PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (**http://bmjopen.bmj.com/site/about/resources/checklist.pdf**) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

ARTICLE DETAILS

TITLE (PROVISIONAL)	RAPP, a systematic e-assessment of postoperative recovery in patients undergoing day surgery: study protocol for a mixed-methods study design including a multicenter, two-group, parallel, single -blind randomized controlled trial and qualitative interview studies
AUTHORS	Nilsson, Ulrica; Jaensson, Maria; Dahlberg, Karuna; Odencrants, Sigrid; Grönlund, Åke; Hagberg, Lars; Eriksson, Mats

VERSION 1 - REVIEW

REVIEWER	Arthur R. Williams Research Associate, Center of Innovation on Disability and Rehabilitation Research (CINDRR), James A. Haley Veterans Affairs Medical Center, Tampa, Florida, and Research Professor, Health Administration and Policy, College of Health and Human Services, George Mason University, Fairfax, Virginia Research Associate, Bay Pines VAMC, Bay Pines, Florida; Research Associate, DC VAMC, Washington, DC Principal, Consult Health, Boca Raton, Florida
REVIEW RETURNED	03-Oct-2015

GENERAL COMMENTS	What the authors wish to accomplish is of considerable interest for ambulatory care. A number of N/A are marked above, since this is a review of a protocol not a completed study. Major concerns are: the illness or conditions to be examined for "outpatient" treatment are unclear. Cataract surgery, for example, requires a number of visits which exceed the time frames as described. The type of illnesses or conditions, very importantly, are likely to be reflected in study results. How will sampling and design deal with this? Is this important in the Swedish context? Do the researchers propose to obtain baseline measures and do the CUA using patients as their own controls? This mitigates this concern, and will permit patients with different conditions and treatments to be analyzed in secondary analyses. (This is suggested by methods cited but not clearly stated in the statistical description.) It seems that data collection for time to recovery may be too short. But, the conditions to be included and examined are unspecified. The authors may want to give attention to alternative data collection procedures. 1. Why collections of data every day? Perhaps, data collection at specified intervals and a lengthening of the time frame for data collection may be better. 2. A source is cited for the 0.03 difference in QALY in the power analysis. Is this a clinically meaningful change? Some attention may be given to this power

	analysis. The use of a larger QALY difference and changes in other parameters may reduce the sample size, and thereby allow lengthened follow-up of patients at no additional study costs. 3. How do the researchers plan to deal with the nature of the intervention? It would seem that if the phone (cases) and paper interventions (controls) are used both sets of patients are being followed up. The only difference is electronic versus the paper intervention. Essentially both groups are receiving the same intervention: more intensive follow-up. Perhaps, there is a misunderstanding on my part of how the intervention is to be understood and will be dealt with by the researchers. 4. The qualitative study and its associated costs may not be very useful, since it is unclear to me what the investigators hope to discover. These studies can be very expensive and time consuming, and a question arises whether the funds used for this work might be better used for other components of the study. It may be possible that at this stage of the examination of the intervention the only relevant issues are the degree to which patients like the intervention and adhere to the treatment protocol. Specific comments: 1. Unclear is the term "native software applications." (Do the authors mean Swedish if so why not say so?) 2. Many journals and funding agencies are requiring definitions specific to the study, even if brief, of "standard of care." Such a definition does not appear in the protocol.

REVIEWER	Dawn Dowding Columbia University School of Nursing, USA
REVIEW RETURNED	07-Oct-2015

