CENTRE FOR CLINICAL BRAIN SCIENCES

The University of Edinburgh
FU.303E, First Floor
Chancellor's Building
49 Little France Crescent
Edinburgh. EH16 4SB

Tel: +44 (0)131 242 7741
Email: FOCUS.trial@ed.ac.uk
http://www.focustrial.org.uk

<<insert GP fax number>>

THIS FAX CONTAINS IMPORTANT SAFETY INFORMATION CONCERNING YOUR PATIENT

Dear Dr <insert>

Re: <patient first and family name> CHI/NHS No.

Your patient was admitted to <randomising hospital> following a stroke. During this admission your patient consented to participate and was randomised into the FOCUS trial – a double blind trial of:

Placebo or Fluoxetine 20mg

The trial aims to establish whether a six month course of Fluoxetine 20mg enhances recovery after stroke. It is co-ordinated from the University of Edinburgh.

Your patient has now been discharged from hospital and you should have received a discharge summary from the hospital including information about their participation in the FOCUS trial and providing details of their discharge medications. The discharge summary should also have confirmed that your patient is taking FOCUS trial medication, which could **either** be a Placebo **or** Fluoxetine 20mg.

Your patient has been provided with their six month supply of trial medication (186 Fluoxetine or identical placebo capsules in a white 150ml bottle). You **DO NOT** need to prescribe this.

Please DO NOT prescribe fluoxetine or any other SSRI until your patient has completed their trial medication without checking with us first. To do so will increase the risk of adverse effects since the patient may already be taking fluoxetine 20mg

If your patient loses their FOCUS trial medication or if you have any question about the FOCUS trial please ring us on our 24 hr Helpline 0131 242 7741

We will be in touch during the next few months to determine how <patient name> is doing.

Thank you for your kind assistance in this matter.

Yours sincerely

Professor Martin Dennis

<Date>

<GPs name>
<Address>
<Postcode>

Dear Dr <GPs surname>

Re: <Patient name>, <NHS/ CHI No.>

One month ago <patients name> consented to participate in the FOCUS trial which aims to find out whether Fluoxetine improves peoples' recovery after a stroke. You should have received a letter about the trial (which included details about reimbursement for your and your staff's time) and a copy of the patient's consent form.

We now want to find out how <he/she> has been getting on. We need to know:

- Whether <he/she> is still alive (because we will be writing to <him/her>)?
- Whether <he/she> has been admitted to hospital in the last month?
- Whether <he/she> has had any new medical problems?
- Whether <he/she> has had any problems due to the FOCUS trial medication (fluoxetine or placebo)?
- What medication <he/she> is currently taking?

Please answer the questions on the attached questionnaire and;

- send it to our secure FAX on 0131 242 7742 **or**
- post it in the FREEPOST envelope provided

If we don't hear from you within the next couple of weeks we will telephone your practice. If you want to speak to a member of the trial team about completing the questionnaire or any other issue please telephone our helpline (0131 242 7741).

Thanks very much for your help

Yours sincerely

Prof Martin Dennis
Professor of Stroke Medicine

Dr Gillian Mead
Consultant Physician

FOCUS trial 1 MONTH GP QUESTIONNAIRE

Please use a black pen & PRINT IN CAPITALS

Please complete this form as soon as possible and either:

- **send it to our secure FAX on 0131 242 7742 or**
- **post it in the FREEPOST envelope provided**

---

1. Has the patient died? Yes ☐ No ☐

If yes, Date of death (dd/mm/yyyy) ☐☐/☐☐/☐☐☐☐

Most likely cause of death? _____

Was the cause of death confirmed on autopsy? Yes ☐ No ☐

---

2. Has the patient been admitted to hospital since <date of randomisation>? Yes ☐ No ☐

If yes, Which hospital? _____

Why were they admitted? _____

Dates of admission and discharge for each admission?

Hospital	Date of admission	Date of discharge

---

3. Has the patient had any of the following problems since < date of randomisation>?

Further stroke? Yes ☐ No ☐

Date of first (dd/mm/yyyy) ☐☐/☐☐/☐☐☐☐ Details _____

Type of Further Stroke? Ischaemic ☐ Unknown ☐

Haemorrhagic ☐ Other ☐ *Please specify* _____

Acute coronary event (confirmed on ECG and/or Troponin)? Yes ☐ No ☐

Date of first (dd/mm/yyyy) ☐☐/☐☐/☐☐☐☐ Details _____

Upper gastrointestinal bleed (requiring blood transfusion and/or endoscopy)? Yes ☐ No ☐

Date of first (dd/mm/yyyy) ☐☐/☐☐/☐☐☐☐ Details _____

Fall with injury (requiring X rays or sutures or other treatment)? Yes ☐ No ☐

Date of first (dd/mm/yyyy) ☐☐/☐☐/☐☐☐☐ Details _____

New fracture (confirmed on X Ray)? Yes ☐ No ☐

Date of first (dd/mm/yyyy) ☐☐/☐☐/☐☐☐☐ Details _____

Definite epileptic seizure (focal or generalised)? Yes ☐ No ☐

Date of first (dd/mm/yyyy) ☐☐/☐☐/☐☐☐☐ Details _____

An episode of symptomatic hypoglycaemia (blood sugar < 3mmol/l)? Yes ☐ No ☐

Date of first (dd/mm/yyyy) ☐☐/☐☐/☐☐☐☐ Details _____

An episode of hyperglycaemia (blood sugar >22mmol/l)? Yes ☐ No ☐

Date of first (dd/mm/yyyy) ☐☐/☐☐/☐☐☐☐ Details _____

New hyponatraemia (Na < 125mmol/l)? Yes ☐ No ☐

Date of first (dd/mm/yyyy) ☐☐/☐☐/☐☐☐☐ Details _____

Has the patient been diagnosed with NEW depression? Yes ☐ No ☐

Date of first (dd/mm/yyyy) ☐☐/☐☐/☐☐☐☐ Details _____

Has the patient been treated for NEW depression? Yes ☐ No ☐

Date of first (dd/mm/yyyy) ☐☐/☐☐/☐☐☐☐ Details _____

Has the patient been prescribed a NEW antidepressant drug? Yes ☐ No ☐

Date of first (dd/mm/yyyy) ☐☐/☐☐/☐☐☐☐ Details _____

Has the patient attempted suicide/self harm? Yes ☐ No ☐

Date of first (dd/mm/yyyy) ☐☐/☐☐/☐☐☐☐ Details _____

Has the patient had any other serious medical problems since <date of randomisation>? Yes ☐ **No** ☐

