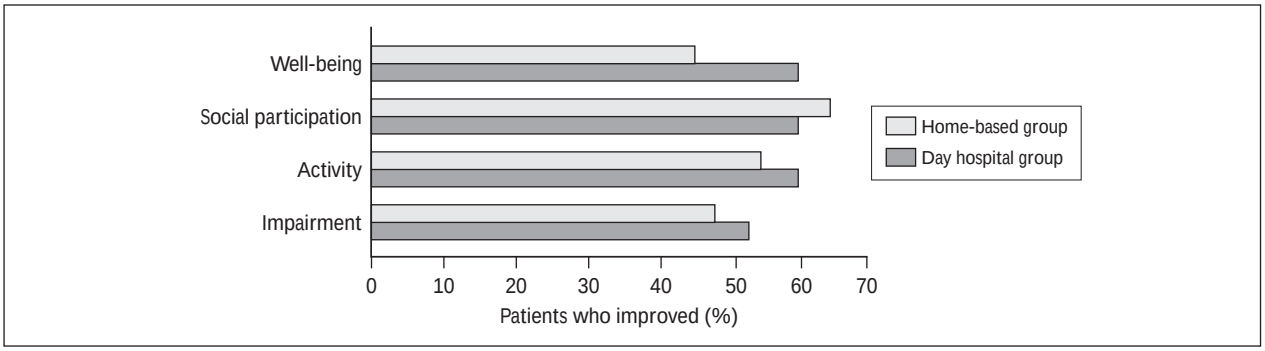

FIGURE 8 Percentage of those who improved between baseline and discharge assessment by randomisation group.

TABLE 48 Frequency of hospital admissions during the 12-month follow-up period

Number of admissions	DHR (n = 42)	HBR (n = 42)	Total
None	20 (47.62%)	24 (57.14%)	44 (52.38%)
One	11 (26.19%)	14 (33.33%)	25 (29.76%)
Two	7 (16.67%)	1 (2.38%)	8 (9.52%)
Three	4 (9.52%)	3 (7.14%)	7 (8.33%)

DHR, day hospital rehabilitation; HBR, home-based rehabilitation.

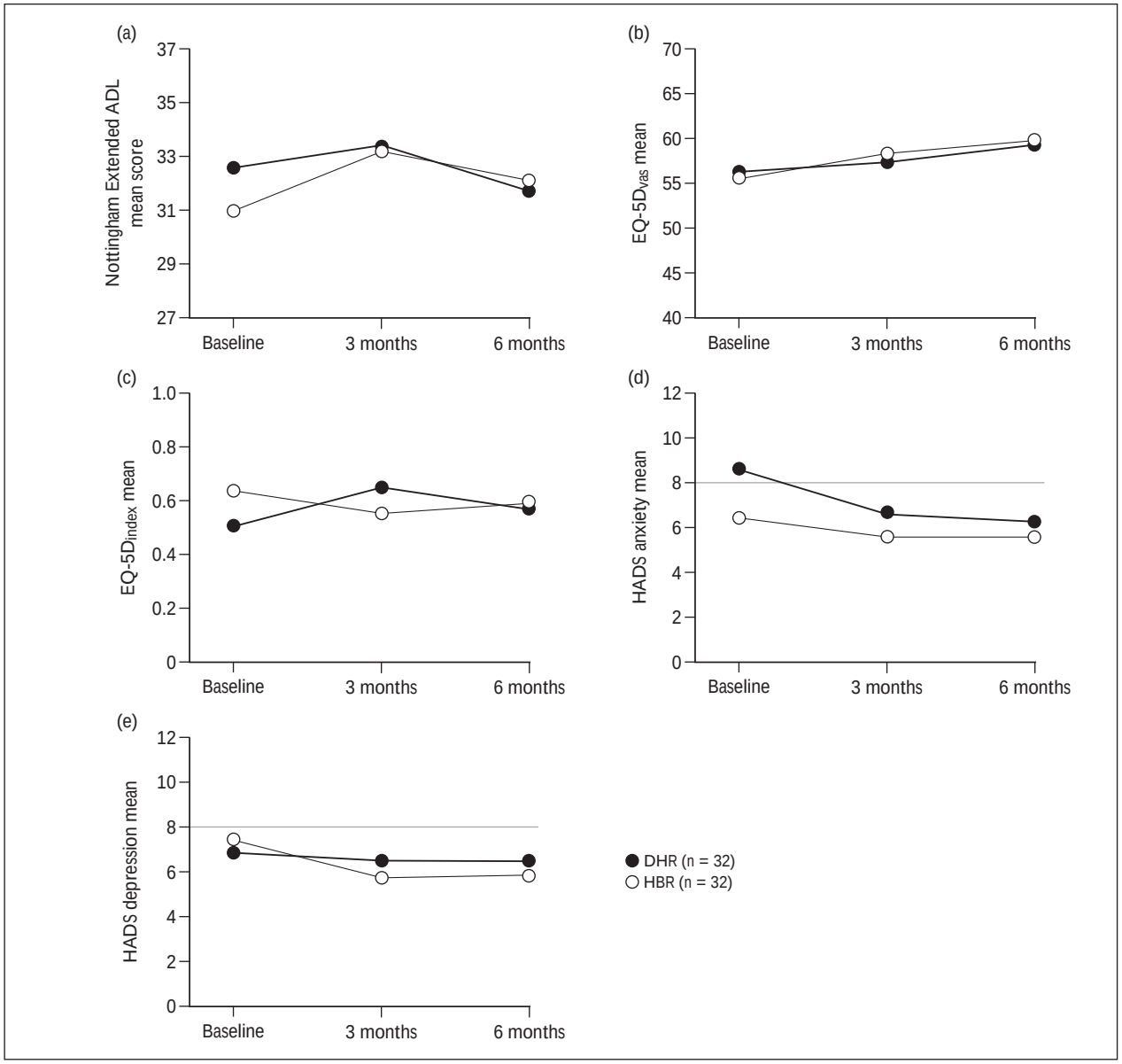

FIGURE 9 Effect of place of care on patient outcomes at baseline, 3 and 6 months.

TABLE 49 p-values for repeated measures analysis of variance (see Figure 9)

Outcome	Group effect	Follow-up effect	Interaction
NEADL total	0.898	0.877	0.410
$EQ\text{-}5D_{index}$	0.815	0.677	0.002
$EQ\text{-}5D_{vas}$	0.954	0.217	0.956
HADS anxiety	0.180	0.001	0.219
HADS depression	0.725	0.017	0.225

ITT analyses with LOCF imputation for missing data due to loss to follow-up

Mean total NEADL scores at 6 months along with those for the other main patient outcomes after replacement of missing data due to loss to follow-up by the LOCF method are shown in Table 50, and estimated differences in group means following adjustment for baseline scores are given in Table 51. A statistically significant difference in outcome was observed for HADS depression, which was estimated to be 1.4 points better in the home-based rehabilitation group. Although no other statistically significant findings were observed, Figure 10 shows that, consistent with the non-LOCF data set, one confidence interval fell outside of the 10% non-inferiority margin – HADS anxiety.

Comparison between observed case, LOCF and MMRM estimates of differences between rehabilitation groups at 6 months

Estimated differences in 6-month patient outcomes (± 95% CI) obtained from the observed case and LOCF data sets are compared in Table 52, along with the estimates provided by the MMRM analysis. These estimates are compared graphically in Figure 11 for the primary outcome measures and in Appendix 2 for secondary measures (see Figures 29–31). For the NEADL (total) outcome it can be seen that the estimated mean effect of place of rehabilitation is larger when derived from the LOCF imputed data set and from the MMRM analysis. Importantly, however, the confidence interval relevant to the non-inferiority range (shown in the shaded area) is similar for each of the three methods and the general conclusion reached from the primary analysis data set remains. Inferences made for the $EQ\text{-}5D_{index}$, HADS anxiety and HADS depression using data from the observed case data set are similarly reinforced by the supplementary analyses.

Analysis of costs

Resource use

Patient resource use in a pragmatic trial covering various morbidities is likely to be diverse. Table 53 provides an overview of the main resources used, grouped into categories. Hospital inpatient stays have been reported earlier under secondary outcomes (see Table 48). 'Use of primary care' records the number of face-to-face contacts with

TABLE 50 Summary of patient outcomes at 6 months following LOCF imputation

Outcome	Possible range (worst to best)	DHR (n = 42), mean (SD)	HBR (n = 42), mean (SD)
NEADL total score	0 to 66	28.34 (15.33)	29.23 (16.66)
$EQ\text{-}5D_{index}$	–0.59 to 1.00	0.51 (0.26)	0.52 (0.34)
$EQ\text{-}5D_{vas}$	0 to 100	56.93 (16.28)	58.23 (18.27)
HADS anxiety	12 to 0	6.12 (4.48)	5.59 (3.83)
HADS depression	12 to 0	7.24 (3.53)	6.07 (3.94)

DHR, day hospital rehabilitation; HBR, home-based rehabilitation.

TABLE 51 Mean estimated difference in outcomes at 6 months adjusted for baseline scores by analysis of covariance (LOCF imputation)

Outcome	Mean estimated difference adjusted for baseline	Lower 95% CI	Upper 95% CI	p-value
NEADL total score	–3.222	–7.687	1.243	0.155
$EQ\text{-}5D_{index}$	0.011	–0.109	0.131	0.857
$EQ\text{-}5D_{vas}$	–2.937	–8.991	3.117	0.337
HADS anxiety	–0.347	–1.843	1.160	0.648
HADS depression	1.357	0.050	2.663	0.042

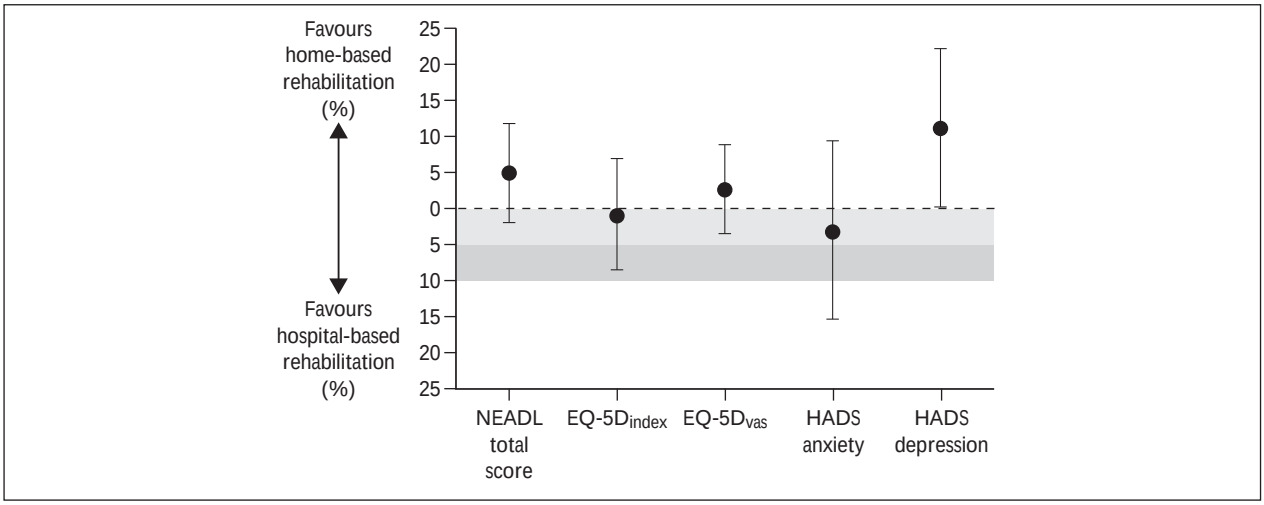

FIGURE 10 Summary of the effect of place of care on patient outcomes at 6 months (LOCF data set).

a doctor or nurse at the surgery, at the walk-in clinic or at home. 'Patient transport service use' excludes transport to the day hospital as part of rehabilitation. 'Nursing home stay' refers to full-time residential care and 'day care use' captures residential care without overnight stays. 'Private care expenditure' refers to all expenses on residential care and home assistance paid for by the patient. 'Home assistance' includes all care at the patient's home provided by the NHS or local authority. 'Informal care' is hours of unpaid care provided by friends, partners and relatives. Resource use is unlikely to be normally distributed around the mean, hence medians are reported and a Mann–Whitney U test performed to indicate whether any of the differences recorded are statistically significant.

Resource use, particularly primary care, appears to be generally higher in the home-based rehabilitation group, although there are some exceptions, notably nursing home stay. The only category in which the difference in resource use is statistically significant is the use of primary care at 6 months. This difference is no longer significant at 12 months but resource use by home-based rehabilitation patients remains higher.

Patient 3607 in the home-based rehabilitation group received more than 12,000 hours of home care from two carers over 13 months. The carers included the patient's relatives and professional carers supported by the local social services department. Shortly after completion of the trial, this patient transferred into a long-term care facility. The analysis of home care was repeated with this patient excluded – 'home help excl. outlier'. All subsequent analysis is presented with this patient both included and excluded. The rationale for excluding this patient is explored in the discussion.

TABLE 52 Comparison between estimated group differences derived from the observed case (primary analysis) and ITT (LOCF) data sets, and those using all available data (MMRM)

Outcome	Estimated value	Observed case data set	LOCF data set	MMRM analysis
NEADL total score	Mean difference	–2.139	–3.222	–4.150
	Upper 95% CI	2.592	1.243	1.784
	Lower 95% CI	–6.870	–7.687	–10.083
$EQ\text{-}5D_{index}$	Mean difference	0.023	0.011	0.161
	Upper 95% CI	0.161	0.131	0.329
	Lower 95% CI	–0.114	–0.109	–0.007
$EQ\text{-}5D_{vas}$	Mean difference	–1.601	–2.937	[a]
	Upper 95% CI	5.607	3.117	[a]
	Lower 95% CI	–8.809	-8.991	[a]
HADS anxiety	Mean difference	–0.578	–0.347	–0.213
	Upper 95% CI	1.253	1.160	1.968
	Lower 95% CI	–2.409	–1.843	–2.393
HADS depression	Mean difference	1.033	1.357	2.280
	Upper 95% CI	2.507	2.663	4.374
	Lower 95% CI	–0.441	0.050	0.185

a Unable to obtain estimate because of limitations of the data set.

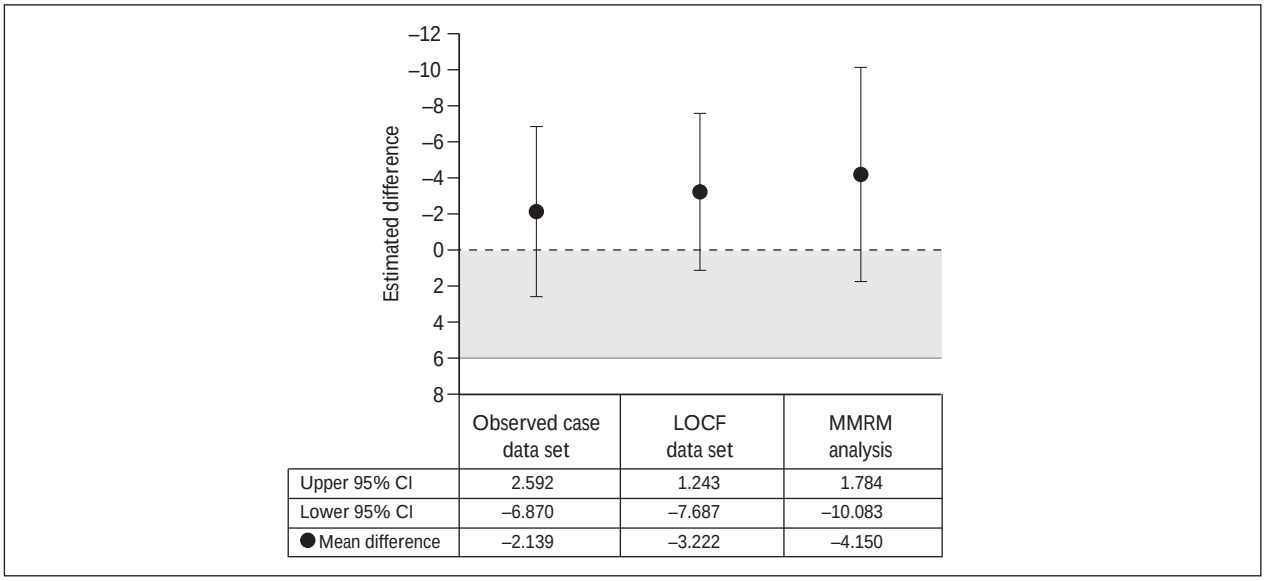

FIGURE 11 Estimated difference in NEADL total scores at 6 months between day hospital rehabilitation and home-based rehabilitation using different statistical approaches. Direction of effect same as in Figure 10.

TABLE 53 Resource use by category

	6 months					12 months				
	DHR		HBR			DHR		HBR		
	Mean	Median	Mean	Median	p-value	Mean	Median	Mean	Median	p-value
Use of primary care	5.4	5.5	10.4	8.5	0.02	9.8	9	13.5	10.5	0.44
Outpatient visits	2.5	1.5	2.5	1	0.71	3.2	2	3.8	2	0.87
Emergency ambulance use	0.1	0	0.4	0	0.84	0.3	0	0.6	0	1
Patient transportation service use	2.0	0	2.9	0	0.76	3.6	1	3.0	0	0.48
Home visits (not incl. GP)	8.3	1	26.2	1.5	0.21	15.4	2	55.0	8	0.27
Drugs (£)	356	231	483	255	0.61	1000	463	800	498	0.46
Nursing home stay (days)	5.6	0	0.8	0	0.32	25.6	0	10.6	0	0.63
Day care use (days)	1.7	0	2.6	0	0.61	1.7	0	9.0	0	0.37
Private care expenditure (£)	35	0	247	0	0.85	796	0	308	0	0.89
Home assistance (£)	267	0	3080	0	0.59	935	0	4854	0	0.97
Home assistance excl. outlier (£)	267	0	684	0	0.76	935	0	1182	0	0.87
Informal care (hours)	885	207	935	191	0.68	2047	316	1776	536	0.88

DHR, day hospital rehabilitation; HBR, home-based rehabilitation.

Breakdown of costs

Table 54 provides a breakdown of the unadjusted costs accumulated by patients in each arm at 7 and 13 months. As previously discussed there was considerable variation in follow-up times for administration of the economic questionnaires, hence the analysis presented here excludes data when the time interval for the questionnaire varied by more than 16% from the intended analysis point. In practice, nine economic questionnaires were excluded because they fell outside the range 179–247 days, and one economic questionnaire was excluded because it fell outside the range 332–458 days. It should be stressed that apart from these exclusions the data have not been adjusted for variations in follow-up times. Statistical analysis and inference were not attempted before adjusting for discrepancies in follow-up times. The data are provided as an illustration of the contributions of different components to overall costs.

The cost data for all patients with three or four economic questionnaires and a rehabilitation log (56 patients) are plotted in Figures 12 and 13. The graphs present costs against the time interval at follow-up for each patient with data at 7 months and at 13 months. Patient 3607 stands out in both plots as having accumulated the highest costs at both follow-up intervals.

The median number of entries on the rehabilitation logs is approximately twice as large for patients in the day hospitals (median 18) as for home-based rehabilitation patients (median 9.5). The difference is statistically significant (Mann–Whitney U test, $p = 0.001$). Although this may simply reflect a more segmented approach to rehabilitative care for the group in the day hospitals, it is possible that illness severity was higher in this group or that the rehabilitation logs did not capture all of the care package for patients rehabilitated at home.

Ancillary care includes primary care, outpatient visits, tests and investigations, ambulance use, home adaptations/equipment, and all home visits by professionals not directly involved in the rehabilitative care (psychologists, etc). Residential/day care covers residential accommodation, sitting services and day care centres (not day hospital rehabilitation). Home care is the cost of care assistance provided at home by the NHS or local authority. Private expenses are all patient costs including drugs, transport, meals on wheels, private treatment and care costs. Informal care is the total unpaid care assistance received by the patient, valued at £8/hour. The rehabilitation cost is the cost of the direct rehabilitative care package provided as home-based rehabilitation or in the day hospital, which includes staff costs, overheads and transport costs. Inpatient costs record the cost of all inpatient stays during the follow-up period (213 and 395 days), valued at £187 per day (UCHSC 2006).

Cost-minimisation analysis

Both NEADL and EQ-5D$_{index}$ scores showed no significant differences between the two arms of the trial. Although the possibility of a difference in outcomes remains, because of under-recruitment in the study, the results do not challenge the a priori assumption of equal efficacy in both arms. The collected data were too limited to allow a meaningful statistical examination of any observed difference in incremental cost-effectiveness. Consequently, a cost-minimisation analysis was undertaken. Costs were imputed at 213 and 395 days when both a rehabilitation log and the appropriate number of economic questionnaires had been received. As noted earlier two patients did not receive an economic questionnaire at 1 month but did receive subsequent questionnaires. These patients were included as it was judged that the subsequent questionnaires should have captured resource use in the first month of rehabilitation. Table 55 presents the mean and median costs at 213 and 395 days with patient 3607 both included and excluded; p-values are reported for analysis of the untransformed costs (Mann–Whitney U test) and the log-transformed data (two-sample t-test).

It should be highlighted here that the Mann–Whitney U test and two-sample t-test consider only the sampling uncertainty; further uncertainty exists over the measurement and costing of resource use. Hence, confidence intervals based on these tests would be misleadingly narrow. Significant areas of uncertainty over the costs of hospital overheads and informal care are explored in the sensitivity analysis. The Mann–Whitney U test is suitable for data that are unlikely to be normally distributed but it is focused on the medians. The cost data were log transformed to facilitate parameterisation and analysis of the means. Anderson–Darling normality tests suggested that the log-transformed data were acceptably approximated as a normal distribution for each of the cost variables except for public sector costs at 213 days for the day hospital patients. Log-transformed public sector and total costs at 213 and 395 days for patients

TABLE 54 Unadjusted costs at 7 and 13 months after randomisation, broken down by category

		Ancillary NHS costs	Residential/ day care	Private expenses	Home care NHS/LA	Informal care	Rehabilitation cost	Inpatient costs	Total private	Total public	Total
7 Months											
Day hospital	Entries	28	28	28	28	28	26	32	28	27	27
	Mean	£1197	£206	£424	£218	£6824	£2803	£1280	£7248	£4043	£11,376
	Median	£788	£0	£82	£0	£1278	£3006	£0	£1469	£3718	£7504
Hospital at home	Entries	28	28	28	28	28	28	33	28	27	27
	Mean	£1626	£101	£306	£3299	£8543	£310	£1003	£8849	£5996	£14,412
	Median	£861	£0	£83	£0	£3090	£231	£0	£3686	£1331	£7870
Hospital at home excl. 3607	Entries	27	27	27	27	27	27	32	27	26	26
	Mean	£1662	£93	£317	£733	£7516	£309	£1005	£7833	£3347	£10,691
	Median	£867	£0	£93	£0	£2596	£190	£0	£3609	£1281	£6522
13 Months											
Day hospital	Entries	16	16	16	16	16	27	32	16	16	16
	Mean	£1993	£936	£2534	£935	£13,652	£1847	£1478	£16,186	£7902	£24,088
	Median	£1589	£0	£227	£0	£2526	£2039	£0	£3120	£4018	£11,405
Hospital at home	Entries	26	26	26	26	26	29	33	26	26	26
	Mean	£2750	£1311	£732	£4855	£14,201	£326	£1320	£14,933	£9982	£24,916
	Median	£1704	£0	£185	£0	£4236	£268	£0	£4504	£2968	£18,218
Hospital at home excl. 3607	Entries	25	25	25	25	25	28	32	25	25	25
	Mean	£2815	£1059	£583	£1183	£12,727	£326	£1332	£13,310	£6113	£19,423
	Median	£1888	£0	£160	£0	£4032	£194	£0	£4343	£2928	£17,400

LA, local authority.

