Author's response to reviews

Title: Feasibility of evidence-based diagnosis and management of heart failure in older people in care: randomised controlled trial

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Author's response to reviews: see over
Response to reviewers’ comments:
Feasibility of evidence-based diagnosis and management of heart failure in older people in care: randomised controlled trial.

Reviewer 1.
Comments
1. The clinical trial on which this paper is based is described on the web site as being in two parts, a diagnostic stage and an intervention stage. It is not described as a feasibility study. I assume that what happened is that the investigators found it difficult to recruit sufficient patients for the intervention stage and are therefore publishing the results they have as a feasibility study. This must be clarified. Also is this intended to be the principal paper describing the prevalence of heart failure, the first stage of their project? Again this must be clarified. In concluding that a study such as theirs is feasible that readers need to know whether this is a statement of opinion or is there any objective criteria of feasibility against which they have made this judgement. Again this must be clarified. One might say that anything is feasible if you have enough resources to throw at a project. Some comments about cost-effectiveness are required. I appreciate that cost-effectiveness may not have been formally measured. These points are commented upon below.
2. My main concern in making my recommendation has been whether there has been an adequate description of the intervention and an adequate discussion of the feasibility of this type of intervention.
3. In general, I would say that this paper has met the standard subject to revision and comment as I have indicated above and in the following sections.
4. The paper is well written, in general easy to follow and presented in a format that is suitable for publication.
5. In writing these comments I am conscious that some of the points I have raised are answered later on in the text. In such cases the authors should reflect whether they need to make reference to the later explanation or to alter the text at the point I have raised the issue.

We are grateful for the referee’s helpful comments. General points have been addressed specifically in the sections below. The issue of feasibility is important and has been clarified: we sought to ascertain whether pragmatic delivery of an onsite intervention was possible (i.e. would patients and care staff participate and could the intervention be delivered within appropriate time scales). This is evidenced in participation rates (97%) and absence of withdrawal from the trial with a 100% completion rate – albeit in the small numbers of a pilot trial. We refer to the time to optimum titration for the intervention group in the results but were unable to assess this for those in usual care. A full assessment of cost-effectiveness would need to be conducted as part of a definitive study; the pilot trial demonstrates that the resources determining this are measurable in terms of GP and specialist nurses’ activity and the use of treatments.

Abstract
6. The primary outcome is described as prescription of ACEi and beta-blockers but in the results section of the abstract the figures relate to optimal prescription. Please confirm what the primary outcome was and give the result for the primary outcome. “Findings” is not sufficiently specific. Changes to the paper have been made to clarify the primary outcome in the abstract, see page 2.
Introduction
7. The basis of the study is that ACEi (the abbreviation needs to be standardised) and beta-blockers improve outcomes of heart failure in care home patients. Is there robust evidence for this? The authors’ reference 4 is a URL which leads to a series of sections. Searching the complete guideline using the term “nursing home” does not help here. The section on the elderly which recommends treatment in the over 80s describes the evidence as category C. The UK NICE Guideline (108) also appears not to mention care home or nursing home. Perhaps I did not serach the document thoroughly enough. The paper must clarify this issue. What is the magnitude of the benefit found in studies 16-19?
The paper has been revised to reflect these points on page 3.

8. The final sentence of the Introduction section refers to a paper under consideration. This also appears to describe acceptability of the intervention. Some reference to the findings would be helpful.
A summary has been added on page 3.

Methods
Participants
9. I found this section inadequate. There is no mention of how the homes were identified, the proportion of homes that agreed to take part and on what basis the 700 plus were excluded from the study. What was the optimal dose that led to ineligibility? HFpEF needs definition as does the basis on which cognition was assessed.
These details have been added to page 4. Optimal dose is defined on pages 6-7.

Intervention
10. It would appear that the difference between the two treatment arms was not that the intervention group had “accurate diagnosis and appropriate management” with the assumption that the usual care group did not. It is stated that in the usual care group the GP received the echocardiograph plus a detailed management plan. Who gave this advice? Was it a cardiologist? What was the advice that was given? The nature of “usual care” in which no recommendations were fully implemented needs discussion. Is this just an example of good care vs. bad care?
We agree that the issue of usual care and the implementation of recommendations are important points, and we address these in the discussion on page 11. We have added further details on pages 5-6 about the consultant cardiologist’s advice to the GP.