If YES, please describe: _____

---

4. Your patient's trial medications

Has the patient had problems associated with the FOCUS trial medication? Yes ☐ No ☐

If yes, please describe: _____

Did the patient have to stop the trial medication? **Yes**, permanently ☐ **Yes**, temporarily ☐ **No** ☐

If yes, permanently, date stopped (dd/mm/yyyy)? ☐☐/☐☐/☐☐☐☐

---

5. According to our records your patient was taking the following medications

Please indicate whether they are still taking each one, or not. Also, please add the names of any additional medications prescribed. (Alternatively just send back a **print out** of current medications if this is more convenient).

Name of medication>>>>>>>>>>>	Still taking?	Stopped?	Name of medication>>>>>>>>>>>	Still taking?	Stopped?

Additional medications which the patient is currently taking but which are not on the list above

1.	5.
2.	6.
3.	7.
4.	8.

---

6. Is the patient's address we hold correct? Yes ☐ No ☐

<Patients Address>

If not please amend or fill out below.

House no/ hospital name: _____

Street name: _____

Town/City: _____ Postcode: _____

Tel No (home): _____ Tel No (work): _____ Tel No (mobile): _____

Name of Person completing form: _____

Signature: _____

Date form completed (dd/mm/yyyy): ☐☐/☐☐/☐☐☐☐

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<Date>

<GPs name>
<Address>
<Postcode>

Dear Dr <GPs surname>

Re: <Patient name>, <NHS/ CHI No.>

Six months ago <patients name> consented to participate in the FOCUS trial which aims to find out whether Fluoxetine improves peoples' recovery after a stroke. You should have received details of the trial, a copy of the patient's consent form and information about reimbursement for your and your staff's time.

We now want to find out how <he/she> has been getting on. We need to know:

- Whether <he/she> is still alive (because we will be writing to him/her)?
- Whether <he/she> has been admitted to hospital in the last 6 months?
- Whether <he/she> has had any new medical problems?
- Whether <he/she> has had any problems due to the FOCUS trial medication (fluoxetine or placebo)?
- What medication <he/she> is currently taking?

Please answer the questions on the attached questionnaire and;

- send it to our secure FAX on 0131 242 7742 **or**
- post it in the FREEPOST envelope provided

If we don’t hear from you within the next couple of weeks we will telephone your practice. If you want to speak to a member of the trial team about completing the questionnaire or any other issue please telephone our helpline (0131 242 7741).

Thanks very much for your help,

Prof Martin Dennis
Professor of Stroke Medicine

FOCUS trial 6 MONTH GP QUESTIONNAIRE

Please use a black pen & PRINT IN CAPITALS
Please complete this form as soon as possible and either:

- **send it to our secure FAX on 0131 242 7742 or**
- **post it in the FREEPOST envelope provided**

---

1. Has the patient died? Yes ☐ No ☐

If yes, Date of death (dd/mm/yyyy) ☐☐/☐☐/☐☐☐☐

Most likely cause of death? _____

Was the cause of death confirmed on autopsy? Yes ☐ No ☐

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2. Has the patient been admitted to hospital since <date of discharge>? Yes ☐ No ☐

If yes, Which hospital? _____

Why were they admitted? _____

Dates of admission and discharge for each admission?

Hospital	Date of admission	Date of discharge

---

3. Has the patient had any of the following problems since leaving hospital on <date of discharge/ date of randomisation (outpatient)>?

Further stroke? Yes ☐ No ☐

Date of first (dd/mm/yyyy) ☐☐/☐☐/☐☐☐☐ Details _____

Type of Further Stroke? Ischaemic ☐ Unknown ☐
Haemorrhagic ☐ Other ☐ *Please specify* _____

Acute coronary event (confirmed on ECG and/or Troponin)? Yes ☐ No ☐

Date of first (dd/mm/yyyy) ☐☐/☐☐/☐☐☐☐ Details _____

Upper gastrointestinal bleed (requiring blood transfusion and/or endoscopy)? Yes ☐ No ☐

Date of first (dd/mm/yyyy) ☐☐/☐☐/☐☐☐☐ Details _____

Fall with injury (requiring X rays or sutures or other treatment)? Yes ☐ No ☐

Date of first (dd/mm/yyyy) ☐☐/☐☐/☐☐☐☐ Details _____

New fracture (confirmed on X Ray)? Yes ☐ No ☐

Date of first (dd/mm/yyyy) ☐☐/☐☐/☐☐☐☐ Details _____

Definite epileptic seizure (focal or generalised)? Yes ☐ No ☐

Date of first (dd/mm/yyyy) ☐☐/☐☐/☐☐☐☐ Details _____

An episode of symptomatic hypoglycaemia (blood sugar < 3mmol/l)? Yes ☐ No ☐

Date of first (dd/mm/yyyy) ☐☐/☐☐/☐☐☐☐ Details _____

An episode of hyperglycaemia (blood sugar >22mmol/l)? Yes ☐ No ☐

Date of first (dd/mm/yyyy) ☐☐/☐☐/☐☐☐☐ Details _____

New hyponatraemia (Na < 125mmol/l)? Yes ☐ No ☐

Date of first (dd/mm/yyyy) ☐☐/☐☐/☐☐☐☐ Details _____

Has the patient been diagnosed with NEW depression? Yes ☐ No ☐

Date of first (dd/mm/yyyy) ☐☐/☐☐/☐☐☐☐ Details _____

Has the patient been treated for NEW depression? Yes ☐ No ☐

Date of first (dd/mm/yyyy) ☐☐/☐☐/☐☐☐☐ Details _____

Has the patient been prescribed a NEW antidepressant drug? Yes ☐ No ☐

Date of first (dd/mm/yyyy) ☐☐/☐☐/☐☐☐☐ Details _____

Has the patient attempted suicide/self harm? Yes ☐ No ☐

Date of first (dd/mm/yyyy) ☐☐/☐☐/☐☐☐☐ Details _____

Has the patient had any other serious medical problems since <date of discharge>? **Yes** ☐ **No** ☐

