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Introduction

VISTA-Rehab is the rehabilitation arm of VISTA: the Virtual International Stroke Trials Archive. This archive was established to promote effective clinical trial design in stroke. At present VISTA includes data from 29 acute trials with over 28,000 patients, and has facilitated 19 peer-reviewed papers.

Purpose

We sought to expand VISTA to include rehabilitation trial data (VISTA-Rehab). This will permit analyses to inform rehabilitation trial design, patient subgroup identification and examination of natural history variables. Currently we have amassed data from 22 rehabilitation trials within VISTA-Rehab.

Methods

Trials are eligible for inclusion in VISTA-Rehab if they meet the following criteria:

1. Patients with a clinical diagnosis of stroke
2. Stroke rehabilitation trials that commenced after 1998
3. Minimum of 20 randomised patients
4. Documented entry criteria
5. Documented onset to intervention time
6. Baseline assessment included recognised measures of impairment or activity limitation (e.g. Barthel Index, Nottingham Extended Activities of Daily Living Score, Functional Independence Measure, Functional Assessment Measure or similar).
7. Outcome assessment used a recognised measure(s)
8. Documented ethical approval
9. Documented consent or approved waiver of consent

Policy

VISTA-Rehab does not permit the re-analysis of the treatment effects of any particular trial; rather the aim is to provide data for novel analyses to aid the conduct of future clinical trials. VISTA-Rehab regulations are detailed on the VISTA-Rehab website: www.vista.gla.ac.uk

Steering Committee

Data dissemination and access are controlled through the VISTA-Rehab Steering Committee, which is composed of VISTA-Rehab founding members and contributing trialists. This ensures that the integrity and confidentiality of each rehabilitation trial are maintained. Anonymised trial data can be accessed by any external investigator through submission of a project proposal for review. The Steering Committee provide feedback for new proposals, lend their expert opinion to analyses and guide publication.

Data Storage and Management

VISTA-Rehab holds only anonymised patient data. Data are stored at the Robertson Centre for Biostatistics, University of Glasgow, UK, on behalf of VISTA-Rehab. All data management tasks are performed using the SAS 9.1 management and statistical package.

Results

Contribution of data from completed rehabilitation trials to VISTA-Rehab have been sought since September 2008. Initial data on 3272 patients from 22 trials have already been lodged, with commitments for data contribution from 3 further trials. Table 1 details the summary statistics for patient data currently available. Variables available for novel analyses include patient demography, medical history, Barthel Index, Nottingham Extended Activities of Daily Living Scores and carer quality of life scores. Trial data within VISTA-Rehab derive from a range of rehabilitation interventions including occupational therapy, physiotherapy and cognitive behavioural therapy.

Table 1: Selected Summary Statistics for Trials Included within VISTA-Rehab

Variable	n	Median [IQR]	Frequency (%)
Age (years)	3272	73 [65,80]	-
Gender	3213	-	Male=53%
Hemisphere Affected	1847	-	Left=27%
Nottingham Extended Activities of Daily Living Score (baseline)	623	26 [14,42]	-
Barthel Index score (baseline)	1902	16 [9,19]	-
Modified Rankin Score at 6 months	490	3 [2,3]	-
Barthel Index at 6 months	1551	17 [13,19]	-
Nottingham Extended Activities of Daily Living Score at 6 months	1339	29 [14,47]	-

Conclusions

VISTA-Rehab is a rapidly growing collaborative initiative which aims to inform stroke rehabilitation trial design. VISTA-Rehab is currently inviting stroke rehabilitation trialists to collaborate by lodging data from further trials and/or offering proposals for use of this archive. Contributing groups will be offered membership of the VISTA-Rehab Steering Committee. Planned analyses include an investigation of sources of variability in outcome in stroke rehabilitation trials. VISTA-Rehab contributes to a more comprehensive stroke trials resource which will benefit the full spectrum of stroke clinicians, researchers, patients and carers.

Further information

This project is being undertaken by the Nursing, Midwifery and Allied Health Professions Research Unit (NMAHP RU), in collaboration with the University of Glasgow. NMAHP RU is funded by the Scottish Government's Health Directorates, Chief Scientist Office. It has academic bases within Glasgow Caledonian University and the University of Stirling. The overall aim of the Unit is to improve the care and treatment of patients through scientific study of direct patient care. The Stroke Programme specializes in the development, conduct and delivery of high quality evidence relating to the effectiveness of stroke rehabilitation interventions.

For further information about the work of the NMAHP RU Stroke Programme please contact: Dr Marian Brady, Programme Leader - marian.brady@gcal.ac.uk

Become a VISTA-Rehab Contributing Trialist

- Do you have data from a completed stroke rehabilitation trial?
- Are you involved in an ongoing stroke rehabilitation trial?
- Would you like to contribute to this growing international trials resource?

We welcome enquiries from anyone who thinks they may be able to contribute relevant trial data to VISTA-Rehab. For more information on VISTA-Rehab please visit www.vista.gla.ac.uk or email myzoon.ali@gcal.ac.uk