GENERAL COMMENTS	I read this paper with interest as I think it is an important topic. However, I had some concerns about your study, both in terms of the actual intervention and the outcomes you propose to measure as follows: 1. I was very unclear what the actual purpose of your intervention is. Is it to collect data on a patients quality of life/surgical outcomes, or is it to provide them with post-operative support and advice on self-management post discharge? I think it is the former, in which case I am not sure what the point is of giving them, what is in effect an electronic survey to fill out on their smart phone - what is this trying to achieve in terms of benefits to patient outcomes? 2. This leads to my second major concern, which is the outcomes you intend to measure, with the primary one being cost-effectiveness. I was not clear what the rationale for this was - cost-effective compared to what? Why is cost-effectiveness the primary concern for an intervention such as this one? Surely it is more important to understand issues to do with patient outcomes - in terms of recovery post day surgery, re-hospitalization rates, use of services etc and the potential benefits of providing ehealth support to these, rather than whether or not it is as cheap to give them an electronic survey as it is to not do anything at all to measure quality of life perceptions? 3. Given my major concerns with regard to the above points, I also felt that the study was not well designed to address a question of importance - ehealth interventions have the potential to provide considerable support to patients post day-surgery, and I wasn't clear that this trial would add to our knowledge base about the potential benefits and pitfalls.

REVIEWER	Nando Campanella Telehealth and Telemedicine Centre of the University of the State of Amazonas (Brazil). Address: Avenida Carvalho Leal, Cachoerinha, Manaus (Brazil)
REVIEW RETURNED	11-Oct-2015

GENERAL COMMENTS	This paper is about the design of the mobile application Recovery Assessment by Phone Points (RAPP) for following-up patients recovering from day-surgery. The design is a multicenter, single - blind randomized controlled trial, enhanced by qualitative interview studies. Definitely, from the methodological point of view, the design is very well drawn The study is supposed to provide interesting suggestions about the feasibility of expanding m-health strategies in feeding back health professionals about the outcomes of day-surgery activities. Furthermore, it is important that e-health, and more specifically m-health, projects can be evaluated properly through controlled randomised studies, which are not always possible to be carried out. By this way, many clinical parameters have to be assessed. Even more importantly, the study should evaluate the adherence of the patients with no bias caused by the encouragement of the supply of the devices by the researchers, because the mobiles are planned to be of property of the patients. Actually we acknowledge the importance of carrying out such a study. However, some remarks must be done about the timeliness of the authors to submit such a study, that reduces the interest of the reader. In practice the whole paper contains hardly the introduction and justification of the study, that is easily understood, and the section Materials and Methods, but beyond the drawing of the protocol and the ethical details so far nothing has been implemented and consequently no results reported. In the abstract the authors regret that "…limited information is available regarding postoperative recovery at home…", but actually their paper does not respond to this missing information and the expectations of the readers keep unatended. As a consequence, the discussion has no sense, because it adds nothing to the paper. As an additional evidence of this, the authors are forced to use the future tense in the discussion, that is quite unusual. Finally, clinical outcomes of day-surgery activities are supposed to be difficult to be categorized, because day-surgery operations may be very heterogeneous. Thus, in the materials and methods, it would have been essential to set the variables of the outcomes, but there is none and therefore the bullets 17a 17b and 18 of the checklist are purely theoretical and generic. For a correct design, the points dealing with the clinical outcomes ought to be defined earlier than implementing the study. We would be interested to read this paper again, but only when it is complete.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
What the authors wish to accomplish is of considerable interest for ambulatory care. A number of N/A are marked above, since this is a review of a protocol not a completed study.
3. Major concerns are: the illness or conditions to be examined for "outpatient" treatment are unclear.

Cataract surgery, for example, requires a number of visits which exceed the time frames as described. The type of illnesses or conditions, very importantly, are likely to be reflected in study results. How will sampling and design deal with this? Is this important in the Swedish context?
--An exclusion criterion regarding visual impairment has been inserted in the section Participants. Information concerning analyzing patients' characteristics, in type of surgery or anesthesia in relation to postoperative recovery has been inserted in the aim and the section Statistical analysis. And in the background an international perspective has been inserted.

4. Do the researchers propose to obtain baseline measures and do the CUA using patients as their own controls?
--Information about baseline and control group can be found in section Data collection procedure and Table 1, and in the Randomization section.