If YES, please describe: _____

---

4. Your patient's trial medications

Has the patient had problems associated with the FOCUS trial medication? Yes ☐ No ☐

If yes, please describe: _____

Did the patient have to stop the trial medication? **Yes**, permanently ☐ **Yes**, temporarily ☐ **No** ☐

If yes, permanently, date stopped (dd/mm/yyyy)? ☐☐/☐☐/☐☐☐☐

---

5. According to our records your patient was taking the following medications

Please indicate whether they are still taking each one, or not. Also, please add the names of any additional medications prescribed. (Alternatively just send back a **print out** of current medications if this is more convenient).

Name of medication	Still taking?	Stopped?	Name of medication	Still taking?	Stopped?

Additional medications which the patient is currently taking but which are not on the list above

1.	5.
2.	6.
3.	7.
4.	8.

---

6. Is the patient's address we hold correct? Yes ☐ No ☐

<Patients Address>

If not please amend or fill out below.

House no/ hospital name: _____

Street name: _____

Town/City: _____ Postcode: _____

Tel No (home): _____ Tel No (work): _____ Tel No (mobile): _____

Name of Person completing form: _____

Signature: _____

Date form completed (dd/mm/yyyy): ☐☐/☐☐/☐☐☐☐

<Date>

<GPs name>
<Address>
<Postcode>

Dear Dr <GPs surname>

Re: <Patient name>, <NHS or CHI No>

Twelve months ago <patients name> consented to participate in the FOCUS trial which aims to find out whether Fluoxetine improves peoples' recovery after a stroke. It is now at least six months since he/she stopped the trial medication.

It is now time for the final follow-up. We need to know:

- Whether <he/she> is still alive (because we will be writing to them)?
- Whether <he/she> has been admitted to hospital in the last 6 months?
- Whether <he/she> has had a new diagnosis of depression?
- What medication <he/she> is currently taking?

Please answer the attached questionnaire and;

- send it to our secure FAX on 0131 242 7742 **or**
- post it in the FREEPOST envelope provided

If we don't hear from you within the next couple of weeks we will telephone your practice. If you want to speak to a member of the trial team about completing the questionnaire or any other issue please telephone our helpline (0131 242 7741).

Thanks very much for your help,

Prof Martin Dennis
Prof of stroke medicine

FOCUS trial 12 MONTH GP QUESTIONNAIRE

Please use a black pen & PRINT IN CAPITALS
Please complete this form as soon as possible and either:

- **send it to our secure FAX on 0131 242 7742 or**
- **post it in the FREEPOST envelope provided**

---

1. Has the patient died? Yes ☐ No ☐

If yes, Date of death (dd/mm/yyyy) ☐☐/☐☐/☐☐☐☐

Most likely cause of death? _____

Was the cause of death confirmed on autopsy? Yes ☐ No ☐

---

2. Has the patient been admitted to hospital since <date of 6mfu>? Yes ☐ No ☐

If yes, Which hospital? _____

Why were they admitted? _____

Dates of admission and discharge for each admission?

Hospital	Date of Admission	Date of Discharge

---

3. Has the patient been diagnosed with NEW depression since <date of 6mfu>? Yes ☐ No ☐

Date of first (dd/mm/yyyy) ☐☐/☐☐/☐☐☐☐ Details _____

---

4. According to our records your patient was taking the following medications

Please indicate whether they are still taking each one, or not. Also, please add the names of any additional medications prescribed. (Alternatively just send back a **Print Out** of current medications if this is more convenient).

Name of medication>>>>>>>>>>>	Still taking?	Stopped?	Name of medication>>>>>>>>>>>	Still taking?	Stopped?

Additional medications which the patient is currently taking but which are not on the list above

1.	5.
2.	6.
3.	7.
4.	8.

---

5. Is the patient's address we hold correct? Yes ☐ No ☐

<Patients Address>

If not please amend or fill out below.

House no/ hospital name: _____

Street name: _____

Town/City: _____ Postcode: _____

Tel No (home): _____ Tel No (work): _____ Tel No (mobile): _____

Name of Person completing form: _____

Signature: _____

Date form completed (dd/mm/yyyy): ☐☐/☐☐/☐☐☐☐

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Crewe Road
Edinburgh EH4 2XU

Telephone 0131 537 1082
Fax 0131 332 5150
Email focus@ed.ac.uk
http://www.focustrial.org.uk

Patients name
Address
Postcode

Date

Dear <Patient name>

We understand that you were diagnosed with a stroke when you attended the <hospital> about a month ago. You/<The person giving consent> kindly agreed that you would participate in the FOCUS trial which aims to find out whether Fluoxetine improves peoples' recovery after a stroke. Therefore, it is very important that we find out how you are getting on.

This is the first of four letters and questionnaires we will send you over the next 12 months. Please answer the following questions and send this completed questionnaire back to us in the FREEPOST envelope provided. Alternatively, you can complete the questionnaire online (www.focustrial.org.uk/ZZZZ). If you cannot answer the questions yourself, somebody close to you can answer them on your behalf. Even if you have stopped taking the FOCUS trial capsules it is very important that we find out how you are, and why you stopped the capsules.