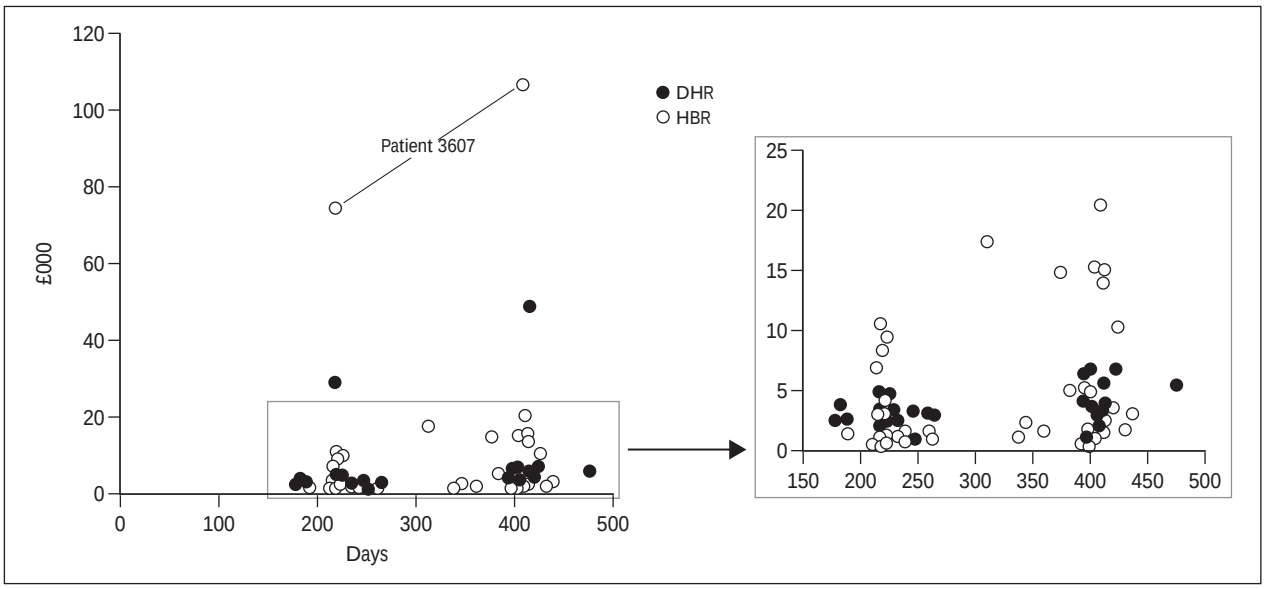

FIGURE 12 Total public sector costs plotted for each patient after 7 and 13 months.

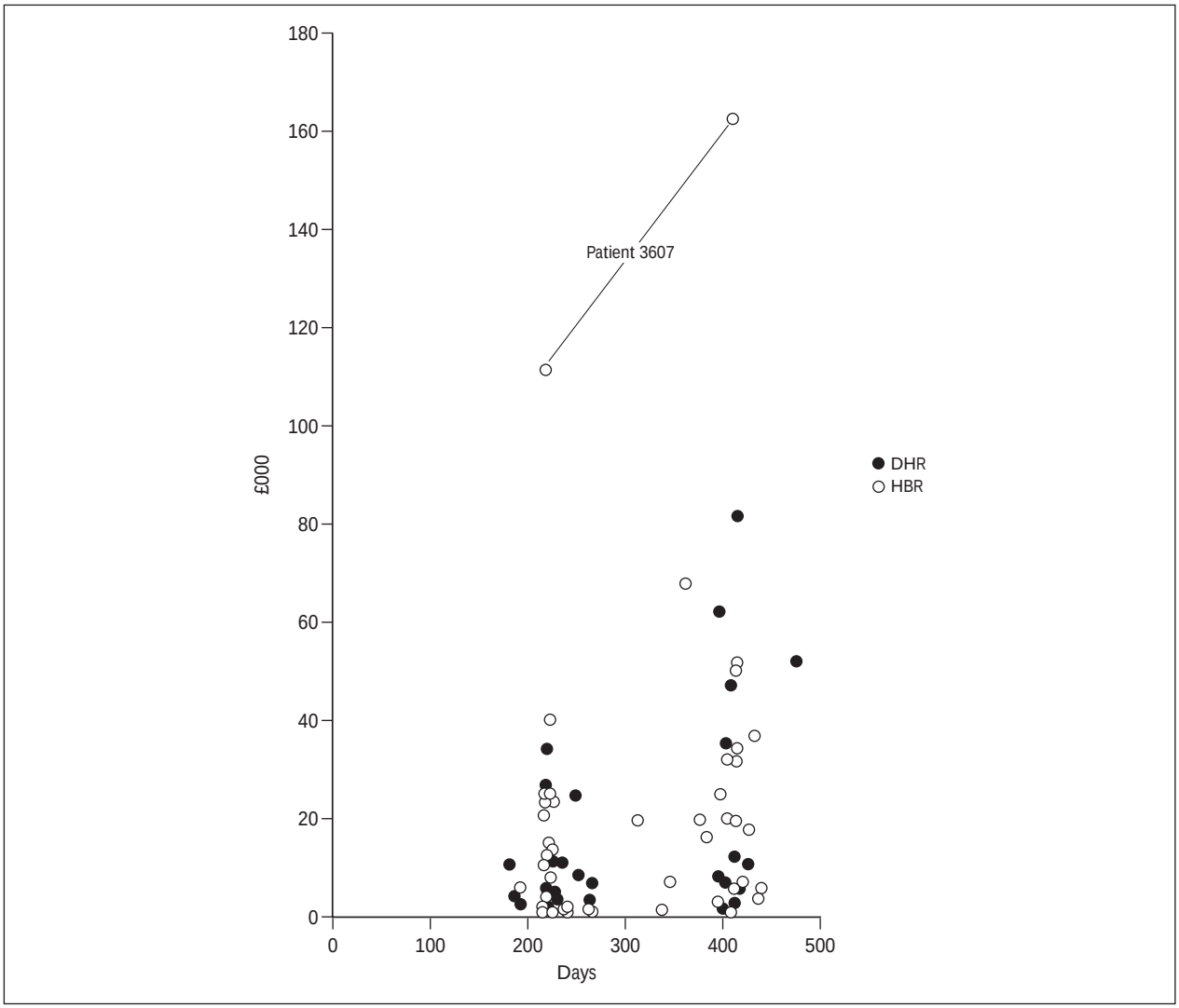

FIGURE 13 Total costs plotted for each patient 7 and 13 months after randomisation.

in the two trial arms were compared using two-sample t-tests. The tests were repeated with patient 3607 excluded. None of the mean differences was significant at 5%.

Sensitivity analysis

Much of the recorded resource use for rehabilitating patients consists of formal and informal care. The contribution of informal carers was quite considerable and a detailed examination of the consequences of the valuation of this input was undertaken. Table 56 compares mean and median total costs, with an hour of informal care valued at £0, £4, £8, £12 and £16. Although changing the value of informal care has a very large impact on total mean and median costs, its impact on the relative differences between the two groups is small. The exception to this is the median cost for the home-based rehabilitation group when informal care is valued at £0. Nevertheless Mann–Whitney U tests suggest the differences are not statistically significant, even with informal care ignored.

A large component of the direct rehabilitative costs in day hospitals comprises the hospital overheads and the cost of patient transport to and from the hospital. Clearly estimation of these costs will have an impact on any differences in costs between home-based rehabilitation and day hospital care. In the main analysis centre-specific day hospital overhead estimates were applied to each day hospital patient's cost. The vast majority of day hospital cases originated from Chippenham and North Tyneside, both of which had overhead estimates that were below average for the four sites in the trial. Replacing the site-specific overhead estimates with the mean overheads of £68.50 marginally increased mean and median costs in the day hospital rehabilitation group, but any differences between the two arms remained non-significant at 5%. A further analysis of overhead and patient transport costs was undertaken in which the total overhead and transport costs attributed to a patient for each day's attendance at the day hospital was varied between £120 and £250. The results are presented in Figure 14. It is evident that mean costs for the day hospital rehabilitation group lie between mean costs for the home-based rehabilitation group with and without the exclusion of the most expensive patient in that group.

Although medians might be regarded as a better measure of location for non-symmetrically distributed data, means are a better indicator of volume costs. Hence, mean costs may be more useful than median costs for decision-makers. Means are susceptible to outliers, and exclusion of patient 3607 from the home-based rehabilitation group has a large impact. Mean public sector and total costs are reduced with most now falling below mean values for the day hospital rehabilitation group. Figures 12 and 13 illustrate the spread of the data. Although patient 3607 incurs the highest costs at 7 and 13 months in both figures, it is not clear that this patient is an outlier. The data spread, particularly in the home-based rehabilitation arm, is considerable, and we would expect it to be right skewed. It is possible that costs in the home-based rehabilitation arm are artificially inflated by the inclusion of this particularly resource-intensive patient, but there appears to be no clear basis for exclusion. It is conceivable that resource-intensive patients might be particularly expensive to treat at home.

The breakdown of costs in Table 54 illustrates the significant burden rehabilitating patients place on carers. Direct rehabilitative care costs do appear to be much lower for patients rehabilitated at home, but given the small numbers of patients in the day hospital rehabilitation arm with data at 12 months (395 days) it might be unwise to search the data looking for significant differences in the breakdown of costs. Nevertheless the data suggest the possibility that costs incurred in the direct rehabilitative care of day hospital rehabilitation patients are being displaced into other areas such as primary care for the home-based rehabilitation patients. The analysis of resource use in Table 53 also suggests an increased burden in primary care for home-based rehabilitation patients.

The total costs in the study include informal care and the contribution of voluntary care was very large. It is possible that the economic questionnaires overestimated the contribution of friends and relatives who may not have been fully occupied with care duties during the time periods given. The methodology to value this care is contentious.[80] A value of £8 an hour was chosen in the base case, which is similar to the average hourly wage of a local authority home care worker (£7.30, UCHSC 2006). A strict replacement cost approach would have substituted the unit cost of an hour of home care provided by the local authority (£16, UCHSC 2006).[81] An opportunity cost approach would require the estimation of the value of the opportunities forgone in providing care[82] (often taken as the subject's wage rate.) This is not easy

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TABLE 55 Imputed costs at 6 months' (213 days) and 12 months' (395 days) follow-up

		Public sector costs				Total costs			
		DHR	HBR	Mann–Whitney U test	Two-sample t-test	DHR	HBR	Mann–Whitney U test	Two-sample t-test
213 Days									
All data	Mean	£4214	£6139			£10,102	£14,330		
	Median	£3031	£1546	0.18	0.29	£5948	£7679	0.76	0.66
	Entries	21	25			21	25		
Excluding patient 3607	Mean	£4214	£3339			£10,102	£10,390		
	Median	£3031	£1379	0.10	0.09	£5948	£6531	0.58	0.37
	Entries	21	24			21	24		
395 Days									
All data	Mean	£7511	£9977			£23,812	£26,105		
	Median	£4035	£2725	0.43	0.52	£9842	£18,432	0.95	0.91
	Entries	13	23			13	23		
Excluding patient 3607	Mean	£7511	£5664			£23,812	£20,052		
	Median	£4035	£2723	0.30	0.32	£9842	£17,707	0.77	0.71
	Entries	13	22			13	22		

DHR, day hospital rehabilitation; HBR, home-based rehabilitation.

TABLE 56 Total care costs at 213 and 395 days with the value of informal care varied from £0 to £16

		Care valued at £0			Care valued at £4		
		DHR	HBR	p-value	DHR	HBR	p-value
213 Days							
All data	Mean	£4484	£6464		£7293	£10,397	
	Median	£3151	£1585	0.20	£4720	£5592	0.77
	Entries	21	25		21	25	
Excluding patient 3607	Mean	£4484	£3677		£7293	£7034	
	Median	£3151	£1444	0.12	£4720	£4747	0.59
	Entries	21	24		21	24	
395 Days							
All data	Mean	£8207	£10,699		£16,010	£18,402	
	Median	£4850	£2882	0.49	£7767	£14,344	0.92
	Entries	13	23		13	23	
Excluding patient 3607	Mean	£8207	£6229		£16,010	£13,140	
	Median	£4850	£2815	0.35	£7767	£13,295	0.75
	Entries	13	22		13	22	

DHR, day hospital rehabilitation; HBR, home-based rehabilitation.

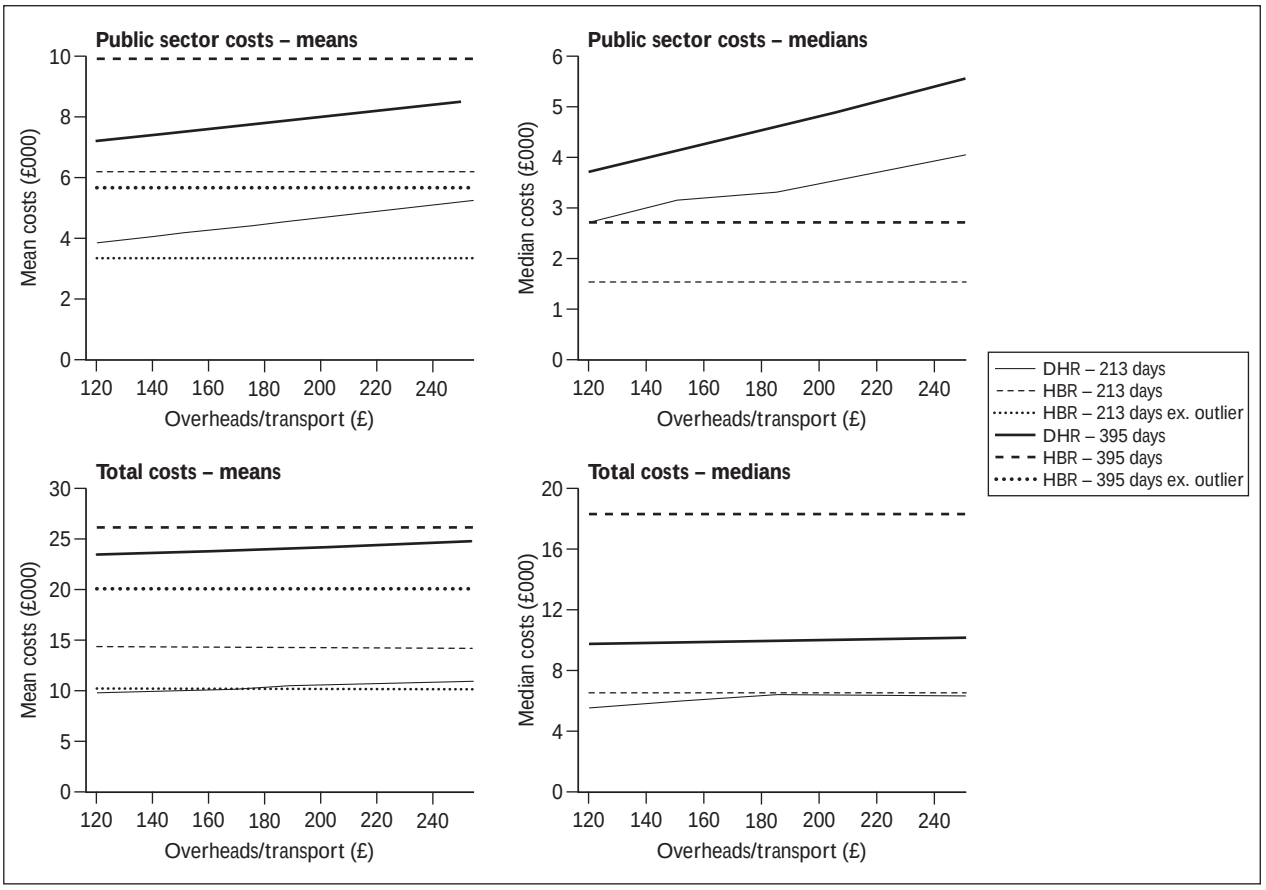

FIGURE 14 Sensitivity analysis examining the effect of changing hospital overheads/transport costs.

Care valued at £8			Care valued at £12			Care valued at £16		
DHR	**HBR**	**p-value**	**DHR**	**HBR**	**p-value**	**DHR**	**HBR**	**p-value**
£10,102	£14,330		£12,910	£18,263		£15,719	£22,196	
£5948	£7679	0.76	£6213	£9,766	0.60	£6,797	£11,854	0.66
21	25		21	25		21	25	
£10,102	£10,390		£12,910	£13,747		£15,719	£17,103	
£5948	£6531	0.58	£6213	£8,524	0.43	£6,797	£10,518	0.49
21	24		21	24		21	24	
£23,812	£26,105		£31,615	£33,808		£39,417	£41,511	
£9,842	£18,432	0.95	£11,445	£20,954	1.00	£13,048	£22,766	1.00
13	23		13	23		13	23	
£23,812	£20,052		£31,615	£26,964		£39,417	£33,876	
£9842	£17,707	0.77	£11,445	£20,588	0.85	£13,048	£22,389	0.82
13	22		13	22		13	22	

to establish for retired carers, but is unlikely to be zero. Ignoring these costs is tantamount to assuming that the carer's time is valued at zero, which is unlikely to be consistent with any of the proposed valuation methods. The sensitivity analysis demonstrates that informal care has a sizeable impact on total costs, but little impact on the relative cost differences between the two arms. In the absence of informal care costs (care valued at £0) there remain no statistically significant differences between costs in the two trial arms.

The efficiency of day hospitals is likely to be a key consideration in the analysis of cost differences between day hospital rehabilitation and home-based rehabilitation. The reference cost submissions from the four trial sites suggest significant variation in the efficiency of day hospital provision. The reference cost submissions include therapeutic staff whereas these costs were netted out when calculating overhead costs. Consequently it is unclear what the national average day hospital overheads are. The mean overheads of £68.50 for the four sites may well be typical. Addition of patient transport costs to the mean overheads suggests that overheads and transport costs for day hospital patients are typically around £170 per day. The impact of these costs on cost differences between day hospital rehabilitation and home-based rehabilitation is illustrated in Figure 14. Median public sector costs are lower for the home-based rehabilitation patients, and Mann–Whitney U tests suggest that the differences are approaching statistical significance at high values for overheads/transport. However, the mean public sector costs are higher for the home-based rehabilitation patients before patient 3607 is excluded. This would suggest that, although 'typical' public sector costs are lower in the home-based rehabilitation arm, volume costs are higher. Although more seriously ill patients are likely to accrue a greater number of day hospital attendances, there may be some efficiencies to be gained by transporting them to the treatment centre. In contrast, the rehabilitative costs of treatment at the patient's home may be more linearly dependent on the number of contacts with professionals. We would expect this to manifest itself as a larger spread of costs for the home-based rehabilitation patients, and Figure 12 supports this. A larger spread in combination with the skewed nature of costs may be responsible for the different inferences drawn from the mean and median data.

The impact of varying the overhead/transport costs on total costs is less ambiguous (Figure 14). Mean and median total costs for the day hospital rehabilitation patients are generally lower although

none of the differences approaches statistical significance.

Theoretically, analysis of the 12-month follow-up data (at 395 days) is preferable to analysis of the 6-month follow-up data (at 213 days) as not all patients have been discharged from formal rehabilitation at 213 days. However, the limited data at 395 days reduce the power of the analysis. Analysis of mean costs paints a different picture to the analysis of median costs. Mean total and public sector costs are higher in the home-based rehabilitation group than in the day hospital rehabilitation group. Median public sector costs are lower in the home-based rehabilitation group but median total costs remain higher. It should be highlighted that none of these differences is statistically significant, hence we must conclude that the analysis of costs does not provide sufficient evidence to determine whether home-based rehabilitation is less costly than rehabilitation at day hospitals.

Chapter 4
Summary and conclusions

We have conducted a literature review, national survey and RCT of day hospital versus home-based rehabilitation with health economic analysis to test the hypotheses that older people and their carers are not disadvantaged by home-based rehabilitation relative to day hospital rehabilitation, and that home-based rehabilitation is less costly.

The literature review revealed that no new reports of RCTs of day hospital versus home-based rehabilitation had been published since the topic was reviewed before the start of this project[40] or for the Cochrane Collaboration.[27] Studies that compared day hospital-based comprehensive care with either inpatient or home-based alternatives (which did not provide comprehensive care) suggested that day hospital-based comprehensive services were advantageous to the recipients, producing shorter inpatient stays and improved functional outcomes. These studies effectively compared treatment with no treatment and established a role for day hospital-based services. Those studies that examined place of care have suggested little advantage or disadvantage of day hospitals over alternative settings for providing 'comprehensive' care.

The national survey of NHS trusts conducted in 2003 showed that services in both settings were usually provided with physiotherapy, occupational therapy and nursing staff. Medical staffing was significantly less likely in the community-based services and day hospitals were very much more likely to provide medical or specialised medical services (such as Parkinson's disease, falls and TIA clinics) and nursing procedures. Home-based services were more likely to be provided by community practitioners (GPs and nurses) and to be time limited in nature (i.e. restricted to a specific number of weeks of service provision). The survey confirmed that health-care organisations in England were actively providing both home-based and day hospital rehabilitation and suggested that there had been recent increases in the provision of home-based care, implying that the research question was one which was directly relevant to the contemporary health service in England.

We proceeded to attempt an RCT of day hospital versus home-based rehabilitation in multiple centres in England, aiming to follow 420 subjects to 12 months after randomisation. However, most (all except 10) of the trusts responding to our questionnaire indicated that they expected changes in the services over the following 3 years. This was a significant factor in site recruitment, as we had initially intended only to recruit services that could foresee service stability over the duration of the trial. Accordingly the criteria for recruitment of participating sites were broadened and a process of site recruitment ensued, resulting eventually in four sites participating in the trial.

The trial was framed as a pragmatic trial with inclusive recruitment criteria and processes in which all eligible subjects in the participating sites would be randomised between home-based and day hospital rehabilitation. A large number of potentially eligible subjects were screened for suitability for the trial and a large proportion of those screened turned out not to be eligible for inclusion. The main reason for this was that the referral to the rehabilitation team was made to a single discipline and the patient was not in need of multidisciplinary rehabilitation. However, of those that were appropriately referred for multidisciplinary rehabilitation, a significant proportion did not proceed to randomisation because of local criteria based on the configuration of local services. Examples of this included a comprehensive falls assessment service located in a day hospital and a motor neurone disease support service provided only in the community. These factors resulted in only around 10% of potentially eligible subjects being randomised between day hospital and home-based rehabilitation.

These factors (changing NHS service landscape, site recruitment issues, subject recruitment) contributed to an overall rate of recruitment that was insufficient for the continued viability of a trial intending to recruit and follow up 460 subjects. Therefore the trial was terminated, using an exit strategy designed to maximise available information and 6-month follow-up rates;

12-month follow-up was not pursued after the exit strategy had been implemented and consequently the data at this time point were sparse and unevenly distributed.

In view of the early termination of the trial, the target sample size was not achieved. Although the hypothesis is stated in terms of non-inferiority, the original sample size calculation was based on the power to detect a clinically significant difference between the two arms of the trial. Subsequently statistical analyses were performed based on testing for non-inferiority. The decision to analyse in this way was made post hoc and influenced by the small sample size.

There is a perception that non-inferiority trials require greater sample sizes than superiority trials, although this is not necessarily the case. The non-inferiority margin is often set at some fraction of an effect seen previously in a placebo-controlled superiority trial of the active control being used in the current trial. Hence, if ds is the effect seen in a retrospective placebo-controlled superiority trial and the non-inferiority margin, d, is set at d = 0.5ds then the inference is that we would require four times the sample size compared with a superiority trial. The logic comes from the following result for a superiority sample size calculation:

$$n_A = \frac{(r+1)\sigma^2(Z_{1-\beta} + Z_{1-\alpha/2})^2}{d_s^2} \quad (1)$$

which for a one-tailed type I error (where the type I error is set at half that for a two-tailed test) becomes:

$$n_A = \frac{(r+1)\sigma^2(Z_{1-\beta} + Z_{1-\alpha})^2}{d_s^2} \quad (2)$$

The equivalent result to (1) for non-inferiority studies can be rewritten as:

$$n_A = \frac{(r+1)\sigma^2(Z_{1-\beta} + Z_{1-\alpha})^2}{r((\mu_A - \mu_B) - 0.5d_s)^2} \quad (3)$$

which for the special case of $\mu_A - \mu_B = 0$ becomes:

$$n_A = \frac{4(r+1)\sigma^2(Z_{1-\beta} + Z_{1-\alpha})^2}{rd_s^2} \quad (4)$$

On the face of it, therefore, equation (4) estimates the sample size to be four times greater than in equation (1). However, the ds in equation (1) is for a trial powered to show an effect of active intervention over placebo whereas equation (4) is for a trial powered to show an effect of an active intervention over an active control.

This point is often lost. It is not uncommon when designing an active controlled trial for it to be designed as a superiority trial because of the erroneous belief that non-inferiority trials are unfeasibly large.

In fact, if a study is being set up as a superiority study it is in effect a non-inferiority study but with a margin equal to zero, i.e. d = 0, i.e.:

$$n_A = \frac{(r+1)\sigma^2(Z_{1-\beta} + Z_{1-\alpha})^2}{r(\mu_A - \mu_B)^2} \quad (5)$$

In this case it could be argued that if we were confident that $\mu_A > \mu_B$, such that a superiority study could be designed, than the effect of having a margin –d in equation (5) would be to greatly reduce the required sample size.

Small sample size was a feature of most of the trials identified in the systematic literature review, so that, despite the small number of subjects randomised in this study, our sample size of 89 represents nearly a doubling of the number of patients ever randomised between day hospital and home-based rehabilitation in a published RCT. Nevertheless, we fully acknowledge that caution is required in interpreting the results because of the sample size achieved.

