

Correction

Hall CL, Walker GM, Valentine AZ, *et al.* Protocol investigating the clinical utility of an objective measure of activity and attention (QbTest) on diagnostic and treatment decision-making in children and young people with ADHD—‘Assessing QbTest Utility in ADHD’ (AQUA): a randomised controlled trial. *BMJ Open* 2014;4:e006838.

Since publication of the original article a change was made to the analysis of the primary outcome. A blinded review of the data of the first 145 participants who had reached the primary end point in the trial revealed that approximately 30% of the sample had not received a diagnosis within the 6 month time frame. Additionally, under 10% of the sample had withdrawn or been excluded from the trial. Given that the primary outcome for this trial is number of consultations to a confirmed diagnosis (either confirming or excluding ADHD); this meant that not all participants could contribute to the primary outcome with the original analysis proposal of Poisson regression. In order to include outcome data from all cases (in accordance with an intention to treat analysis) followed-up to 6 months with respect to diagnosis (i.e. those receiving a diagnosis before 6 months and those ‘censored’ at 6 months without a diagnosis) we have changed our analysis plan for the primary outcome from Poisson regression to a survival analysis. The team sought independent statistical advice from four experienced statisticians (one member of the independent trial steering committee, two experienced independent statisticians with expertise in randomised control design, and our trial statistician) to inform this decision. Each member was unanimous in supporting the change to the analysis. As such, survival analysis will be performed to quantify the treatment effects on the number of visits needed for a confirmed diagnosis between Qb open and Qb blind arm (primary outcome). Additionally, we have added a secondary outcome, to assess the proportion of the sample who receive a correct diagnosis (either confirming or excluding ADHD) by 6 months. The addition of this secondary outcome arose from the advice of a patient and public involvement member, who felt the delay to diagnosis was a serious concern for parents and young people and should be captured in our analysis.

Sample size and justification

The revised sample size was based on the same audit data reported in the original paper. Based on the person-period dataset for discrete survival analysis using logistic regression modelling, results showed that the percentage of patients with an ADHD diagnosis was 34.07% for the group without the QbTest and 45.98% for the group with the Qb test result, with 19.45% outcome variability due to time variables. 196 participants would be needed to detect the difference between the proportion of 34% and 45% with 80% power at two tailed 0.05 significance level, assuming 20% total variability to be explained by time. With 90% power at two-tailed 0.05 significance level, the number of participants required would be 268. To check the robustness of the sample size calculation, a Cox regression was performed with the same data yielding a hazard ratio (HR) of 1.67. By performing power analysis with a log rank test assuming 30% censor rate in the Qb blind arm and 10% withdrawal, 238 participants would be required to detect an effect of HR=1.67 with 90% power at two sided 0.05 significance level. Using a more conservative HR of 1.65, 250 participants would be required. As a result of these calculations the sample size was increased to a maximum of 268 participants. Stata powerlog and power logrank command were used to perform the power analysis.

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