Author’s response to reviews

Title: Rationale and protocol for the Assessment of Impact of Real-time Continuous Glucose Monitoring on People Presenting with Severe Hypoglycaemia (AIR-CGM) Study

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We thank the editor and the reviewers for their comments and suggestions to improve our manuscript. Please find below our responses to the comments highlighted in bold. The new changes in the manuscript have been highlighted in bold blue.

Editor comments:

1. Reference which studies and discuss the heterogeneity of your proposed population in relation of data variance which informed your sample size calculation. This is in relation to reviewer 1’s comment regarding the loose inclusion criterion chosen. Please be more explicit in aims.

In the section for inclusion/exclusion criteria we have included the following paragraph:

“The aim of this study is to recruit people with type 1 diabetes at high-risk for recurrent severe hypoglycaemia who may benefit from CGM usage. The study population is in keeping with other clinical studies of adults at highest risk of hypoglycaemia (eg. HypoDE, IN CONTROL and I-HART CGM) and will include participants with long diabetes duration, hypoglycaemia-associated autonomic failure, as well as people experiencing their first episode of severe hypoglycaemia resulting from transient risk factors. People with enduring risks that may not be modified by CGM (such as drug or alcohol use) will be assessed on an individual basis and may be excluded with these data reported at the study end.” (Page 8, eligibility section)
2. The corresponding author differs in system to manuscript. - This has been changed on the system.

3. Statement “all authors have read and approved the manuscript” is missing in authorship contributions. – This has been included in the authorship contributions

4. Move Consent to participate statement into declaration. – Done

5. Remove funding information from acknowledgements to funding info. -Done

Many thanks.