

Thank you for the invitation to respond to the submission from LDAA which you provided.

I am happy to respond as their submission is clearly incorrect in regard to our overall study, and I hope that in correcting this I may address some of the concerns in the community.

To do so I must first explain, in outline, what we have done in our study.

We were funded to develop and test the feasibility of a new psychology-based intervention for DSCATT.

To do so we had to undertake a number of preparatory steps before we could launch the trial of that new intervention.

We had to understand the condition by examining available data and talking to people with the condition. We had to develop a way of determining who had the condition, suitable for use in a scientific trial. We had to develop a way of measuring the effects of the condition, so we could measure whether what we were doing was helping. And we had to develop the intervention itself, and find out whether that intervention could be delivered, could be followed, could be tolerated and was safe, by trying it with a handful of people with DSCATT. This latter step is encompassed in what we call a pilot trial, and is the last step before we launch the final trial, our “feasibility randomised controlled trial”, which is the ultimate goal of the study. The other steps, while essential, are mainly conducted as preparation for the final trial.

The criticism of LDAA relates to the pilot trial, but it is misconceived. They criticise it as though the pilot study was the final trial of the study, which it is not. The final trial of the study is the “feasibility randomised controlled trial”, which has been underway for a year now. Their concerns - that our study is not randomised, that there is no control group, that it is unblinded, that there are no clinical measures, that it is too small, that our statistics are too simple – are not relevant criticisms of a pilot study, and are simply not true of our main study, which is conducted to the highest standards of clinical trials. As the information about our main study has been publicly available for over a year I am unclear why LDAA chose to focus on our pilot trial in this way, but I fear they have confused the pilot with the main study. I hope it has not misled the inquiry but I am happy to correct any misunderstanding.

Yours faithfully

Professor Richard Kanaan

Principal Investigator

<https://blogs.unimelb.edu.au/dscatt/participation/>