Measuring outcomes in elderly patients in ambulatory care may not be straightforward. Physical functioning is usually regarded as an essential component of outcome and physical function scales are often used to demonstrate effectiveness of services in elderly care. When the changes in health are large (such as those associated with medical inpatient care and inpatient geriatric rehabilitation), scales that focus on core daily living activities (such as the Barthel Index) are often chosen. These scales are generally insensitive to the less dramatic changes in health associated with the provision of specific services that patients and their professional advisors recognise and value. One way to attempt to overcome this is to use instrumental activities of daily living scales. These scales generally reflect

domestic and leisure activities and therefore capture changes in physical functioning in a wider and potentially more relevant set of domains. We chose the NEADL scale as a primary outcome measure for this reason, because previous experience of its use suggested that at least some of the subscales may be sensitive to clinical change in day hospital patients[20] and because it had been used in previous trials of older people in receipt of rehabilitative intervention.[36,56] Assessment of quality of life is implicit within the choice of outcome measures. Multiple measures in multiple domains were used as there is no evidence that a suitable single measure exists for this particular patient group. Taken together the outcome measures used cover the traditional domains of quality of life.

In addition, consultation with practitioners in day hospital and home-based rehabilitation in the development phase of the trial suggested that outcome measurement related to treatment goals was more likely to reveal the relevant changes in health. To take account of this view we also used TOMs, which is an instrument in which outcomes are expressed relative to specific therapeutic goals, which are defined in the context of the normal therapist/client interaction that takes place routinely in clinical care.

At the outset of the trial we were confident (but not certain) that changes in health status attributable to the interventions would be likely to be picked up in at least some of the outcome domains that our assessment processes were designed to capture.

The trial was conducted as a two-arm RCT with patients providing data at baseline and at 3-, 6- and 12-month follow-up points, with 6 months prespecified as the primary end point of interest. Primary statistical analyses were based upon the observed case data set (i.e. those with complete data) as this was considered to be the most conservative approach. To fully conform to ITT principles, a secondary set of analyses were also conducted on a data set in which data missing because of loss to follow-up were replaced using the LOCF method. As a further attempt to deal with the issue of missing data an MMRM analysis was also conducted.

In total, 42 patients randomised to each care setting received the intervention and, of these, 33 patients in the day hospital rehabilitation arm (79%) and 32 in the home-based rehabilitation arm (76%) were available for analysis at the primary end point of 6 months. Withdrawal was the most common reason for loss to follow-up at 6 months. Four patients in the home-based rehabilitation group and two in the day hospital rehabilitation group died before this point. Loss to follow-up was similar in each treatment group and there was no evidence of any systematic differences between the comparison groups in the loss of participants from the study (attrition bias) at 6 months. Two variables predicted study retention at 6 months: whether the participant had a carer and baseline EQ-$5D_{index}$ score. Patients with carers were around seven times more likely to be followed up at 6 months than those without carers, and each unit increase in the index score of the EQ-5D was associated with a seven times increase in the likelihood of being retained in the study.

Given the study hypothesis – that home-based rehabilitation produces outcomes that are no worse than outcomes of day hospital rehabilitation – the approach to the statistical analysis generally recommended is to use confidence intervals (International Conference on Harmonisation, 1998[83]). Non-inferiority of the comparison treatment is inferred when the boundary of the confidence interval falls within a prespecified limit based upon the largest difference that is judged to be clinically acceptable. In the current study this was chosen to be 10%, equivalent to an approximate 7-point difference on the NEADL total (0–66) scale, which is justifiable as clinically significant, of the order of magnitude observed in previous studies of hospital and home-based rehabilitation in older people,[56,57] and the same magnitude (10%, or 2 points on the 0–22 version of the NEADL) as the difference regarded as significant in the original sample size calculation. Applying this method, the confidence interval around the estimate of the primary outcome measure was found to lie well within this limit, and was in fact within 5%. More specifically, based upon the data observed in the trial we can say that, after 6 months' rehabilitation at home, NEADL total scores are estimated to be no more than 3.9% worse than if this rehabilitation had taken place at day hospital. Although similar statements could be made at 6 months for the EQ-$5D_{vas}$ and the depression scale of the HADS, a greater than 10% treatment benefit in favour of home-based care could not, on the basis of the present study, be ruled out for the EQ-$5D_{index}$ or HADS anxiety scale. These inferences proved to be robust to alternative analyses conducted in an attempt to deal with the issue of loss to follow-up. In particular, the same conclusion was reached using estimates obtained from the MMRM approach, which has repeatedly

been shown to provide less biased estimates of treatment effect than other approaches to missing data.[84]

Outcome data measured at the 3-month follow-up point displayed a similar pattern to data measured at the primary end point, although a statistically significant difference in the mean EQ-5D$_{index}$ score was seen in favour of day hospital care at 3 months ($p = 0.047$), and a marginally significant result in favour of home-based care was seen for the HADS depression scale ($p = 0.056$). These results were consistent with those observed at 6 months in suggesting non-inferiority in terms of all outcomes with the exception of the EQ-5D$_{index}$ and HADS anxiety scale.

The findings at the 12-month follow-up should be treated with caution as, when the trial was ended prematurely, 12-month follow-up data collection was sacrificed to achieve timely closure of the study and has resulted in limited data at 12 months, including less data for members of the day hospital group.

Taken together, and applying the caution we must exercise in interpretation of results from an underpowered study, we can say that the statistical analyses of the trial outcomes do not provide sufficient evidence to conclude that patients in receipt of home-based rehabilitation were disadvantaged compared with those receiving day hospital rehabilitation.

Clearly the conclusions from the cost analysis are also limited by the power of the study. Analysis of the cost data provides insufficient evidence to support the hypothesis that rehabilitation is cheaper in a home-based setting. The sample size was insufficient to detect a significant difference in costs between the two care settings. Valued at £8 per hour, informal care comprises a large portion of overall total costs. Nevertheless, exclusion of informal care does not significantly impact on the direction of mean and median cost differences between the two arms. It is apparent that some patients accrue very large costs during and following rehabilitation. The exclusion of a single patient from the home-based rehabilitation arm reverses the trend of higher mean costs for the home-based rehabilitation patients. It is not clear whether exclusion of this patient is appropriate. A much larger study might be required if we are to accurately estimate mean costs.

In comparing the costs of the two groups we are tacitly assuming that the identified costs can be saved if patients are transferred to care in the other setting. Shortly after the completion of the trial the day hospital at Chippenham was closed and the services transferred into the community, which supports the view that this assumption may be being made in practice. However, it seems likely that some of the overheads assigned to the day hospital would be reallocated to other departments rather than simply being eliminated. Similarly, as the community rehabilitation teams often provide other services apart from rehabilitation at home, some of the overheads identified for these teams would not be saved if care were transferred to the day hospital.

Previous RCTs conducted in day hospitals can be divided into those that have examined place of care specifically and those that have examined the provision of comprehensive care in a day hospital setting versus 'usual care' (by implication not comprehensive) in another setting. Those that have examined place of care have suggested that there is little advantage (and therefore, of course, little disadvantage) of day hospitals over alternative settings for providing 'comprehensive' care. In this context 'comprehensive' is taken to mean multidisciplinary and holistic, based on the principles of comprehensive geriatric assessment, and we can argue that geriatric rehabilitation in the day hospital or in the home is an intervention that falls into this category.

Limitations of the present trial include the small sample size, which increases the probability for error in interpretation of the results as essentially negative (no differences between the settings in terms of clinical outcomes or costs). Further, we need to exercise caution in interpreting the borderline significant variations in secondary psychosocial outcomes.

One of the features observed in the national survey of NHS trusts in England was a degree of heterogeneity between trusts in the nature and staffing of services in different settings. This led us to propose that at least six sites (and preferably eight) should be recruited as randomising sites. Therefore there is an implication for the generalisability of the findings that only four sites were able to recruit and randomise participants in the trial. Further, the majority of subjects were randomised in two of the four participating sites.

Although it was our intention to encourage randomisation of all potentially eligible subjects, it is clear from the recruitment statistics that local referral processes meant that a large number of

ineligible subjects were considered for the trial and a significant number of those who were potentially eligible did not agree to participate or were excluded on local, service-specific grounds. This meant that, far from inclusivity of recruitment, we achieved a relatively low rate of recruitment of subjects who were not selected out by multiple local referral and service-specific criteria. This suggests that, although our results may be applicable to patients referred for rehabilitation, the setting for rehabilitation may already have been fixed for some types of service in some of the settings, further limiting the potential applicability of our findings in specific locations.

Implications for practice

- Compared with day hospital rehabilitation, providing rehabilitation in patients' own homes confers no particular disadvantage for patients and carers.
- Our results are consistent with the non-inferiority of home-based rehabilitation compared with day hospital rehabilitation.
- The cost of providing home-based rehabilitation does not appear to be significantly different from that of providing rehabilitation in a day hospital.
- Rehabilitation providers and purchasers need to consider the place of care in the light of local needs, to provide the benefits of both kinds of services.

Taking account of the limitations of this study, the findings provide useable new information to inform decisions on the provision of rehabilitation services for older people in local areas. Our findings suggest that patients receiving rehabilitation in their own homes are not disadvantaged and that the cost of providing home-based rehabilitation is not significantly different from that of providing rehabilitation in a day hospital. This concurs with the literature evidence about alternatives to day hospital care, which shows that provided an active and comprehensive alternative is provided in the community then there is no particular disadvantage for patients and carers. This point is of course vital when decisions are being made about which services to provide in which setting.

It is clear that we have not shown that either setting for rehabilitation offers decisive advantages over the other. We have also shown that costs are probably fairly similar. However, it is also apparent that home-based and day hospital rehabilitation teams tend to offer somewhat different mixes of clinical skills and services, and that many referrals are made outside of even the relatively unrestricted inclusion criteria for this trial.

In considering the implications for future research we can see that it was ambitious to attempt a definitive trial of day hospital versus home-based rehabilitation in essentially unselected older people with rehabilitation needs. We believe that the approach was correct but acknowledge that the challenges we experienced in recruiting sites and subjects resulted in disappointingly low levels of participation in the trial.

Implications for research

- Future research in this area should examine syndrome- or condition-specific approaches to providing for the needs of older people in ambulatory care.
- Further attempts to address issues of cost-effectiveness and place of care in elderly rehabilitation research should focus more on the cost-effective use of specific day hospital services, rather than on whether they compete with community care settings.
- The development and assessment of approaches and instruments for measuring outcomes for older people in receipt of rehabilitation in ambulatory care remains a justifiable focus for future research and development.
- Rather than comparing these settings for efficacy, future research might focus on identifying those services that are better provided in one or other setting, and will take account of the current commissioning environment that explicitly supports choice in the provision of health services for patients.

The reasons for referral for rehabilitation fell into a small number of categories (stroke, falls, mobility assessment). Each of these is likely to be associated with differences in processes, costs and outcomes and this may well have been reflected in the wide range of costs that were observed. This suggests that future research may need to focus on condition- or syndrome-specific questions in establishing the effectiveness of services provided in day hospitals.

Day hospitals have a long tradition of providing specialist services for older people, including rehabilitation, but there has been little previous

and no recent research on their use as a setting for rehabilitation. Overhead calculations suggested a significant difference in costs in the four day hospitals studied. This, together with rapid change in the service infrastructure and environment, may mean that further attempts to address issues of cost-effectiveness and place of care in elderly rehabilitation research should focus more on the cost-effective use of specific day hospital services (such as falls and mobility assessment services), rather than on whether they compete with community care settings.

We have not demonstrated equivalence of effect between the two settings; rather our results are consistent with the non-inferiority of home-based rehabilitation compared with day hospital rehabilitation. More research would be required to provide a definitive answer to this question; however, the large numbers of subjects whose needs were met outside of the clinical pathways leading to recruitment and randomisation suggests that local service providers may already be directing older people to home-based or day hospital services according to local custom, practice and patterns of service provision, adding further weight to the assertion that future research in this area will need to examine these syndrome- or condition-specific approaches to providing for the needs of older people in ambulatory care.

Choice of primary outcome measure for future studies in this area is of key importance. Despite some evidence of responsiveness in similar patient populations, the NEADL scale did not prove sufficiently responsive for use as a primary outcome measure. Other approaches are suggested by the fact that some of the psychosocial domains were apparently responsive to change in this clinical setting, and the use of goal-oriented, patient-focused measurement of outcome using TOMs has shown some promise. Therefore the development and assessment of approaches and instruments for measuring outcomes for older people in receipt of rehabilitation in ambulatory care remains a justifiable focus for future research and development.

Although the results of the literature review, national survey of NHS trusts and this small RCT taken together can be informative for local providers, purchasers, commissioners and other stakeholders in relation to rehabilitation for older people, local decisions will need to be made in the context of local service delivery infrastructure and development needs. Therefore, in deciding about the settings in which to provide rehabilitation services, stakeholders will need to consider the benefits of home-based rehabilitation and ambulatory support provided in day hospitals in the light of local needs, to provide the benefits of both kinds of services.

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All authors reviewed drafts of the manuscript for critical intellectual content and gave their approval to the final version.

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Appendix 1

Trial protocol

Rehabilitation for Elderly Patients: Day Hospitals Compared to Rehabilitation at Home

This project comprises two phases: phase 1 is an initial scoping study with pilot work and phase 2 is a proposed randomised controlled trial. Phase 1 is now complete and the results and their implications for the proposed randomised controlled trial are presented here.

First we will outline the background to the project as a whole and the hypotheses to be tested. Then we will describe the phase 1 study and it's results. Finally we will present an amended trial protocol, which is modified to take account of the lessons learnt in Phase 1. The trial protocol is now accompanied by a proposed add on study which addresses key issues related to the context and generalisability of the trial results.

The structure of this document in therefore as follows

1) Background
2) Literature
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1. Background

There is current debate as to the most appropriate setting for rehabilitation, with Health Trusts increasingly providing community based services. This has been a response to evidence from randomised controlled trials showing the need for and effectiveness of alternatives to acute hospital care for the health of elderly patients, and the practical need to relieve the pressure on hospitals, bought on partly by the ageing population, for which the NHS was not originally designed to cope with(1), and evidence that older people prefer community based care (find reference2). One of the concepts to emerge and develop from this has been 'intermediate care', a phrase coined to describe the gap being bridged between primary and acute care. In clinical terms the challenge this creates is for providers to develop a holistic approach to rehabilitative care at or near the patients home. In research terms the challenge is to develop methods to evaluate this fast changing and complex system (1).
Home-based rehabilitation (HBR) for older people is considered to be appropriate and effective because it is provided within the patient's usual environment rather than an institution, arguably reducing the need to generalise learning from one environment to another. Support for this view underpins the wider development of hospital at home and early discharge schemes (3). In addition to this the day hospital has long been regarded as a central resource in medicine for older people, and almost every health district in the UK has one. Although there are considerable variations in practice, most day hospitals provide functional and medical assessment, rehabilitation, physical maintenance, and medical and nursing procedures within an ambulatory care setting as an alternative to community based or hospital inpatient care. The majority of day hospital patients receive rehabilitation (DHR) and the majority of day hospital resources are consumed by rehabilitation patients(4).

2. Literature

Despite long-standing concerns over cost and effectiveness (5,6) and a number of descriptive studies of day hospitals (7 8), the question "what is the best setting for rehabilitation for older people with disability and rehabilitation needs?" has only ever been partly addressed in well constructed controlled trials. We propose a pragmatic randomised controlled trial (RCT) in which HBR will be compared with DHR as it is usually delivered.

A 1998 systematic overview of systematic reviews in rehabilitation has confirmed evidence for the efficacy of comprehensive multidisciplinary assessment and rehabilitation in care of the elderly and particularly those having suffered a stroke (9). Little evidence in respect of setting for rehabilitation was available and no systematic reviews of DHR were included. In a recent systematic literature review, day hospital care (10) was compared with comprehensive care, no comprehensive care, or domiciliary alternatives. Day hospitals were shown to provide services that were as effective as other forms of comprehensive care and more effective than no comprehensive care.

A systematic review of day hospitals as a setting for rehabilitation was carried out as part of the Best Place of Care (BPOC) commission (HTA project 96/43/01) (11). The main conclusions of the BPOC review were that overall, the day hospital has not yet been adequately evaluated as a *setting* for rehabilitation. It is unlikely that the day hospital offers significant advantage over alternative settings for delivering comprehensive care for the outcomes considering mortality, hospital bed use or gross disability. However, it is possible that the day hospital impacts differentially over alternative settings for delivering comprehensive care for quality of life, quality of life for patient and carer, or health care provider costs. Costs for patients, carers and social care providers have not been adequately evaluated, and neither have patient and carer preferences for day hospital or alternative comprehensive care settings. Trials comparing home rehabilitation to other forms of rehabilitative care have so far been condition specific and not generalisable to the elderly rehabilitation population as a whole.

This literature review was last formally updated in the original application for funding for this study.

3. Best Place of Care research programme

As part of the iterative commissioning programme 'Best Place of Care for Older People' the National Health Service Research and Development Health Technology Assessment Programme placed a call for proposals for a randomised controlled trial comparing day hospital with home based rehabilitation. The successful bid was for a two-phase research proposal. Phase 1 of the project was a pilot study designed to establish the continuing relevance of the research question and feasibility of an RCT in this area. Phase 1 is now complete. Phase 2 was proposed as a mutli-centre pragmatic randomised controlled trial with health economic analysis, comparing day hospitals to home based rehabilitation for elderly patients. Phase 2 would, however, be influenced by the outcomes of Phase 1. We will now report on Phase 1, before outlining the design modifications that it suggests are necessary for Phase 2.

4. Overview of the project

Phase 1 consisted of a National Survey of Trusts in England to find out about current rehabilitation services and identify possible trial sites for a RCT, a pilot study in local trusts to test out the suitability of the research questionnaires and iron out any problems, and the gathering of feedback on the usefulness of the trial and it's methodology.
Phase 2 is a proposed RCT comparing Day Hospital to Home Based Rehabilitation for elderly patients, with health economic analysis.
In addition, for reasons disussed in detail below, we are also proposing an additional Observational Study of Day Hospitals and Home Based Rehabilitation services, to elucidate the philosophy, processes and outcomes associated with different provision within health trusts in England.

5. Phase 1. A scoping study and pilot work for the proposed RCT

a) A National Survey of NHS Trusts in England

Objective

The objective of the survey was to create a picture of current service provision in rehabilitation, and to identify potential trial sites for a RCT.

Methods

All trusts in England were identified by contacting each of the 28 Strategic Health Authorities for a list of their Primary Care and Hospital Trusts. Where this information was difficult to obtain, the Department of Health website was consulted. 578 trusts were identified but 44 (such as children's and ambulance trusts) were excluded as irrelevant. A 1st contact questionnaire, which simply asked whether or not the trusts provided home based and/or day hospital rehabilitation for elderly patients. (see appendix 1) was sent out to 534 trusts 13 were later found to no longer exist or have merged with another trust, leaving 521 possible replies. 391 trusts replied (75%). In the responses we received information on a total of 400 trusts (77%). See table 1 for results.

We then sent out a second contact questionnaire (see appendix 2) asking for more detail about these services, initially to those trusts with co-existing HBR and DHR and later to all trusts, to enable us to identify the range of provision in more detail and to identify potential trial sites from information about the service characteristics. See Table 2 for results.

Results

Service provided	Number	Percentage%
HBR and DHR	184	46
HBR no DHR	80	20
DHR no HBR	60	15
Neither	48	12
Incomplete	8	2
Irrelevant	20	5
Total	400	100

Table 1. Trusts providing home based and / or day hospital rehabilitation. Forty six percent of trusts responding to the first contact questionnaire reported providing both types of service.

2nd contact questionnaire					
	Home based		Day hospital		
Replies received	150		114		p-value
SERVICES	***n***	***%***	***n***	***%***	
Fn Assessment	115	77%	108	95%	<0.01
Medical assessment	53	35%	102	90%	<0.01
Rehabilitation	103	69%	94	83%	<0.01
Respite & Social Care	45	30%	32	28%	>0.2
Specialist medical assessment	33	22%	69	61%	<0.01
Nursing procedures	87	58%	104	91%	<0.01
Specialised Stroke	61	41%	76	67%	<0.01
Specialised TIA	35	23%	61	54%	<0.01
PD	45	30%	74	65%	<0.01
Movement disorders	31	21%	49	43%	<0.01
Falls	69	46%	91	80%	<0.01
Continence	50	33%	50	44%	>0.05
Physical maintenance	34	23%	43	38%	<0.01
STAFF					
Other	77	51%	75	66%	<0.05
Community Nurse	65	43%	18	16%	<0.01
GP	32	21%	21	18%	> 0.1
Hospital nurse	11	7%	62	54%	<0.01
Hospital Doctor	14	9%	70	61%	<0.01
OT	103	69%	99	86%	>0.2
PT	100	67%	97	84%	>0.2
Therapy assistant	88	59%	81	70%	>0.2
Admin staff	63	42%	82	71%	>0.2
Other	59	39%	54	47%	<0.05
Time limited service	75	50%	54	47%	>0.2

(P-value refers to the significance of the difference in provisions between home based and day hospital service (chi))

Table 2. Results of 2nd contact questionnaire received from trusts providing home based and / or day hospital rehabilitation. Note that day hospitals are very much more likely to provide medical or specialised medical services and, home based services are more likely to be provided by community practitioners (GP and Nurse).

b). Pilot work in 3 Trusts to prepare for the RCT

We have piloted the research in 3 trusts, to enable us to establish and resolve practical difficulties in conducting the trial.

Methods

Ethical approval was sought and granted to work in 3 sites, Sheffield, Barnsley and North Tyneside, using both day hospital and home based rehabilitation services. It was agreed that a pre-pilot was necessary, the main purpose being to test out the length and difficulty of the economic questionnaire which had been developed from that used in a RCT on cardiac pace making of older people at CHSR, University of Newcastle, and the Northern Region Day

Hospital Audit (NRDHA). 10 Pre-pilot interviews were done with day hospital rehabilitation patients in Barnsley.

Pre-pilot Interviews

Patients receiving rehabilitation in the day hospital were eligible for inclusion. The researcher approached the patients in the day hospital, explained the research and asked if they would be willing to be interviewed. Patients who agreed were taken to a private consultation room and given an Abbreviated Mental Test (AMT). If their AMT score was below 7, it would be explained that the assent of their carer was also needed. Otherwise, consent was taken and the interview performed then and there.

The economic questionnaire (see Table 5 for detail) was found to be of suitable length and some minor alterations to some questions were made. It was decided that certain information e.g. tests undergone (x-rays etc), should be checked against hospital notes due to problems for some patients in remembering. From the other standardized measures we had originally included both the HADS and GHQ (for full list of measures used see Table 5, for justification of measures used see appendix 3). The GHQ proved to be too upsetting and therefore unsuitable with this group of patients, so was excluded. When we were satisfied that these questionnaires were suitable we continued onto pilot research, in North Tyneside Jubilee Day Hospital, Sheffield Assessment and Rehabilitation Centre, and Barnsley Community Rehabilitation Service.

Staff were consulted and recruitment/consent procedures modified in Sheffield to fit in with local concerns. Staff were then left with Patient Information Sheets (see appendix 4) and Consent Forms (see appendix 5), which they passed on to the researcher when patients were recruited. The researcher then contacted the patients in their own homes. This recruitment procedure would be necessary for the blinding of the researcher in the RCT.

If the patient had an informal carer (e.g. spouse, child), they would be approached if permission was given by the patient, and asked to be interviewed. The interview included the General Health Questionnaire and economic data (see Table 1 for detail).

Location	Number of subjects
Pre-pilot	
Barnsley Day Hospital	10 (5 FU)
Pilot	
Barnsley HBR	7
Sheffield Day Hospital	11
North Tyneside Day Hospital	8
Total	36

Table 3. Completed Pilot Interviews

c) Dissemination and feedback to inform protocol development

Objectives
An integral part of Phase 1 was to gather feedback as to the usefulness and feasibility of the proposed RCT, as well as to seek opinions regarding outcome measures and methodological issues.

Methods
Views were actively sought through:

- *Conferences and presentations*

Poster at BGS Conference Spring Meeting
Poster at Trent Research Unit Conference
Presentation at Newcastle University
Poster at September 2003 BSG Conference
Presentation at Barnsley Research and Development Unit

Information received from these sources has been fed back to the trial management team and was used to inform the recommendations for alterations to the second stage protocol and suggestions for add on studies.

- *A staff and Patients Advisory Group*

An advisory group has been formed, comprising 6 members, consisting of patient representatives and healthcare staff. The group has been consulted separately (either patient representatives or healthcare staff), by holding small informal meetings. This group has been consulted on a variety of issues, including design of patient information leaflets, and for feedback on trial as a whole.

- *Patients and Health care professionals in the pilot sites*

Patients and staff involved in pilot have been asked for feedback on practical matters (e.g. consent procedures and questionnaire length) and for feedback on trial as whole.

