TAPERS END OF PROJECT HRA REPORT

Project Reference	RfPPB-17-1409
Project Title	Treating Anxiety to PrevEnt Relapse in pSychosis (TAPERS) - a feasibility trial.
Lead Researcher	Professor Jeremy Hall
Host Institution	Aneurin Bevan University Health Board
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LAY SUMMARY

A total of 285 patients were screened for eligibility. Of these, 238 were found to be ineligible, and only 47 were found to be eligible. Reasons for not recruiting the 43 patients who were eligible was the majority of patients (n=29) declined to participate for multiple reasons, including associating sertraline with their first episode (n=1); not wanting to participate in research (n=2); or did not wish to take additional medication or change their current treatment regime (n=5), whilst others declined without providing a reason (n=21).

Four participants were recruited. All four were single males, three British and one African. They completed their baseline assessments, and were randomised to either placebo (n=2) or sertraline (n=2). Both the placebo arm patients received their allocated treatment after randomisation, whilst none of those randomised to the sertraline arm received their assigned treatment for the following reasons: one patient withdrew from the trial after their baseline visit, and although the other patient remained in the study, placebo was mis-allocated during randomisation, and mediation for this arm (placebo) distributed to them in error. With the patient already taking the medication upon discovery, the allocated treatment was maintained for the remainder of the study and documented as a non-compliance as per regulations.

The three patients who remained in the study after their baseline visit completed all follow-up assessments, albeit two patients (n=1 in each arm) withdrew from the trial treatment at week 22 due to the clinical need to introduce new medication. No SAEs were reported in this trial.

Progression to full trial: Although retention over the 24-week period was green (≥50%); the individual adherences by timepoint (weeks 4, 18 and 22) were green (≥50%); the overall adherence to antidepressant medication (all patients) was amber (25-50%); and recruitment into the trial was red (<25%).

Future trial: Progression criteria indicate that an effectiveness trial would not be feasible as TAPERS was currently designed. We would recommend the following modifications and literature searches:

-Understanding of when antidepressants are currently prescribed e.g., are patients already on antidepressants before their first psychotic episode or does this happen afterwards?

-Recruitment to trial and data collection in a clinic, and at a much earlier timepoint in diagnosis.

-How important is therapeutic alliance and does it impact on recruitment into trials?

-Resource and support structure for recruitment.

-Investigate the setup of mental health teams at the nominated trial sites, as these work to different models.

Overall interpretation and main findings

-More people were ineligible than we had expected - especially because more than expected were already on SSRIs.

-The trial regime was very demanding with regards to staff resourcing and trial assessments (partly due to requirements of ethics and all the additional assessments requested by the MHRA) and future studies could consider a more pragmatic design to maximise inclusion.

-The study was negatively impacted by the COVID-19 pandemic.

-Overall however due to the results and the items discussed in this report, it does not make a case for a larger scale trial.