Author’s response to reviews

Title: HATRIC: A feasibility study of Pelargonium sidoides root extract EPs®7630 (Kaloba®) for the treatment of acute cough due to lower respiratory tract infection in adults: study protocol for a double blind, placebo-controlled randomised trial

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Dear Reviewers,

Thank you for your help and your time spent reviewing our manuscript. Please see below our responses to your comments, we hope that we have addressed them all to your satisfaction.

Thank you again,
The HATRIC Study Team.

Reviewer 1:

With regards to progression criteria, it is important to state what will inform the decision to proceed to a larger trial. Stating the same issue will be considered is insufficient.

Please note that describing progression criteria does not affect your funding arrangement or ethics approval as it doesn't touch on the design, analyses or reporting of your pilot study. It affects the interpretation and the concern here is that if these are not stated upfront, unsuccessful pilots may be moved to larger studies or successful pilots may be abandoned.

The progression criteria are not held in stone and for the most part adaptations can be made to the larger trial to make things work. It would be helpful to comment on this as this is now an academic paper and it is reasonable to position it in the context of current knowledge. If these have not been discussed with the team, it is also fine to say they are in the works.

Although no formal progression criteria were set for the trial I have added the following to the text to explain how the results will inform the decision to proceed to a larger trial or not.

‘Although no formal progression criteria were set at the start of this trial or written into the protocol, the feasibility of a definitive trial will be assessed against the objectives as set out in Table 1 alongside the data collected in the qualitative study, i.e.:

- Is the recruitment rate per site per month adequate to make the required sample size for a definitive trial possible within a reasonable timeframe?
- Is the proportion of patients recruited from those eligible sufficient to allow the definitive trial results to be generalizable?
- Is the amount of data completion in the diaries sufficient to allow the definitive trial results to be generalizable?
- Do participants comply with either the liquid or the tablet intervention sufficiently to make a definitive trial worthwhile?
- Can we collect sufficient health economic data from participants so that a health economic analysis would be possible alongside the definitive trial?
• Is the rate of outcome measures in the control group compatible with conducting a definitive trial in the UK, with an achievable sample size, within a reasonable timeframe?

In addition to this, I have also updated the SPIRIT checklist.