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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 | Fluoxetine Or Control Under Supervision |
| 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 | <p>Inclusion</p> <ul style="list-style-type: none"> • age \geq 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 <p>Exclusion</p> <ul style="list-style-type: none"> • 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 <p>current participation in another Controlled Trial of a Medicinal Product (CTIMP)</p> |
| 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 |