Sample Size
11. Here the concept of an original trial is introduced. What was the original trial? Phase I and Phase II make no sense here. Was the original concept that of a clinical outcome study that then morphed into a feasibility study for lack of participants? This point is raised in my introductory comments. The section on sample size is the wrong place to mention the change of plan. Be upfront that this was a pilot study in the introduction and paper title.
We agree; references to study phases have been removed and replaced by ‘screening study’, ‘trial’ and ‘pilot trial’ on page 4 and throughout. ‘Pilot’ has also been added to the title and introduction.
Outcomes

12. The optimum dose was defined in absolute terms. Surely the optimum dose of an individual patient will vary from patient to patient according to response and tolerability. The choice of outcome should be explained.

The reviewer raises an important issue. Each patient had a personal optimum – however this benchmark would not allow a comparison between groups, as we did not have this information for control patients. Titration to a percentage of the theoretical optimum provided a consistent and measurable benchmark for comparing groups, where it was not assumed that 100% was achievable or necessarily desirable. Thus we based our primary outcome on absolute values based on recommendations from clinical guidelines. Recognising that the optimal dose would vary for individual patients according to response and tolerability, we conducted secondary analysis on ‘any dose’ with similar results (see pages 6-7 for addition).

Ethical approval

13. Can the authors confirm that the terms used to describe the ethics committees are correct? The clinical trial record makes reference to the Leeds committee but no others.

Our thanks to the reviewer for highlighting this; the text has been amended slightly on page 7.

Additional Point

14. Between what dates did the study take place?

These details are now included on page 4.

Results

Baseline characteristics

15. Here we are introduced to the HFinCH diagnostic study. Was the intervention study part of a larger diagnostic study? If so we should be told.

The prevalence study had been introduced earlier into the paper – see pages 4-5.

16. Is “higher” higher than lower level nursing care or residential care? Clarify for those not familiar with UK system.

‘Higher’ has been removed from the text, and an explanation of three types of care provided in long term care in the UK added to page 4.

Follow-up

17. In the abstract the primary outcome is described as the prescription of ACEi and beta-blockers whilst in this section the first result is optimal dose. I assume in the abstract that the nature of the primary outcome is simplified. Is it the change of prescribing to “optimal” or “maximum tolerated” for one of the two drugs or for both that is the primary outcome? Clarification please. It is noted that not all patients were suitable for “optimum” dosage in which case it seems rather odd that optimum dosage was defined in fixed terms. Such an eventuality must have been envisaged.

These points have now been addressed in previous responses (above and, in particular, point 12).

18. It should be clarified whether the numbers of patients and percentages in the usual care group who received a step change refers to the whole sample or just those already receiving the drug.

This refers to all residents in usual care: the text has been revised to clarify this on page 8.
19. I have already mentioned that the 0% change in prescribing described in the abstract is confusing when read alongside against the change in prescribing for the control group described here. The wording of the abstract (page 2) has been revised to clarify this.

20. What happened between 6 and 12 months is interesting in that the increased prescribing in the intervention group was not maintained. Needs discussion with reference to the issue of feasibility e.g. does the intervention need to be continued indefinitely! We acknowledge this is an important issue. We have added to the discussion on page 11.

**Discussion**

21. The negative results of the study obviously cause difficulties in discussing the results. This was a pilot trial and thus we are careful not to overstate our conclusions, since the risk of a type II error is high by virtue of the small sample size.

22. Are the issues related to heart failure any different from those related to say osteoporosis? It is possible that variable access to services is a generic issue for this group, though it was beyond the scope of the study to explore this rigorously.

23. The authors should discuss feasibility in more detail. For example is it cost-effective? Are there the cardiologists available to undertake this work across the country? Are there potential alternative approaches? How often might residents have to be screened to detect incident cases? Would things be different if the additional nursing staff worked directly for the GPs? These are important (and understandable) questions: the answers emerge stepwise. Reconfigurations and new service models evolve because of an evidence base developed by innovators, favouring a new pattern. Demonstrably on a local scale the new service was feasible and acceptable. Broader adoption would depend upon robust evidence of effectiveness and cost-effectiveness. The pilot trial is primarily useful to design the definitive trial, which will incorporate a full cost-effectiveness analysis and demonstrate deliverability. These latter data would inform pragmatic adoption on a wider scale.

24. I am also not clear which group of residents are recommended for this intervention or for a further trial. Is there a better way of screening so many (399) to find such a small sample (28)? In addition to this study we conducted a diagnostic accuracy study (Mason et al., 2012 in submission) to evaluate a range of biomarkers. None were as effective as echocardiography in the diagnosis of heart failure. Given a larger cohort it is possible that higher rates of detection might emerge.

