'ational Institute for Health Research

ToSCA

Trial of Sertraline versus CBT for generalised Anxiety

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Study Objective

ToSCA is an NHS NIHR funded randomised controlled trial comparing the effectiveness of CBT and an SSRI medication (Sertraline) for patients with Generalised Anxiety Disorder (GAD).
Both CBT and SSRI medication are effective treatments for GAD and recommended in the NICE GAD guideline, but there has never been a study directly comparing their effectiveness. The current guidelines say that if a patient with GAD has not responded to step 1 (GP based) or step 2 (Low Intensity IAPT) interventions then the choice of treatment between a pharmacological or psychological treatment at step 3 should be based mainly on patient preference.

This trial aims to provide a clear answer to the clinical query of which is likely to be the most effective: 14-16 sessions of high intensity CBT delivered by IAPT **or** the SSRI sertraline at a recommended dose

How are we recruiting patients for this study?

Potential participants will be identified by Low Intensity (LI) IAPT workers from those people they see who score > 10 on the GAD-7, are likely to suffer from GAD and have not responded to step1 or 2 interventions for this. With the patient's permission they will pass their details across to the research team who will send them full details of the study and see them to assess and consent them for the trial.

What would we like local general practices to do?

- We would like the practice to agree in principle to prescribe sertraline for any of your patients randomised to that arm of the trial
- If any of your patients are identified by the LI IAPT service as potentially eligible we would like you to check their medical suitability to take part and fax / email this information to the research team For any of your patients randomised to the sertraline arm we would like you to prescribe this according to the trial protocol for this. This would involve 6 patient visits over a 12 month period, but only mean seeing and treating people according to recommended normal clinical practice.
- We would like to health services data at the end of the study, including the number of GP appointments attended, secondary care referrals and psychotropic medication prescribed. We are happy to do the relevant search, but can also fund someone at the practice to help with this.

Benefits of taking part in the study

For the patients – best practice treatment for GAD whichever trial arm they are in
For the practice – reimbursement of £ 35 per patient checked for medical suitability to take part, + £140 per patient treated in the medication arm (likely to only be one or two patients per practice)
+ £20 per participant for helping to collect health services data

Recruitment period

Spring 2015 to December 2017

To find out more about the study please contact

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