

Medication Suitability Review

Date

Dear [GP contact]

Re: ToSCA – a Trial of Sertraline versus CBT for generalised Anxiety
[Patient name and DOB]

We have obtained the above patient's consent to contact you regarding their medical suitability to take part in the ToSCA trial.

ToSCA is a randomised controlled trial comparing the clinical and cost effectiveness of an SSRI treatment (sertraline) versus Cognitive Behavioural Therapy in people with Generalised Anxiety Disorder (GAD) who have not responded to step 1 or step 2 interventions. It is funded by the National Institute of Health Research Health Technology Assessment programme, and coordinated by UCL.

In order for them to take part in the study, we need to know that there is no medical contra-indication to them receiving treatment with sertraline for generalised anxiety disorder if they end up being randomised into that treatment arm. We have been asked to check this at the participant recruitment stage, whichever arm of the trial the patient is randomised into.

Please could you complete the checklist on the next page and email this to [Trial confidential email address] or fax back to [add local fax number]

If you have any questions, please contact us using the details below.

The research team will be seeing this patient within a week of the date of this letter to assess their suitability for the trial and **we would be grateful if you could send your reply to reach us by then.** [Give date here if possible to do this via mail merge.]

Many thanks for your time. The practice will be reimbursed at the agreed rate of £35.

Yours Sincerely

[Site to add local contact details]

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Patient name:	YES	NO
Is the patient unable to complete trial questionnaires due to insufficient English or cognitive impairment?		
Does the patient have significant dependence on alcohol or illicit drugs?		
Does the patient have any comorbid psychotic disorder, such as schizophrenia, schizo-affective disorder or bipolar disorder?		
Has the patient received any treatment with antidepressants in the last eight weeks?		
Has the patient received monoamine oxidase inhibitors or pimozone within the past 14 days?		
Does the patient have poorly controlled epilepsy?		
Does the patient have any known allergies to sertraline?		
Is the patient currently participating in another clinical trial involving medication?		
Does the patient have severe hepatic impairment?		
Is the patient currently receiving anti-coagulant medication?		
Does the patient have any form of bleeding disorder?		

In addition, for female patients could you please confirm:

	YES	NO
The patient is current pregnant, planning pregnancy or lactating		
The patient is able to conceive		
The patient cannot conceive as post-menopausal		
The patient cannot conceive as they have had a hysterectomy or surgical sterilisation		

Name of GP completing checklist:

Signature of GP completing checklist:

Date: