

Correction

Dan Siskind

Treatment of clozapine-associated obesity and diabetes with exenatide (CODEX) in adults with schizophrenia: study protocol for a pilot randomised controlled trial. *BJPsych Open*, 2015; 1(1): 67–73

Since the publication of this article in *BJPsych Open*, some protocol changes have been introduced to the study.

We have not yet begun recruiting for this study. In the original protocol we planned to recruit 60 obese ($\text{BMI} \geq 30 \text{ mg/kg}^2$) adults with schizophrenia on stable treatment with clozapine with or without poorly controlled diabetes ($\text{HbA1c} \geq 7.5\%$). In order to avoid diabetes being a confounding factor in the study, the participants are to be recruited into two arms: arm A is to include obese participants with poorly controlled diabetes and arm B participants who are obese without diabetes. The participants in each arm are then to be randomised into a control group (treatment as usual) and an intervention group (receiving the exenatide treatment). The participants are to be recruited from the Metro South Addiction and Mental Health Service outpatient population.

Prior to recruiting participants, we reviewed the rates of obesity, diabetes and poorly controlled diabetes among people on clozapine at our clinical service. We noted that there were very few potential

participants who meet the poorly controlled diabetes criteria for the arm A group within the recruitment population, with the majority of people treated for type 2 diabetes with $\text{HbA1c} \leq 7.5\%$. Given this, we would be unable to meet our recruitment targets for arm A and have adjusted the protocol accordingly:

1. Removed the exclusion criteria for arm A of $\text{HbA1c} \geq 7.5\%$ to allow all people with type 2 diabetes to be offered the opportunity to participate.
2. Adjusted the primary objective for arm A participants to be the same as for Arm B participants (previously improved glycaemic control, now change in weight and proportion of patients with $>5\%$ weight change from baseline to week 24), with glycaemic control now as a secondary objective for Arm A.
3. Provided clarification in the protocol for the treatment of diabetes for the participants in the arm A intervention group with an HbA1c of $\leq 7.5\%$. Participants who are taking metformin and a sulphonylurea will have their sulphonylurea ceased to minimise risk of hypoglycaemic episodes. Treatment for participants with an HbA1c of $\geq 7.5\%$ will be unchanged from the existing protocol.

Dan Siskind, Professor of Psychiatry, Metro South Addiction and Mental Health Service, MacGregor, Queensland, Australia. Email: d.siskind@uq.edu.au
© The Royal College of Psychiatrists 2016