5. This mitigates this concern, and will permit patients with different conditions and treatments to be analyzed in secondary analyses. (This is suggested by methods cited but not clearly stated in the statistical description.)
--Information about this has been inserted in the aim and in the Statistical analysis section

6. It seems that data collection for time to recovery may be too short. But, the conditions to be included and examined are unspecified. The authors may want to give attention to alternative data collection procedures. Why collections of data every day? Perhaps, data collection at specified intervals and a lengthening of the time frame for data collection may be better.
--Data collection is not performed daily, see Table 1. Data collection procedure However, the patients in the intervention group will report their recovery daily. We do not think that the duration of data collection, 14 days, is too short - measuring recovery after 7 and 14 days is common in research with focus on postoperative recovery.
Gornall BF, Myles PS, Smith CL, Burke JA, Leslie K, Pereira MJ, et al. Measurement of quality of recovery using the QoR-40: a quantitative systematic review. Br J Anaesth. 2013;111(2):161-9.
A flowchart has been inserted to clarify data collection of the RCT study.

7. A source is cited for the 0.03 difference in QALY in the power analysis. Is this a clinically meaningful change? Some attention may be given to this power analysis. The use of a larger QALY difference and changes in other parameters may reduce the sample size, and thereby allow lengthened follow-up of patients at no additional study costs.
--As no study like this has been done earlier it has been hard to perform a power analysis. The power analysis was therefore guided by values of QALY weights in patients with asymptomatic gallstone diseases (0.76) and a surgical scar (0.76) (Bass et al 1994). We think that it is better to conduct a study with a high number of participants and an assumption of a low effect of the intervention instead of the opposite.

8. How do the researchers plan to deal with the nature of the intervention? It would seem that if the phone (cases) and paper interventions (controls) are used both sets of patients are being followed up. The only difference is electronic versus the paper intervention. Essentially both groups are receiving the same intervention: more intensive follow-up. Perhaps, there is a misunderstanding on my part of how the intervention is to be understood and will be dealt with by the researchers.
--The reviewer seems to have misunderstood the intervention. Information about the intervention and the control group can be read in the section Intervention and a flowchart has been inserted to clarify this.

9. The qualitative study and its associated costs may not be very useful, since it is unclear to me what the investigators hope to discover. These studies can be very expensive and time consuming, and a

question arises whether the funds used for this work might be better used for other components of the study. It may be possible that at this stage of the examination of the intervention the only relevant issues are the degree to which patients like the intervention and adhere to the treatment protocol. The qualitative studies with patients are important to perform as we want explore the participants' experience of postoperative recovery and how using the app for postoperative follow-up influenced this recovery. It is obviously important to understand how people experience interventions so as to be able to design them optimally. Further questions will be asked regarding the participants' experience of being contacted by a nurse; in addition, descriptions and eventual expectations about the help that was received will also be solicited
--The other qualitative study is also important as we will describe the staffs' experience of using a systematic postoperative follow-up tool and their willingness to pay for the follow-up service.
The headings of these two studies has been reformulated.

10. Unclear is the term "native software applications." (Do the authors mean Swedish if so why not say so?)
--Native software application has been changed to mobile application

11. Many journals and funding agencies are requiring definitions specific to the study, even if brief, of "standard of care." Such a definition does not appear in the protocol.
--"Standard of care" has been defined in the manuscript as "no follow up". In the Background section there is information about this nonexistence of systematic follow-up care after day surgery.

Reviewer: 2
I read this paper with interest as I think it is an important topic. However, I had some concerns about your study, both in terms of the actual intervention and the outcomes you propose to measure as follows:
1. I was very unclear what the actual purpose of your intervention is. Is it to collect data on a patients quality of life/surgical outcomes, or is it to provide them with post-operative support and advice on self-management post discharge? I think it is the former, in which case I am not sure what the point is of giving them, what is in effect an electronic survey to fill out on their smart phone - what is this trying to achieve in terms of benefits to patient outcomes?
--The aim and benefits of it is both the systematic data collection to provide information about patients' postoperative recovery and to provide support after discharge to those patients who need it. This has been clarified in the Discussion section.

