

Rehabilitation Trials within the Virtual International Stroke Trials Archive: VISTA-Rehab

On Behalf of the VISTA-Rehab Steering Committee.



Background:

Rehabilitation after stroke can be complex: no two stroke survivors will have the same problems with activities of daily living, societal participation or bodily functions. The experiences and expectations of each stroke survivor will also differ, further adding to this complexity. Consequently, the design, development and conduct of trials to test new therapies can be challenging. Practical and financial barriers also hinder the pace of stroke research; the design of trials, recruitment of patients, analysis of data, and publication of findings can take years and cost millions of pounds. The end result may not be positive. Data from completed trials often reside unused in industry or academic archives long after their results have been published. However re-use of these valuable data in the form of exploratory analyses can describe patterns of recovery, answer new research questions and help to determine whether new therapies have the potential to help stroke survivors.

Aims and Objectives:

The Virtual International Stroke Trials Archive (VISTA) was developed as a collaborative stroke trials resource. The aim was to collate and provide access to anonymised clinical trial data for new exploratory analyses. This resource was initially established in 2001 and was primarily concerned with data from acute stroke trials. We sought to develop an archive of stroke rehabilitation trials (VISTA-Rehab), a subsection of the wider archive, to expand the application of VISTA principles to benefit a wider stroke community. We aimed to provide access to this resource to researchers, clinicians and trialists to inform the design of future stroke rehabilitation studies.

Methods:

We set eligibility criteria for the trial data that we wished to collect. We sought stroke rehabilitation trials that had been conducted since 1998 in which at least 20 patients with a stroke were included. We required that an assessment of the severity of the stroke be carried out at baseline and final follow up, using a recognised impairment/activity limitation scale such as the Functional Independence Measure, Barthel Index or Modified Rankin Scale. We imposed no time limit between stroke onset and treatment, reflecting the long-term nature of stroke rehabilitation. We established an international Steering Committee to oversee projects and publications and commenced recruitment of rehabilitation trials into this resource.

Results & Implications:

As of February 2013, anonymised data are available for 10,719 patients from VISTA-Rehab. We have secured commitments for contribution of data from an additional 14 trials. Demographic data available for analysis include patient age, sex, and initial dependency. Outcome measures available include the modified Rankin Scale, Barthel Index, Rivermead Motor Assessment, Fugl Meyer Assessment, General Health Questionnaire and Nottingham Extended Activities of Daily Living Scale. Data from this resource have been used to answer questions about the prevalence of, and recovery from visual and communication impairment following stroke, and the relationships between dependence on carers for activities of daily living and levels of carer strain. Planned analyses include studies of the prevalence of urinary incontinence and spasticity following stroke. Collaborative work developed through the VISTA-Rehab network includes plans to standardise the information that is collected in stroke rehabilitation trials.

Conclusion:

VISTA-Rehab expands the Virtual International Stroke Trials Archive (VISTA) to include rehabilitation trials. Anonymised data can be used to examine questions specific to stroke rehabilitation. New research can be developed quickly and cheaply. Potentially beneficial therapies can be examined thoroughly before deciding whether to commit to more costly clinical trials.

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