Fluoxetine to improve functional outcomes in patients after acute stroke: the FOCUS RCT

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Declared competing interests of authors: Martin Dennis, Maree Hackett, Graeme J Hankey, Gillian Mead and Erik Lundström report grants from the National Health and Medical Research Council (Australia) and funding from the Swedish Research Council Framework grant in clinical therapy research during the conduct of the study. Maree Hackett also reports grants from The Stroke Association (London, UK), grants from the National Institute for Health Research (NIHR) Stroke Research Network and a grant in clinical therapy research during the conduct of the study, and grants from the National Heart Foundation of Australia outside the submitted work. She also held a National Health and Medical Research Council (Australia) Career Development Fellowship, level 2 (reference APP1141328) (2018–21). Stephanie Lewis reports being a member of the NIHR Health Technology Assessment General Committee (2016 to present). Peter Sandercock reports lecture fees from Bayer AG (Leverkusen, Germany) paid to his department, outside the submitted work.

Published May 2020
DOI: 10.3310/hta24220
Plain English summary

The FOCUS RCT
Health Technology Assessment 2020; Vol. 24: No. 22
DOI: 10.3310/hta24220

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Fluoxetine, sometimes referred to by the drug company name Prozac, has been used for many years to treat people who are depressed, including after a stroke. However, studies have suggested that treatment with fluoxetine started soon after a stroke might improve patients’ physical recovery. The Fluoxetine Or Control Under Supervision (FOCUS) trial recruited 3127 volunteers who had had a stroke within the previous 2 weeks from 103 UK hospitals between 2012 and 2017. Participants were randomly allocated to take a 6-month course of fluoxetine or an identical placebo capsule containing no fluoxetine. They were followed up at 6 months and 12 months after recruitment. Patients completed questionnaires that indicated how much they had recovered, and also measured their mood, fatigue and quality of life. The results of the trial showed that the physical recovery of patients was very similar in both groups. This indicates that fluoxetine does not improve physical outcomes of stroke patients. However, participants receiving fluoxetine were less likely to develop depression after the stroke but once the fluoxetine was stopped these effects on mood disappeared. Unfortunately, patients on fluoxetine were slightly more likely to fall and fracture a bone than those on placebo. The FOCUS trial is the first of three large randomised controlled trials testing fluoxetine in stroke patients to be completed. The FOCUS trial results suggest that patients with stroke should not routinely be treated with fluoxetine.

The other two trials will give us further information about the effects of fluoxetine after stroke and whether or not its effects differ between countries or ethnic groups.
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This report

The research reported in this issue of the journal was funded by the HTA programme as project number 13/04/30. The contractual start date was in October 2014. The draft report began editorial review in May 2019 and was accepted for publication in November 2019. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors’ report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health and Social Care. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health and Social Care.

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