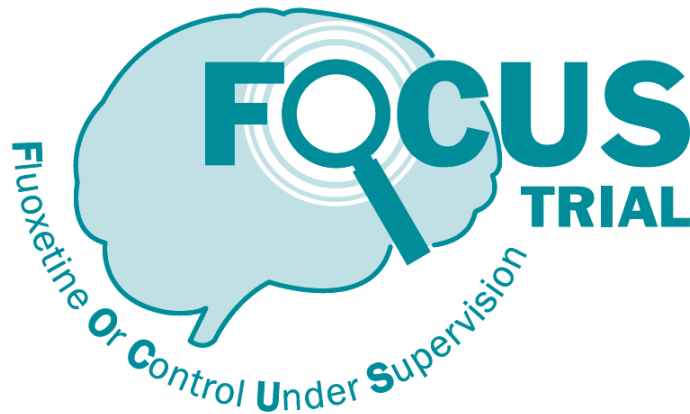


Easy access patient information booklet. [Text in red will be removed prior to use with patients].

PLEASE GIVE 1 BOOKLET TO THE PATIENT, FILE 1 IN THE PATIENT MEDICAL NOTES AND ATTACH 1 TO A COPY OF THE CONSENT FORM FOR THE PATIENT PACK.

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## ***Does Fluoxetine Improve Recovery After Stroke?***

Would you take part in research about stroke?

Funded by the Stroke Association & the Health Technology Assessment Programme



NHS TRUST LOGO

## A stroke may cause



- weakness of arms and legs
- problems with speech, writing or reading
- problems with vision
- problems with memory and
- problems with concentration.

**Fluoxetine is a medicine.**

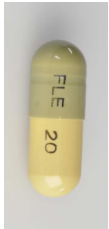


**It is used to treat people with depression.**

**It may help to repair the brain.**

**It may help recovery after stroke.**

**We want to find out...**



**Does Fluoxetine improve recovery after stroke?**

**We need 3,000 people to take part.**

**They all will have had a stroke.**



**Why ask me?**



**You had a stroke**

**You have some problems since your stroke**



**Taking part is your choice.**

**It will not change your care.**



**Talk about this with your FAMILY.**

**Talk about this with your DOCTOR.**

**If you take part ...**



**You can stop at any time.**

**It is your choice.**

**You don't need a reason.**



**Everything is PRIVATE.**

**We will not publish your name.**



## If you take part we will collect ...

- your contact details
- contact details for your family
- information from your medical notes



## If you take part ...

- half of those taking part will get Fluoxetine
- half of those taking part will get a placebo drug
- a computer will decide by chance which capsule you get

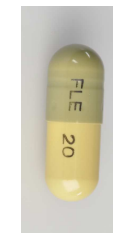
If you take part ...



Decided by chance



**Fluoxetine 20mg**



**Placebo or Dummy Drug**

All capsules will look the same.

They are small and easy to swallow.

No one will know which is Fluoxetine.

We do not do extra tests.

**A**



**B**



You will take 1 capsule a day

You will take the capsules for 6 months

January	February	March
1	2	3
April	May	June
4	5	6
July	August	September
October	November	December



**Fluoxetine has few side effects.**

**They are listed at the end.**

**Tell your doctor or nurse if you have symptoms**

**We will contact you**

- **at 1 month**
- **at 3 months**
- **at 6 months**
- **at 12 months**

January	February	March
1		3
April	May	June
		6
July	August	September
October	November	December
		12

**If we don't hear back we will contact your family**

## At 1 month we will ...

- collect information from your medical notes
- ask you how you are
- ask you about the capsules
- ask about any side effects
- ask about your medication
- ask your GP about any side effects

January	February	March
1		
April	May	June
July	August	September
October	November	December

## At 3 months we will ...

- ask you how you are
- ask you about the capsules
- ask about any side effects

January	February	March
		3
April	May	June
July	August	September
October	November	December

## At 6 months we will ...

- send you a questionnaire about your recovery
- stop your capsules
- ask you to return unused capsules
- pay the cost of posting unused capsules back to us
- ask your GP about any hospital admissions
- ask your GP about any depression

January	February	March
		6
April	May	June
July	August	September
October	November	December



## At 12 months we will ...

- send you a questionnaire about your recovery
- ask your GP about any hospital admissions
- ask your GP about any depression

January	February	March
April	May	June
July	August	September
		12
October	November	December

## Later we will ...

- collect information from central NHS bodies



## What the benefits of taking part?

- We will follow your progress for 12 months
- Information will be shared with your GP
- Study results will help others who have a stroke
- Our study may find Fluoxetine helps recovery
- If you are taking Fluoxetine it may help your recovery



## What are the disadvantages or risks?

- It will take up a little of your time
- There are no major risks
- There are some side effects from Fluoxetine
- They are uncommon
- Most are mild
- All possible side effects are listed on pages 23-26



## If you want to stop



- you can at any point
- you don't need a reason
- we will keep the information we collected

We would still like to keep you in the study if

- you become unwell
- you cannot take the capsules

## What happens at the end of the study?

- We will publish the results in a medical journal
- We will report the results to the Stroke Association
- If you'd like, we will send you the results by post
- You can visit a website to see the results

## What if there is a problem...

with your NHS treatment?

- Contact the local Complaints Officer



with the FOCUS study?

- Contact Professor Martin Dennis



## Contact details



**Prof. Martin Dennis**

**Professor of Stroke Medicine**

**Royal Infirmary, Edinburgh**

**Helpline: 0131 242 7741**

## Possible side effects

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- drop in blood pressure on standing or sitting
- blurred vision or eyesight problems
- dry mouth, loss of appetite
- nausea, bad taste in mouth, weight loss, vomiting, indigestion, swallowing problems
- abnormal muscle movement (twitches, tremors, jerks, rigidity), unable to sit still
- balance or co-ordination problems



- bruising and bleeding problems
- feeling anxious, nervous, agitated, panic attacks
- dizziness, drowsiness, tiredness, yawning, abnormal dreams
- concentration problems, confusion, restlessness
- hallucinations, unusual thoughts, de-personalisation, euphoria, mania
- allergic reactions, hypersensitivity, skin rashes, swelling of face or tongue, mouth ulcers, sore throat, anaphylactic reaction



- hair loss, chills, sweating, production of breast milk
- unable to urinate or urinating more often
- headaches, seizures
- joint pain, muscle pain, bone fractures
- sexual dysfunction, delayed or absent ejaculation, difficulty achieving an orgasm
- breathing difficulties, lung problems
- abnormal laboratory test results, liver problems, metabolic problems, blood sugar control changes (in diabetics)

- **serotonin or neuroleptic malignant-type syndrome** (high body temperature, muscle twitches, jerks or rigidity, mental changes, confusion, irritability, agitation, delirium or coma). If you have these symptoms, seek immediate medical help.
- **thoughts of suicide** (risk is extremely low and slightly more common in depressed adolescents than in older people)

### **Withdrawal symptoms if medicine is stopped suddenly**

- **dizziness, tremors, headaches**
- **sensory changes, tingling**
- **weakness**
- **agitation, anxiety, sleeping problems, intense dreams**