Reviewer’s report

Title: EmPhAsIS: Empowering Pharmacists in Asthma management through Interactive SMS. Study protocol for a pragmatic, pharmacy-based, cluster randomized controlled trial.

Version: 2 Date: 2 October 2014

Reviewer: Cindy Cooper

Reviewer’s report:

1. Recommendations for overall improvements - voluntary

There are a few improvements that could be made to the background to set it into context, give more support to the study, and bring it up to date.

The references are quite old (over a decade), refs: 10, 12, 13, 14 especially and the authors discuss “landmark studies in the 90’s”. There is more up to date literature available which could be included to bring this up to date.

The authors state mobile phone technology has had an impact on behaviour change, and how this technology has been evaluated in other studies of asthma care but don’t expand on this. It would be useful to report study outcomes and give examples of how this supports what the study aims to do - even though it is not delivered in pharmacy it would show application of the technology for asthma care in other health settings and state the potential applicability to pharmacy (refs 28 & 29).

2. Mandatory revisions required to allow replication of the work

The study assistant (doing data collection via phone at 0, 6, 12 with participant) is blind to allocation - how will they keep this concealed & is it the same person collecting the data throughout? Are they blinding at analysis/statistician level? Further clarification is required.

No time mentioned for recruitment of sites (n=74) this needs to be included

Recruitment of 5 participants, per site, over 12 months. This seems a long recruitment period for 5 people how is this justified?

The authors identify a 12 month follow up period but no intervention period so are we to assume this is when the intervention is also delivered? This isn't clear and needs to be specified.

The authors do not include an overall timescale for the study anywhere in the paper so this needs to be included.

Pharmacy training:

Training components given to pharmacists aren’t described fully. The authors
don't mention giving training on the Asthma Control Test which will be administering at follow up. Some of the elements of the training (i.e. inhaler technique) are then not discussed elsewhere so it's not clear if this is being done as part of the education or not.

Pharmacists will be giving 'counselling' to the participants; what does this entail and who is training the pharmacist to be counsellors?

How long will the training take?

What are the components of the action plan – these are not mentioned and need including

Clarification is needed on all above aspects of the pharmacy training

Participants:
Are there any issues related to taking consent in under 14s? The protocol requires further clarification on ethical issues relating to consent in children and then subsequently how they will manage the consent process as a result.

What recruitment strategies will be used? Are participants recruited opportunistically/consecutively? Will the study monitor the number of non eligible/non consenting?

Intervention:
Consists of 3 parts; 1. Education, 2. SMS 3. telephone follow up

The timing of the intervention is described as 'monthly'. Do we assume it is SMS monthly over the 12 month follow up period? This needs clarifying.

The authors show a flow chart for the steps of the intervention but don't mention how many repeated attempts they will use for follow up phone contacts and at what point they will record missing data / attrition – this needs to be included.

Pharmacists follow up the SMS, in 24 hours, if participant scores high on the screening questions as advised by an electronically generated report. Will this report tell them which parts of the AAAQ the participant scored high on so they can adjust their telephone 'counselling' accordingly? (the AAAQ looks at why someone doesn't adhere i.e. side effects, cost, forgot, severity of asthma) This needs to be addressed and clarified.

What happens if pharmacist can't respond within 24 hours?

If they refer to physician how will this activity be captured, will attendance at the physicians be monitored and what if repeated referrals are made? Repeated attendance at a physician may have an impact on improving adherence rather the intervention so how will this be handled in the analysis?

Usual care;
Sites in the control arm will receive the educational plan so that they can assess
the 'impact of the intervention itself' assuming they mean the SMS? But the authors don't account for the impact of the follow up phone call which may also be monthly depending on scores from the AAAQ. How will the effect of the SMS be isolated or is the follow up phone call also part of the overall intervention? Will acceptability of delivering the intervention be measured?

Usual care participants will have had 1 contact with pharmacist in 12 months. The intervention is up to 12 contacts (and potential referrals to a physician) depending on AAAQ results. Will this be accounted for in the analysis?