Rehabilitation aimed at improving outdoor mobility for people after stroke: a multicentre randomised controlled study (the Getting out of the House Study)

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Scientific summary

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Background

Impaired mobility affects half of all stroke patients, with one-third still being dependent on others to get outside 6 months after stroke. As a result, stroke patients become housebound, leading to increased immobility, poor health, isolation and misery. This diminution of quality of life provides the justification for an intervention aimed at enhancing outdoor mobility for those with mobility restrictions.

Stroke guidelines do not contain evidence-based recommendations to treat patients who have outdoor mobility limitations. In the UK, the routine care for outdoor mobility limitations is provision of leaflets and verbal information. A Cochrane review concluded that the passive provision of leaflets is not effective.

An outdoor mobility intervention for people with stroke was developed and evaluated in a single-centre pilot randomised controlled study. This pilot study found clear benefits in people who received the intervention, with 65% being able to get out of the house as much as they wished compared with 35% in the control group. In addition, the participants who received the intervention took significantly more journeys.

Aim

Although the intervention and its components in relation to the care pathways and social and health contexts were well developed, it was not clear whether:

1. the benefits could be replicated by other therapists across the health system
2. the intervention could improve health-related quality of life
3. such an approach was cost-effective.

Design

A multicentre, multitherapist, multisetting, parallel-group randomised controlled study [randomised controlled trial (RCT)] with economic evaluation and nested qualitative study. Randomisation was provided by the Nottingham Clinical Trials Unit (NCTU). The groups were compared at 6 and 12 months, accounting for baseline differences and adjusting for the multiple membership random effects caused by having numerous therapists delivering the intervention in several sites. The incremental cost-effectiveness of the intervention compared with control, was analysed using a UK NHS and Personal Social Services (PSS) perspective. Qualitative interviews were completed with a subset of intervention participants to explore feelings of confidence.

Setting

The study was conducted within the stroke pathway in 15 NHS stroke services throughout England, Scotland and Wales.

Participants

People who had experienced a stroke were identified between November 2009 and August 2011 through general practices, primary care therapy teams, community stroke teams or outpatient clinics. Overall, 11,126 patient invitations were sent, with 1448 (13%) interested people replying. Research assistants contacted respondents to arrange 852 (8%) baseline visits.

People were eligible if they provided written informed consent, were > 18 years old, had a stroke at least 6 weeks previously and wished to get out of the house more often. People were not eligible if they were not able to comply with the protocol and therapy programme or if they were in active rehabilitation.

In total, 568 invited people (5.1%) were eligible to take part and were randomly allocated to the rehabilitation intervention group (287) or control group (281). Participants ranged in age from 32 to 96 years [mean of 71.6 years, standard deviation (SD) 12.1 years] and the time since stroke was from 2 to 479 months (mean of 40 months, SD 52.7 months). Overall, 253 (44%) were men and 315 women (56%). Ten intervention participants took part in the qualitative study.

Intervention and control

All participants received the control, which was verbal advice and leaflets given at the baseline assessment visit. Research assistants at each site provided a personalised pack of local travel information containing, for example, leaflets and bus timetables. The intervention group received additional face-to-face rehabilitation from NHS therapists, up to 11 times over 4 months. This was a mixture of exercise and practical activities to increase outdoor mobility; psychological interventions to improve confidence and targeted information with therapist training; and a treatment manual. Treatment fidelity was assessed by a research assistant in 10% of intervention sessions, who compared treatment records and treatment sessions with a checklist.

Main outcome measures

Outcomes were collected 6 and 12 months after recruitment and by monthly travel diaries.

The primary outcome was health-related quality of life, as measured by Social Function domain score from the Short Form questionnaire-36 items, version 2 (SF-36v2) at 6 months' follow-up. These two questions ask participants to rate their social activity away from home.

The secondary outcome measures at 6 and 12 months were (1) functional activity using the Nottingham Extended Activities of Daily Living Scale; (2) mobility using the Rivermead Mobility Index; (3) the number of journeys (travel journeys) made outside the house, using participant-completed travel diaries; (4) satisfaction with outdoor mobility using a yes/no question: 'Do you get out of the house as much as you would like?'; (5) psychological well-being using the General Health Questionnaire-12 items (GHQ-12); (6) carer psychological well-being using the GHQ-12; (7) quality-adjusted life-years (QALYs) using the European Quality of Life-5 Dimensions (EQ-5D) and Short Form questionnaire-6 Dimensions (SF-6D); (8) resource use (NHS, PSS, carer input and some patient-borne costs); and (9) participant mortality collected from NHS Information Centre (NHS-IC)/NHS Central Register.

