PB-PG-0214-33076 – NIHR Research for Patient Benefit Programme – Final report

Project title: Does early targeted trunk training improve mobility outcome at 6 months for patients who are unable to sit unsupported at admission? A mixed method feasibility study

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Plain language summary

Many people after stroke report considerable difficulties with moving about within their home and outside environments and this continues to be an area of concern for many years. Given that trunk function is a good predictor of mobility outcomes, directing more therapy at the trunk early after stroke could improve rehabilitation outcomes. The aim of this study was to investigate the possibility of providing additional trunk training (ATT) during early post stroke rehabilitation and to determine if the ATT was acceptable to people with severe trunk weakness, their carers and physiotherapists. Twenty-one (21) adults with inability to sit independently for 30 seconds after the third day of stroke and who were well enough to participate were recruited from 5 NHS hospitals. They were given ATT in addition to usual stroke rehabilitation during in-hospital rehabilitation.

We found that 1 in 5 stroke patients admitted had severe trunk weakness. While only a quarter of these individuals were suitable, the majority of them were willing to join the study. Delivering ATT was challenging due primarily to the limited capacity of the physiotherapists to deliver the additional intervention and patient related issues such as excessive fatigue. Nevertheless, two-thirds of participants in the study completed more than a quarter of the planned dose of ATT. Large improvements were seen in individuals' use of the trunk, their mobility and quality of life after ATT, similar to findings in people with less severe trunk weakness in previous studies.

The participants, their carers, and physiotherapists found ATT to be beneficial and acceptable as an intervention. They also reported the assessment outcomes were appropriate and not burdensome. Physiotherapists expressed that they would be unwilling to withhold ATT intervention, if their patient was in a control group as they considered it to be beneficial. Participants also felt that they would be unhappy if they were randomised to a control group.

This study has shown that ATT is an acceptable intervention and that participants are willing and able to be recruited. However, there is a need to modify the recruitment criteria to ensure that more individuals who have severe trunk weakness can be included in a future trial. Secondly, the willingness of people to be randomly allocated to different groups in a clinical trial needs to be carefully considered. Thirdly, the clinical outcomes are encouraging that large effects may be achieved.

Keywords
stroke, recovery, trunk, quality of life, mobility, cost effectiveness, rehabilitation

Summary of research findings

Stroke can cause significant long-term disability with considerable impact on independence and quality of life for both patients and their families. Previous studies have found between 20–40% of stroke survivors do not regain independence in walking ability at 6 months and this persists for many years. Individuals with stroke have also reported the loss of independence in mobility as the most disabling consequence of stroke affecting almost every aspect of their activities of daily living (ADL). The long-term impact of this on family members, friends and health and social services to support activities of daily living is also considerable. There is a body of evidence suggesting that trunk performance is a strong predictor of the functional outcome of stroke rehabilitation including mobility. This makes targeting trunk impairments during stroke rehabilitation, a potential approach for improving mobility outcomes. Recent meta-analyses have reported the beneficial effects of additional trunk training (ATT) on trunk performance, balance and mobility outcomes post stroke. In individuals with significant trunk impairments, where return to independent mobility is very poor, ATT could be very beneficial for optimising this outcome. To plan a clinical trial to investigate the efficacy and cost-effectiveness of ATT, there is a need to investigate the feasibility of conducting a randomised clinical trial and acceptability of ATT in this population of stroke patients.

Aims and Objective

To determine the:

- proportion of eligible participants and probable recruitment rate to a subsequent trial,
- amount of trunk-specific training delivered during regular rehabilitation,
- length of time and support required to deliver the ATT,
- cost associated with the delivery of ATT,
- completeness of planned dose of ATT,
- completeness of post-intervention assessments,
- variability of proposed outcome measures in this patient population,
- frequency of and type of adverse events associated with ATT,
- fidelity of ATT intervention,
- appropriateness of the proposed outcome measures,
- views of participants to determine the acceptability of ATT,
- impact of the intervention process on carers,
- experiences of physiotherapists involved in early stroke rehabilitation, in hospital or community, to gauge their willingness to recruit and randomise participants, as would be required by a future clinical trial.