If we don't hear from you within the next couple of weeks we will telephone you to find out how you are. If you want to speak to a member of the trial team about completing the questionnaire or any other issue please telephone our helpline (0131 242 7741).

We look forward to hearing from you.

Yours sincerely

Professor Martin Dennis
Professor of Stroke medicine

FOCUS trial One Month Questionnaire

Please answer ALL the relevant questions!

1. Are you still taking the FOCUS trial medication? **Yes** ☐ **No** ☐

How often on average do you take the capsules (tick one box only)

- 7 days per week ☐
- 5-6 day per week ☐
- 3-4 days per week ☐
- 1-2 days per week ☐
- 0 days per week ☐

2. If you have stopped taking the FOCUS trial medication, when did you stop?
(insert your best guess if you don't know the exact date)

☐☐/☐☐/☐☐☐☐ **(dd/mm/yyyy)**

Please explain why you stopped: _____

_____

3. Have you had any problems which you think are related to the FOCUS trial capsules? **Yes** ☐ **No** ☐

If yes, please describe briefly: _____

4. Please check the contact details we have for you and amend them if necessary.

<Patients Address>

<Patients Telephone Numbers>

Other contact telephone numbers (family members and close friends)

Name	Relationship	Number	New Number

<Patients additional contact details>

Name of Person completing form: _____

Date form completed? ☐☐/☐☐/☐☐☐☐

(dd/mm/yyyy)

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Telephone 0131 537 1082
Fax 0131 332 5150
Email focus@ed.ac.uk
http://www.focustrial.org.uk

Patients name
Address
Postcode

Date

Dear <Patient name>

We understand that you were diagnosed with a stroke when you attended <hospital name> about 3 months ago. <You kindly agreed>/ <Name of person giving consent kindly agreed for you> to participate in the FOCUS trial which aims to find out whether Fluoxetine improves peoples' recovery after a stroke. Therefore, it is very important that we find out how you are getting on.

If you have **stopped** taking the FOCUS trial capsules, please answer Question 1 of the attached questionnaire.

If you **have** developed any **NEW** medical problems since you left hospital, please answer Question 2 and tell us about them.

Please can you send these questionnaires back to us in the FREEPOST envelope provided. Alternatively, you can complete the questionnaire online (www.focustrial.org.uk/YYYY).

If you are still taking the FOCUS trial capsules each day **and** have **not** had any **NEW** medical problems develop since you left the hospital, you do not need to complete a questionnaire at this time. You will need to continue to take the FOCUS trial capsules.

If you cannot answer the questions yourself, somebody close to you can answer them on your behalf. If you want to speak to a doctor about the FOCUS trial either:

- contact your own General Practitioner (GP) who will know about the study **or**
- telephone our helpline (0131 242 7741).

We will contact you again in about three months' time.

Prof Martin Dennis
Professor of Stroke Medicine

FOCUS trial Three Month Questionnaire

Please answer ALL the relevant questions!

1. Have you stopped taking the FOCUS trial medication? **Yes** ☐ **No** ☐

If yes, when did you stop taking the capsules?

☐☐/☐☐/☐☐☐☐ **(dd/mm/yyyy)**

If yes, please explain why you stopped: _____

_____

2. New medical problems?

Since you joined the FOCUS trial, have you been diagnosed with a:

- further stroke (not counting the one 3 months ago) **Yes** ☐ **No** ☐
- heart attack **Yes** ☐ **No** ☐
- bleeding stomach **Yes** ☐ **No** ☐
- broken bone confirmed by an X Ray **Yes** ☐ **No** ☐
- a fall causing injury (needing medical attention) **Yes** ☐ **No** ☐
- epileptic seizure **Yes** ☐ **No** ☐
- a low blood sugar (hypoglycaemia) **Yes** ☐ **No** ☐
- high blood sugars requiring an increase in any diabetic medication **Yes** ☐ **No** ☐
- low sodium level in your blood **Yes** ☐ **No** ☐
- new depression **Yes** ☐ **No** ☐

3. Have you had any other problems which you think are related to the FOCUS trial capsules? **Yes** ☐ **No** ☐

If yes, please describe briefly: _____

Name of Person completing form: _____

Date form completed? ☐☐/☐☐/☐☐☐☐

(dd/mm/yyyy)

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The University of Edinburgh
Bramwell Dott Building
Western General Hospital
Crewe Road
Edinburgh EH4 2XU
Telephone 0131 242 7741
Fax 0131 242 7742
Email focus@ed.ac.uk

Patients name
Address
Postcode

Date

Dear <Patient name>

<You kindly agreed>/ <Name of person giving consent kindly agreed for you> to participate in the FOCUS trial which aims to find out whether Fluoxetine improves peoples' recovery after a stroke. You should now have finished the course of FOCUS trial capsules so it is very important that we find out how you are getting on.

Please answer the attached questionnaire and send it back to us in the **small** FREEPOST envelope provided. If you cannot answer the questions yourself, somebody close to you can answer on your behalf. Even if you did not take the whole course of FOCUS trial capsules it is very important that we find out how you are, and why you stopped the capsules early.

Also, if you have any FOCUS trial capsules left, please put the bottle containing any remaining capsules in the **large** FREEPOST envelope and send it back to us for checking and safe disposal.

If we don't hear from you within the next couple of weeks we will telephone you to find out how you are. If you want to speak to a member of the trial team about completing the questionnaire or any other issue please telephone our helpline (0131 242 7741).

We look forward to hearing from you,

Prof Martin Dennis
Prof of Stroke Medicine

FOCUS trial Six Month Questionnaire

Please answer ALL the relevant questions!