The statistical methods of analysis were stated prior to the start of the study. All main outcomes were presented descriptively by group and then the results of the multivariable analysis adjusting for age, baseline outcome value, therapy effect and site effect were presented as differences in means for continuous data, odds ratios for binary data or rate ratios for count data (adjusted results), with 95% credible intervals as a measure of significance. The analysis was adjusted for therapist effect

and site effect, as recommended for trials of complex interventions in which one participant might receive the intervention from a number of therapists. Site and therapy effect sizes were presented for each of the outcomes, apart from travel journeys (analysed as rate ratios) for which these were not calculable.

No serious adverse events were recorded. Study-specific adverse events were collected from the intervention group: any fall that resulted in assistance of a health-care professional. In addition, all participants had the opportunity to record falls on the travel diary.

Interview study

Ten intervention participants were interviewed. A semistructured interview was used to guide a digitally recorded interview in the participants' own homes. The interviews were transcribed and analysed using interpretive phenomenology by two researchers.

Results

Follow-up rates

In total, 264 out of 287 (92%) intervention participants and 239 out of 281 (85%) control participants completed the 6-month follow-up, and 232 out of 287 (81%) intervention participants and 211 out of 281 (75%) control participants completed the 12-month follow-up. The differences in follow-up rates between the two groups did not affect the power of the study. A total of 192 carers completed the baseline assessment: 148 out of 192 (77%) completed the 6-month follow-up and 127 out of 192 (66%) completed the 12-month follow-up. Follow-up was completed in August 2012.

Characteristics of the participants

The two groups were well matched in age, ethnicity, residence, functional ability, functional ability and psychological well-being. Time from stroke to recruitment was 6 months less in the control group (mean 37 months vs. 43 months) than the intervention group and there were more men in the control group (47%) than intervention group (42.2%). Adjustment for gender had no effect on the primary outcome.

Characteristics of the intervention

In total, 29 therapists delivered the intervention a median of seven times [interquartile range (IQR) 3–11 times] per participant, with a median duration of 369.5 minutes (IQR 170–691.5 minutes). The intervention was completed satisfactorily 67.3% of the time and delivered 100% of the time according to the protocol.

Primary outcome measure

The variability of the social function score was similar in the two groups, although the mean score was slightly higher in the intervention group (47.0) at 6 months compared with the control group (43.9). The adjusted difference in means between groups was 4.630, with a 95% credible interval of –0.549 to 9.848.

Secondary outcome measures

No significant difference was observed for the secondary outcome measures at 6 or 12 months for psychological distress, activity, mobility or satisfaction with outdoor mobility (52 of the control group said 'yes', 72 of the intervention group said 'yes'). Adjusting for therapist and site effect did not affect these results. Participants in the intervention group took more journeys than the control group when the results were adjusted for therapist and site effect. Those in the intervention group were 42% more likely to make a journey than those in the control group at 6 months [rate ratio 1.42, 95% confidence interval (95% CI) 1.14 to 1.67] and 76% were more likely to make a journey at 12 months (rate ratio 1.76, 95% CI 1.36 to 1.95).

Economic evaluation

In the base-case analysis, the mean incremental cost (total NHS and PSS cost) of the intervention was £3413.75 (95% CI –£448.43 to £7121.00) with an incremental QALY gain of –0.027 (95% CI –0.060 to 0.007) according to the EQ-5D and –0.003 (95% CI –0.016 to 0.006) according to the SF-6D. Thus, the intervention was not estimated to be cost-effective compared with the control. The probability that the intervention was cost-effective, compared with the control, was 5.2% at a threshold of £20,000 per QALY (based on the EQ-5D). The sensitivity analyses support these conclusions, as the 95% CI surrounding the incremental net benefit was never wholly positive at the £20,000-per-QALY threshold.