Methods

This is a one group, pre-and post-clinical trial with nested qualitative explorations of the views of participants, carers, and physiotherapists. Twenty-one (21) adults within day 3 and 7 of a supratentorial or infratentorial lesion, associated with an ischaemic or haemorrhagic stroke or multiple stroke lesions, with significant trunk deficit evidenced by an inability to sit

independently for 30 seconds at day 3, able to understand and follow a one-stage command, without severe symptoms of dizziness or positional vertigo or significant pre-morbid levels of disability (Modified Rankin Score > 2) and medically stable were recruited from 5 NHS hospital sites. All participants were given up to 16 hours of ATT in addition to usual stroke rehabilitation during in-hospital rehabilitation. Feasibility outcomes on recruitment, intervention delivery and completeness of outcome measures were assessed. In addition, clinical outcome measures of Trunk Impairment Scale (TIS), Modified Rivermead Mobility Index (MRMI), Stroke Specific Quality of Life (SSQOL), Euroqol (EQ-5D) were assessed at baseline, after ATT and 6 months post-stroke. Summary statistics of mean with standard deviation were calculated for the clinical outcome measures. Participants, their carers, and physiotherapists delivering ATT were also interviewed to explore their views on the acceptability of ATT. Transcripts of interviews were analysed using a framework approach.

Key findings

In total, 578 stroke patients were screened for eligibility over a 16 months period across 5 sites, out of which 140 (22.7%) had severe trunk deficits. Of these, only 31 were eligible for recruitment into the study, implying a study eligibility rate of 5.4% across all sites. Notable reasons for exclusion from the study included pre-stroke disability (11.4%) and medical stability (11.4%). Sixty eight percent of all eligible participants consented to participate in the study. One of the participants passed away during the study due to a stroke-related event. No other adverse event was reported.

ATT was designed to deliver 16 hours (960 mins) of trunk training within 6-8 weeks. Participants spent 68 ± 37.3 days (9.7 ± 5.3weeks) in hospital after stroke and received between 0.12 and 16.25 hours (7mins and 975mins) of ATT, with an average of 8.1 ± 5.6 hours (463.2 ± 345.9 mins) delivered over an average of 5.6 weeks (range 1-15 weeks). A third of participants completed below 4 hours of ATT, 24% had between 5-8hours, 14% received 9-12hours and 13-16 hours was delivered to 29%. The main challenges affecting ATT delivery were: physiotherapy staff capacity, excessive stroke-related fatigue, and cognitive impairments. Only 4 participants received all the planned 16 hours of ATT and this was completed within an average of 28 sessions comprising 4 to 5 sessions per week. Three of these participants required some additional support during their ATT sessions but the majority (>88%) of the sessions delivered to individuals who completed more than half (8 hours) of the intended hours required no support. The qualitative exploration of the physiotherapists' views suggest that additional support was mainly required to deliver the functional aspect of ATT that was designed to provide only one third of the training with strengthening exercises for two-thirds of the training period. On average 79% of therapy time was spent on the strengthening exercises and 21% on functional exercise. The average cost of ATT intervention delivered in this study was £436.65 ± 326.06 and a typical 16-hour intervention would cost £906 per participant based on a Band 6 Physiotherapist delivering it. ATT was delivered in addition to regular post-stroke rehabilitation given by physiotherapists, of which a substantial proportion (83%) was spent on trunk related functional activities. This suggests that there is less need to provide functional exercise as part of ATT.

The mean with standard deviation (SD) of outcome measures at baseline assessment for the main outcome measures was 4.0±4.4 (TIS); 7.4±5.0 (MRMI); 104.1±33.3 (SSQOL); -0.09 ± -0.36 (EQ-5D indexed value); 43.5± 30.3 (EQ-5D-VAS). At the end of ATT, mean change

(SD) in outcome measures at post-treatment was 7.9±7.1 (TIS); 12.4±9.6 (MRMI); 26.4±19.7 (SSQOL). The changes observed at 6 months follow-up were: 6.9±7.1 (TIS); 18±13.5 (MRMI); 31.3±37.0 (SSQOL); 13.6±43.0 (EQ5D-VAS). These improvements are larger than a recent study in a similar population of patients.

Participants felt that clinical outcome measures were relevant and acceptable and there was very little missing data at all time-points. At baseline, all participants (21) were assessed for the TIS & MRMI but only 14 and 17 could be assessed for SSQOL & EQ5D (due to cognitive and communication impairments). Post therapy assessments were completed in 18 participants for TIS, MRMI and EQ5D (missing data due to death, discharge planning issues and one patient declining assessment) and only 16 completions for SSQOL. Six month follow up data were completed in 19 participants for the TIS & MRMI but only 17 and 16 were assessed for MRMI and EQ5D. Reasons for non-completion of outcomes include learning disability, anxiety, language, aphasia, death, declining to participate and medical admission. The VAS component of the EQ-5D measure was challenging to some participants and could be excluded from future studies in this population. With regards to service use, the scale was acceptable to most participants except that employment data was not relevant as most of them were either retired or have been medically retired since the stroke.

Most of the participants and their carers could identify the aims of ATT and reported improvements in general function and mobility. In addition, they acknowledged the importance of their own motivation and desire to do as much as they could to try and get back to their previous levels of functioning on the outcome of the intervention. Participants indicated an unwillingness to be in a control arm of a study that may have benefit on their recovery.

