ToSCA - Trial of Sertraline versus CBT for generalised Anxiety

The trial design comes from an NIHR HTA commissioned call, which state that participants should have generalised anxiety disorder (GAD) and have not responded to step 1 or step 2 psychological interventions for this as recommended by NICE. This follows from a research recommendation in the NICE GAD guidelines aiming to establish whether CBT or medication is more effective for these step 3 patients – no direct comparison has ever been made.

Because of the design required to answer this question we will be recruiting participants via the IAPT (Increasing Access to Psychological Therapies) services which is where the step 2 psychological interventions are delivered. They will be identified by the low intensity IAPT workers reviewing their case and if they are interested in being considered for the trial their details will be passed across to a member of the research team who will make contact, send them a full patient information sheet (PIS) and then consent and assess them for eligibility if they wish to take this forward. The IAPT centres will be full sites if they are involved in the research team processes listed above – this will be via their Clinical Study Officers (CSOs) or other appropriately trained research active staff.

We will only know at the point of participant consent and randomisation which general practice they are linked with. In order to mirror usual practice we have designed the medication arm with the patient's GP prescribing the medication if they are randomised to this arm of the trial. We will be working with up to 180 general practices nationally for this arm, as each participant may come from a different general practice. We will not be asking the GPs to follow any formal protocol, rather we will be advising them to follow usual clinical guidelines in the way they prescribe Sertraline for GAD. They will be free to alter their patient's treatment as they consider necessary and clinically indicated. This design has been approved by the MHRA who have approved the trial as a level A CTIMP or lowest risk.

A single site-specific information (SSI) form has been created to address the only general practice aspect of the study which differs from usual clinical practice, which is data collection for research purposes. Once a potential participant has expressed an interest in the trial, at the same time as arranging a baseline assessment to check eligibility, the research team member will contact the patient's GP (with the patient's consent) to ask them to complete the medical suitability form. This is a simple form asking for yes/no answers with regard to whether there are any known contra-indications to the patient being prescribed Sertraline if they are randomised to that arm of the trial. We consider that this must be established for safety reasons and before randomisation to avoid any bias between the two trial groups.

The other component of patient data we will need to collect from the patients' general practices is the health service outcome data for all trial participants. This will cover items such as the number of GP and practice nurse appointments attended, referrals to secondary care psychology, psychiatry and general medical services and prescriptions of psychotropic medication. This will either be collected by a member of the practice staff or a member of the research team with a valid local research passport. All data will be pseudonymised before leaving the practice and identifiable only by a numerical ID. NHS assurance is being requested at former PCT level as there is no requirement to gain individual assurance from each general practice.