Exploratory analysis

Effect of the control

There was very strong evidence that the control group improved markedly. At baseline 259 out of 281 (92.2%) participants were dissatisfied with outdoor mobility but at the 6-month assessment this had reduced to 78% (160/205), a 15% reduction. The corresponding reduction in the intervention group was slightly greater (18%), with 268 out of 287 (93.4%) expressing dissatisfaction with outdoor mobility at baseline and 17 out of 227 (75.5%) expressing this at 6-month assessment.

Falls

The total group had a median of three (IQR 1–6.5) falls per year. Fall rates between the control and intervention groups were the same.

Qualitative interview study

All participants said they understood the term confidence but found it difficult to describe. However, they were able to describe how loss of confidence had 'robbed them of identity', 'made them fearful', made them 'reliant on others', and that they had 'lost their role', 'lost skills' and 'felt low self-worth'.

Interviews identified that fear of falling and fear of another stroke was a huge barrier to participating in outdoor mobility. Avoidance behaviours further limited competence and confidence in these activities. Confidence appeared to have a temporal component and increased confidence in one domain impacted on other areas. Meaningful roles, such as, gardener, cook or driver, or engagement in replacement roles such as volunteer or card maker, were associated with a positive increased confidence. Social confidence, fear of social interactions and stigma were identified as leading to a poor psychosocial outcome.

Discussion

Main findings

An intervention provided by NHS therapists to improve outdoor mobility neither improved health-related quality of life (social function) or any other health outcomes measured nor did it prove more cost-effective than the control intervention. There was strong evidence that some participants were able to make significantly more journeys and that personalised outdoor mobility information and self-completed daily travel diaries could improve satisfaction with outdoor mobility (SWOM). Stroke patients wish to improve their confidence.

We conclude that at present the intervention evaluated in this study does not improve outdoor mobility for all stroke patients. However, the provision of personalised information and monthly diaries should be considered for all people who wish to get out more and some patients could increase their outdoor mobility through face-to-face intervention sessions from therapists with certain skills.

Research in context to other studies

There is only one study to which we can compare the results. This was the single-centre study on which this multicentre study was based. The intervention provided in the multicentre study was similar in number and duration to that in the single-centre study [median of six sessions (IQR 4–6 sessions), duration 240 minutes (IQR 180–310 minutes)] but was delivered by 29 therapists over 15 sites instead of one therapist in one site. The participants were similar in age. The two studies differed in two areas. Control-group participants in the present study were provided with personalised outdoor mobility information and monthly travel diaries. This was an augmented version of that provided in the single-centre study and completely different to routine care late after stroke, which would be no intervention. The second difference was participants in the single-site study were 1 year after stroke, whereas participants in the present study were 3.5 years after stroke.

Strengths and limitations

Strengths

Recruitment rates were consistent over the duration of the study, the target sample size was reached, participant retention rates were high, eligibility criteria was inclusive and the intervention was delivered in a pragmatic manner by NHS therapists in numerous locations, making the results generalisable across the UK.

A strength was that the sample size and between-group comparisons were analysed using a therapist and site adjustment. This type of analysis is not yet routinely used but is recommended for this type of trial. We accept that the only one secondary outcome became significantly in favour of the intervention when the adjustment was applied, so the results need to be read with caution.

Limitations

A limitation of this study was that the control participants were inadvertently provided with an intervention that may have affected a change in the SWOM scores.

Another limitation was that no process evaluation was completed to let us understand how some therapists were able to increase journeys.

Clinical implications

- Stroke patients are not getting out of the house as much as they would like.
- An outdoor mobility intervention can be delivered by NHS occupational therapists and physiotherapists at a range of geographical locations.
- There was no observed improvement in health-related quality of life (social function), psychological distress and functional activity in the intervention group over the control group.
- The intervention was not cost-effective compared with control.
- Some therapist/participant combinations are more successful than others.
- The provision of information and the daily completion of travel diaries improved participant SWOM.
- Outdoor mobility does not cause falls.
- Loss of confidence can affect outdoor mobility.

Research implications

- Recruitment, retention and follow-up rates provide evidence that high-quality stroke rehabilitation research can be completed.
- Multicentre studies of rehabilitation interventions are possible.
- Stroke patients are able to successfully complete outcome assessments and monthly travel diaries.
- Using data adjustments for therapist and site effect needs further exploration.
- The control intervention needs evaluation.
- The relationship between number of journeys and quality of life needs examining.

Trial registration

This study is registered as ISRCTN58683841.

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