Key Concerns
Trial Usefulness and Feasibility

- Many people we have spoken to (e.g. at the BGS conference) see this as a useful trial.
- Feedback has suggested that the current climate is of continual change, and this is confirmed by our survey. 36 of the 63 replies (57%) to 2nd contact questionnaires returned by trusts providing both HBR or DHR state than one or both of the services will be undergoing significant change in the next 3 years.

Methodological Concerns

- Our measures may not detect the holistic gains of rehabilitation, or pick up on small but important changes. To understand the key difference in therapy outcomes between HBR and DHR we need to understand the aims. These may differ between HBR and DHR, and between different trusts, dependant on local factors, and on an individual patient level. This concern has been addressed by including the use if Therapy Outcome Measures.In terms of the economic evaluation, staff at South West Primary Care Trust felt that services, which seemed to incur more extra costs may do so through having good relationships with other organisations (e.g. referring patients on), and there was concern that this would be seen in a negative light. However, we feel that this will be accounted for by considering extra costs against positive outcomes.

6. Interpretation of the results and experience of phase 1 of the project.

Key findings
Scoping study:

- 46% of trusts provide home based and day hospital rehabilitation, and the majority of the remaining trusts provide one or the other, implying that decisions about settings are still current. Elderly rehabilitation is not yet a standardised service.
- Due to the marked heterogeneity of services the number of sites involved in the RCT needs to be higher, to allow broader representation of services.
- Marked heterogeneity and rapid service development and change suggest that observational studies would be of value alongside an RCT.

Pilot:

- The research has been found to be feasible in the settings piloted (including day hospital and home based rehabilitation teams), and flexible to differential local needs, suggesting that it will be practically possible to incorporate the research into a variety of rehabilitation teams.

- Recruitment processes and inclusion criteria are appropriate and can be managed. A recruitment and consent procedure has been designed that can be flexible if necessary due to local issues:

    1. Rehabilitation staff explain research to patient
    2. Rehabilitation staff assess cognitive function as part of usual professional interaction, using usual local method supplemented by AMT as necessary

    (1 and 2 could be other way around depending on preference of staff)

    3. If patient willing consent will be taken, either from patient alone, or from patient with carer assent if AMT score below 7 or professional doubt.
    4. Use of pre-interview questionnaire to determine patients understanding of the type of questions being asked.

- Questionnaires are acceptable to research subjects in terms of both duration and content, and yield a satisfactory level of response and data completeness (out of 43 patients recruited, 35 were interviewed (81%)).

	Patient questionnaire schedule		**Patient economic questionnaire**		**Carer questionnaire**	
Number of questions	**N=54**	**%**	*N=360*	*%*	*N=60*	*%*
Average numbers of questions complete per questionnaire	53.4	99	355.5	99	53.4	99
Minimum number completed	49	91	322	89	49	97
Maximum number completed	54	100	360	100	54	100

Table 4. Patient questionnaire response rates.

The questionnaires have been developed as a result of piloting, and the main differences before and after piloting are shown in the table below.

	Before piloting	After piloting
Questionnaire 1 – Patient	Nottingham Extended Activities of Daily Living Scale	Included
	Hospital Anxiety and Depression Scale	Both were included to see which was most suitable, with the intention of choosing just one for the main trial. HADS was decided upon as many patients found the GHQ distressing.
	General Health Questionnaire	
	Euroquol 5D	Included
Questionnaire 2 – Patient – Economic Data (for full copy see appendix 6)	Use of health and social services, excluding rehabilitation	Included with minor changes
	Use of NHS transport, excluding that used for rehabilitation	Included with minor changes and checked against medical records
	Use of private treatment	Included
	Use of medication	Included and checked against medical records
	Acquiring of aids and equipment/alterations to house, excluding that which has been provided by rehabilitation service	Included with minor changes
	Costs of moving house or residential care	Included
	Travel Costs and other expenses	Included
	Assistance at home other than NHS and Social Services	Included with minor changes
	Social class, married status and use of benefits.	Included with minor changes
Questionnaire 3 – Carer (see appendix 7)	Social class and effect of caring on work status/costs to carer	Included with minor changes
	General Health Questionnaire 30	Included
Proforma for rehabilitation service use (see appendices 8 and 9)	Staff seen, for how long, and what grade, and mileage per patient	Included, but mileage worked out retrospectively later.
		Use of special equipment e.g. ultrasound, and aids/alterations provided for the home, and personal services such as bathing.
Additional	Need identified for holistic goal related measurement (see section 4.3.3.3)	Therapy Outcome Measures (12) See appendix 10.
	No specific provision	Semi structured Interview for determining patient and carer views of treatment.

Table 5. Changes to research instruments.

Feedback:

- The current policy environment continues to stimulate change in healthcare provision in the area, and the results of this trial will be informative in evidence-based policy making.
- Our methodology may not be sensitive to key differences between the 2 groups at the level of achieving rehabilitation goals.. When the protocol was originally proposed there was no practical research tool which would take into account the aims of rehabilitation. Goal Attainment Scaling was available but time consuming for professionals and researchers. Since this time, Therapy Outcome Measures has been validated with this patient group, therefore will be included. TOMS is based on observations of the goals of therapy and aims to provide a reliable and valid way of collecting data for the purpose of outcome measurement. It is administered by rehabilitation staff, who will be trained in it's use.

Protocol modifications suggested by Phase 1 data.

The Trial Management Group has met to consider findings of Phase 1 and the implications of this to Phase 2. Table 2 outlines the main changes to the protocol which the trial management team believe are suggested by the pilot work

Key Finding	Original Protocol	Recommendation
There is considerable heterogeneity between potential trial sites which is independent of the urban / rural setting. Less than 10% of potential trial sites satisfied explicit inclusion criteria based on throughput and range of services.	3 trial sites, 460 patients (after allowing for attrition and non-response).	6-8 trial sites, with a smaller number of patients in each site, to better represent the range of services provided. Total sample size remains the same.
The majority of sites with co-incident day hospital and home based rehabilitation services report ongoing or imminent changes to their service. This suggests that previous descriptive work is likely to be, or soon to become out of date.	Not addressed.	Add-on contextual study. A descriptive analysis of service models and processes across a range of sites will be essential to accurately contextualise the findings of a contemporaneous trial.
Concern from health workers in trial sites that we needed to know aims of rehabilitation to understand whether rehabilitation had been effective, and that our measures did not take account of the many factors affecting the rehabilitation process.	No goal attainment measure and no qualitative data collection.	Use of Therapy Outcome Measures (TOMS) as an alternative to goal attainment measurement, and semi-structured interviews with patients and carers (interview schedule attached).

Table 6. Proposed changes to study protocol.

Phase 2. A proposed randomised controlled trial

Revised protocol
For key differences between this and the original protocol, see table 6.

Hypotheses
Older people and their informal carers:

- are not disadvantaged by home based rehabilitation (HBR) relative to day hospital rehabilitation (DHR) and
- HBR is less costly.

Research Sites
Research sites are being selected from the national survey of trusts. Those identified as potential trial sites are contacted and if willing, visited by the Principle Investigator and the Project Manager, to gather further information and further assess suitability. We aim to recruit 8 research sites (allowing for possible loss of sites during trial), recruiting a total of 640 patients, in order to meet a sample size of 460 patients (allowing for attrition). At the time of writing, 5 sites have given positive responses to our approaches for recruitment. The recruitment process continues, and the protocol revision, expanded recruitment process and multi-centre research ethics application are running in parallel. As this is a pragmatic trial, we wish to compare existing services, and so no service recruited to the trial will undergo major changes to participate in the trial.

The length of the intervention will be determined according to patient need by the local clinical team. Data from the Northern Regional Day Hospital Study (unpublished data) indicates a median length of time receiving the service as 7 weeks. We would expect 95% of subjects to have been discharged within 16 weeks.

Inclusion/exclusion criteria
Subjects should have a permanent address within the defined catchment area of the service. No age criteria will be used for inclusion but in practise 90% of patients will be over the age of 70. As this is a pragmatic trial exclusion criteria will be kept to a minimum. No more than a 3rd of patients will be from one single diagnostic category (e.g. not more than a third being stroke patients). We will record the presence of cognitive difficulties but will endeavour not to exclude patients because of such difficulties.

Recruitment
When referred for rehabilitation the patient will be assessed for suitability for rehabilitation and if defined as suitable, will be informed of the research with the help of a Patient Information Sheet (Appendix 4). If the patient agrees to research, then consent will be taken. Staff will make a professional judgement about whether assent of carer would be appropriate, (e.g. in cases of cognitive impairment), with the use of an Abbreviated Mental Test (assent taken if score below 7), or their instrument of choice. Where the AMT is not used to determine this, the researcher will perform the AMT to confirm the staffs decision.

Carers will be approached by a researcher with the permission of the patient following the baseline interview, and informed of the research with a Carer Information Sheet (appendix 6). If they agree to research consent will be taken and they will be interviewed at the 3 month follow up point.

A chart of anticipated recruitment is shown below which makes the following assumptions: Six sites. First site begins data collection in August 2004. Sites enter trial at 2 monthly intervals during 2004/5. Average 50 subjects per randomisation arm per calendar year available from each site. Assume start at smallest site. Figures adjusted for each site in proportion to annual day hospital rehabilitation throughput. This represents recruitment of about one third of potentially eligible patients from participating day hospitals and one seventh of potentially eligible patients from participating home rehabilitation services.

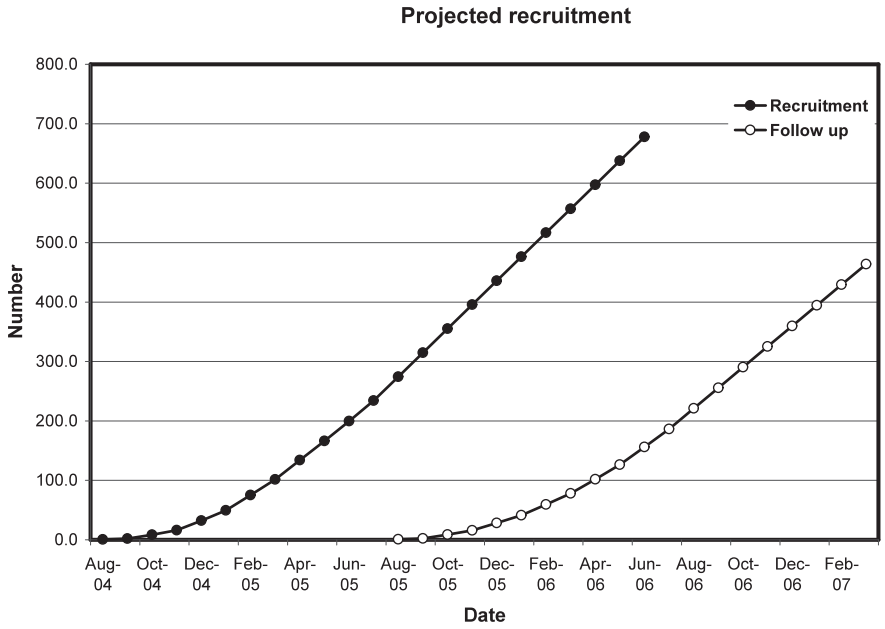

Figure 1. Chart of recruitment expectations

Milestones

A suggested table of milestones is shown below:

June 04	MREC Approval
Aug 04	LREC and local research governance approval(s)
Aug 04	1st Ra appointed*
Aug 04	Begin data collection Site 1**
Oct 04	Begin data collection Site 2**
Nov 04	2nd RA Appointed*
Dec 04	Begin data collection Site 3
Feb 05	Begin data collection Site 4
Mar 05	3rd RA appointed*
Apr 05	Begin data collection Site 5
Jun 05	Begin data collection Site 6
July 06	End of randomisation all sites
July 07	Complete 12 month follow up all sites
Nov 07	Complete date prep
Feb 07	Complete analysis
Aug 08	Complete final report

**RA appointments for data collection will vary between sites. The project milestones assume 3 appointments, but multiple part time appointments may be made across 6 (or more) sites to achieve projected recruitment rates within the budget.*

***Sites 1 and 2 are in close proximity (<10 miles) and subject to the same local ethics process. Data collection may be able to begin almost simultaneously on these sites if necessary.*

Randomisation, stratification and assessment
Patients referred for rehabilitation will be routed through a central point. They will be assessed for their need for rehabilitation and the assessor will complete the Oxford Handicap Scale and Abbreviated Mental Test. The patient will be informed of the research using a Patient Information Sheet. If the patient consents to research they will be randomised to home based or day hospital rehabilitation following a baseline interview,using computer generated block randomisation within each centre, managed by an independent member of the research team and available during the normal opening times of conventional day hospital services. Feasibility of randomisation has been explored with professionals working in pilot and potential trial sites, and while there were some concerns there was a level of understanding about the necessity of randomisation. Time for piloting randomisation processes is built in to the running time in each site to accommodate local issues, and in the first sites to begin randomisation an initial period of piloting will test and resolve any problems in procedures. The scoping study will have identified variation between sites on a number of key variables (e.g. age distribution, range of clinical conditions, sources of referral), which will inform a final decision about stratification. Eligible patients will be stratified by source of referral (hospital inpatient or primary health care team) and the Oxford Handicap Scale using a cut point of 2/3. It is possible that patients will be referred for rehabilitation more than once in the course of the year that they are part of the research. Subjects re-referred to the trial will continue treatment in the arm of the trial to which they were first randomised and study follow-up will continue from the point of randomisation.

Informing GPs about the research
Prior to patient recruitment we will inform all GP surgeries local to the trial site about the research. As patients are recruited we will inform their GP's individually that they are a participant in the trial and that we will contact the GP prior to contacting the patient for follow-up, to check for death.

Outcome measures
Outcomes will be assessed by interview but in addition (to assess potential bias due to ineffective blinding of interviewers) self-completed questionnaires will be completed by a randomly selected 50% of surviving subjects at 6 months and by the other 50% at 12 months. The primary outcome will be functional health status as measured using the Nottingham Extended ADL scale13. All outcomes will be measured at base line and at 3, 6 and 12 months after recruitment by interviewers who are unaware of the treatment allocation (see below). Carer interviews will take place within 1 month of patient interviews. Secondary outcome measures will include survival (death certifications) and changes in subject's perceived mental state (Hospital Anxiety and Depression Scale(14)), change in household or residential or nursing home circumstances (study records), informal caregiver's psychological health (General Health Questionnaire (GHQ(15)) and patient's and informal caregiver's views of 'treatment' (semi-structured interviews). Therapy Outcome Measures (TOMS) will be used to measure outcomes in relation to rehabilitation aims.

Assessment of quality of life is implicit within the choice of outcome measures, (including EuroQOL). No generic and comprehensive quality of life measure is proposed since there is no evidence that a suitable measure exists for this particular patient group. Taken together the proposed outcome measures cover the traditional domains of quality of life included in generic measures. In the absence of reliable patient reported data, data collected from informal caregivers will be substituted where appropriate since previous studies have indicated that informants are a source of reliable data(16 17 18) . The applicants have used all the proposed outcome measures identified in recent studies and found them to be appropriate to the study.

Patient Interviews
Patients will be interviewed in their own homes, following prior arrangement by telephone or letter, by a researcher unaware of their treatment allocation. The interviews have been shown in the pilot to take between 30 minutes to an hour. Patients' welfare will be considered of paramount importance at all times. Proxy information will be used if the interviewer feels that the patient is not capable of answering questions accurately. This will be judged by a combination of AMT score and ability to answer pre-interview questions. The interview will

consist of the instruments outlined in Table 2, and a short semi-structured interview to ascertain views of treatment.

Carer Interviews
It was found in the pilot study that many carers are present at the patient's interview, in which case consent will be taken then and their (see appendices 6 and 7 for Carer Information Sheet and Consent Form) and the interview carried out, in private with the carer where possible. If not, the researcher will ask permission to contact the carer, and then arrange with the carer to visit them at their home. The interview will consist of the instruments outlined in Table 5, and a short semi-structured interview to ascertain views of treatment. In the pilot this was estimated to take about 30 minutes.

Education of data collectors
The data collectors will be trained and monitored to ensure inter rater and intra rater reliability. There will be a 3-day training course at the start of the trial and refresher days will be organised during the trial. There was some discussion about the possible use of videos for this, but it was felt that the effort and expense of producing a video was likely to be more than organising a venue and travel for data collectors.

Data collectors/interviewers will be taught a standard procedure when asked to respond to or faced with a clinical problem during the interview (experience is that this is an uncommon occurrence). In addition, each data collector will be assigned an experienced mentor, who will be available for counselling over unfamiliar and/or potentially distressing experiences during interviews, and can be contacted in cases of concern and these will be logged.

Generalizability, cost and compliance
Variability between centres in terms of size of day hospital and patient case mix will provide a robust basis for generalisability. Variability between services will be documented as part of a description of resource use in each centre. Case mix will be monitored during the trial to ensure comparison with other centres. An additional observational study will also provide a context for the research and the research team are currently designing a potential "add-on" study. The impact of services will be measured in terms of both resource use and cost. Costs to patients, informal caregivers and health and personal social services will be estimated. The unit of analysis will be "cost per patient" (see below). Sub-group analysis, will examine the costs and benefits to specific patient groups. The records of patients recruited to the trial will be reviewed independently by one of the applicants (PE), plus an appropriate dual observer, in order to assess differences in professional inputs within and between centres. Where subjects fail to comply with treatment but where compliance with continuing data collection is achieved subjects will be analysed on an intention to treat basis. Clinician compliance, including nursing and therapist involvement will be given high priority by the project manager. A member of the rehabilitation professions among the applicants (PE) will provide support and encouragement for all centres. We will provide regular newsletters to each centre showing target and actual response rates as well as visits from the research team, as mechanisms for encouraging staff compliance.

Sample size
We estimate a sample of 460 patients (230 propositi and 230 controls) will have 90% power to detect a difference of two points on the Nottingham EADL scale(19) using a significance level of 5%. NRDHS data estimates about a 10% attrition over the course of the study but we have used the more conservative estimate of 15% in estimating sample size, throughput and budgeting for data collection. Therefore allowing for initial non-response of 20% and attrition between times 1 and 2 of 15% we need to recruit 680 patients, probably from 6-8 participating clinical centres.

Analysis
Analysis of the trial data will be on an 'intention to treat' basis. Univariate and multivariate techniques including survival analysis, non-parametric analysis of variance and log-linear modelling will be used to evaluate the relationships between inputs and outcomes. Interim analysis of throughput, case mix and difference in primary outcome will be done by an independent data monitoring committee 9 and 21 months after recruitment has begun (at the end of the first and second year of the study). We will monitor throughput but all other analysis will wait until the end of data collection.

Economic Evaluation
Perspective of the study
An economic evaluation will be conducted alongside the clinical trial to compare home-based rehabilitation (HBR) vs. day hospital rehabilitation (DHR). DHR is considered to be the current practice. The aim of the study is to test the hypothesis that for older people requiring rehabilitation, HBR: (i) is not less effective than DHR, (ii) is not less preferable than DHR to the patients and their carers, (iii) is less costly than DHR.
The economic evaluation will address the study question from the NHS decision making and societal perspectives (20). We recognise that a decision making perspective is particularly suitable to address the study questions posed by the NHS research programme. However, we believe the societal perspective to be also important because the problem under investigation has an impact on other agents beyond the health service, and the decision maker may want to be informed about such implications.
The societal perspective is aimed at including all costs and health effects regardless of who incurs the costs and who obtains the benefits (21). We will try to make the collection of the most important data to address the societal perspective practically feasible, without making the data collection instruments too cumbersome. Therefore, we will consider the costs (and benefits) to the providers of health and social services, the patients and their carers. Although a wide range of cost items and outcomes will be included, the core analysis will focus on the subsets of costs and effects relevant for allocating the health service budget.

Measures of benefits used and study type
A Cost consequences analysis and a Cost-effectiveness analysis (which will become a Cost minimisation analysis if no significant difference in costs will be found) will be conducted. In Cost consequences analysis all the outcome results from the clinical study will be listed and will not combined with the (incremental) costs. In Cost effectiveness analysis the benefits will be measured in terms of the primary clinical outcome (functional ability score measured by the Nottingham EADL scale). Patients included in the study sample will be comparable in terms of clinical and prognostic features across sub-samples.
We are aware that the use of specific-condition health status measures in economic evaluations has some limitations, given the assumption of no interactions between dimensions. Alongside the specific-condition health status measure, a generic validated instrument which allows to combine different aspects of health status will be adopted (EQ-5D). We will investigate the nature of the correlation within and between instruments.

Resource data collection and costing methods
The use of health and social services will be monitored and costed. These services will include not only the therapy and direct costs related to the rehabilitative interventions ('packages of care') under investigation, but also those related to any subsequent use of health care and social services. Any difference in carers' use of time will also be considered.
Estimation of resources included in 'packages of care': It is expected that day hospital interventions will vary within and between centres. The contents and quantities of service inputs used in relation to the packages of care delivered in day-hospital (local geriatric day hospital service) or at home (own home or residential and nursing homes) will not be established by rigid protocols within the study. The present trial is in fact pragmatic; moreover, we think it may not be practically feasible to obtain health care professionals' compliance to the protocols, given the nature of the interventions and actual variety of care.
The contents of the packages of care and their measurements will therefore be assessed by observation. Data will be collected prospectively for each patient in each centre. Pro-formas for data collection will be completed by the NHS staff. The final aim is to estimate a cost per patient day in both DHR and HBR, in relation to the provision of physiotherapy, occupational

therapy, speech therapy, nursing, medical assessment and intervention, and transportation costs of patients/carers to and from day hospital centres; and of health care professionals to and from patients' homes; use of special aids and equipment; introduction of home alterations; personal care received through rehabilitation service. The provision of social and personal services which do not contribute directly to the rehabilitation process is excluded from the evaluation of these packages of care. However, they will be considered within the economic evaluation:
Information on personal and social services received at home will be collected through interviews (see below); information on personal and social services provided in day hospital will be monitored in each centre.
To estimate the use of resources made by the rehabilitation team, service elements will be recorded for each patient in a proforma. These will include date of visits, job title of the health care professional(s) seen on that day, the grade, the length of visit, the mileage per patient. The total time per patient will be the time spent on all service elements for that patient. This will allow to estimate labour costs. All material items/ equipment used during each action will be also be recorded. Fixed costs, such as overheads and general costs will be allocated pro-rata according to relevant parameters such as floor area used, number of staff, throughput.
Estimation of subsequent use of resources. Use of services - other than those included as part of the packages of care - to be monitored in both patient groups via questionnaire include: outpatient visits and hospitalisations, investigations, A&E admissions, use of ambulance services, visits and telephone consultations to and from the general practitioner and any other health care professionals, use of medications, personal and social services, attendance to day care centres, short-term respite or permanent care.
Details on procedures/investigations undertaken in hospital (eg, during hospitalisation or casualty attendance) will be extracted from patients' records, at 3, 6, 9, 12 months post-randomisation, as well as being including in questionnaire, to double check. Records will be reviewed over the previous three months.
Data on the use of all the other services/resources will be collected through questionnaire interviews to the patients. The interviews will be carried out at 1, 3, 6 and 12 months post-randomisation. Patients will be asked which services they used, and how often, over the previous month. Manpower data will be collected separately for each main category of staff. Moreover, the interview will collect information on the patients' expenditures due to travel, use of any equipment/special aids, changes introduced to accommodations/living environments, private medical/paramedical visits, assistance received by informal caregivers, any other out-of-pocket expenditures. Whenever practically feasible, patients will be asked to provide details for their financial expenditures and quantities separately.
Data collection instruments (hospital, patients and carers) have been prepared adapting those used in a randomised controlled trial on cardiac pacemaking of older people being carried out at CHSR, University of Newcastle(22). Questions on modifications of living environments have been adapted from a questionnaire used in a study of early supported hospital discharge for stroke(23). Questionnaires have been prepared thinking of the clinical management strategies and event pathways.

Costing methods: Costing of health and social care will be undertaken in a parallel study and a mixed approach using microcosting and gross costing methods will be used(24). The perspective used in the study affects the way in which resources have to be costed (25). Generally, resources should be valued at their (marginal) opportunity costs, and market prices are usually used as a proxy measure. We will cost resources using national average cost figures (26);(27);(28). We expect scarcity of published cost data in relation to rehabilitative care. Whenever necessary, cost estimation procedures will be developed and local NHS and social service accounting figures will be used to estimate total costs. Then, two methods of costing will be used and compared as suggested by the methodological literature(29): at first, unit costs averaged across centres will be applied to centre-specific volume of resources used; therefore, these results will be compared with those obtained using centre-specific information for both the unit costs and the resources volumes, and averages across centres will be calculated. Where relevant, costs will be broken down into capital, staff, consumable and overhead costs. This will aid the production of different cost scenarios, and the understanding of the implications on the marginal cost evaluation.
Other costs to carers: The impact of the interventions on carers' daily activity and their use of time will also be monitored. Informal carers will be identified through the patients' interviews.

