FINAL PROJECT REPORT

Date: 13th June 2012

Name:

Dr Claire Dowson

Project Title:

Cognitive/behavioural function in long term SSRI antidepressant use

Please copy the "Specific Objective(s)" statement, entered on your application form, in the space below.

Aim: Randomised Controlled Trial: to determine the effect of continued antidepressant use for long term maintenance treatment on cognitive and behavioural functioning of previously depressed but currently well people.

Objectives:

1. To determine whether there are cognitive and behavioural adverse effects in those who remain on an SSRI antidepressant as long term maintenance treatment after they have recovered.
2. If there are such deficits are there factors (for example sociodemographic or illness factors) that might be helpful in predicting who is and is not affected.

Briefly describe how successful you were in achieving the stated objective(s). If the objective(s) was not achieved, explain why that is the case and describe what you did manage to achieve.

The above objectives will be achieved but this has not been feasible within the original timeframes outlined in the CMRF Grant proposal. As everyone is aware the series of Christchurch Earthquakes have continued to disrupt people's personal and working lives including research. Recruitment for the Antidepressant Cessation Trial (Assoc Prof Mangin) from which this study draws its participants has continued to be slow and erratic in Christchurch. Fortunately the computer tablet (CANTAB) is portable and we have been able to use it to assess those recruited from Wellington and Nelson increasing the overall numbers. Currently n=154 participants have completed the 6 month CANTAB assessment and behavioural questionnaire, with a subset of this group completing 2 assessments at week 1 & 6 months (for longitudinal subanalyses). Originally the study expected to obtain n=200 participants. We still have n=50 people to recruit for the Antidepressant Cessation Trial so I expect numbers to increase from =154 to approximately n=180. Although it was estimated that we would need to recruit approximately 200 people, we have already well exceeded the number of participants sited in any related studies. Therefore I am confident that these data when analysed should be able to at least answer the first objective above.
Unfortunately the final analyses and objectives of this study cannot be conducted until the Antidepressant Cessation Trial is completed. This is because the design of the Antidepressant Cessation Trial study requires that we (I am an Investigator in this study as well) cannot unblind participants for analysis until the study is finished. Hence we cannot analyse the cognitive & behavioural data for the 2 groups of interest i.e., those remaining on the antidepressant fluoxetine and those who have tapered off it.

Briefly describe any interesting outcomes which might not have been considered in your original objectives (if any).

One outcome we did not originally anticipate both for this study and it's parent study the Antidepressant Cessation Trial was the number of participants who exited n-103 (this group, now not taking the study medication are also being followed at additional cost to the parent study). Of the group who have exited, n=70 exited prior to the 6 month data collection point, hence they did not complete the 6 month CANTAB assessment. Although the exit numbers

were larger than we anticipated, fortunately for this study few people have declined to participate or have not proceeded for other reasons (n=10).

Summary & Plan

The above objectives are achievable but this has not been feasible within the original timeframes outlined in the CMRF Grant proposal. At this point, the Antidepressant Cessation Trial from which this study draws it's participants has approximately 50 people to recruit and then 18 months from recruitment to completion for each participant. There is no reason to stop this cognition and behavioural function study as all equipment and questionnaires have already been purchased and the assessments are either completed by the already trained interviewers or myself. It is likely that we can recruit at least another 20 participants.

Given the above and the potential much longer timeframe to completion than originally anticipated, I will do my best to be available for consultation and write up when these data are analysed. As I am currently on a fixed term contract with the University of Otago, I cannot guarantee to will continue to be employed by the end date of this study. I am sure you are aware that the other two investigators i.e., Associate Professor Derelie Mangin (Dept of General Practice, Christchurch) & Professor Roger Mulder (HOD Dept of Psychological Medicine, Christchurch) are both tenured employees of the University of Otago and will therefore undertake their responsibilities in relation to this study at it's conclusion.