

**POSTER PRESENTATION****Open Access**

# Developing easy access patient information booklets and consent forms for use in multicentre stroke trials

Gillian Mead<sup>1</sup>, Martin Dennis<sup>1\*</sup>, Marian Brady<sup>2</sup>

From 2nd Clinical Trials Methodology Conference: Methodology Matters  
Edinburgh, UK. 18-19 November 2013

Global cognitive impairment is a common consequence of stroke, and some stroke patients will have had dementia prior to their stroke. Thus, many people with acute stroke are often considered unable to consent to participation in research and proxy consent is standard. Aphasia is a common neurological consequence of stroke, affecting several aspects of language including speaking, writing, reading and understanding but not necessarily impacting on self determination. Ethically, patients with capacity to consent should be enabled to engage in the information provision and consent process rather than making an assumption of incapacity.

For our ongoing multicentre FOCUS trial (<http://www.focustrial.org.uk>), we developed 'easy-access' patient information booklets and consent forms to facilitate information provision and informed consent with people with communication impairment.

Co-produced in an iterative process with stroke survivors with aphasia (Speakeasy, Dundee) the information provided in the standard forms was refined into a more accessible format. Short sentences, simple grammatical structures and large well spaced text was supplemented with photographs, where possible, to support the information provision process. Approved by Scotland A Research Ethics Committee, preliminary experience suggests the 'easy-access' versions have supported patients with mild aphasia. Recording which version of the information booklets was used and the presence and severity of aphasia (National Institute of Health Stroke Scale) will enable us to report how many patients with aphasia were enabled to independently consent to participation in the FOCUS trial.

**Authors' details**

<sup>1</sup>University of Edinburgh, Edinburgh, UK. <sup>2</sup>Glasgow Caledonian University, Glasgow, UK.

Published: 29 November 2013

doi:10.1186/1745-6215-14-S1-P58

Cite this article as: Mead et al.: Developing easy access patient information booklets and consent forms for use in multicentre stroke trials. *Trials* 2013 **14**(Suppl 1):P58.

**Submit your next manuscript to BioMed Central and take full advantage of:**

- Convenient online submission
- Thorough peer review
- No space constraints or color figure charges
- Immediate publication on acceptance
- Inclusion in PubMed, CAS, Scopus and Google Scholar
- Research which is freely available for redistribution

Submit your manuscript at  
[www.biomedcentral.com/submit](http://www.biomedcentral.com/submit)



<sup>1</sup>University of Edinburgh, Edinburgh, UK  
Full list of author information is available at the end of the article