Questionnaires will be interview administered up to one month after the patients' interview, to allow adequate time to identify, locate and contact the carers.
For carers in paid/unpaid work (eg. doing housing or voluntary work), time will be valued in monetary terms. Carers' lost leisure time will also be measured. However their impact will be assessed through HRQoL instruments(30), and therefore will not be valued in monetary terms.

Methods of data analysis
Average total costs between groups will be compared at the time points of data collection, in relation to the outcome results. Costs will be expressed in UK pounds sterling. No conversion to other currencies will be made. Costs will be expressed in the prices of the year in which the final analysis will be carried out and inflation method will be used to update costs data. Given the length of follow-up period, no discounting will be necessary.

We expect skeweness in the distribution of use of resources/costs(31). In the presence of skeweness, the logarithmic transformation of data is not recommendable, and the application of non-parametric tests can provide misleading results (in fact economic studies should aim to base the analysis on arithmetic means and not median values) (32);(33). The non-parametric bootstrap test can be the most appropriate (34), since it does not require any assumptions about the normality of data and equality of the variance or shape of the distributions. The t-test can be safely used if the sample size is not too small (33). Therefore, depending on the level of skeweness of data we will obtain and our sample size, we will make a judgement on which of these two methods can be safely applied.

Synthesis of costs and benefits
Summary results will be presented in aggregate and for each sub-group of analysis (groups will be defined in terms of severity and functional disability). Depending on the outcome measure, if there will not be evidence that one strategy is more effective than another, a cost-minimisation framework will be used and the less expensive form of care expressed in terms of cost per patient will be recommended. If one strategy appears to be dominant (ie. to be more effective and less costly than the alternative), its' uptake will be recommended. If one form of care appears to be more effective and more expensive than the comparator, the results of the study will provide useful information, and a judgement will be required in a decision making context to establish whether the additional benefits should be achieved sustaining the additional costs. In any case, recommendations will be made taking into account of the generalisability of the results. Incremental costs will be calculated overall and in relation to any reduced use of services included in the packages of care.

Sensitivity analysis
To handle uncertainty not related to sampling variations and to enhance the generalisability of the results, one-way; multi-way and extreme scenario analysis will be undertaken as appropriate, and Confidence Intervals for cost-effectiveness ratios will be estimated under different scenarios (34). A sensitivity analysis taking into account differences in resource use which are practically significant (i.e. potentially costly) but which have not been shown to be statistically significant, will also be undertaken. The sensitivity analysis will also make explicit all the simplifying assumptions made to collect the data, and will allow for 'learning effects' in HBR service provision.
Particular attention will also be given to whether the costs data used reflect the (marginal) opportunity costs of the resources used. When more than one reliable source of information will be available, such data will be used as a term of comparison. In this way, the sensitivity analysis will also be aimed to inform decision making at different levels and therefore to make the findings relevant to other perspectives. Finally, the use of different costing methods for multi-centre studies will be explored, as suggested by the recent literature (30).

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1st contact questionnaire for trusts

A RANDOMISED CONTROLLED TRIAL

OF DAY HOSPITAL REHABILITATION

COMPARED WITH

REHABILITATION AT HOME

QUESTIONNAIRE FOR TRUSTS:
1st Contact

Name of trust

Location

Name, address and telephone number for:

Lead clinician for rehabilitation for older people

Name: **Address:**   **Tel:** **Fax:** **Email:**

Research Department

Contact Name: **Address:**   **Tel:** **Fax:** **Email:**

Person filling in this form, if not one of the above

Name: **Address:**   **Tel:** **Fax:** **Email:**

Please could you fill in the following questionnaire as discussed in the accompanying letter?

(Questionnaire for trusts)

1. Is your trust a District General Hospital? YES ☐ NO ☐

   Primary Care Trust? YES ☐ NO ☐

   Other(please specify)_____

2. If a District General Hospital, which Primary Care Trusts do you serve?

   _____

   _____

   _____

   _____

   _____

   If a Primary Care Trust to which District General Hospital do you principally refer?

   Main_____

   Other_____

3. Does your trust provide a home based rehabilitation service for elderly patients?

YES ☐ NO ☐

IF YES please answer the following:

a) is this service restricted to older patients YES ☐ NO ☐

or

b) open to other age groups YES ☐ NO ☐

IF NO which trust(s) provide this in your area?

_____

4. Does your trust provide a day hospital rehabilitation service for elderly patients?

YES ☐ NO ☐

IF YES please answer the following:

a) is this service restricted to older patients YES ☐ NO ☐

or

b) open to other age groups YES ☐ NO ☐

IF NO which trust(s) provide this in your area?

_____

Thank you for your cooperation. Please return questionnaire in the envelope provided. You may be contacted again regarding this issue in the future.

2nd contact questionnaire for trusts

	Home based rehabilitation service		Day hospital rehabilitation service	
1. Does the service provide:				
1a. Functional assessment (assessment of personal independence)?	Yes	No	Yes	No
Medical assessment?	Yes	No	Yes	No
1b. Rehabilitation (a co-ordinated approach to the assessment and treatment of physical, cognitive, psychological impairment and disability)?	Yes	No	Yes	No
1c. Respite and social care?	Yes	No	Yes	No
1d. Specialist doctor related to rehabilitation?	Yes	No	Yes	No
1e. Nursing procedures?	Yes	No	Yes	No
1f. Specialist assessment services for specific groups of patients: ***Please circle***	***Stroke*** ***TIA*** ***Parkinsons*** ***Movement Disorder*** ***Falls*** ***Continence*** ***Other (please specify)*** ***Physical Maintenance*** ***Other (please explain)***		***Stroke*** ***TIA*** ***Parkinsons*** ***Movement Disorder*** ***Falls*** ***Continence*** ***Other (please specify)*** ***Physical Maintenance*** ***Other (please explain)***	
2. Approximately how many new elderly (e.g. over 55) patients have been referred to the service in the past 12 months?				
3. How many patients can the service provide for on any one day?				
4. Who delivers the service: ***Please circle***	**Community Nurse (s)** ***G.P(s)*** ***Acute hospital nurse (s)*** ***Acute hospital doctor (s)*** ***Occupational Therapist (s)*** ***Physiotherapist (s)*** ***Assistant (s)*** ***Administrative Staff*** ***Other (please give details)***		**Community Nurse (s)** ***G.P(s)*** ***Acute hospital nurse (s)*** ***Acute hospital doctor (s)*** ***Occupational Therapist (s)*** ***Physiotherapist (s)*** ***Assistant (s)*** ***Administrative Staff*** ***Other (please give details)***	
5. Does the service have defined time limits for the attendance of it's patients?	Yes	No	Yes	No
6. What proportion of the patients in the service are stroke/non-stroke?	Stroke	Non-Stroke	Stroke	Non-Stroke
7. Are there any major plans to change the service within the next 3 years?	Yes Please explain over leaf	No	Yes Please explain overleaf	No

- Would you be interested in taking part in a Delphi survey? Yes/No
- Would your trust be interested in the possibility of taking part in a randomised controlled trial? Yes/No
- **Thank you for your help. If you wish to elaborate on any questions please do this overleaf, numbering accordingly.**

Justification of measures used

Hospital Anxiety and Depression Scale

HADS was developed by Zigmond and Snaith (1983), to identify anxiety disorders and depression among patients in non-psychiatric hospital clinics. It contains an anxiety subscale and a depression subscale. They reported it to have good reliability and validity and be unaffected by the presence of physical illness. They found it to be easily understandable by and acceptable to patients (Bowling 1995).

Other studies since have confirmed it's usefulness. Aylard et al (1987, cited in Bowling 1995) found it to have good correlations with other well known scales. Mykletun et al (2001), tested the psychometric properties of HADS in a large population and found it to be good in terms of factor structure, intercorrelation, homogeneity and internal consistency. They also found that these properties were robust across a wide spectrum of sub-samples, including age, gender and education. Mykletun et al (2001) studied HADS as a self-administered scale, but Zigmond and Snaith (1983) recommend it to be interviewer administered (Bowling 1995).

Bjelland et al (2002) reviewed 747 papers on the validity of HADS. A 1996 review by Herrmann, had concluded that "HADS is a reliable and valid instrument for assessing anxiety and depression in medical patients" (cited p3). Since this was published however, the number of papers on HADS had increased four fold. Bjelland et al concluded that HADS has good internal consistency in the hospital population, with substantial evidence to support that it works well in general and other populations. They felt is was at least as good a screening tool and other similar screening instruments.

HADS has been used extensively in studies of patients receiving rehabilitation, recent examples include Wolf et al's (2001) study to establish the effect of an exercise intervention on balance dysfunction in elderly rehabilitation patients, and Wade et al (2003)used HADS in a study to determine the effect of a rehabilitation and support group on people with Parkinson's disease.

Therefore we can conclude that HADS will be a reliable and valid measure of anxiety and depression and is considered acceptable for use with elderly and rehabilitation patients patients.

General Health Questionnaire

Bowling (1995), describes the GHQ as "The most commonly used international scale of general psychiatric morbidity, across a wide range of patients" (p76). Specifically the GHQ-30 is the most popular, for it's good psychometric properties and brevity.

Bowling stated that it has been extensively tested for reliability, validity and sensitivity to change with good results. It has also been used with elderly populations successfully, including where help has been needed to fill it in.

It has recently been used by Watts et al (2002) in their study of mental health problems in older people in primary care, and by Bautz-Holter et al (2002) in their study of Early Supported Discharge following acute stroke compared to a normal rehabilitation package.

The reliability and validity of the GHQ is well documented, and specifically the 30 question version is most popular. It has been well used with elderly populations and is acceptable for use with rehabilitation patients.

Nottingham Extended Activities of Daily Living

The EADL was designed by Nouri and Lincoln in 1987 for use with stroke patients. I-Ping et al (2000) state that "The EADL is one of the most popular IADL scales used in rehabilitation

centres in the UK" (p449), it is recommended for use in clinical and research settings and includes items which are suitable for patients living at home. Bowling (1995) had found evidence for the reliability of EADL but found that few studies had evaluated it's validity.

Studies since though, have established the validity of the EADL, for example I-Ping et al's (2000) study evaluating it's use with stroke patients in Taiwan. They have also shown it to be sensitive to clinically important changes.

Other studies have also evaluated it's usefulness with non-stroke patients. Harwood et al (2002) concluded that EADL is valid for use with patients with arthritis of the hip, and Nichol et al (2002) evaluated it's usefulness with Multiple Sclerosis patients. Both of these studies support the reliability and validity of the method, and suggest that this is a useful tool for a wider rehabilitation population that stroke patients.

Euro-quol

Euro-quol was designed to provide a standardised non-disease-specific instrument for assessing health related quality of life (Bowling 1995), and has been widely used in health economic evaluation. The EQ 5-D has been widely used in rehabilitation studies, including a 2003 RCT by Wade et al, looking at rehabilitation for Parkinson's patients.

Schrag et al (2000) state that the EQ-5D "has been extensively validated and been shown to be sensitive, internally consistent and reliable in the general population and other patient groups".

Summary Table

	Reliability	**Validity**	**Appropriate to population**
HADS	Zigmond and Snaith (1983) Bjelland et al (2002)	Zigmond and Snaith (1983) Bjelland et al (2002)	Bjelland et al (2002) Wolf et al (2001)
GHQ	Bowling (1995)	(Bowling 1995)	Watts et al (2002) Bautz-Holter et al (2002)
NEADL	Bowling (1995)	I-Ping (2000)	Harwood et al (2002), Nichol et al (2002)
EUROQUOL	Schrag et al (2000)	Schrag et al (2000)	Wade et al (2003)

Patient Information Sheet

Patient Information Sheet

University of Sheffield

Rehabilitation for the elderly. Day hospitals compared to rehabilitation at home. A randomised controlled trial.

Invitation to participate in the above study
You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take your time to read the information carefully and discuss it with friends, relatives and your GP if you wish. Ask us if there is anything which is not clear or if you would like more information. Take time to decide whether you wish to take part.

Consumers for Ethics in Research (CERES) publish a leaflet entitled 'Medical Research and You'. This leaflet gives more information about medical research and looks at some questions you may want to ask. A copy may be obtained from CERES, PO Box 1365, London, N16 0BW.

Thank you for reading this.

What is the purpose of this study?
We want to compare elderly patients who are having rehabilitation in a day hospital, to those having rehabilitation in there own homes, and see if there are any advantages of one over the other in terms of cost or patient and carer preference. The study is a National Randomised Controlled Trial, which means it is taking place nationally, and patients who agree to be involved are randomly assigned to receive either home based or day hospital rehabilitation. From previous studies we don't expect there to be any difference in effectiveness between these two, so you will not be disadvantaged by being assigned to either one. What we hope to find out is which of these is preferable according to the patient and carer, and which is most cost effective.

Why have I been chosen?
You have been chosen because you are an elderly person who has been identified as needing rehabilitation.

Do I have to take part?
It is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time without giving a reason. This will not affect the standard of care you receive.

What will happen to me if I take part?
If you agree to take part in this study, you will be randomly assigned to receive either day hospital or home based rehabilitation. Then your rehabilitation will start and the service you receive will be unaffected by your taking part in this study. A researcher will come to your home, at your convenience, and interview you within the next 2 weeks. This interview will involve questions about how you feel in yourself and what you can and can't do, and also questions about your use of health services. The interview will take between half an hour and an hour. This interview will be repeating in 3 months, 6 months and 12 months time. The researcher will always make an effort to fit around your commitments and your health and welfare will always be the top priority.

What do I have to do?
Taking part in the study does not require you to make any changes to your lifestyle, and the researcher will arrange to see you at a time convenient to you.

What is the procedure being tested?
The study aims to find any differences between home based and day hospital rehabilitation.

What are the alternatives to being involved in this study?
If you choose not to be involved in this study, you will receive rehabilitation, and if you have a preference to being treated at home, or in a day hospital, this can be taken into account.

What are the possible disadvantages or risks to being involved in this study?
We don't think there are any risks or disadvantages for being involved in this study, but you have the option to withdraw at any time, for any reason.

What are the possible benefits of taking part?
Information we get from this study will help us to find out the best way of treating patients in the future.

What happens when the research stops?
When the research stops we will analyse the information we have gathered, and report our findings, which may have implications for funding and resources in the future.

What if something goes wrong?
We don't think that being part of this study will cause you any problems, and the researchers will do there best to make sure we interrupt your day to day life as little as possible. However, if you are unhappy about the way you have been approached or treated during the study, there will be complaint procedures that you can follow.

Should you have a complaint about anything during the course of the research, please phone SISA on :
0114 271 5924

Will my taking part in the study be kept confidential?
All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which we take away from the hospital/scheme will have your name and address removed from it so that you can not be recognised.

What will happen to the results of the study?
We hope that the results of this study will be published in journals and conferences, and help to decide on future policy development. There will be an opportunity for you to see the results of the study when it is completed.

Who is organising and funding this study?
The research is funded by the Department of Health, and organised by researchers at the Universities of Sheffield, Newcastle and Leicester.
If there is any else you would like to know please contact me.

Kate Fryer
Project Manager
Sheffield Institute for Studies on Ageing
Community Sciences Centre
Northern General Hospital
Sheffield
S5 7AU
Phone: 0114 XXXXXXX
Mobile:
Email:

Consent form

Consent form. Rehabilitation of older patients:
day hospital compared to rehabilitation at home.
Randomised controlled trial.

Centre No. Patient ID No.

Name of researcher:

I have spoken to…….about the study. ☐

This conversation took place on ……(date). ☐

I have read the information sheet ☐

I know enough about the study ☐

I have had the chance to ask questions ☐

I have been told that I don't have to take part if I don't want to ☐

I have been told I can change my mind at any time if I don't want to carry on ☐

I have been told that what I decide to do will not effect any help I get now or in the future ☐

I understand that if I agree to take part in the study, I will be randomly assigned to receive rehabilitation either in the day hospital or at my home ☐

I have been told I will be asked to meet with the researcher in my own home up to 4 times ☐

I have been told my name will not be used in anything written about the study ☐

I have been told that nothing I say will be repeated to anyone else unless it is discussed with me first ☐

I am happy for my GP to be informed of my participation in the study ☐

I am happy for the researcher to contact my GP or other relevant health professional, in the event that they visit me ay my home and feel that is necessary ☐

Name of patient	Date	Signature

Name of person taking consent (if not researcher)	Date	Signature

Researcher	Date	Signature

(If AMT below 7)

Primary Informal Carer	Date	Signature

1 for patient, 1 for researcher, 1 to be kept with hospital notes

Carer Information Sheet

UNIVERSITY OF SHEFFIELD

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Invitation to participate in the above study

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We want to compare elderly patients who are having rehabilitation in a day hospital, to those having rehabilitation in there own homes, and see if there are any advantages of one over the other in terms of cost or patient and carer preference. The study is a National Randomised Controlled Trial, which means it is taking place nationally, and patients who agree to be involved are randomly assigned to receive either home based or day hospital rehabilitation. From previous studies we don't expect there to be any difference in effectiveness between these two, so the patient will not be disadvantaged by being assigned to either one. What we hope to find out is which of these is preferable according to the patient and carer, and which is most cost effective.

Why have I been chosen?

You have been chosen because you are the carer of an elderly person who has been identified as needing rehabilitation.

Do I have to take part?

It is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time without giving a reason.

What will happen to me if I take part?

If you agree to take part in this study, a researcher will come to your home, at your convenience, and interview you in about 3 months time. This interview will involve questions about how you feel in yourself and how you have been

affected by the illness of the person you are caring for. The interview will take about half an hour. This interview will be repeated 6 months and 12 months time from now. The researcher will always make an effort to fit around your commitments and your health and welfare will always be the top priority.

What do I have to do?
Taking part in the study does not require you to make any changes to your lifestyle, and the researcher will arrange to see you at a time convenient to you.

What is the procedure being tested?
The study aims to find any differences between home based and day hospital rehabilitation.

What are the alternatives to being involved in this study?
If you choose not to be involved in this study neither you or the person you are caring for will be affected. The person you are caring for can still be part of the study if you decide not to be.

What are the possible disadvantages or risks to being involved in this study?
We don't think there are any risks or disadvantages for being involved in this study, but you have the option to withdraw at any time, for any reason.

What are the possible benefits of taking part?
Information we get from this study will help us to find out the best way of treating patients in the future.

What happens when the research stops?
When the research stops we will analyse the information we have gathered, and report our findings, which may have implications for funding and resources in the future.

What if something goes wrong?
We don't think that being part of this study will cause you any problems, and the researchers will do there best to make sure we interrupt your day to day life as little as possible. However, if you are unhappy about the way you have been approached or treated during the study, there will be complaint procedures that you can follow.

Should you have a complaint about anything during the course of the research, please phone SISA on :
0114 271 5924

Will my taking part in the study be kept confidential?
All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which we take away from the hospital/scheme will have your name and address removed from it so that you can not be recognised. We will not share anything you tell us with the person you are caring for unless you ask us to.

What will happen to the results of the study?
We hope that the results of this study will be published in journals and conferences, and help to decide on future policy development. There will be an opportunity for you to see the results of the study when it is completed.

Who is organising and funding this study?
The research is funded by the Department of Health, and organised by researchers at the Universities of Sheffield, Newcastle and Leicester.
If there is any else you would like to know please contact me.

Kate Fryer
Project Manager
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Community Sciences Centre
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S5 7AU
Phone: 0114 XXXXXXX
Mobile:
Email:

Consent form. Rehabilitation of older patients:
day hospital compared to rehabilitation at home.
Randomised controlled trial. Carer.

Centre No. Patient ID No.

Name of researcher:

I have spoken to…….about the study. ☐

This conversation took place on ……(date). ☐

I have read the information sheet ☐

I know enough about the study ☐

I have had the chance to ask questions ☐

I have been told that I don't have to take part if I don't want to ☐

I have been told I can change my mind at any time if I don't want to carry on ☐

I have been told that what I decide to do will not effect the person I care for now or in the future ☐

I have been told I will be asked to meet with the researcher in my own home up to 3 times ☐

I have been told my name will not be used in anything written about the study ☐

I have been told that nothing I say will be repeated to anyone else unless it is discussed with me first ☐

Name of carer	Date	Signature

Name of person taking consent (if not researcher)	Date	Signature

Researcher	Date	Signature

Economic Questionnaire for patients

University of Sheffield **Sheffield Institute for Studies on Ageing** **Rehabilitation of Older Patients: day hospital compared to rehabilitation at home – HTA Project No: 97/26/01**	
Patient Interview Schedule 2 – Economic	
Patient study number	1
Interviewer (Kate=1)	2
Interview done in home(1)/hospital(2)	3
Date	4
Baseline(0)/3 months (1)/6 months(2)/1 year(3)	5
Proxy? Yes(1)/No(2)	6
Relationship of proxy to patient Husband/wife (1) Son/daughter (2) Grandchild (3) Other relative (4) Friend (5) Paid carer (6)	7

0	So, when did you start your rehabilitative treatment (date)?	8
	*Now I will ask you a series of questions about the use of health and social services through the NHS. I only want to know about things you have had **in addition to** your rehabilitation treatment:*	
1	In the last 8 weeks have you done any of the following because of your condition or other health reasons? Can you please also remember how many times these events have happened? Please do not count visits you have made as part of your rehabilitation treatment.	
a)	**Have you been seen by the family doctor or another GP at a doctor's surgery?** Yes.....1 no. times ☐☐	9 10

	No 2	
b)	**Have you been seen by a nurse at a surgery?** Yes.....1 no. times ☐☐ No 2	11 12
c)	a) **Did you or anyone else speak to a nurse from a doctor's surgery about you on the telephone?** Yes.....1 no. times ☐☐ No 2	13 14
d)	**Did you or anyone else speak to a doctor at the surgery about you on the telephone?** Yes.....1 no. times ☐☐ No 2	15 16
e)	**Did you or anyone else telephone NHS Direct?** Yes.....1 no. times ☐☐ No 2	17 18
f)	**Have you visited an emergency doctor at an "out of hours" clinic?** Yes.....1 no. times ☐☐ No 2	19 20

2	In the last 8 weeks, have you been seen in an outpatient department at a hospital because of your condition or other health reasons? Please do not count the times you went there for tests/investigations only, I will ask you about these later. Only count those in addition to your rehabilitation treatment. Can you remember which hospital/clinic departments you have been seen as an outpatient? I will also ask you how many times this has happened. I have a list, which might help you.	
a)	**Have you been seen in a geriatric department?** Yes.....1 no. times ☐☐ No 2	21 22
b)	**Have you been seen in an orthopaedics department?** Yes.....1 no. times ☐☐ No 2	23 24
c)	**Have you been seen at a rehabilitation/physiotherapy department?** Yes.....1 no. times ☐☐ No 2	25 26

d)	**Have you been seen at a generic medical department?** Yes ..... 1 no. times ☐☐ No 2	27 28
e)	**Have you been seen at a neurology department?** Yes ..... 1 no. times ☐☐ No 2	29 30
f)	**Have you been seen at an ophthalmologist department?** Yes ..... 1 no. times ☐☐ No 2	31 32
g)	**Have you been seen at an ENT department?** Yes ..... 1 no. times ☐☐ No 2	33 34
h)	**Have you been seen in an Accident and Emergency department?** Yes ..... 1 no. times ☐☐ No 2	35 36
i)	**a) Have you been seen in any other department?** Yes ..... 1 Specify where……no. times ☐☐ No 2	37 38

3	In the last 8 weeks, have you had to stay in hospital as a day patient or overnight because of your condition or other health reasons? **(RECORD GENDER OF PATIENT).** Yes (1) No (2) If yes ask name of hospital**……**	39
4	In the last 8 weeks, did you have any tests/investigations because of your condition or any other health reasons? Please do not count those you have had while admitted to hospital or those you have had during the outpatient visits you reported earlier on. I have got a list of tests and investigations some people might have had. You may be familiar with some of the words, but don't worry if you do not recognise all of them. Can you please tell me if you have any of the following and how many times? **Ring all that apply**	
a)	***Blood tests*** Yes (1) No (2) no. times ☐☐	40 41
b)	**Urine test** Yes (1) No (2) no. times ☐☐	42 43
c)	**X-ray** Yes (1) No (2) no. times ☐☐	44 45
d)	**CT (computerised tomography) brain scan**	46

	Yes (1) No (2) no. times ☐☐	47
e)	**MRI (magnetic resonance imaging) brain scan** Yes (1) No (2) no. times ☐☐	48 49
f)	**ECG, Heart tracing** Yes (1) No (2) no. times ☐☐	50 51
g)	**Ultrasound** Yes (1) No (2) no. times ☐☐	52 53
h)	**EEG (brain wave recording)** Yes (1) No (2) no. times ☐☐	54 55
i)	**Other (SPECIFY):** Yes (1) No (2) no. times ☐☐	56 57
j)	**Other (SPECIFY):** Yes (1) No (2) no. times ☐☐	58 59