1. Did you complete the 6 month course of the FOCUS trial medication? **Yes** ☐ **No** ☐

How often on average did you take the capsules (tick one box only)

- 7 days per week ☐
- 5-6 day per week ☐
- 3-4 days per week ☐
- 1-2 days per week ☐
- 0 days per week ☐

2. Have you finished all of the capsules? **Yes** ☐ **No** ☐

If you did not complete the course of the FOCUS trial medication, when did you stop taking it? (insert your best guess if you don't know the exact date)

☐☐/☐☐/☐☐☐☐ (dd/mm/yyyy)

Please explain why you stopped: _____

3. Have you had any problems which you think were related to the FOCUS trial capsules? **Yes** ☐ **No** ☐

If yes, please describe briefly: _____

4. Since you left hospital following your stroke on <insert date> have you had to be admitted to hospital again? **Yes** ☐ **No** ☐

Which hospital: _____

Why were you admitted: _____

5. Where do you live now? (*please tick one box only*)

My own home ☐
Relative's/ friends home ☐
Care/Nursing home ☐
Long term NHS care ☐
In hospital ☐
Other ☐ *please specify* _____

6. Do you have any carers coming into your home (other than family or friends) each week? **Yes** ☐ **No** ☐

If yes, how many time per week? ☐☐

The purpose of the following questions is to find out how much the stroke has affected your health and life. We want to know from YOUR POINT OF VIEW how the stroke has affected you.

7. If you had to, could you live alone without any help from another person? (This means being able to bathe, use the toilet, shop, prepare or get meals, and manage finances) **Yes** ☐ **No** ☐

8. Can you do everything that you were doing right before your stroke? (even if slower and not as much) **Yes** ☐ **No** ☐

9. Are you completely back to the way you were right before your stroke? **Yes** ☐ **No** ☐

10. Can you walk from one room to another without help from another person? **Yes** ☐ **No** ☐

11. Can you sit up in bed without any help? **Yes** ☐ **No** ☐

Please answer ALL the following questions by circling the most appropriate number

12. These questions are about the physical problems which may have occurred as a result of your stroke

In the past week, how would you rate the strength of your….	A lot of strength	Quite a bit of strength	Some strength	A little strength	No strength at all
a) Arm that was **most affected** by your stroke?	5	4	3	2	1
b) Grip of your hand that was **most affected** by your stroke?	5	4	3	2	1
c) Leg that was **most affected** by your stroke?	5	4	3	2	1
d) Foot/ankle that was **most affected** by your stroke?	5	4	3	2	1

If you have no affected, or weaker, side then score your dominant side i.e. your right side if you are right handed, or your left side if you are left handed.

13. These questions are about your memory and thinking

In the past week, how difficult was it for you to…..	Not difficult at all	A little difficult	Somewhat difficult	Very difficult	Extremely difficult
a) Remember things that people just told you?	5	4	3	2	1
b) Remember things that happened the day before?	5	4	3	2	1
c) Remember to do things (e.g. keep scheduled appointments or take medication)?	5	4	3	2	1
d) Remember the day of the week?	5	4	3	2	1
e) Concentrate?	5	4	3	2	1
f) Think quickly?	5	4	3	2	1
g) Solve everyday problems?	5	4	3	2	1

14. These questions are about how you feel, about changes in your mood and about your ability to control your emotions since your stroke

In the past week, how often did you….	None of the time	A little of the time	Some of the time	Most of the time	All of the time
a) Feel sad?	5	4	3	2	1
b) Feel that there is nobody you are close to?	5	4	3	2	1
c) Feel that you are a burden to others?	5	4	3	2	1
d) Feel that you have nothing to look forward to?	5	4	3	2	1
e) Blame yourself for mistakes that you made?	5	4	3	2	1
f) Enjoy things as much as ever?	5	4	3	2	1
g) Feel quite nervous?	5	4	3	2	1
h) Feel that life is worth living?	5	4	3	2	1
i) Smile and laugh at least once a day?	5	4	3	2	1

15. The following questions are about your ability to communicate with other people, as well as your ability to understand what you read and what you hear in a conversation

In the past week, how difficult was it to…..	Not difficult at all	A little difficult	Somewhat difficult	Very difficult	Extremely difficult
a) Say the name of someone who was in front of you?	5	4	3	2	1
b) Understand what was being said to you in a conversation?	5	4	3	2	1
c) Reply to questions?	5	4	3	2	1
d) Correctly name objects?	5	4	3	2	1
e) Participate in a conversation with a group of people?	5	4	3	2	1
f) Have a conversation on the telephone?	5	4	3	2	1
g) Call another person on the telephone, including selecting the correct phone number and dialling?	5	4	3	2	1

If you do not do any, or all, of these code them as <u>Extremely Difficult</u>.

f) If you do not call but are handed the phone this is OK.

g) If you cannot hold a phone book, but if you can read it, this is OK. This item addresses whether you are able to initiate a phone call, look up the number, and dial this number correctly.

16. The following questions ask about activities you might do during a typical day

In the past 2 weeks, how difficult was it to….	Not difficult at all	A little difficult	Somewhat difficult	Very difficult	Could not do at all
a) Cut your food with a knife and fork?	5	4	3	2	1
b) Dress the top part of your body?	5	4	3	2	1
c) Bathe yourself?	5	4	3	2	1
d) Clip your toenails?	5	4	3	2	1
e) Get to the toilet on time?	5	4	3	2	1
f) Control your bladder (not have an accident)?	5	4	3	2	1
g) Control your bowels (not have an accident)?	5	4	3	2	1
h) Do light housework tasks/chores (e.g. dust, make a bed, take out rubbish, do the dishes)?	5	4	3	2	1
i) Go shopping?	5	4	3	2	1
j) Do heavy household chores (e.g. hoover, laundry or gardening)?	5	4	3	2	1

If you do not do any, or all, of the activities listed, code them as Could not do at all.

a) If you are on pureed food code as Could not do at all.

c) Bathing oneself does not include getting into the bath.

e) This question is about having the physical ability to get to the bathroom on time?

f) Dribbling is considered an accident. If you have a catheter, code as Could not do at all.

g) Constipation is not counted here, person has to have an accident.

i) "Shopping" means any type of shopping and does not include driving.

