PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	An effectiveness-implementation hybrid type 2 trial evaluating two psychoeducational programmes for severe hypoglycaemia in type 1 diabetes: Implementation study protocol
AUTHORS	Soukup, Tayana; Hull, Louise; Smith, Emma; Healey, Andy; Bakolis, Ioannis; Amiel, Stephanie; Sevdalis, Nick; Kendall, Mike

VERSION 1 – REVIEW

REVIEWER	M. de Wit Amsterdam UMC, the Netherlands
REVIEW RETURNED	04-Jun-2019

GENERAL COMMENTS	This study protocol describes the implementation part of an effectiveness-implementation hybrid type 2 trial evaluating two psychoeducational programmes for severe hypoglycaemia in type 1 diabetes. The study is ambitious and aims to collect a vast amount of implementation related data alongside the effectiveness trial. The rationale for the design and measures is well explained. The mixed methods approach is a strength. A few questions remain: - Please add the dates of the study (start and expected end date) - How many participants do you aim to include in the quantitative part and in the qualitative part? How are participants selected for the interviews (assuming that not all participants will be interviewed)? - The study takes place in the UK and in one site in the US. As the healthcare systems are very different, this might affect the results of the implementation. How will you take these differences into account? A bit more information on the selection of participants, consequences on data analyses and discussion of the advantages and disadvantages of involving 2 countries would be appreciated.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Comments to the Author

This study protocol describes the implementation part of an effectiveness-implementation hybrid type 2 trial evaluating two psychoeducational programmes for severe hypoglycaemia in type 1 diabetes. The study is ambitious and aims to collect a vast amount of implementation related data alongside the effectiveness trial. The rationale for the design and measures is well explained. The mixed methods approach is a strength. A few questions remain.

We thank the reviewer for their positive reaction to our work. Please find below our responses to their queries.

1. Please add the dates of the study (start and expected end date)

Start and expected end date for the study is July 2018 to December 2019, and this is now included in the Methods section under Settings on page 11 of the manuscript:

2. How many participants do you aim to include in the quantitative part and in the qualitative part? How are participants selected for the interviews (assuming that not all participants will be interviewed)?

The target sample size and method of recruitment for quantitative and qualitative parts is now included in the Methods section under Participants on pages 11 and 12 of the manuscript. For the quantitative part we will use census approach and recruit the entire available population in the context of the trial i.e. all patients participating in the trial interventions (N=96 people with diabetes), and all healthcare professionals involved in the intervention delivery (N=28 professionals). For the qualitative part, we will use availability sampling where we will recruit those HCPs and patients within the participating hospitals who are recruited into or delivering one of the two programmes and are available and willing to partake in the interview. The latter will culminate in a sample of approx. 32 patients (4 sites x 2 patients x 2 types of courses x 2 sets of courses per site), and 28 HCPs in total. Availability sampling will also be used to recruit people who declined to take part in the programme.

3. The study takes place in the UK and in one site in the US. As the healthcare systems are very different, this might affect the results of the implementation. How will you take these differences into account? A bit more information on the selection of participants, consequences on data analyses and discussion of the advantages and disadvantages of involving 2 countries would be appreciated.

The point on UK-US differences is an excellent one. We have clarified this point in the Methods section under Settings on page 11 of the manuscript, Data Analysis on pages 18 and 19, as well as in the Discussion on page 22. Below is also summary of our response.

While the healthcare system in the UK and US is fundamentally different, this difference is important to consider for the subsequent implementation and scale up of our complex interventions worldwide. In fact, understanding the difference between the participating sites is one of the focal points of the implementation analysis. Hence both qualitative and quantitative implementation analyses will be stratified according to the sites. Taken that 2246% of people with type 1 diabetes experience severe hypoglycaemia and would therefore benefit from the availability of the trialled interventions, building our understanding of the factors affecting implementation not only across different hospitals but also different systems is critical. While the current protocol includes only one site from the US, our vision is that the follow-on study (hybrid type 3 trial focused on implementation) will include more international sites thus deepening out understanding of how to increase successful implementation so that more patients will benefit from the interventions.

For the purposes of the current study however, pragmatic considerations had to be made given the complexity of the trialled programmes that require specialist educators, and niche patient group. Hence we recruited four specialist care diabetes centres that (i) provide structured education for patients with type 1 diabetes and therefore availability of the on-site diabetes educators, (ii) have clinical capability and expertise in the diabetic hypoglycaemia management, and (iii) routinely receive tertiary referrals for problematic hypoglycaemia thus access to the niche group of adults with type 1 diabetes and problematic hypoglycaemia that the interventions are designed for (the US sites is a leading tertiary referral centre for adults with type 1, for example). In addition, our US site is world renowned for expertise in diabetes treatment and research providing the necessary expertise around educational principles of hypoglycaemia recognition, treatment and avoidance.