5	In the last 8 weeks, have you used an emergency ambulance service because of your condition or any other health reasons? Can you please remember the number of times? (please count journeys both to and from the hospital as separate journeys) Yes (1) No (2) no. times ☐☐	60 61
6	In the last 8 weeks, have you used a pre-booked NHS transport service (e.g. minibus, ambulance, taxi) because of your condition or any other health reasons? Can you please remember the number of times? (please count journeys both outwards and inwards journeys as separate journeys) Yes (1) No (2) no. times ☐☐	62 63

	Now I will ask you about visits you have received at home through the NHS or the social services.	
7	In the last 8 weeks, have you received any visits at home because of your condition or other health reasons and can you remember how many times? Please do not include the visits you have had as part of your rehabilitation treatment since we will get this information from the Centre.	
a)	**Have you been seen by your GP or another doctor at home?** Yes (1) No (2) no. times ☐☐	64 65
b)	**Have you been seen by a health visitor at home?** Yes (1) No (2) no. times ☐☐	66 67

c)	**Have you been seen by a social worker at home?** Yes (1) No (2) no. times ☐☐	68 69
d)	**Have you been assisted by a home carer?** Yes (1) No (2) no. times ☐☐	70 71
e)	**Have you been seen by a disablement resettlement officer at home?** Yes (1) No (2) no. times ☐☐	72 73
f)	**Have you been seen by a psychologist at home?** Yes (1) No (2) no. times ☐☐	74 75
g)	**Have you been seen by a counsellor at home?** Yes (1) No (2) no. times ☐☐	76 77
h)	**Have you been seen by a district nurse at home?** Yes (1) No (2) no. times ☐☐	78 79
i)	**Have you been seen by some other person at home?** Yes (1) No (2) no. times ☐☐	80 81
j)	**Have you received meals on wheels?** Yes (1) No (2) no. times ☐☐	82 83
8	In the last 8 weeks, have you seen anybody privately (e.g. at your expenses or through a private insurance scheme) because of your condition or other health reasons? Yes (1) No (2) **If no skip to question 10**	84
9	*Who have you seen privately?* **Fill in the second column first, then fill in each applicable row** Tick=1 No tick=2	

	(TICK ALL THAT APPLY).	How many times did this happen since in the past 8 weeks.	How much did it cost altogether? **£**		
A physiotherapist					85 86 87
A speech therapist					88 89 90
A chiropodist					91 92 93
An occupational therapist					94 95 96
An osteopath					97 98 99
					100 101 102

		A chiropractor					103 104 105
		An acupuncturist					106 107 108
		A psychologist					109 110 111
		A counsellor					112 113 114
		A naturopathologist					115 116 117
		Other **(SPECIFY):**					
10	In the last 8 weeks, have you taken any medications because of your condition or other health reasons? Yes (1) No (2) **If no skip to question 12**						118
11	I would like to ask you some detailed questions about your medication(s). **Go to medications list on next page**						

What is the **name** of the medication and **type of preparation** (e.g. tablets, capsules, syrup, inhaler, drops etc)? *(Brand name if possible)*	What is the strength of the medication taken? *(as written on the pack)*	For how many days have you been taking this medication? *(Please ask this question even if the respondent is not taking the medication now)*	What is the dose taken in a day (e.g. number of tablets, capsules, drops or puffs of inhaler)?	Did you buy the medication over the counter? *(Please write 'yes' or 'no')*	
Example: Nurofen tablet	400mg	Five	3 tablets per day	No	119 120 121 122
					123 124 125 126
					127 128 129 130
					131 132 133 134
					135 136 137 138
					139 140 141 142
					143 144 145 146
					147 148 149 150
					151 152 153 154
					155 156 157 158
					159 160 161 162
					163 164 165 166
					167 168 169 170
					171 172 173 174
					175 176 177 178

					179 180 181 182

12	In the last 8 weeks, have you had to get any special aid/equipment (e.g. wheelchair, zimmer frame, walking stick, special shoes because of your condition or other health reasons)? Yes (1) No (2) **If no skip to question 14**	183
13	Over the last 8 weeks what type of aid/equipment did you get?	

(FILL IN THE SECOND COLUMN FIRST, THEN FILL IN EACH APPLICABLE ROW).

Tick=1 No tick=2	**Tick all that apply**	**If there was a charge how much was it? If no charge write N/A and stop here.** **£**	**If someone else paid for it how much was paid? If the patients paid the total amount write N/A and stop here.** **£**	**Who made the payment?**	
Manual Wheelchair					184 185
Electric Wheelchair					186 187
Zimmer Frame					188 189
Walking Stick					190 191
Walking Trolley					192 193
Crutches					194 195
Helping Hand					196 197
Special Clothing					198 199
Special Footwear					200 201
Sheepskins					202

					203
Mattresses					204 205
Cushions					206 207
Special Chair					208 209
Chair Raise					210 211
Bed Table					212 213
Kitchen Gadgets					214 215
Special Cutlery					216 217
Special Crockery					218 219
Feeding Tubes					220 221
Commode					222 223
Bedpan					224 225
Catheter					226 227
Incontinence aids					228

					229
Book Rests					230 231
Typewriter/ Lightwriter					232 233
Talking Books					234 235
Page turners					236 237
Alarm system (personal)					238 239
Telephone					240 241
Special telephone					242 243
Door answering unit					244 245
Door opening unit					246 247
Hearing Aid					248 249
Other …….					250 251
Other …….					252 253

Other …….					254 255

14	In the past 8 weeks have you had to make any alterations to your house because of your condition or other health reasons? Yes (1) No (2) **If no skip to question 16**	256
15	In the past 8 weeks, what type of alteration did you make?	

(FILL IN THE SECOND COLUMN FIRST, THEN FILL IN EACH APPLICABLE ROW).

	Tick all that apply	**If there was a charge how much was it? If no charge write N/A and stop here.**	**If someone else paid for it how much was paid? If the patients paid the total amount write N/A and stop here.**	**Who made the payment?**	
		£	**£**		
Bath rails					247 248
Grab rails (bath)					249 250
Special taps					251 252
Shower					253 254
Bath hoist (mechanical)					255 256
Hoist with slings					257 258
Bath seat/board					259 260
Grab rails (toilet)					261

					262
Raised toilet seat					263 264
Toilet on bedroom/ living level					265 266
Bed hoist					267 268
Bed raise					269 270
Special bed					271 272
Fracture board					273 274
Widened doorways					275 276
Banisters					277 278
Stair lift					279 280
Ramp at front/rear					281 282
Grab rails (external doors)					283 284
Other ……					285 286
Other ……					287

					288
Other ……					289 290

16	Because of your condition or other health reasons have you had to either rent new accommodation or sell your house since in the last 8 weeks? Yes (1) No (2) **If no skip to question 19**	291
17	Has this caused a financial loss to you or your family? Yes (1) No (2) If yes how much was the loss? **£……**	292 293
18	How much did it cost you to move your furniture and personal things? **£……**	294
19	In the last 8 weeks, have you moved into residential/nursing home or made use of day care centres/sitting services at home because of your condition or other health reasons? Yes (1) No (2) **If no skip to question 22**	295
	How many days in the last 2 months? *Permanently*	296
	Short stay	297
	Day care centre	298
	Sitting services	299
20	*Do you pay personally for you to stay in residential/nursing care or make* use of day care centre/sitting services? Yes (1) No (2) If no, who pays?……..	300
21	How much are your bills monthly? **£……**	301

22	In the last 8 weeks, did you have to meet any travel costs because of your condition or other health reasons (e.g. to attend clinical appointments, or to get the prescribed treatment/equipment)? Yes (1) No (2) **If no skip to question 26**	302
23	n you please provide as much information as you can about the travel	

sts you had to meet because of your condition or other health reasons?
ease include costs for return journeys).

Can you tell me how you travelled? Tick=1 No tick=2	Please tick all that apply.	**How many miles did you travel overall** *(If you can't remember exactly, can you please estimate it)*	How much did these journeys cost you **altogether**? *(If you can't remember exactly, can you please estimate it)*	
			£	**p**
By train/metro				
By bus				
By private car				
By taxi				

303 304 305
306 307 308
309 310 311
312 313 314

24 If you travelled by car, did you have to pay any tolls or parking fees? 315

Yes (1) No (2)

If no skip to question 26

25 How much did you pay for tolls or parking fees? 316

£……

26 In the last 8 weeks, did you have any other extra expenses because of your condition or other health reasons (e.g. purchase of books or videos about your condition)? 317

Yes (1) No (2)

If no skip to question 28

27 If yes, please tell me the item and how much you have spent on each item: 318

Item 1:

Description of item……

Amount spent……

319

Item 2:

Description of item……

Amount spent……

28 *In the last 8 weeks have you received any assistance at home to help in* your personal care or home care because of your condition or other 320

	health reasons? Please exclude the visits through the NHS and social services you have already mentioned earlier on. Yes (1) No (2) **If no please go to question 30**	
29	If yes, who helped you?	

	Partner/Spouse (1)	Relative (2)	Friend (3)	Nurse (4)	Paid Home carer (5)	Other e.g. grand child(6)	Other (6)	
Tick								321 Helper 1 322 Total hours 323 Cost 324 Paid by Patient – 1 Other – 2 325 Helper 2 326 Total 327 Hours 328 Cost 329 Paid by Patient – 1 Other – 2 330 Helper 3 331 Total hours 332 Cost 333 Paid by Patient – 1 Other - 2
For how long in total?								
Days								
Hours								
Minutes								
Total cost	£	£	£	£	£	£	£	
Paid by? (Tick)								
Patient								
Other (please state)								

30	Now I will ask you a few questions about your work. If you are retired, please answer these questions about your **last main** job. **If the patient has never worked please tick this box and skip to question 32** ☐ a) What is your job title? b) What do/did you actually do? c) What does the firm or organisation you work(ed) for make or do? d) Are/were you?: An employee 1 or self-employed..... 2 e) Are/were you a manager, foreman or supervisor of any kind? Yes, manager..... 1 Yes, supervisor..... 2 No, neither..... 3	Tick = 2 No tick=1 334 335 +336
31	Because of your condition or other health reasons have you done any of the following in the last 8 weeks? Gone on sick leave? 1 Gone on long-term sickness benefit(s)? ..... 2 Retired early from work? ..... 3 Given up work altogether? ..... 4 Already retired? 5	337

	None of these happened? 6	
32	Who do you live with at home? With your husband/wife or a partner ..... 1 With your children ..... 2 With your parents ..... 3 With a brother or sister ..... 4 With some other person ..... 5 No one - I live alone 6	338
33	Are you: Married or living with a partner ..... 1 Divorced or separated ..... 2 Widowed ..... 3 Single 4	339
34	Are you or your family members currently receiving any of the following allowances? Jobseeker's allowance (Ex-Unemployment benefit) ..... 01 Income support ..... 02 Working tax credit (Ex-working families tax credit) ..... 03 Statutory sick pay ..... 04 Incapacity benefit (Ex-Invalidity benefit) ..... 05 Severe disablement allowance ..... 06 Health benefits ..... 07 Attendance allowance ..... 08 Carers allowance (Ex-Invalid care allowance) ..... 09 Council tax benefit ..... 10 Housing benefit ..... 11 Disability living/allowance ..... 12 State retirement pension ..... 13 Disabled persons tax credit ..... 14 Other (*Please write in what*) ..... 15 Not receiving any.....16	340 341 342 343 345 346 347 348 349 350
35	What is your date of birth? **.....**	351
36	(Record gender of patient). Male (1) Female (2)	352

Carer questionnaire

University of Sheffield Sheffield Institute for Studies on Ageing Rehabilitation of Older Patients: day hospital compared to rehabilitation at home – HTA Project No: 97/26/01	
Carer Interview Schedule	
Patient study number	1
Interviewer (Kate=1)	2
Interview done in home(1)/hospital(2)	3
Date	4
Baseline(0)/3 months (1)/6 months(2)/1 year(3)	5

1	So, when did you start to assist Mr/Mrs (Patients name) ……..	6
2	What is your relationship to the person you are assisting? Are you: His/her spouse/partner 1 His/her child 2 His/her grandchild 3 A friend 4 A paid carer 5 Other (*please write in relationship*) 6	7

3	Which of the following **best** describes your **current** position about work? (*Please ring one number only).* Full or part time 1 Retired 2 At home and not looking for paid employment 3 (eg looking after your home, family or other dependants) Unable to work due to illness or disability 4 Unemployed and looking for work 5 Other *(please write in*) 6 **……..**	8
4	Now I will ask you a few more detailed questions about your work. If you are not working at present for any reason, can you please tell me about your last main job. **If the carer has never worked, please tick this box and go to Q15** ☐ How many hours do you/did you work? ☐☐ hours per week	9 10
a)	How many hours do you/did you work? **……..**hours per week	11
b)	Can you please tell me your job title? **……**	12
c)	What do/did you actually do? **……**	13
d)	What does the firm or organisation you work(ed) for make or do? **……**	14
e)	Are/were you? An employee 1 or self-employed 2	15
f)	Are/were you a manager, foreman or supervisor of any kind? Yes, manager 1 Yes, supervisor 2 No, neither 3	16
5	In the past 8 weeks, have you been in paid employment/self employment at all? Yes 1 No 2 **If no skip to Q10**	17

6	In the past 8 weeks, have you taken any time off work as a carer *(eg to look after* *him/her at home or to accompany them to the doctor or hospital*)? Do not include times when you took work home or made up the time later. Yes 1 No 2 **If no skip to Q10**	18
7	How many days or hours did you take **altogether** in that time? Days/hours……	19
8	Did you lose any pay while off work in that time? Yes 1 No 2 If no, skip to Q10	20
9	Can you tell me the amount of earnings that you lost? £……..	21
10	In the past 8 weeks has your work situation been affected in any way because of your role as a carer (including changes due to an improvement in their condition)? *(please ring all that apply)* No, no effect on my work at all 1 **Skip to Q15** I took some time off work but no other effect 2 Yes, I have not been able to work at all 3 Yes, I stopped working and haven't started again 4 Yes, I was not working but I am now 5 Yes, I changed the type of job or tasks I do 6 Yes, I changed my place of work 7 Yes, I changed the number of hours I work 8 Yes, I retired early from work 9 Paid as carer for patient 10 Other *(please write in what)* 0 ……	22
11	In the past 8 weeks has there been any change in your earnings from paid or self-employment because of your role as a carer? Yes, earnings have changed 1	23

	No, no change 2 **If no, skip to Q13**	
12	If your earnings have changed:	
a)	What were your earnings before the change? *(please give the amount before tax)* £…… ***Per (please circle) week /month /year***	Work out and record total for year 24
b)	b)What are your earnings now? *(please give the amount before tax)* £…… Per (please circle) week /month /year	Work out and record total for year 25
c)	Was the change in your earnings due to: A change in the number of hours you work 1 An increase in your wage 2 A decrease in your wage 3 Loss of a job 4	26
13	In the past 8 weeks, has there been any change in the number of hours you work because of your role as a carer? Yes 1 No 2 *If no, skip to Q14*	27
a)	How many hours per week were you working before the change? ……	28
b)	How many hours per week are you working now? ……	29

14	In the past 8 weeks have you been unemployed at any time because of your role as carer? *Please include all times when you were not working even if you were not eligible for unemployment benefits.* Yes 1 No 2 **If no, skip to Q15**	30
a)	**If yes,** altogether, how many days were you unemployed in that time? ……	31
b)	**And** what were your earnings before you lost or gave up work? £ Was that per … *(please circle the one that applies)* week month year 1 2 3 (Work out and record per year)	32

15	How many hours per week do you usually assist Mr/Mrs……. **……..**	33
a)	What would you have otherwise been doing normally if you were not assisting Mr/Mrs……..? Housework…… 1 Caring for children……2 Caring for an adult friend/relative……3 Voluntary Work……..4 Leisure Activities……5 Attending school/college/university…….6 On sick leave……..7 Working…….. 8 Other……9 Don't know……10	34
16	Are you: Married or living with a partner 1 Divorced or separated 2 Widowed 3 Single 4 17. What is your date of birth? ☐☐ ☐☐ ☐☐ ..... **day** **month** **year** ..... 18. Is there anything else you would like to tell me about the condition of the person you are assisting, any related costs you have had to meet, or this interview?	

TOMS

Therapy Outcome Measures Data Collection Sheet

Therapist identity/code:
Patient Identity:
(Name or Code Number)
N.B. This information is for local use and will be removed before the Data Sheet leaves the Trust

Employing Authority:_____Enter Authority_____

Locality:___Enter place/s treated___

Profession: Speech and Language Therapy, Physiotherapy, Occupational Therapy

Patient/Client Details
Age at Entry
Date of Birth : ____/____/_____ **Carer :_____**(person rated)
dd mm yyyy

Aetiology Code 1: _____ _____ **Disorder Code 1 : _____ _____**
number letter number letter
Aetiology Code 2: _____ _____
number letter **Disorder Code 2 : _____ _____**
number letter

Ratings

Code*	Impairment Code 1	Code 2	Activity	Social Participation	Well-being Patient	Carer	Date Rated
A-							
I-							

* A = Admission to therapy, First rating: I = Intermediate ratings (when placed at the first entry it denotes previous interventions from therapy) F= Final rating.

Number of Contacts :_____ **Total time:** _____hrs_____mins **Discharge Code _____**
Use R0 not if analysing rating but case is not discharged

Comments:_____
_____
_____
_____
_____
Please send this form to your key worker for checking and data entry.

Tom Core Scale

Use 0.5 to indicate if patient is slightly better or worse than a descriptor.

Impairment

0 The most severe presentation of this impairment.
1 Severe presentation of this impairment.
2 Severe/moderate presentation
3 Moderate presentation
4 Just below normal/mild impairment
5 No impairment

Activity

0 Totally dependent/unable to function
1 Assists/co-operates but burden of task/achievement falls on professional or caregiver.
2 Can undertake some part of task but needs a high level of support to complete
3 Can undertake task/function in familiar situation but requires some verbal/physical assistance
4 Requires some minor assistance occasionally or extra time to complete task
5 Independent/able to function

Participation

0 No autonomy, isolated, no social/family life
1 Very limited choices, contact mainly with professionals, no social or family role, little control over life
2 Some integration, value and autonomy in one setting.
3 Integrated, valued and autonomous in limited number of settings.
4 Occasionally some restriction in autonomy, integration or role.
5 Integrated, valued, occupies appropriate role

Wellbeing/Distress

0 **Moderate frequent**: upset/frustration/anger/distress/embarrassment/concern/withdrawal.
Controls emotions with assistance, emotionally dependant on some occasions, vulnerable to change in routine etc, spontaneously uses methods to assist emotional control.

4 **Mild occasional**: upset/frustration/anger/distress/embarrassment/concern/withdrawal.
Able to control feelings in most situations, generally well adjusted/stable (most of the time/most situations), occasional emotional support/encouragement needed.

5 **No inappropriate**: upset/frustration/anger/distress/embarrassment/concern/withdrawal.
Well adjusted, stable and able to cope with most situations, opportunity to self-analyse, accepts and understands own limitations.

1 **Severe constant**: upset/frustration/anger/distress/embarrassment/concern/withdrawal.
High and constant levels of concern/anger/severe depression or apathy, unable to express or control emotions appropriately

2 **Frequently severe**: upset/frustration/anger/distress/embarrassment/concern/withdrawal.
Moderate concern, becomes concerned easily, requires constant re-assurance/support, needs clear/tight limits and structure, loses emotional control easily.

3 **Moderate consistent**: upset/frustration/anger/distress/embarrassment/concern/withdrawal.
Concern in unfamiliar situation, frequent emotional encouragement and support required.

Appendix 2

Supplementary analyses

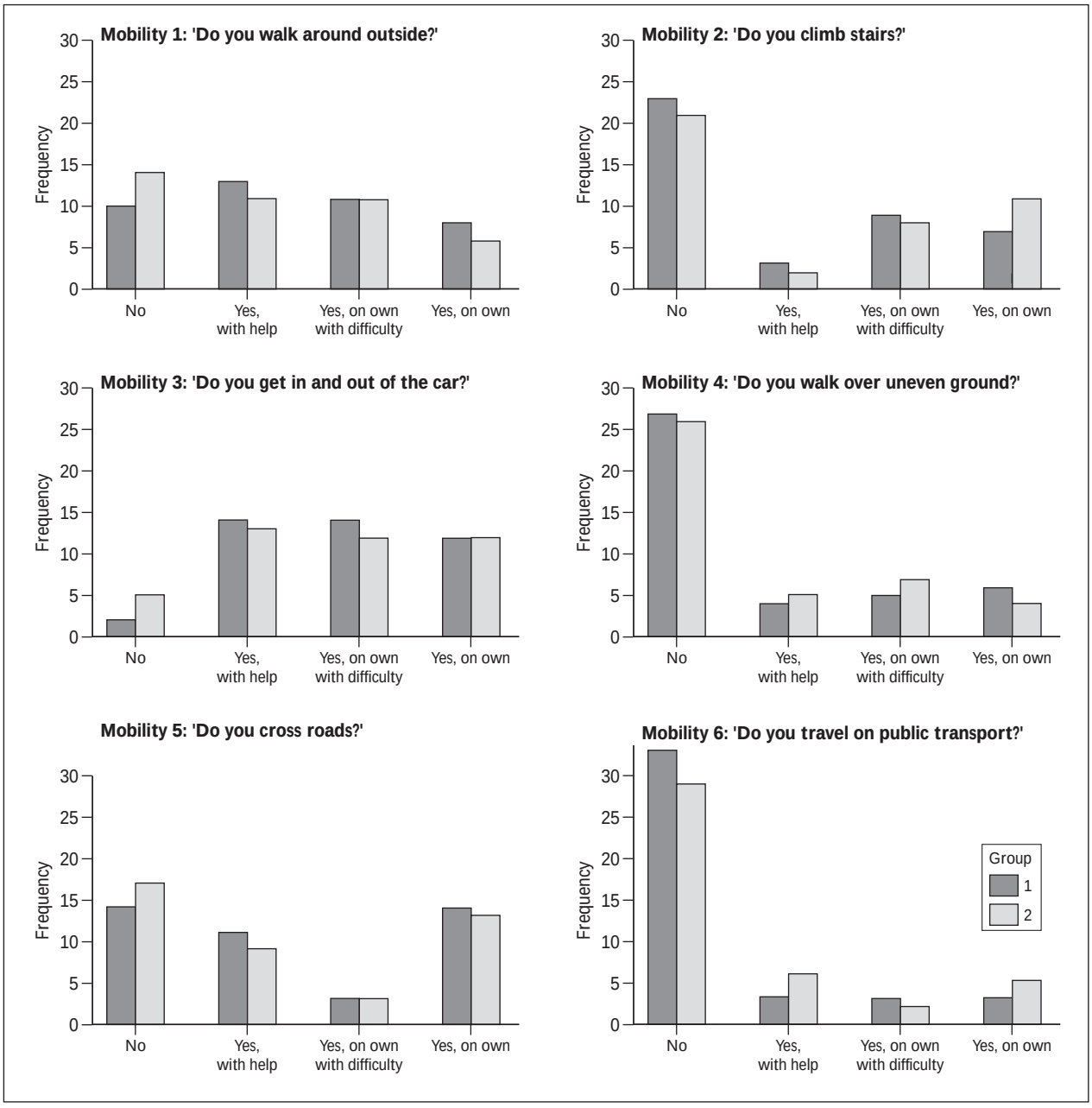


FIGURE 15 Frequency of item responses by randomisation group (group 1: day hospital rehabilitation; group 2: home-based rehabilitation) – NEADL baseline frequency tables: mobility subscale items 1–6.