17. The following questions are about your ability to be mobile, at home and in the community

In the past 2 weeks, how difficult was it to….	Not difficult at all	A little difficult	Somewhat difficult	Very difficult	Could not do at all
a) Stay sitting without losing your balance?	5	4	3	2	1
b) Stay standing without losing your balance?	5	4	3	2	1
c) Walk without losing your balance?	5	4	3	2	1
d) Move from a bed to a chair?	5	4	3	2	1
e) Walk one block?	5	4	3	2	1
f) Walk fast?	5	4	3	2	1
g) Climb one flight of stairs?	5	4	3	2	1
h) Climb several flights of stairs?	5	4	3	2	1
i) Get in and out of a car?	5	4	3	2	1

If you have not done an, or all, of the items in the past two weeks code as <u>Could not do at all</u>.

18. The following questions are about your ability to you use your hand that was <u>Most Affected</u> by your stroke

In the past 2 weeks, how difficult was it to use your hand that was most affected by your stroke to….	Not difficult at all	A little difficult	Somewhat difficult	Very difficult	Could not do at all
a) Carry heavy objects (e.g. bag of groceries)?	5	4	3	2	1
b) Turn a doorknob?	5	4	3	2	1
c) Open a can or jar?	5	4	3	2	1
d) Tie a shoe lace?	5	4	3	2	1
e) Pick up a penny?	5	4	3	2	1

If you have no affected, or weaker, side then score your dominant side i.e. your right side if you are right handed, or your left side if you are left handed.

19. The following questions are about how stroke has affected your ability to participate in the activities that you usually do, things that are meaningful to you and help you find purpose in life

In the past 4 weeks, how much of the time have you been limited in….	None of the time	A little of the time	Some of the time	Most of the time	All of the time
a) Your work (paid, voluntary or other)?	5	4	3	2	1
b) Your social activities?	5	4	3	2	1
c) Quiet recreation (crafts, reading)?	5	4	3	2	1
d) Active recreation (sports, outings, travel)?	5	4	3	2	1
e) Your role as a family member and/or friend?	5	4	3	2	1
f) Your participation in spiritual or religious activities?	5	4	3	2	1
g) Your ability to control your life as you wish?	5	4	3	2	1
h) Your ability to help others?	5	4	3	2	1

If you don't do any, or all, of the specific items, or have never done them, code as <u>None of the time</u>.

20. The following questions are about your energy

In the past 4 weeks did you….	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a) feel full of life?	5	4	3	2	1
b) have a lot of energy?	5	4	3	2	1
c) feel worn-out?	5	4	3	2	1
d) feel tired?	5	4	3	2	1

21. The following questions are about how you feel

During the past 4 weeks, how much of the time….	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
a) were you a happy person?	6	5	4	3	2	1
b) have you felt calm and peaceful?	6	5	4	3	2	1
c) have you been a very nervous person?	6	5	4	3	2	1
d) have you felt downhearted and blue?	6	5	4	3	2	1

22. Another question about how you feel

During the past 4 weeks how much of the time….	Always	Very often	Fairly often	Sometimes	Almost never	Never
did you feel so down in the dumps that nothing could cheer you up?	6	5	4	3	2	1

Under each heading, please tick the ONE box that best describes your health TODAY

23. Mobility

I have no problems in walking about ☐
I have slight problems in walking about ☐
I have moderate problems in walking about ☐
I have severe problems in walking about ☐
I am unable to walk about ☐

24. Self-care

I have no problems washing or dressing myself ☐
I have slight problems washing or dressing myself ☐
I have moderate problems washing or dressing myself ☐
I have severe problems washing or dressing myself ☐
I am unable to wash or dress myself ☐

25. Usual Activities

(e.g. work, study, housework, family or leisure activities)

I have no problems doing my usual activities ☐
I have slight problems doing my usual activities ☐
I have moderate problems doing my usual activities ☐
I have severe problems doing my usual activities ☐
I am unable to do my usual activities ☐

26. Pain / Discomfort

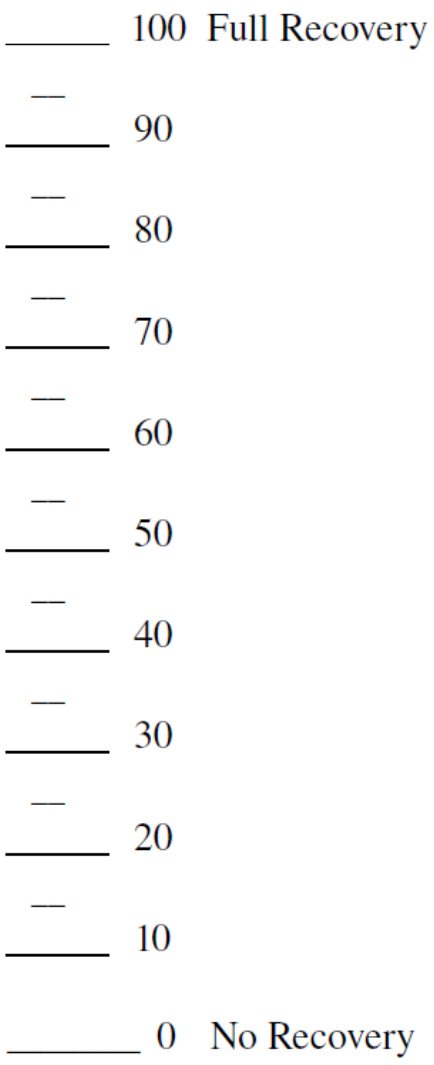
I have no pain or discomfort ☐
I have slight pain or discomfort ☐
I have moderate pain or discomfort ☐
I have severe pain or discomfort ☐
I have extreme pain or discomfort ☐

27. Anxiety / Depression

I am not anxious or depressed ☐
I am slightly anxious or depressed ☐
I am moderately anxious or depressed ☐
I am severely anxious or depressed ☐
I am extremely anxious or depressed ☐

28. Stroke recovery

On a scale of 0 to 100 with 100 representing full recovery and 0 representing no recovery, how much have you recovered from your stroke?



