Reviewer’s report

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

Version: 0 Date: 05 Jul 2019
Reviewer: Alistair Lumb

Reviewer's report:

No major comments, but quite a few minor ones. Please see below:

Abstract:

First 2 sentences - suggest rework for clarity. Eg "Severe hypoglycaemia carries a significant risk of morbidity and mortality for people with type 1 diabetes. Economic costs are also high, estimated at £13 million annually in England."

Suggest replace "glycaemic control" with "glycaemia", (also in other places through the manuscript - "Language Matters statement suggests avoiding using the word "control")

Suggest "and is cost effective" rather than "as well as being cost effective"

Why use the phrase "Continuous glucose sensing technology" rather than "Continuous glucose monitoring"?

"Changing service demands" sentence would benefit from clarification. Perhaps something like "Changing demand means that novel approaches need to be taken to healthcare provision. This study has the potential to shape future national standards."

P16 L1 - delete comma after "severe hypoglycaemia"

Keywords:

Not 3-10 words

Background:

P5L32 Suggest say people with T1D "report" this number of hypos rather than "have", especially as the authors then quite rightly point out this may be an underestimate.

P5L37 "However, it is likely this may well be under-reported by individuals" might read better as "This may be an underestimate."

P5L54 delete comma after "both"
P7L53-58 suggest replace "early follow-up" with "early review"

Suggest "there are low levels of follow-up, therapy change and specialist input following an episode of hypoglycaemia"

Sentence beginning "This corroborates the delay…" adds little. If to include something, would suggest something along the lines of "This is in line with the clinical experience of the authors."

P8L17: "and is therefore used" needs fleshing out - perhaps "and therefore this is used as the basis for the primary study outcome"

Eligibility criteria:

General point - may be better as bullet point lists

Inclusion

P8L56 suggest "through ambulance call-out…" be replaced with "with potential participants identified following ambulance call-out or ED attendance"

Exclusion

"Participants" not "subjects"

Sample size and feasibility:

Not clear of the relevance of the Greater London LAS figures here, except to say that conveyance rates are comparable.

Recruitment:

Delete comma after "eligibility checks of individuals"

"who will make a welfare ring back to the patient within 2 hours" is not clear. I think I know what is meant, but perhaps "will contact the person within 2 hours by telephone to check on their welfare. If the person has capacity and is well…"

"Potential participants will be identified"

Screening visit and enrolment:

There is a mixture of future and present tense. Would use one (future?) for consistency.

Bloods will need to be taken at 9am, this should be made explicit (otherwise a 9am cortisol will not be obtained). TFT, 9am cortisol and TTG are to be checked. Will potential participants be excluded eg if 9am cortisol is low, thyroid function is abnormal or untreated coeliac disease is identified? These are not currently in the exclusion criteria.
Are there any limitations on access to education? Is education/educational material available in languages other than English? If not, then perhaps have lack of English as an explicit exclusion criterion.

Could the "desirable range" be defined for sensor glucose? This should be consistent across participants. 3.9-10 mmol/l (as per secondary outcomes)?

Secondary outcomes:

Would consider also adding "Number of episodes of severe hypoglycaemia requiring third party assistance" as a secondary outcome. Ambulance call-out rates is included (this will have an impact on cost-effectiveness assessments) but not all episodes will necessarily require third party assistance.

Statistics and data analysis

Please define what is mean by "nocturnally" (e.g. midnight to 6am)

References:

References 1 & 8 are identical papers although given different names. Should delete one

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

Not relevant to this manuscript
Quality of written English
Please indicate the quality of language in the manuscript:

Needs some language corrections before being published

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