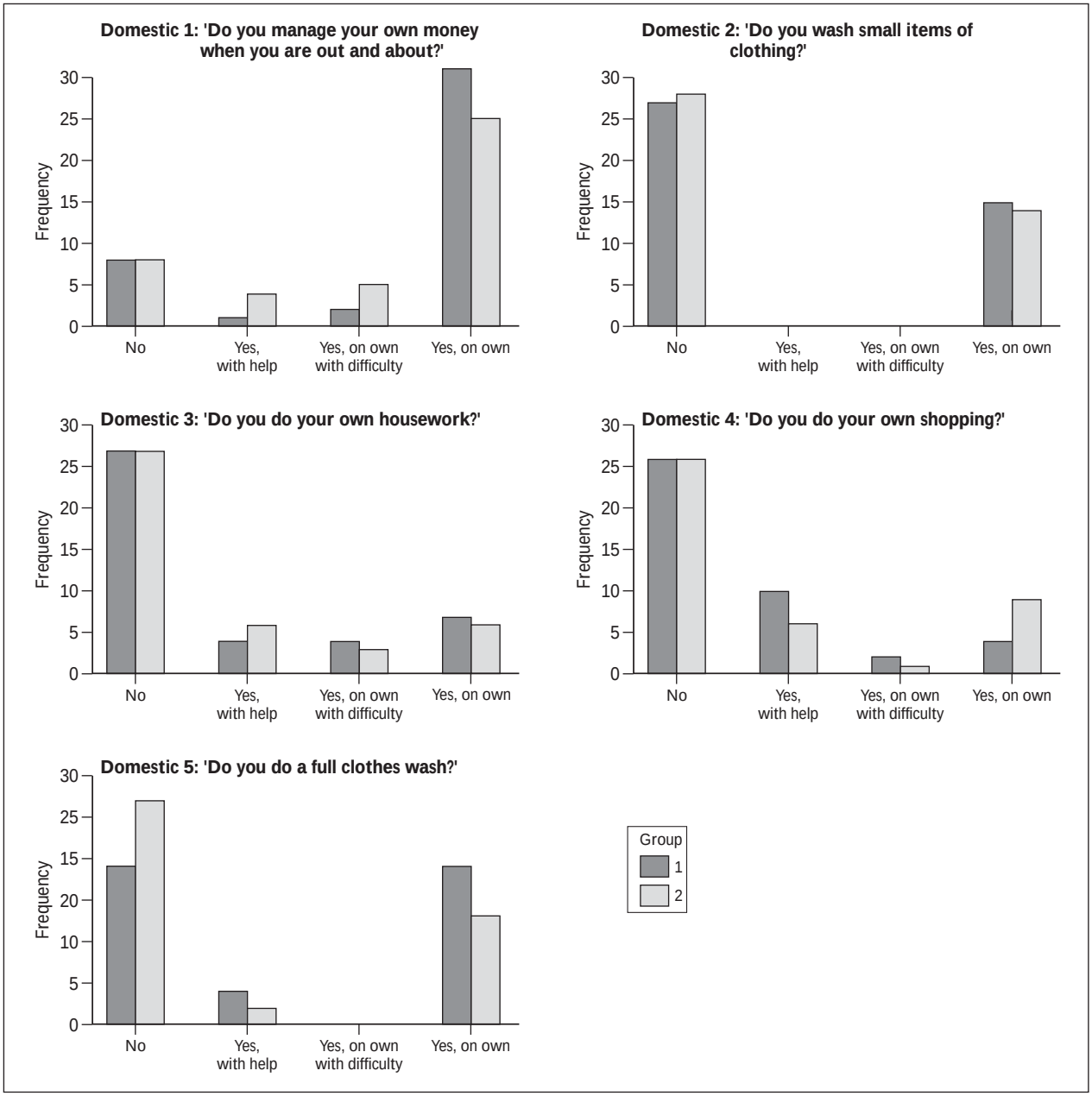


FIGURE 16 Frequency of item responses by randomisation group (group 1: day hospital rehabilitation; group 2: home-based rehabilitation) – NEADL baseline frequency tables: domestic subscale items 7–11.

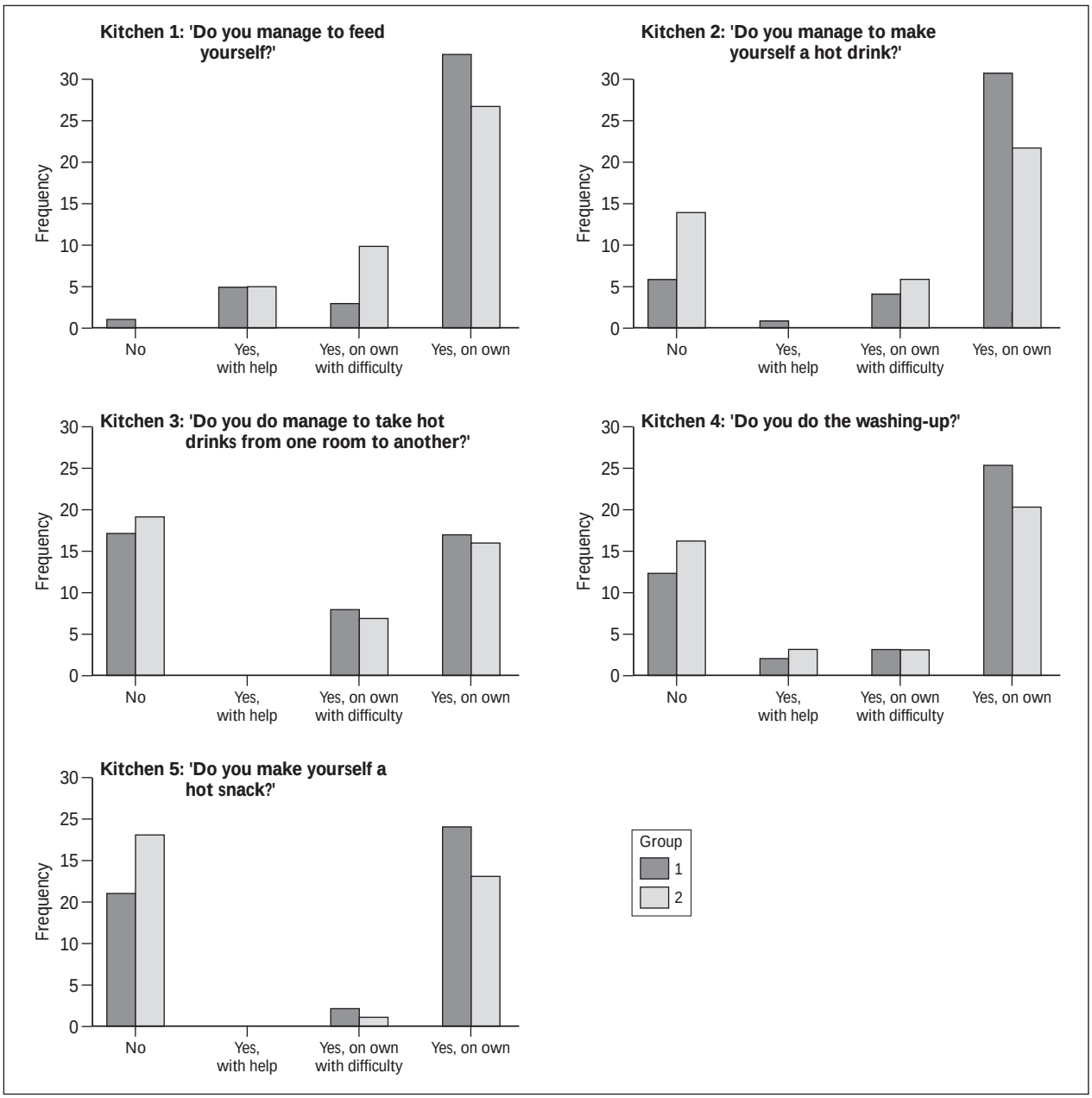


FIGURE 17 Frequency of item responses by randomisation group (group 1: day hospital rehabilitation; group 2: home-based rehabilitation) – NEADL baseline frequency tables: kitchen subscale items 12–16.

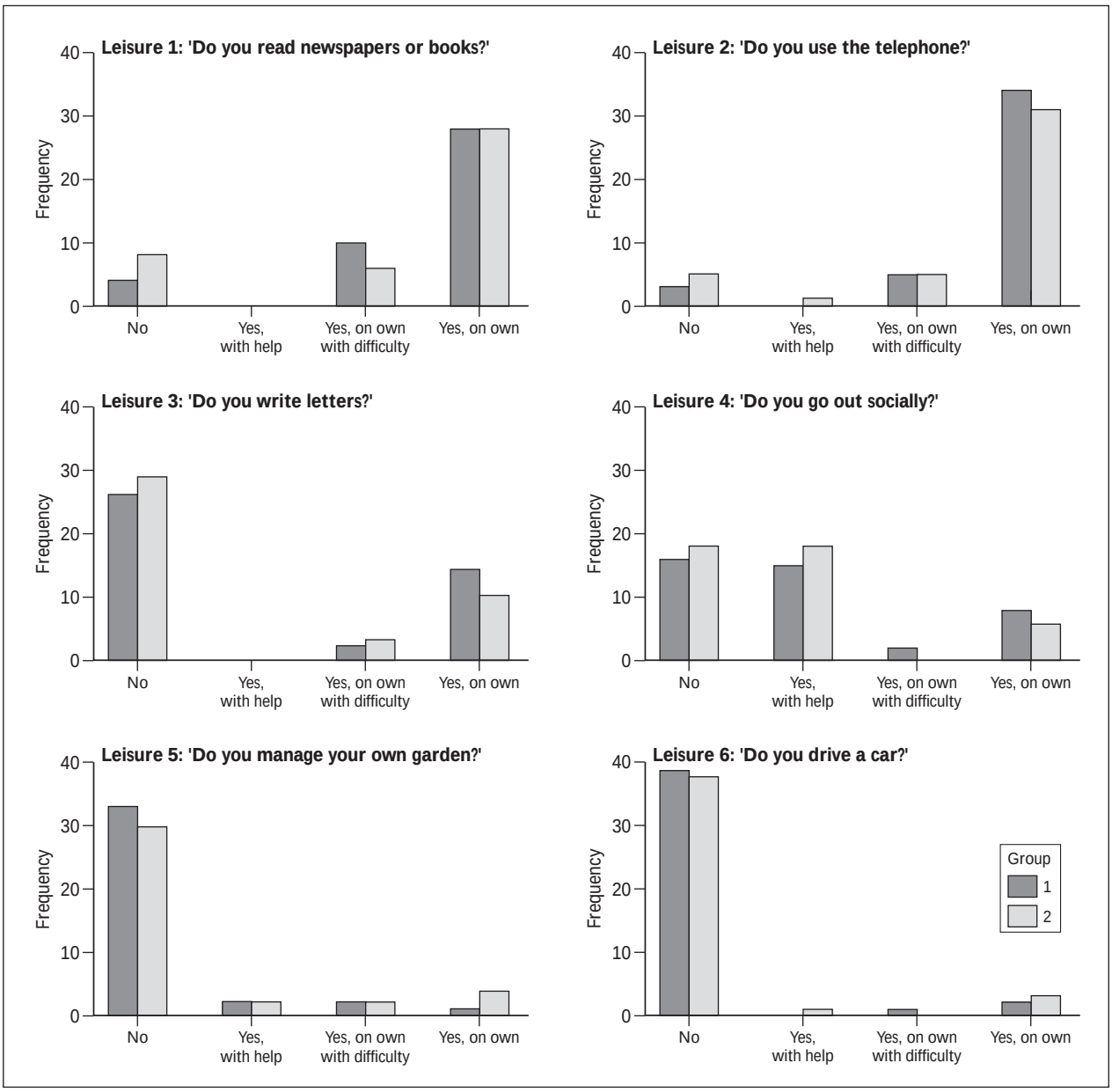


FIGURE 18 Frequency of item responses by randomisation group (group 1: day hospital rehabilitation; group 2: home-based rehabilitation) – NEADL baseline frequency tables: leisure subscale items 17–22.

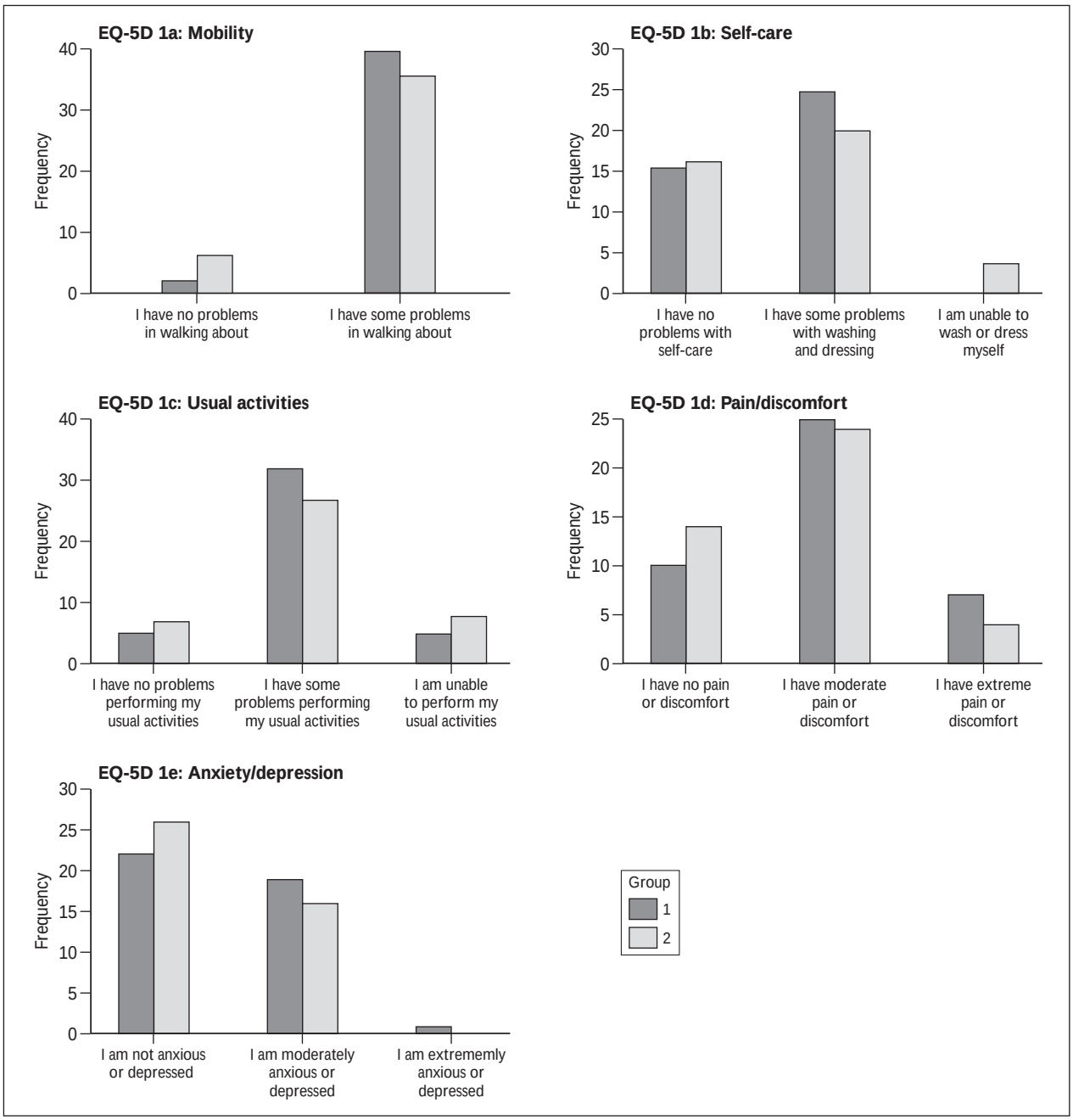


FIGURE 19 Frequency distributions for EQ-5D dimensions at baseline by randomisation group (group 1: day hospital rehabilitation; group 2: home-based rehabilitation).

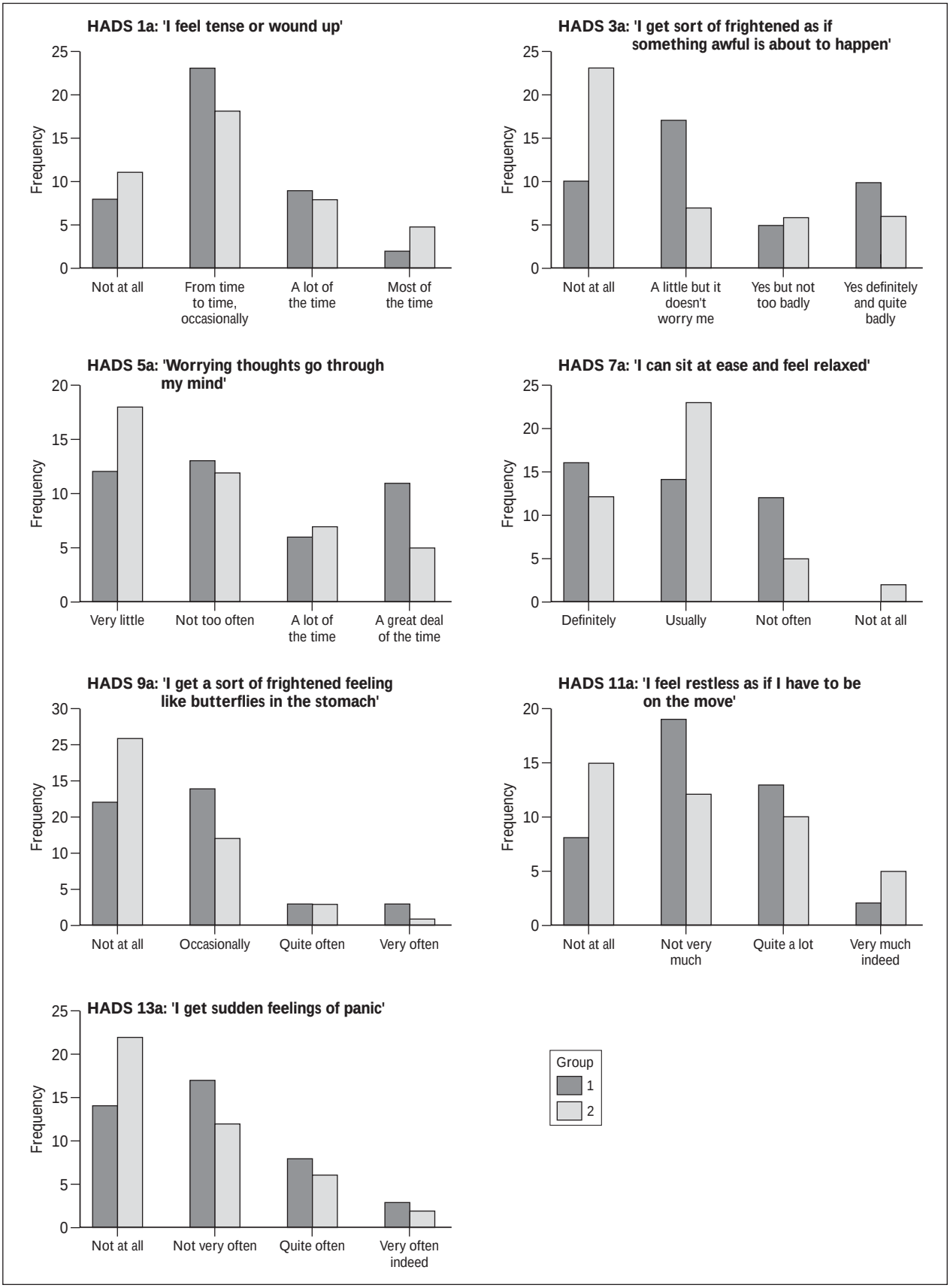


FIGURE 20 Frequency of item responses by randomisation group (group 1: day hospital rehabilitation; group 2: home-based rehabilitation) – HADS anxiety questions.

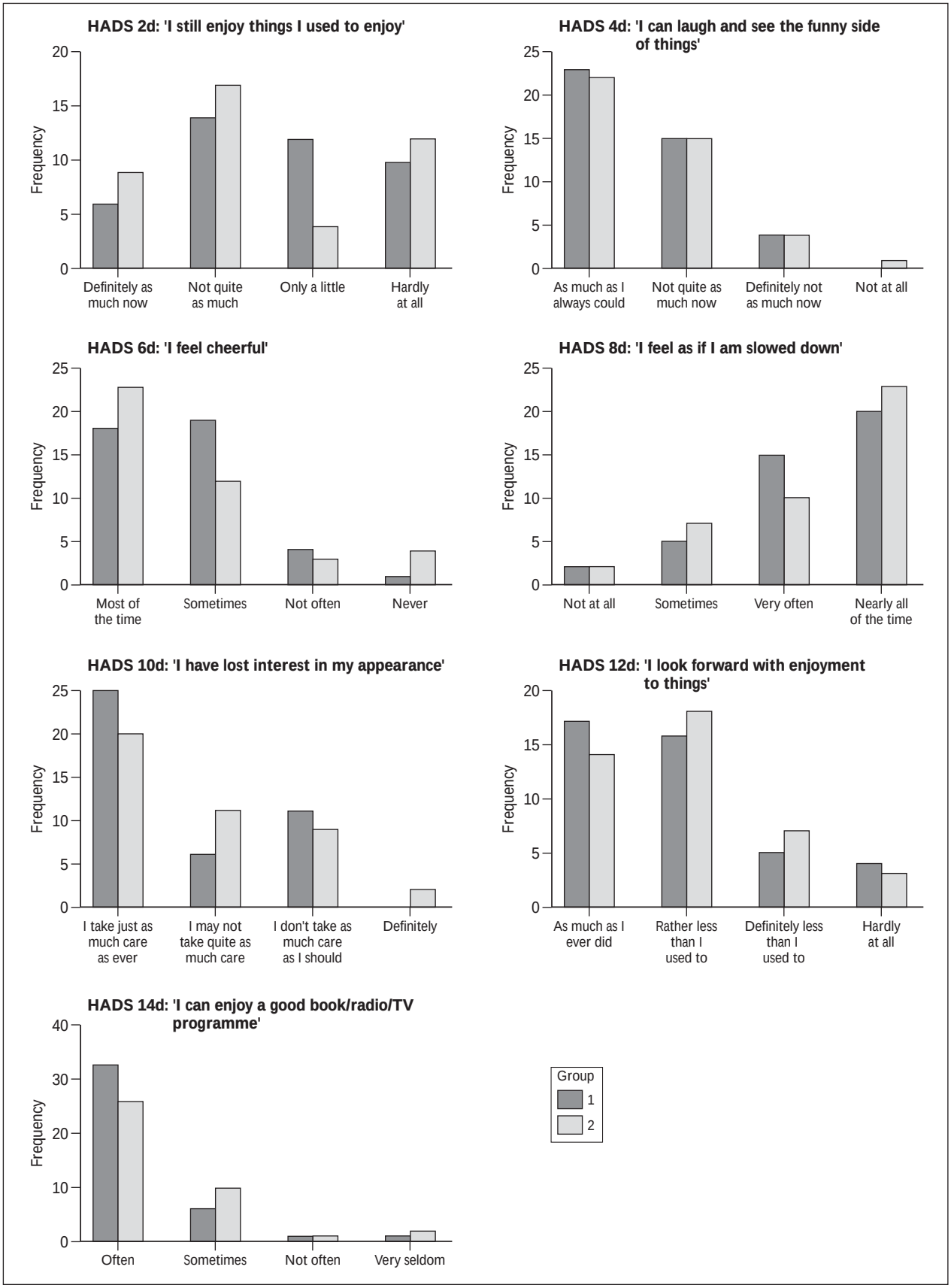


FIGURE 21 Frequency of item responses by randomisation group (group 1: day hospital rehabilitation; group 2: home-based rehabilitation) – HADS depression questions.

The University Of Sheffield. | Clinical Trials Research Unit.

Report on differences between expected and actual dates of interview from the best place of care trial, 31 July 2007

Introduction

Following a research team meeting on 18 July 2007 it was decided to investigate the extent of the delays in interviewing patients at each of the three follow-up periods with a view to making a decision about whether it would be prudent to exclude those participants with considerable delays from secondary (per protocol) analyses. This report summarises the findings from this investigation and makes recommendations about how best to proceed.

Summary of follow-up interview timings

In total, 65 interviews were conducted at 6 months' follow-up with a mean absolute difference between the actual and expected interview timings of 36 days (SD 18 days; min. 0, max. 93). This was similar at 3 months' and 12 months' follow-up (Table 57), with little difference between randomisation groups at the primary 6-month end point.

Fewer than 10% of interviews were conducted within 14 days either side of the expected interview date (Figure 22) at each time point; most took place between 30 and 44 days outside of the expected interview date.

For the most part interviews tended to take place later than expected rather than earlier than expected with a great many taking place with several weeks' delay at each given time point (Tables 58–60).

Applying an arbitrary 45-day cut-off point (approximately 6 weeks), at the primary end point (6 months), 11 participants (17%) would be excluded from subsequent analyses (five from group 1 and six from group 2). More stringent cut-offs would result in significant reductions in the size of the data set. For example, only 34% of the 6-month follow-ups fall within 29 days of the expected interview date.