2. This leads to my second major concern, which is the outcomes you intend to measure, with the primary one being cost-effectiveness. I was not clear what the rationale for this was - cost-effective compared to what? Why is cost-effectiveness the primary concern for an intervention such as this one? Surely it is more important to understand issues to do with patient outcomes - in terms of recovery post day surgery, re-hospitalization rates, use of services etc and the potential benefits of providing ehealth support to these, rather than whether or not it is as cheap to give them an electronic survey as it is to not do anything at all to measure quality of life perceptions?
--We think that cost-effectiveness is of primary concern as it is hard to implement something that will cost money and time. There is a great need for systematic follow-up that could lead to quality improvement and patients' safety and self-care. The rationale for this intervention is that until today no such follow-up exists. This is also what we compare the intervention to i.e no follow-up. If we and our colleagues, working with day surgery care, want to implement this e-assessed follow-up we have to show cost-effectiveness of such an intervention to our decision-makers and politicians. This is also reflected on in the Discussion section.

3. Given my major concerns with regard to the above points, I also felt that the study was not well designed to address a question of importance - ehealth interventions have the potential to provide

considerable support to patients post day-surgery, and I wasn't clear that this trial would add to our knowledge base about the potential benefits and pitfalls.
--See the response above and the comments from reviewer 3.

Reviewer: 3

This paper is about the design of the mobile application Recovery Assessment by Phone Points (RAPP) for following-up patients recovering from day-surgery. The design is a multicenter, single - blind randomized controlled trial, enhanced by qualitative interview studies.
Definitely, from the methodological point of view, the design is very well drawn The study is supposed to provide interesting suggestions about the feasibility of expanding m-health strategies in feeding back health professionals about the outcomes of day-surgery activities. Furthermore, it is important that e-health, and more specifically m-health, projects can be evaluated properly through controlled randomised studies, which are not always possible to be carried out. By this way, many clinical parameters have to be assessed. Even more importantly, the study should evaluate the adherence of the patients with no bias caused by the encouragement of the supply of the devices by the researchers, because the mobiles are planned to be of property of the patients. Actually we acknowledge the importance of carrying out such a study.
However, some remarks must be done about the timeliness of the authors to submit such a study, that reduces the interest of the reader.
4. In practice the whole paper contains hardly the introduction and justification of the study, that is easily understood, and the section Materials and Methods, but beyond the drawing of the protocol and the ethical details so far nothing has been implemented and consequently no results reported.
--This manuscript is a study protocol, therefore no results are presented.

5. In the abstract the authors regret that "…limited information is available regarding postoperative recovery at home…", but actually their paper does not respond to this missing information and the expectations of the readers keep unatended.
--The sentence cited above is followed by " …though there is a current lack of a standard procedure regarding postoperative follow-up". This is the aim of the study; to test an e-assessed follow-up after day surgery.

6. As a consequence, the discussion has no sense, because it adds nothing to the paper. As an additional evidence of this, the authors are forced to use the future tense in the discussion, that is quite unusual.
--It is hard to discuss a study protocol in terms of results as there are no results yet. They are indeed in the future. However, a study protocol has to include a discussion and we have tried to discuss the effort and needs for an intervention such as ours.

7. Finally, clinical outcomes of day-surgery activities are supposed to be difficult to be categorized, because day-surgery operations may be very heterogeneous. Thus, in the materials and methods, it would have been essential to set the variables of the outcomes, but there is none and therefore the bullets 17a 17b and 18 of the checklist are purely theoretical and generic. For a correct design, the points dealing with the clinical outcomes ought to be defined earlier than implementing the study.
--Information about analyzing clinical outcomes has been inserted in the aim and the Statistical analysis section as well as information about analyzing the effect size.