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Title	A multicentre randomised trial to establish the effect(s) of routine administration of Fluoxetine for 6 months in patients with a recent stroke
Short title	**F**luoxetine **O**r **C**ontrol **U**nder **S**upervision
Acronym	FOCUS
Chief Investigators	Dr Gillian Mead & Prof Martin Dennis
Primary Research Question	Does the routine administration of fluoxetine (20mg od) for 6 months after an acute stroke improve patients' functional outcome?
Trial design	An investigator lead, UK based, multicentre, parallel group, double blind placebo controlled trial with broad entry criteria and follow up at 6 and 12 months.
Setting	UK stroke services
Eligibility criteria	**Inclusion** • age ≥ 18 years • brain imaging is compatible with intracerebral haemorrhage or ischaemic stroke • randomisation can be performed between 2 and 15 days after stroke onset • persisting focal neurological deficit is present at the time of randomisation severe enough to warrant 6 months trial treatment from the patient's or carer's perspective **Exclusion** • subarachnoid haemorrhage • unlikely to be available for follow up at 12 months • patient and/or carer unable to understand spoken or written English • other life threatening illness • pregnant or breast-feeding or of child bearing age not taking contraception • history of epileptic seizures • attempted suicide or self-harm • allergy or contra indication to fluoxetine • taken a monoamine oxidase inhibitor in last 5 weeks • current or recent depression requiring treatment with SSRI current participation in another Controlled Trial of a Medicinal Product (CTIMP)
Randomisation	Central, via a web based randomisation system utilising a minimisation algorithm
Descriptions of interventions	Fluoxetine 20mg once daily or matching placebo capsules for 6 months.
Outcome measures	Primary outcome measure: modified Rankin scale. Secondary outcome measures: Survival at 6 & 12 months, Stroke Impact Scale, EQ5D-5L, MHI 5, Vitality subscale of SF36, diagnosis of depression, adherence to medication, adverse events, resource use
Follow up	***Local*** at hospital discharge (for inpatients) or ***Central*** at one month (for outpatients) and at 6 and 12 months via postal, web or telephone questionnaires to patients and GPs
Sample size estimate	90% power to detect an improvement in proportion of patients with an mRS of 0-2 at 6 months from 27% to 32.6%.
Number of participants	At least 3000
Statistical methods	Based on an ordinal analysis of mRS adjusted for baseline variables included in minimisation algorithm
Timetable	Start up phase: 2012-2014 Main phase: 2014-2018