Card for participants randomised to CBT:

ToSCA
Trial of Sertraline versus CBT for generalised Anxiety

You are taking part in a CTIMP **trial of** Sertraline Vs Cognitive Behavioural Therapy **in** generalised anxiety

Your treatment = Cognitive Behavioural Therapy

In case of any serious medical problems please contact the Coordinating centre at UCL: [redacted]

If you would like further information please call the Trial Manager on: [redacted] in working hours only.

ToSCA is coordinated by University College London (UCL)

Please carry this card while you are on treatment and show it to any other doctor who may be treating you.

Card for participants randomised to sertraline:

ToSCA
Trial of Sertraline versus CBT for generalised Anxiety

You are taking part in a CTIMP **trial of** Sertraline Vs Cognitive Behavioural Therapy **in** generalised anxiety

Your treatment = Sertraline, dose: 25-150 mg/daily

In case of any serious medical problems please contact the Coordinating centre at UCL: [redacted]

If you would like further information please call the Trial Manager on: [redacted] in working hours only.

ToSCA is coordinated by University College London (UCL)

Please carry this card while you are on treatment and show it to any other doctor who may be treating you.

SAE sheet for GPs

Add local header/details

A Trial of Sertraline versus Cognitive Behavioural Therapy in generalised Anxiety

Safety reporting information for GPs

To help us to ensure the safety of our patients please let us know if any of your patients involved in the TOSCA trial experience any untoward medical events.

We only need to know about the events that meet one of the following criteria:

- Results in death
- Is life-threatening at the time of the event
- Requires hospitalisation or prolongation of existing hospitalisation
- Results in a significant or persistent disability or incapacity
- Consists of a congenital abnormality or birth defect
- Any other important medical condition that carries a real (not hypothetical) risk of one of the outcomes above

Please ask your trial patients whether they have experienced any illnesses at every visit.

If any illness meets one of the above criteria please email the trial team as soon as possible on:

[redacted]

We would need to know as much as possible about the event including, as an absolute minimum:

- Patient name
- Trial number
- Reason for seriousness (one of the above criteria)
- Trial arm i.e. CBT or Sertraline
- Your name and contact telephone number
- What happened to the patient?
- e.g. (patient had a heart attack at home, patient has been diagnosed with diabetes)
- Start and end dates of the event

Please also include the following information if possible:

- Treatment given for the event
- Whether the trial intervention was changed as a result of the event (dosage, frequency)
- If hospitalised, hospitalisation dates
- Where the event happened
- Concomitant medication at the time of the event
- Other medical conditions at the time of the event

If you are unsure about whether or not to notify us of an event please contact a member of the trial team on the above email address or contact the PRIMENT Pharmacovigilance Coordinator on

[redacted]

Thank you for working with us on the ToSCA trial.

SAE sheet for IAPT

Add local header/details

A Trial of Sertraline versus Cognitive Behavioural Therapy in generalised Anxiety

Safety reporting information for IAPTs

To help us to ensure the safety of our patients please let us know if any of your patients involved in the TOSCA trial experience any untoward medical events.

We only need to know about the events that meet one of the following criteria:

- Results in death
- Is life-threatening at the time of the event
- Requires hospitalisation or prolongation of existing hospitalisation
- Results in a significant or persistent disability or incapacity
- Consists of a congenital abnormality or birth defect
- Any other important medical condition that carries a real (not hypothetical) risk of one of the outcomes above

Please ask your trial patients whether they have experienced any illnesses at every visit.

If any illness meets one of the above criteria please call the trial team as soon as possible on:

[redacted]

Thank you for working with us on the ToSCA trial.