25. The authors have called for a larger trial. Can they indicate how it might be done? What outcomes (in general terms) should be used? What administrative changes are needed?

26. It seems that older people do not want to take part in research? Or was it that they did not think too much of the project? Is there an issue about the information they were given prior to be asked to consent?

27. A huge caveat is needed in discussing clinical outcomes given the small numbers.

28. The authors have rightly drawn attention to the difficult issues of undertaking trials in care homes – perhaps more could have been said about this.

29. Reference should be made to the DeNDRoN ENRICH project which provides a toolkit
for researchers carrying out projects in care homes. This may have helped if it had been available when the trial was planned.

We acknowledge these comments and suggestions, which are addressed in part within the word limit and in part go beyond the scope of the paper. Unless we remove other essential text we are not able to go further, but happy to take editorial direction on these points.

Table 1
30. Abbreviations need explanation.
31. There is a + in the NYHA row. What does this mean?
32. There is a * in the ACE and beta blocker row. What does this mean?
These changes as requested have been made.

Flow chart
33. 756, 4, 9, 4 and 7 add up to 780 and not to 773. This needs explanation or correction.
Many thanks for noting this; we have revised the flow chart.
Reviewer 2.
Title: Feasibility of evidence-based diagnosis and management of heart failure in older people in care: randomised controlled trial
Version: 1 Date: 28 May 2012
Reviewer: George Heckman
Reviewer's report:
Comments on “Feasibility of evidence-based diagnosis and management of heart failure in older people in care: randomized controlled trial” by Hancock et al. Synopsis: The authors present the results of a small pilot RCT in UK care homes. In this trial, residents with a history of heart failure (HF) associated with left ventricular systolic dysfunction (LVSD) were randomized to assessment by a cardiologists to develop a plan of treatment (based on guidelines), and follow-up with HF specialist nurses at 1-2 weekly intervals in order to implement this plan. General practitioners (GP) were sent notes / letters, and when HF medications were optimized, residents were discharged from the program to be follow-up by the GP. In all, 399 residents were screened, 34 of whom had LVSD. Finally, 28 agreed to participate, 16 of whom were in the intervention and 12 served as controls.
Mean age was 83.6 years and most residents met criteria for “residential care”, as opposed to “higher level nursing care”. After 6 months of follow-up, intervention residents were more likely to achieve optimal dosing of ACE inhibitors 57% vs. 27% but not beta-blockers or spironolactone. At 12 months, rates of drug utilization in the intervention group reverted back towards those of usual care, with no significant differences in utilization or hospitalization.

Major compulsory revisions:
1. “Long-Term Care” means different things in the UK, the US, Canada and elsewhere. It sounds like the residents in this study were relatively high functioning. However, the authors do not provide any information in Table 1 related to cognition, basic and instrumental activities of daily living, number and type of other comorbidities, number of other prescribed medications, renal function (particularly relevant here), falls, and other outcomes relevant to frail seniors. It is therefore not possible to place this trial and its results in the broader context of the literature on HF in frail seniors. I suspect that the residents in this study are most like the ones in the paper by Foebel at al (Clinical, Demographic and Functional Characteristics Associated with Pharmacotherapy for Heart Failure among Older Home Care Clients. Drugs and Aging. Drugs Aging. 2011 Jul 1;28(7):561-73), though hospitalisation rates suggest that they are even less frail. This should be remedied in a revised version of this paper.

We acknowledge the importance of clarifying baseline characteristics of this cohort and have included details of the number of other prescribed medication and renal function; cognition and activities of daily living are reported in table 3 as MMSE and EQSD respectively (this table also shows changes in these functional characteristics over time). We collected data on co-morbidities and other outcomes relevant to the frail elderly but were limited by the prospective nature of data collection which required the co-operation and not-insignificant time of residents, carers and GPs. We thank Prof Heckman for highlighting this reference which will inform the clinical assessments to be included in the definitive trial.

2. The authors excluded patients with HF and preserved ejection fraction. Among frail seniors, this population consists of up to, if not more than, half of the population with HF. More recent
epidemiological data suggests that outcomes in this population may be as severe as those in the population of persons with HF and LVSD. While recommendations on prescribed pharmacotherapy are limited by negative clinical trials, these patients nonetheless may benefit from optimized prescribing as well as disease management strategies. Any intervention intended to reduce “mortality and morbidity and improve quality of life” must take this population into account. Optimal HF management is more than improving prescribing. What are the authors’ thoughts on this?

