Research networks for stroke rehabilitation: opportunities and barriers

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ABSTRACT – The previous negative attitude to stroke care is gradually giving way to a more positive approach, stimulated by a growing evidence base and policy initiatives such as the requirement that stroke units be established in all district general hospitals. There is now a new opportunity to link groups of stroke units into research networks to support the implementation of multi-centre trials. Such trials have the potential to increase patient recruitment rates, and will enhance the generalisability of the findings. Recent experience in establishing a stroke rehabilitation research network is reported in this paper.

KEY WORDS: multi-centre trials, rehabilitation, research networks, stroke

Stroke care is now characterised by a more dynamic and positive approach, underlined by the development of stroke medicine as a clinical specialty, rigorous reviews of services,[1] and the production of evidenced-based guidelines.[2] Although successful preventative measures (for example, carotid endarterectomy) and drug interventions (for example, thrombolysis) have been identified, they are appropriate for only a minority of patients, and rehabilitation remains the cornerstone treatment for the majority. Members of a multidisciplinary team work with the patient and their family to reduce stroke-related impairments and disability, and to enhance participation. These activities and interventions require consideration and judgement and ideally should be informed by an evidence base. However, although some research progress has been made, the research agenda generated by this complex web of interactions remains substantial.

To date, much rehabilitation research has been undertaken as single-centre studies. These have inherent limitations as results may be skewed by factors particular to the centre; for example, enhanced expertise, commitment and/or enthusiasm of the participating rehabilitation staff; potential for patient selection bias; or a distinctive local setting. These special factors cannot be easily quantified and there is therefore a natural caution about external generalisability. One consequence has been that single-centre rehabilitation studies have had little influence on routine clinical practice.

Additionally, there are pressing practical limitations for future single-centre evaluation studies. Most emerging treatments are applicable only to a selected proportion of all disabled stroke patients. It is therefore inappropriate to test effectiveness on a heterogeneous group of stroke patients.[3] For example, resistive training for the lower limb can produce significant strength gains but only for those patients who are at least six months post-stroke and already able to walk independently.[4] Upper limb therapies are likely to be restricted to patients who have some residual limb function.[5] In the future, therefore, single-centre studies investigating a specific therapy approach are unlikely to succeed in recruiting sufficient patients for a large enough study within a reasonable time frame. The need for larger, multi-centre randomised trials is paramount but the planning and implementation of such trials presents major organisational, educational and logistical challenges.

The National Service Framework for Older People has set down a requirement that all general hospitals in England develop stroke rehabilitation units.[6] This policy has been welcomed as a clinical care initiative but will also create the potential for a new research resource. If a group of stroke units could become linked through a shared agenda of empirical research, an infrastructure might be constructed capable of supporting multi-centre stroke studies. We report here our recent experience in establishing such a rehabilitation research network.

Stroke United Network Yorkshire (SUNY)

A local clinical meeting on stroke was used to explore interest in developing a stroke unit research network. There was a favourable response and several meetings then followed to formalise the network, agree an outline research programme and investigate funding opportunities.

The research network is called Stroke United Network Yorkshire (SUNY) and its agreed purpose is to conduct multi-centre stroke rehabilitation evaluation research. Membership currently encompasses 20 units/teams providing access to a combined pop-

ulation of approximately two and a half million people. The sites represent a continuum of research experience, from existing research centres to units developing an interest in research. The network also includes consumers, experienced university research staff, and explicit links with a clinical trials unit (University of Leeds) and a health economic department at the University of York. Membership is open to any healthcare staff with a clinical interest in stroke care, as members will be able to participate in various ways, such as discussing and identifying clinically relevant research questions, assisting in development of research protocols, and participation in the implementation of the research. It was acknowledged that research infrastructure support would be required but it was unclear what form this might take and what practical difficulties would need to be overcome in conducting research in busy clinical units.

For these reasons, it was considered appropriate to start cautiously with a project primarily involving multi-site data collection rather than more ambitious work such as the introduction of a new rehabilitation technique. Thus, initial funding was secured to investigate the utility of STRATIFY, a falls risk assessment tool,[7] for patients recovering from stroke. It was anticipated that the project would serve a double purpose: it would be of interest in its own right, but also provide an opportunity to identify the practical difficulties and obstacles associated with mounting multi-centre stroke studies through a collaborative rehabilitation research network.

STRATIFY and falls risk assessment in stroke

Falls are one of the most common medical complications after stroke.[8,9] It is important therefore to develop a falls risk indicator that can reliably identify stroke patients at high risk of falls, so that preventive interventions can be appropriately targeted. The STRATIFY assessment instrument[7] has been developed for an elderly population with mixed conditions and is able to predict with clinically useful sensitivity and specificity patients at high risk of falling. However, its applicability for patients with stroke is uncertain. We aimed to evaluate the predictive validity of STRATIFY when applied to stroke patients in an inpatient setting, and to determine the score threshold which optimises sensitivity and specificity for a group of stroke patients at high risk of falls. As explained above, the wider aim of the project was to provide practical experience of the opportunities and barriers to conducting multi-centre stroke rehabilitation research.

Method

A research nurse (JS) was appointed to facilitate implementation of the project across the participating stroke units. The principal investigator (AF) and the research nurse (JS) visited the stroke units that expressed an interest in the study to clarify expectations. Applications were made for multi-centre ethics approval, local ethics approval and Trust approval (which included addressing data protection issues). Trust-specific honorary contracts for the research nurse were obtained.

The research nurse initiated the project by arranging meetings with key staff in each centre. A minimum of two training sessions per centre were organised to which all clinical staff likely to be involved in the project were invited. The sessions included familiarisation with the STRATIFY falls risk assessment tool, an overview of study rationale, methods and procedures and baseline outcome measures. The training was supported by a detailed manual and study checklist.

The study involved collection of baseline data on patients sequentially admitted to the participating stroke units. This included the abbreviated mental test score[10] (cognitive impairment); Barthel index[11] (disability); Albert's test[12] (sensory neglect); and Rivermead Mobility Index[13] (mobility). The expectation was that the stroke unit staff would collect this information and that the primary nurse responsible for the patient would complete a STRATIFY risk assessment for each of his/her patients each week. Records of any falls were collected using a standardised proforma. Informed consent was required in order to make contact with the patients three months after hospital discharge to ask if they had fallen.

The research nurse (JS) was asked to keep notes during the implementation phase of the study with particular emphasis on any difficulties or practical problems encountered. These were then interpreted in the context of future research resources needed to develop the stroke rehabilitation research network.

Key Points

Existing stroke rehabilitation clinical trials are almost exclusively single-centre studies with limited external generalisability

The recent widespread introduction of stroke units provides a new opportunity to implement multi-centre studies

Establishing a stroke rehabilitation research network is feasible

A collaboration that links stroke units into a clinical research network is feasible but will require considerable support for research governance, training and individual study implementation

Results

Recruiting sites

Seven units initially expressed interest in participating. Subsequent 'first contact' with each site was through various routes: consultant; consultant and senior nurse; senior nurse; and through the multidisciplinary team. Participation in the research process, reflected by attendance at training sessions, and high rates of completion of baseline data and assessment measures, was best when the decision to participate was taken by senior members of the multidisciplinary team (lead nurse, therapist and doctor) who then acted as local champions for the research by actively promoting the research process. In those centres where this did not occur, tensions developed between

individual senior staff who initially agreed to participate and other clinical colleagues, and this created difficulties and delays in initiating the research.

Research governance procedures

The process of obtaining ethical and organisational approval for each centre was time-consuming, convoluted and took six months to complete. Because of the wish to recruit all types of stroke patients (patients with aphasia, cognitive impairment, with or without relatives), the ethical issues proved complex. The ramifications of the Data Protection Act 1998 posed additional problems; for example, accessing medical records and clarifying in what form data could be taken off-site. Procedures had to be negotiated for contacting patients after discharge from hospital, and for obtaining access to the medical records of patients for whom only assent was available. In the event, three different versions of the consent form were required. Despite structures to facilitate multi-centre research (Multi-centre Research Ethics Committees), some sites had additional local requirements that needed to be addressed. These included, for example, demonstrating that the research project would not impede implementation of the local organisation's policy on falls, and reaching an agreement to comply with existing mandatory local practice for contacting patients after hospital discharge.

These research governance issues had consequences. One centre withdrew during the early stage of the project due to the complexities of the local ethical and Trust level approval processes.

Research resources

Taking on activities additional to busy work schedules was a concern for most clinical staff. Meetings designed to introduce the research project were less successful than anticipated because of staff rotas, sick leave and sub-optimum staffing levels, and staff with other commitments and pressure of clinical work. However, whilst acknowledging the additional work involved, the participating centres were prepared to undertake the additional assessments of patients required for the study. Obtaining consent from patients to participate in the study was a greater problem. Many patients were unable to provide consent and therefore assent had to be obtained from relatives who were available at unpredictable times, making the process complicated and time consuming. It was difficult for this procedure to be undertaken successfully (to recruit enough patients to the study) unless responsibility was specifically delegated and the person involved had sufficient time flexibility to respond to patient and carer availability. The negotiated solution in four of the six centres was a paid secondment of clinical staff for four hours each week, supported by the central research assistant. In another centre, the research duties were undertaken jointly by a half-time research assistant funded by NHS Priority and Needs money[14] and a senior stroke nurse. The duties of the seconded staff included local coordination of the project, ensuring that informed consent/assent was obtained, that baseline assessments and weekly STRATIFY forms were completed, and that falls records were checked on a regular basis.