Potential consequences for statistical analyses

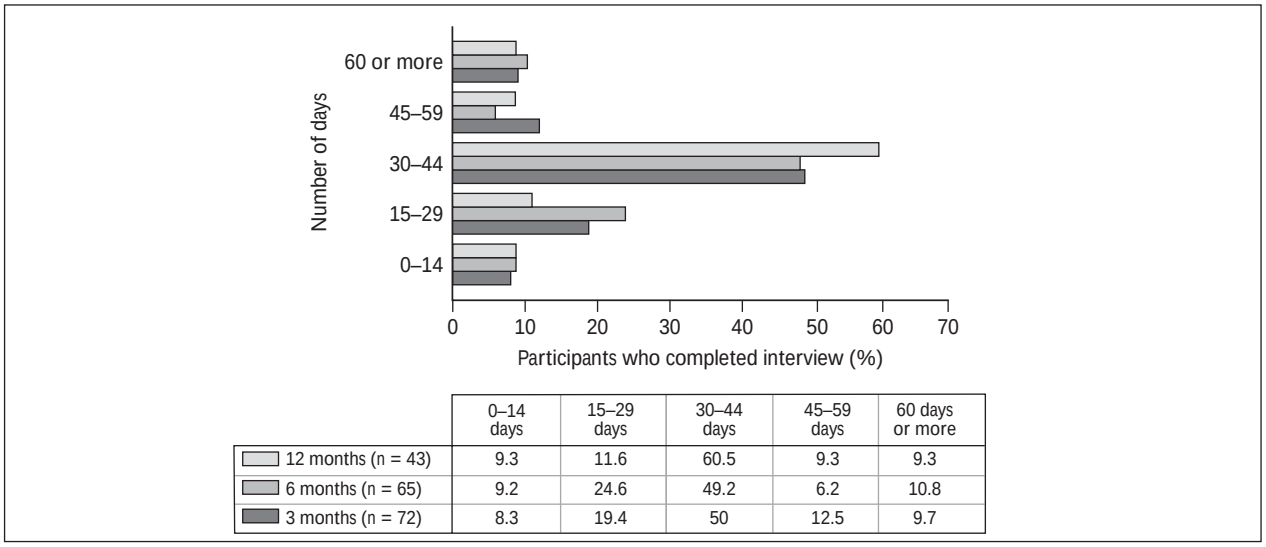
To investigate the possibility that interview delays introduce bias, the relationship between interview delay and the primary outcome measure (NEADL at 6 months) was examined by simple linear regression. There was no evidence that delays in interview at 6 months affected mean NEADL total scores at 6 months' follow-up ($\beta = 0.021$, 95% CI –0.142 to 0.185, $p = 0.794$) as illustrated in the scatter plot shown in Figure 26. There was a –5.6 point difference in NEADL total score between those who completed their 6-month follow-up interview within 44 days ($n = 54$) and those outside of this cut-off point ($n = 11$). This difference was not statistically significant ($p = 0.305$). It is also noted that there was very little difference in the mean absolute delay seen between the two randomisation groups at 6 months (Table 57).

Recommendations

This issue is generally tackled in RCTs by conducting separate analyses: an ITT analysis containing all observations and a per protocol analysis in which observations outside of a prespecified cut-off are excluded. The extent of delays in conducting 6-month follow-up interviews makes applying a stringent cut-off period difficult because it would result in per protocol analyses with very small numbers. Given this, and the lack of evidence to suggest that these delays affect outcomes, our recommendation would be to conduct the ITT analysis only but to refer to these considerations in the final report, perhaps with this document referred to and made available as an electronic reference/appendix.

TABLE 57 Mean absolute difference between expected and actual interview timings at each time point

	Mean absolute difference in days (SD) [min.– max.]		
	Group 1	**Group 2**	**Total**
3 months (n = 72)	36.43 (19.62) [0–89]	34.86 (15.57) [4–82]	35.63 (17.55) [0–89]
6 months (n = 65)	36.06 (18.63) [0–82]	35.63 (17.72) [10–93]	35.85 (18.04) [0–93]
12 months (n = 43)	41.12 (18.93) [27–107]	35.08 (15.96) [3–66]	37.47 (17.23) [3–107]



	0–14 days	15–29 days	30–44 days	45–59 days	60 days or more
12 months (n = 43)	9.3	11.6	60.5	9.3	9.3
6 months (n = 65)	9.2	24.6	49.2	6.2	10.8
3 months (n = 72)	8.3	19.4	50	12.5	9.7

FIGURE 22 Frequency of absolute differences between expected and actual interview timings .

TABLE 58 Differences between expected and actual interview dates at 3 months' follow-up

	Frequency	**Percentage**	**Cumulative percentage**
–15 days or less	1	1.2	1.4
–14 to +14 days	6	7.1	9.7
15 to 43 days	50	59.5	79.2
44 to 72 days	11	13.1	94.4
73 days or more	4	4.8	100.0
Total	72	85.7	

TABLE 59 Differences between expected and actual interview dates at 6 months' follow-up

	Frequency	Percentage	Cumulative percentage
–15 days or less	4	4.8	6.2
–14 to +14 days	6	7.1	15.4
15 to 43 days	41	48.8	78.5
44 to 72 days	10	11.9	93.8
73 days or more	4	4.8	100.0
Total	65	77.4	

TABLE 60 Differences between expected and actual interview dates at 12 months' follow-up

	Frequency	Percentage	Cumulative percentage
–15 days or less	2	2.4	4.7
–14 to +14 days	4	4.8	14.0
15 to 43 days	29	34.5	81.4
44 to 72 days	7	8.3	97.7
73 days or more	1	1.2	100.0
Total	43	51.2	

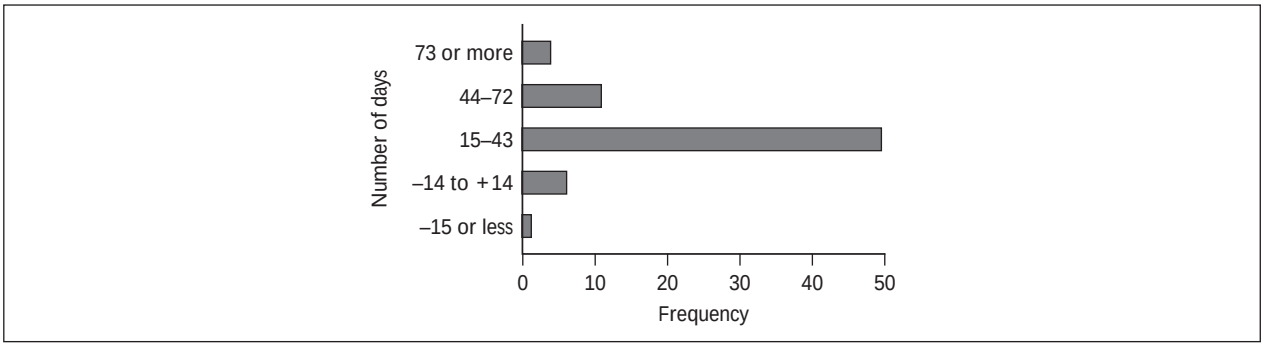


FIGURE 23 Distribution of number of days between actual and expected 3-month interview date (n = 72).

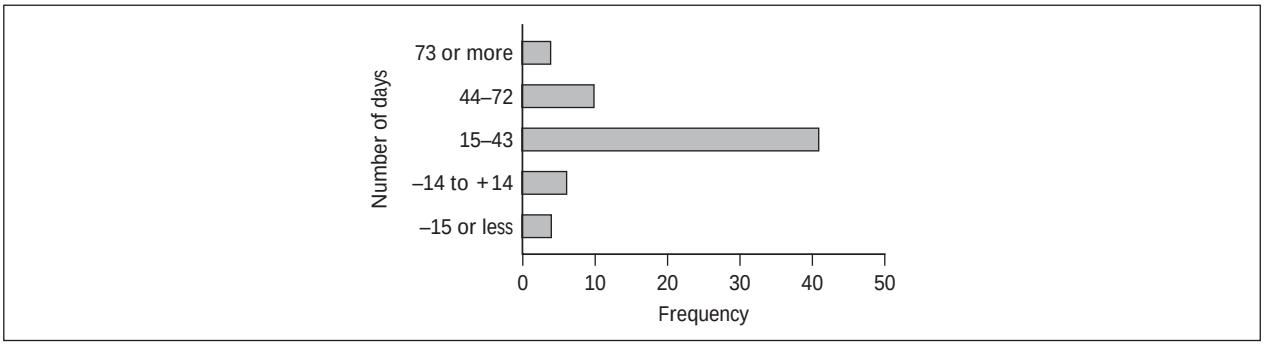


FIGURE 24 Distribution of number of days between actual and expected 6-month interview date (n = 65).

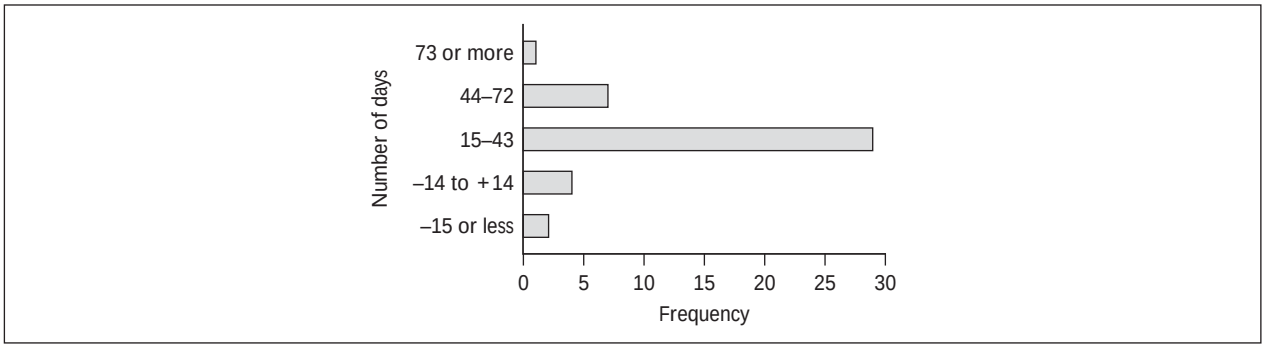


FIGURE 25 Distribution of number of days between actual and expected 12-month interview date (n = 43).

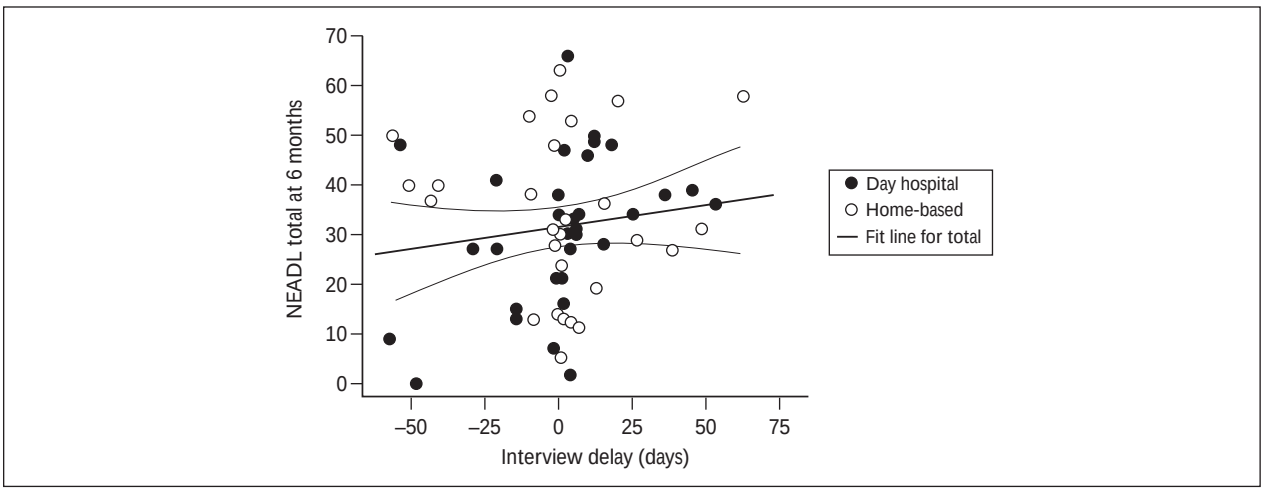


FIGURE 26 Scatter plot of interview delay versus NEADL total score at 6 months.

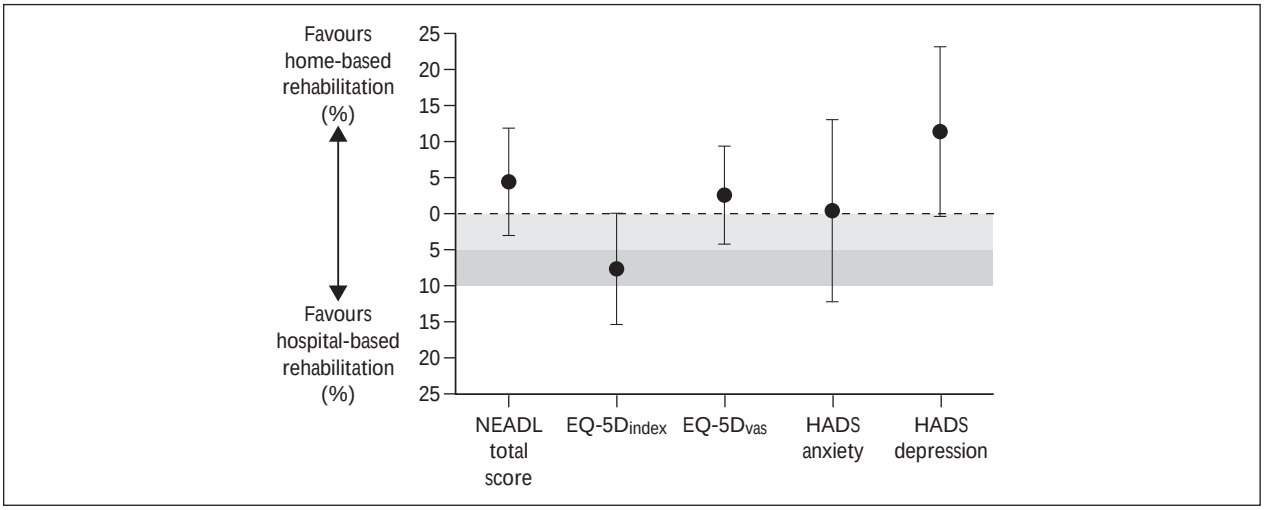


FIGURE 27 Outcomes at 3 months expressed as a percentage of scale range (n = 35 vs n = 37).

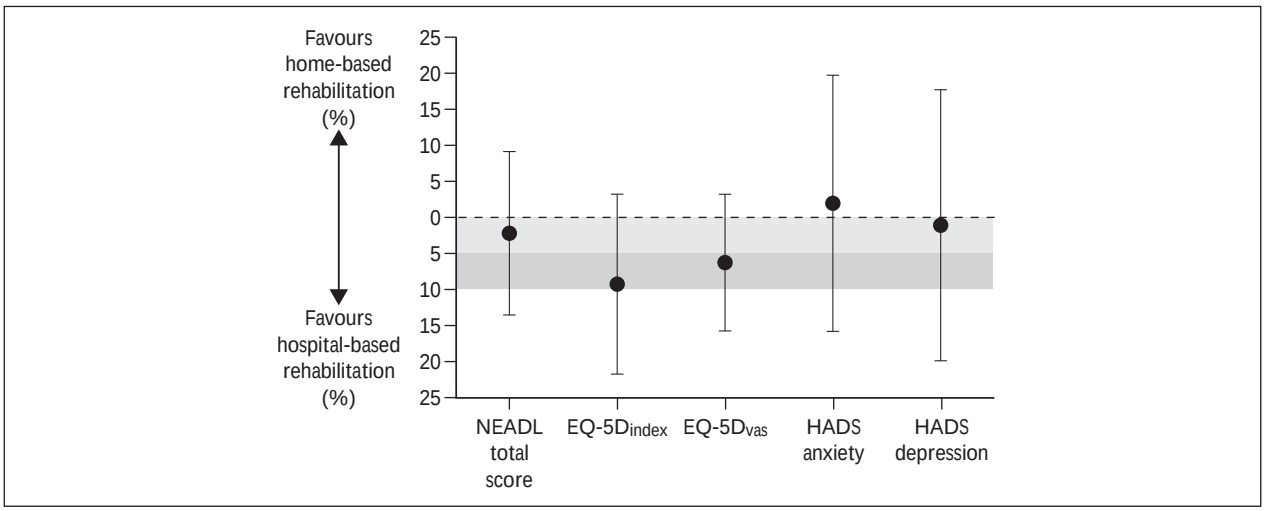
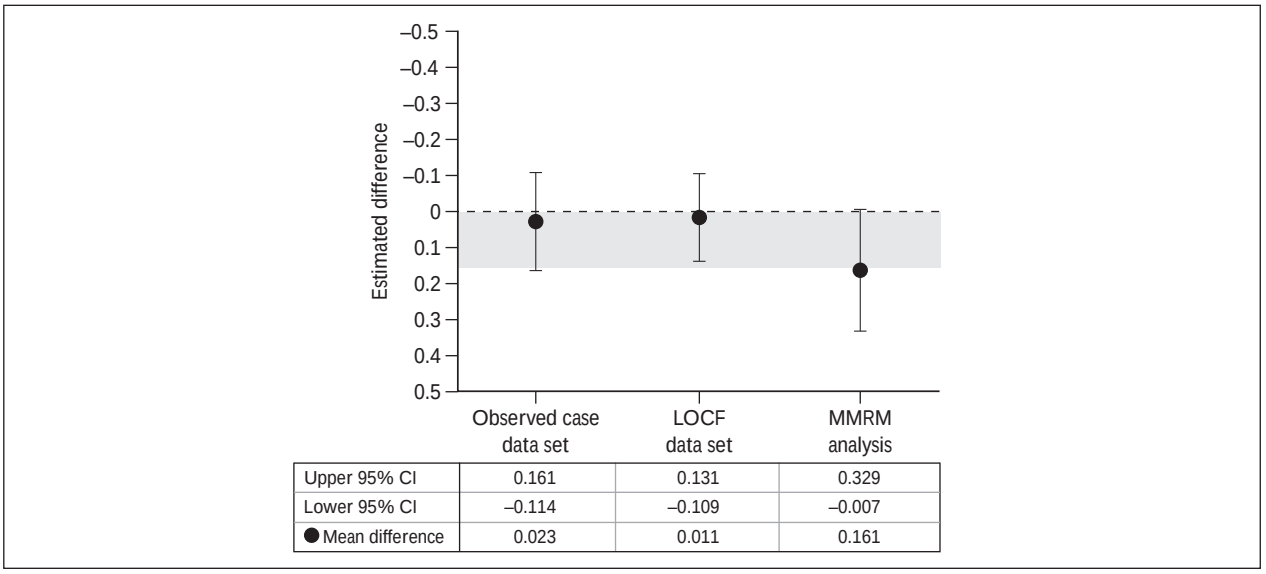
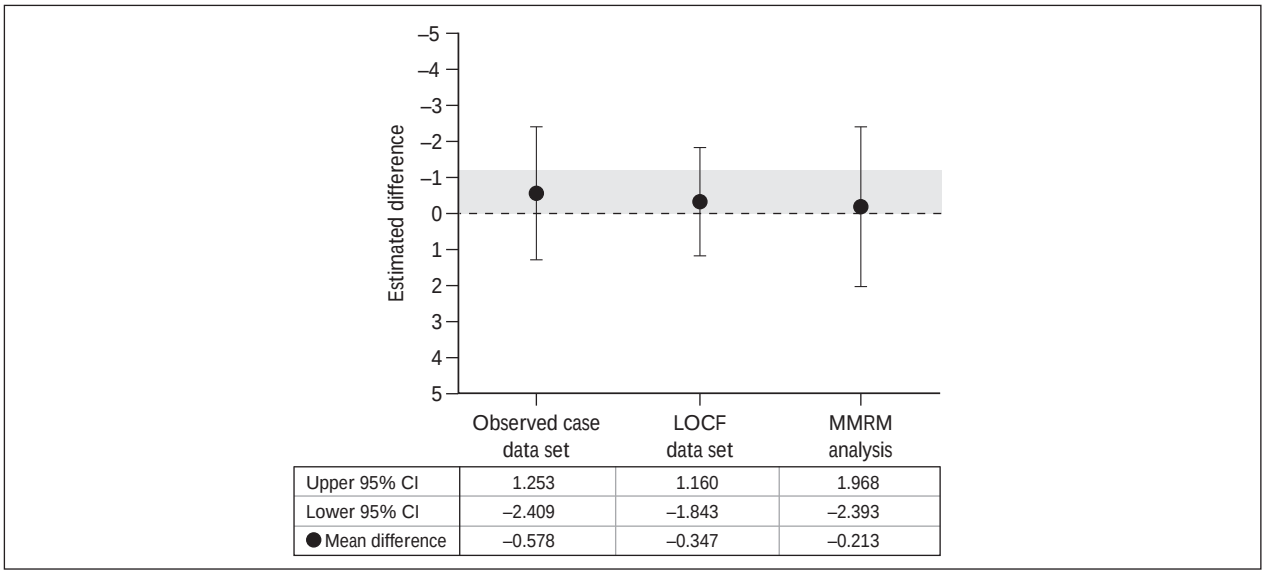


FIGURE 28 Outcomes at 12 months expressed as a percentage of scale range (n = 17 vs n = 26).



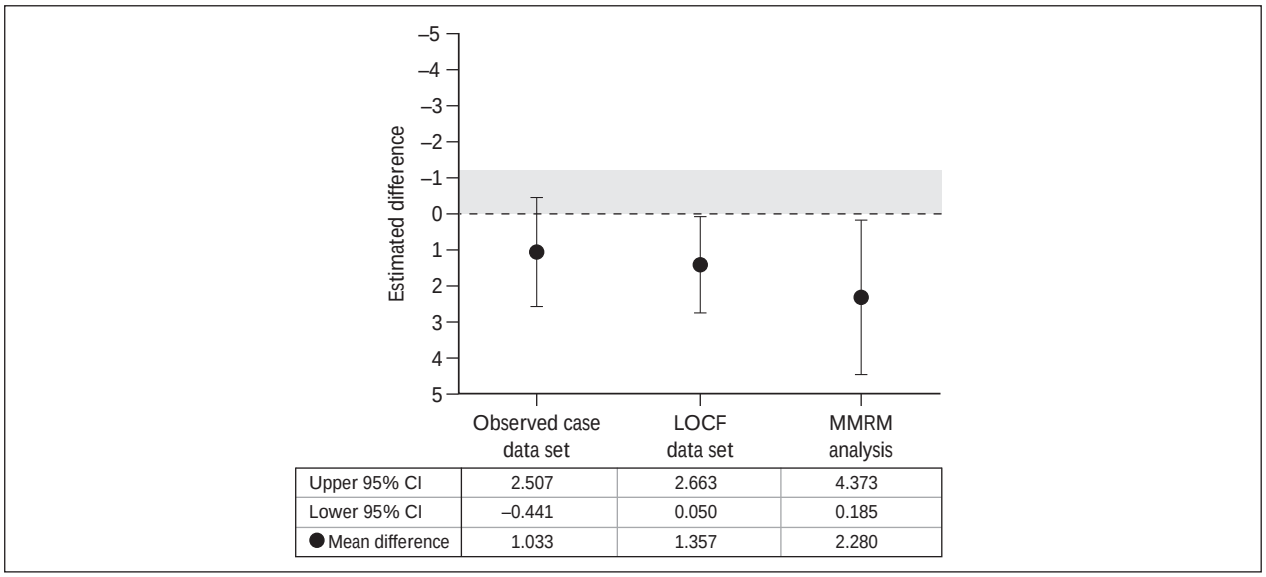
	Observed case data set	LOCF data set	MMRM analysis
Upper 95% CI	0.161	0.131	0.329
Lower 95% CI	–0.114	–0.109	–0.007
● Mean difference	0.023	0.011	0.161

FIGURE 29 Estimated difference in EQ-5D$_{index}$ scores at 6 months between day hospital rehabilitation (DHR) and home-based rehabilitation (HBR) using different statistical approaches.



	Observed case data set	LOCF data set	MMRM analysis
Upper 95% CI	1.253	1.160	1.968
Lower 95% CI	–2.409	–1.843	–2.393
● Mean difference	–0.578	–0.347	–0.213

FIGURE 30 Estimated difference in HADS anxiety scores at 6 months between day hospital rehabilitation (DHR) and home-based rehabilitation (HBR) using different statistical approaches.



	Observed case data set	LOCF data set	MMRM analysis
Upper 95% CI	2.507	2.663	4.373
Lower 95% CI	–0.441	0.050	0.185
● Mean difference	1.033	1.357	2.280

FIGURE 31 Estimated difference in HADS depression scores at 6 months between day hospital rehabilitation (DHR) and home-based rehabilitation (HBR) using different statistical approaches.

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A double-blind randomised placebo-controlled trial of topical intranasal corticosteroids in 4- to 11-year-old children with persistent bilateral otitis media with effusion in primary care.
By Williamson I, Benge S, Barton S, Petrou S, Letley L, Fasey N, et al.

No. 38
The effectiveness and cost-effectiveness of methods of storing donated kidneys from deceased donors: a systematic review and economic model.
By Bond M, Pitt M, Akoh J, Moxham T, Hoyle M, Anderson R.

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We look forward to hearing from you.

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