The physiotherapists involved in the trial reported that ATT was appropriate for the population being recruited and that it was generally perceived as beneficial to participants in terms of improved trunk control, sitting balance, strength and subsequent functional activities with no negative impact on rehabilitation outcomes. Other benefits also included improvements in mood, confidence, and insight.

Conclusions

22% of individuals admitted with stroke had severe trunk impairments but only 5.4% were eligible for recruitment. By amending exclusion criteria e.g. eligible MRS score of 3 and recruiting participants up to one month after stroke, the eligibility rate may be significantly increased resulting in a greater proportion of people with severe trunk impairment potentially being able to benefit from ATT. Increasing the number of participating research sites would also facilitate recruitment for a definitive trial. All these suggest feasibility of a definitive trial.

Acceptability of ATT is indicated by a high consent rate, low attrition and positive views from both participants and physiotherapists. However, careful consideration of a flexible model of delivery of ATT is needed to ensure delivery of any planned dose.

Finally the large changes in all 4 clinical outcomes after ATT at post-treatment and follow-up indicate that ATT is promising in the stroke population.

Patient and public involvement

The study had PPI involvement during the development and throughout the execution of the project. At the early stage, a two-stage consultation was completed for patient and public involvement. Four stroke survivors who met the criteria for inclusion in the proposed study at admission and who were undergoing inpatient rehabilitation at St Thomas NHS Foundation Hospital were interviewed. In addition, the proposed research questions and plans were discussed with members of the South London Stroke patients and family group (King's College London). Both sets of discussions were aimed at eliciting potential participants' views on the impact of the loss of/reduced mobility on everyday life; current therapy services received during in-patient stay; perceived therapy needs; and the willingness to participate in additional training at the early stage of rehabilitation as proposed in this study. Through these discussions, it was clearly identified that mobility is an important goal for patients after stroke to regain independence and reduce reliance on carers. In addition, some of the respondents identified that more exercise therapy was desirable at this early stage, as their experience was that therapy was less often directed specifically at trunk function compared to other aspects. Therefore, providing more therapy would be welcomed.

With regards to the study design, PPI participants (patients and physiotherapists) made it clear that some patients are discharged earlier than 6-8 weeks so may not be available in the hospital to receive the required dose of trunk training planned. Therefore, it was advised that the study include plans to continue trunk training exercises at home. In view of this, the study planned that the additional trunk training intervention would be continued into the post-discharge rehabilitation received by participants in the community to achieve the necessary therapeutic dose suggested in literature. As this would mean that the therapy is delivered over potentially many sites (depending on the discharge destinations of these patients), it became necessary that we plan a feasibility study to examine the practicalities of delivering the required amount of additional training.

Furthermore, the discussion also yielded some practical suggestions on how therapists could gain access to participants in the home environment particularly when they have severe deficits affecting their mobility. We utilised the views of those individuals we consulted into the design of the study; for example, the need for more trunk training to cover both in-patient periods and community rehabilitation periods.

At the start of the study, we invited members of the South London Stroke group to participate in the study as members of our steering group committee. Unfortunately, no-one from the group expressed an interest in continuing so we recruited one previously interested stroke survivor stakeholder, to continue with as a steering committee member on the trial. She attended two of our steering committee meetings and made valuable contributions throughout, especially when we had difficulties recruiting participants. We also recruited 2 practicing senior physiotherapists from GSTT as members of our steering committee to contribute to our discussions.

PPI participants were instrumental in co-designing the interview schedule for the qualitative exploration of participants' views of the intervention. The interview schedule was presented again to the South London Stroke Group, who provided constructive critique of the interview

guide. Similarly, the Physiotherapists at GSTT also provided beneficial criticism of the interview guide for the practicing Physiotherapists involved in the trial.

There is a dissemination plan to invite participants and their carers for a post-study presentation of the results and get their views on the plans for the definitive study. In addition, there is a plan to have a stakeholders meeting with the following groups of individuals: stroke care managers, physiotherapists, and stroke participant carers.

Data sharing statement

See link [https://www.nihr.ac.uk/documents/nihr-position-on-the-sharing-of-research-data/12253] for the NIHR position of the sharing of research data. The NIHR strongly supports the sharing of data in the most appropriate way, to help deliver research that maximises benefits to patients and the wider public, the health and care system and which contributes to economic growth in the UK. All requests for data should be directed to the award holder and managed by the award holder.

Disclaimer

This project is funded by the National Institute for Health Research (NIHR) under its Research for Patient Benefit (RfPB) Programme (Grant Reference Number PG-PB-0214-33076). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

This project was carried out between December 2015 and December 2017. This final report has not been peer-reviewed. The report was examined by the Programme Director at the time of submission to assess completeness against the stated aims.