Author's response to reviews

Title: The Y-Worri Project: study protocol for a randomized controlled trial.

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Author's response to reviews: see over
Dear Editors,

Thank you for the opportunity to revise our manuscript titled “The Y-Worri Project: study protocol for a randomized controlled trial”. Responses to editor and reviewer comments are detailed below. All changes have also been highlighted in the revised manuscript.

We look forward to hearing about the acceptability of our manuscript in due course.

Yours sincerely,

Alison Calear

Editorial requests:

1) Please ensure the title conforms to journal style for study protocol articles. The title should follow the format ?__________: study protocol for a randomized controlled trial.? The title has been changed to conform to the journal style for study protocols. It now reads: The Y-Worri Project: study protocol for a randomized controlled trial.

Reviewer requests:

1) Trial status: Please clarify “ongoing” as Trials does only publish protocols of studies with ongoing patient recruitment.

At the time of submitting the manuscript six months ago, recruitment was ongoing. The trial status has subsequently changed and has been clarified as: Participant recruitment was completed in June 2012. Data collection is ongoing and is expected to be completed in June 2013.

2) Primary outcome: The (single or combined) primary outcome needs to be stated explicitly (including measurement tool and timepoint): 0.3 SD on the GAD-7 scale
postintervention? Please discuss how multiple testing will be addressed in case of interim analyses and how this effects power.

Further detail has been added to the description of the measures to make the primary outcome clearer: Generalised anxiety disorder (GAD) symptoms will be the primary outcome of interest for the study and will be measured on the Spence Children’s Anxiety Scale (SCAS) [32] and the GAD-7 [33]. An effect size of approximately .3 is expected at both post-intervention and follow-up. The expected .3 effect size is further discussed in the power calculations.

No interim analyses will be conducted, as all data will be analysed at the same time using mixed models repeated measures (MMRM) analyses.