29. Please check the contact details we have for you and update them if necessary.

<Patients Address>

<Patients Telephone Numbers>

Other contact telephone numbers (family members and close friends)

Name Relationship Number New Number

<Patients additional contact details>

30. Who completed this questionnaire?

Please tick **one** of the following 3 boxes

I completed the questionnaire without help ☐

I had some help ☐

I was unable to complete the questionnaire so it was completed for me ☐

Please specify relationship _____

31. Date form completed?

☐☐/☐☐/☐☐☐☐ **(dd/mm/yyyy)**

Thank you very much for taking part in the FOCUS study and for completing this form. We will send you a very similar questionnaire in about 6 months time – that will be the last part of the study from your perspective. If you want to find out more about the trial and its results (in about 2018) please enter an email address where we can contact you, or a person close to you.

Email address: _____@_____

DIVISION *of* CLINICAL NEUROSCIENCES

The University of Edinburgh
Bramwell Dott Building
Western General Hospital
Crewe Road
Edinburgh EH4 2XU

Telephone 0131 537 1082
Fax 0131 332 5150
Email focus@ed.ac.uk
http://www.focustrial.org.uk

Patients name
Address
Postcode

Date

Dear <Patient name>

<You kindly agreed/ <Name of person giving consent kindly agreed for you> to participate in the FOCUS trial which aims to find out whether Fluoxetine improves peoples' recovery after a stroke. It is now 12 months since you joined the trial and at least 6 months since you finished the course of capsules. We want to find out how you are getting on now.

Please answer the attached questionnaire and send it back to us in the FREEPOST envelope provided. Alternatively, you can complete the questionnaire online (www.focustrial.org.uk/cccc). If you cannot answer the questions yourself, somebody close to you can answer on your behalf.

If we don't hear from you within the next couple of weeks we will telephone you to find out how you are. If you want to speak to a member of the trial team about completing the questionnaire or any other issue please telephone our helpline (0131 242 7741).

This is the last time we will be contacting you, so we would like to thank you very much for taking part in this important study.

We look forward to hearing from you,

Prof Martin Dennis
Prof of Stroke Medicine

FOCUS trial Twelve Month Questionnaire

Please answer ALL the relevant questions!

1. Where do you live now? (*please tick one box only*)

My own home	☐	
Relative's/ friends home	☐	
Care/Nursing home	☐	
Long term NHS care	☐	
In hospital	☐	
Other	☐	*please specify* _____

2. Do you have any carers coming into your home (other than family or friends) each week? **Yes** ☐ **No** ☐

If yes, how many time per week? ☐☐

The purpose of the following questions is to find out how much the stroke has affected your health and life. We want to know from YOUR POINT OF VIEW how the stroke has affected you.

3. If you had to, could you live alone without any help from another person? (This means being able to bathe, use the toilet, shop, prepare or get meals, and manage finances) **Yes** ☐ **No** ☐

4. Can you do everything that you were doing right before your stroke? (even if slower and not as much) **Yes** ☐ **No** ☐

5. Are you completely back to the way you were right before your stroke? **Yes** ☐ **No** ☐

6. Can you walk from one room to another without help from another person? **Yes** ☐ **No** ☐

7. Can you sit up in bed without any help? **Yes** ☐ **No** ☐

Please answer ALL the following questions by circling the most appropriate number

8. These questions are about the physical problems which may have occurred as a result of your stroke

In the past week, how would you rate the strength of your….	A lot of strength	Quite a bit of strength	Some strength	A little strength	No strength at all
a) Arm that was **most affected** by your stroke?	5	4	3	2	1
b) Grip of your hand that was **most affected** by your stroke?	5	4	3	2	1
c) Leg that was **most affected** by your stroke?	5	4	3	2	1
d) Foot/ankle that was **most affected** by your stroke?	5	4	3	2	1

If you have no affected, or weaker, side then score your dominant side i.e. your right side if you are right handed, or your left side if you are left handed.

9. These questions are about your memory and thinking

In the past week, how difficult was it for you to…..	Not difficult at all	A little difficult	Somewhat difficult	Very difficult	Extremely difficult
a) Remember things that people just told you?	5	4	3	2	1
b) Remember things that happened the day before?	5	4	3	2	1
c) Remember to do things (e.g. keep scheduled appointments or take medication)?	5	4	3	2	1
d) Remember the day of the week?	5	4	3	2	1
e) Concentrate?	5	4	3	2	1
f) Think quickly?	5	4	3	2	1
g) Solve everyday problems?	5	4	3	2	1

10. These questions are about how you feel, about changes in your mood and about your ability to control your emotions since your stroke

In the past week, how often did you….	None of the time	A little of the time	Some of the time	Most of the time	All of the time
a) Feel sad?	5	4	3	2	1
b) Feel that there is nobody you are close to?	5	4	3	2	1
c) Feel that you are a burden to others?	5	4	3	2	1
d) Feel that you have nothing to look forward to?	5	4	3	2	1
e) Blame yourself for mistakes that you made?	5	4	3	2	1
f) Enjoy things as much as ever?	5	4	3	2	1
g) Feel quite nervous?	5	4	3	2	1
h) Feel that life is worth living?	5	4	3	2	1
i) Smile and laugh at least once a day?	5	4	3	2	1

11. The following questions are about your ability to communicate with other people, as well as your ability to understand what you read and what you hear in a conversation

In the past week, how difficult was it to…..	Not difficult at all	A little difficult	Somewhat difficult	Very difficult	Extremely difficult
a) Say the name of someone who was in front of you?	5	4	3	2	1
b) Understand what was being said to you in a conversation?	5	4	3	2	1
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If you do not do any, or all, of these code them as <u>Extremely Difficult</u>.

f) If you do not call but are handed the phone this is OK.

g) If you cannot hold a phone book, but if you can read it, this is OK. This item addresses whether you are able to initiate a phone call, look up the number, and dial this number correctly.