Outcome

Of the seven units that initially expressed interest in the study, six participated. This included one unit that was being established during the time of the STRATIFY study. All the units were rehabilitation wards with 12 to 24 beds. All held weekly multidisciplinary team meetings which included a consultant physician with specialist knowledge of stroke. Contact with carers for information exchange included informal drop-in sessions, fortnightly goal-setting meetings, and more formal meetings on admission to the ward. The number of patients admitted to each different centre during the six-month recruitment period ranged from 42 to 101. Of these, 48% to 93% of patients were recruited. Informed consent was obtained for 285 patients against our target of 250–300.

Discussion

To develop novel rehabilitation strategies and techniques, greater collaboration is required between neuroscientists, neuropsychologists and mechanical engineers.[15] However, potentially beneficial interventions will still require robust clinical effectiveness evaluation and the central role of clinicians in delivering and disseminating evidenced-based rehabilitation must not be overlooked.

Although examples of multi-centre stroke rehabilitation trials are available,[16,17] they comprise a small minority of stroke rehabilitation trials, are time-limited collaborations to support a particular study, and usually involve units experienced in research. Our proposal is that multi-centre stroke rehabilitation research should become expected practice rather than the exception. Moreover, the findings from the proposed multi-centre studies (if positive) should be more persuasive in terms of generalisability and clinical relevance, and therefore more likely to influence practice. The notion of a geographically based stroke unit collaboration has considerable parallels with the cancer research networks.[18] Within cancer care, however, research networks evolved from existing and well developed clinical networks. Stroke care in the UK is an emerging specialty and clinical networks are not yet in place. Much greater preliminary development work will therefore be required to establish a cohesive, truly multidisciplinary collaboration. The funding available for stroke research is small compared to that available for cancer research,[19] and new sources of research infrastructure funding will need to be identified and mechanisms developed to ensure a steady stream of research projects, available for widespread dissemination through the networks.

The STRATIFY project demonstrated the feasibility of undertaking research through a local, clinical network. The participating units demonstrated great commitment and were interested in the work. This project was more complex to implement and conduct than initially anticipated because of the

concurrently developing research governance framework.[20] Whilst administrative support assisted with these processes, liaising with numerous committees, addressing data protection issues, ensuring access to data and dealing with matters related to implementation of the research in the clinical setting, required considerable input from an experienced researcher.

Recruiting patients to this study was a time-consuming, complex process. The secondment of local staff part-time to the project proved helpful but still lacked sufficient flexibility. Ideally, staff should be seconded for more hours per week, or additional designated research staff should be employed, to undertake the research implementation, consent procedures and data collection. The seconded healthcare staff had the confidence and skills required to initiate contact with the patients and their carers but were relatively inexperienced in research methods. This could be addressed by providing more explicit training, including role-play around obtaining consent/assent. Increasing the amount of resources available to support the research will be an important cost burden for future projects. NHS Priority and Needs funding is available to support specified programmes of research, and one participating Trust used this funding to employ a half-time researcher to assist with the project. If, as we propose, a consecutive series of trials is established within stroke rehabilitation networks, employment of dedicated research assistants in Trusts participating in Priority and Needs programmes of research might be a productive way forward.

We have demonstrated that involvement of multidisciplinary teams in stroke rehabilitation research is achievable and the experience has been a positive one. Whilst there is considerable literature on postulated barriers to allied health professionals and nurses undertaking research,[21,22] and rehabilitation research,[23] our experience highlighted the practical problems and solutions that occur in real settings, and will substantially contribute to the process of establishing the multi-centre rehabilitation trial infrastructure. Previous studies have reported cultural and structural impediments to collaborative research,[17] but preliminary work helped to generate shared ownership of the study so that the participating units acted constructively to resolve problems. This type of facilitative approach to encourage a clinical research network is one that could be adopted and replicated in other disease areas.

Information about the aims and objectives of SUNY has been provided for patients and their families through ward posters with contact numbers if further information is required. There are explicit links with local stroke groups who will contribute to developmental work within the planned research programme. Previous work has demonstrated that consumers provide valuable understanding and insight into trial design.[24]

Research networks have long been established in other areas of medicine, particularly in primary and cancer care.[25,26] It is now time to seize the opportunities presented by the creation of organised inpatient stroke care and move stroke rehabilitation research onto firmer foundations. This will ensure that stroke patients receive the most appropriate interventions founded on evidenced-based rather than opinion-led practice.

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