12. The following questions ask about activities you might do during a typical day

In the past 2 weeks, how difficult was it to….	Not difficult at all	A little difficult	Somewhat difficult	Very difficult	Could not do at all
a) Cut your food with a knife and fork?	5	4	3	2	1
b) Dress the top part of your body?	5	4	3	2	1
c) Bathe yourself?	5	4	3	2	1
d) Clip your toenails?	5	4	3	2	1
e) Get to the toilet on time?	5	4	3	2	1
f) Control your bladder (not have an accident)?	5	4	3	2	1
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h) Do light housework tasks/chores (e.g. dust, make a bed, take out rubbish, do the dishes)?	5	4	3	2	1
i) Go shopping?	5	4	3	2	1
j) Do heavy household chores (e.g. hoover, laundry or gardening)?	5	4	3	2	1

If you do not do any, or all, of the activities listed, code them as Could not do at all.

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c) Bathing oneself does not include getting into the bath.

e) This question is about having the physical ability to get to the bathroom on time?

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14. The following questions are about your ability to you use your hand that was <u>Most Affected</u> by your stroke

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a) Carry heavy objects (e.g. bag of groceries)?	5	4	3	2	1
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15. The following questions are about how stroke has affected your ability to participate in the activities that you usually do, things that are meaningful to you and help you find purpose in life

During the 4 past weeks, how much of the time have you been limited in….	None of the time	A little of the time	Some of the time	Most of the time	All of the time
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b) Your social activities?	5	4	3	2	1
c) Quiet recreation (crafts, reading)?	5	4	3	2	1
d) Active recreation (sports, outings, travel)?	5	4	3	2	1
e) Your role as a family member and/or friend?	5	4	3	2	1
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b) have you felt calm and peaceful?	6	5	4	3	2	1
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18. Another question about how you feel

During the past 4 weeks how much of the time….	Always	Very often	Fairly often	Sometimes	Almost never	Never
did you feel so down in the dumps that nothing could cheer you up?	6	5	4	3	2	1

Under each heading, please tick the ONE box that best describes your health TODAY

19. Mobility

I have no problems in walking about ☐
I have slight problems in walking about ☐
I have moderate problems in walking about ☐
I have severe problems in walking about ☐
I am unable to walk about ☐

20. Self-care

I have no problems washing or dressing myself ☐
I have slight problems washing or dressing myself ☐
I have moderate problems washing or dressing myself ☐
I have severe problems washing or dressing myself ☐
I am unable to wash or dress myself ☐

21. Usual Activities

(e.g. work, study, housework, family or leisure activities)

I have no problems doing my usual activities ☐
I have slight problems doing my usual activities ☐
I have moderate problems doing my usual activities ☐
I have severe problems doing my usual activities ☐
I am unable to do my usual activities ☐

22. Pain / Discomfort

I have no pain or discomfort ☐
I have slight pain or discomfort ☐
I have moderate pain or discomfort ☐
I have severe pain or discomfort ☐
I have extreme pain or discomfort ☐

23. Anxiety / Depression

I am not anxious or depressed ☐
I am slightly anxious or depressed ☐
I am moderately anxious or depressed ☐
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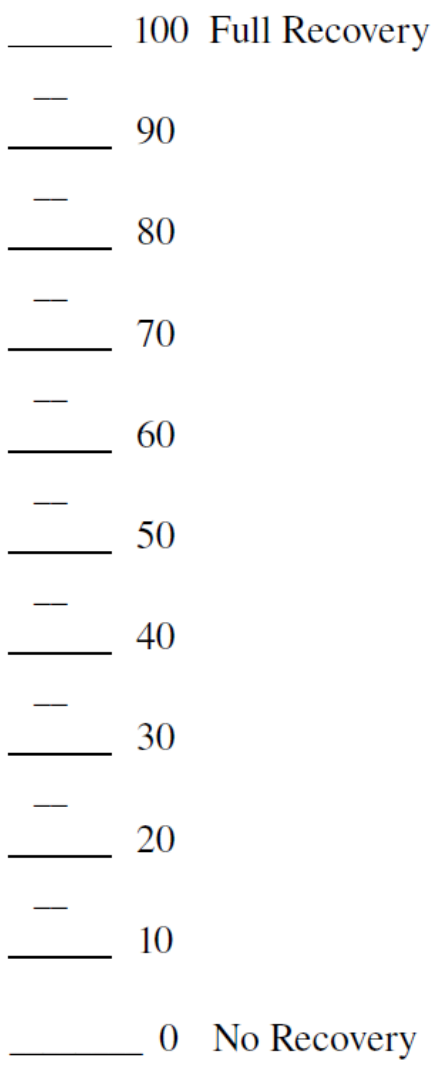
I am extremely anxious or depressed ☐

24. Stroke recovery

On a scale of 0 to 100 with 100 representing full recovery and 0 representing no recovery, how much have you recovered from your stroke?



25. Who completed this questionnaire?

Please tick one of the following 3 boxes

I completed the questionnaire without help ☐

I had some help ☐

I was unable to complete the questionnaire so it was completed for me ☐

Please specify relationship _____

26. Date form completed?

☐☐/☐☐/☐☐☐☐ **(dd/mm/yyyy)**

Thank you very much for taking part in the FOCUS study and for completing this form. This is the last part of the study from your perspective. If you want to find out more about the trial and its results (in about 2018) please enter an email address where we can contact you, or a person close to you.

Email address: _____@_____