This is an important point and one on which it sounds as though our thoughts align with the referee: we have added text to the discussion (page 11) to highlight the complexity of HFpEF management and to clarify further why this group were excluded from this trial. We further address the issue of HFpEF in associated papers (in submission) and have plans for further research in this important and under-served group.

3. In the introduction, the authors mention that “research indicates the challenges of HF management in primary care”. Why then did they design an intervention that ignores these challenges? Ultimately, this paper shows that cardiologists and HF nurse specialists are better at prescribing ACE inhibitors than GPs – this is hardly surprising. In the discussion, the issue of trying to understand why GPs altered management plans is raised. Several papers (Fuat BMJ 2003, Remme Eur H J 2008, Steinman Am J Geriatr Pharmacotherapy 2010) already address some of these issues. Ultimately, unless GPs are targeted by a properly designed and sustainable capacity-building / educational strategy, interventions structured such as the one in this paper will continue to fail. The authors are clearly biased towards a viewpoint that variations in HF management result from “difficulty accessing specialist care”. Evidence exists to suggest that well-supported primary care platforms can deliver good quality care for HF and other conditions such as dementia (Peters-Klimm 2010; Meeuwsen et al BMJ 2012; Lee et al J Am Geriatr Soc 2010). What are the authors’ thoughts on this? Other than letters and notifications to the GP, were any active efforts made to improve GP knowledge about HF? Ultimately, this study shows that insertion of a specialty team can temporarily improve prescribing in relatively low risk residential care residents with HF and reduced LVSD, but that without any apparent effort to improve that ability of the GPs to assume follow-up care over the longer run, the effects of the intervention were modest and short-lived. This paper might be interesting to publish if the issues above were addressed. and the discussion substantially enhanced to reflect the above concerns and shortcomings.

We agree that a stand-alone intervention raises important questions about sustainability and capacity building in general practice. Fuat (2003), mentioned above, is a colleague and co-author and his paper and our more recent work with him (in submission) has provided some of the impetus for this research: ostensibly to assess the feasibility of a different model of care in primary care. Although we agree that the findings regarding prescribing quality might not be surprising, this is the first study to empirically demonstrate that this type of additional support can raise standards in primary care for this group (in care homes). Thus this study has provided the first step upon which a programme of research will build which aims to develop the well supported primary care platform you mention. We acknowledge that additional steps might have been taken to improve GP knowledge about heart failure, however the purpose of this study was to assess baseline practices from which to inform the development of a subsequent structured interventional study. We have added the points above to the discussion in the paper (page 11).
Thank you for the opportunity to review this paper.
Quality of written English: Acceptable
Statistical review: No, the manuscript does not need to be seen by a statistician.
Declaration of competing interests: I declare that I have no competing interests.
Reviewer 3.
Older people in care: randomised controlled trial

Version: 1 Date: 31 May 2012
Reviewer: Robert McKelvie

Reviewer’s report:
Summary

This paper examines the benefits of an onsite heart failure service compared to usual care in the long term care setting. The main aim of the study was to establish the feasibility of accurate diagnosis and appropriate management. This was a pilot study of 28 patients who consented and were randomized to either the heart failure service (16 patients) or usual care (12 patients). The primary outcome was the prescription of ACE-inhibitors and beta blockers at 6 months. The original plan was to recruit 125 residents which would require 500 residents to get the sample. However, as the study went on it was clear there was an underestimation of the prevalence of heart failure with reduced LVEF and thus the proposed sample size could not be achieved. Therefore the study was converted into a pilot study of 25 to 30 patients. The revised sample size suggested that 25-30 patients would be required to show a difference in the primary outcome if it existed. The findings of the study did not show a statistically significant difference in the pattern of drug use for the heart failure service group compared to the usual care group. The authors state that despite an absence of a statistically significant difference there was a trend for a consistent pattern of increased drug use in the heart failure service group compared to usual care.

Major Compulsory Revisions
1. This paper purports to examine evidence based diagnosis however details about the manner in which the diagnosis was made are lacking. Heart failure is a clinical diagnosis but all that is stated is that there was an echocardiogram performed and they were assessed by a cardiologist. There was no mention of where the testing was done, whether natriuretic peptides were measured, chest x-ray or other details about the diagnosis.

   Our thanks to Professor McKelvie for highlighting this omission. We have added details of the assessment schedule, which includes blood tests and other investigations completed, on pages 4-5.

2. The manner in which the intervention group was followed is unclear. It seems the cardiologist made the initial plans of management and then the HFSNs carried out the plan and followed the patients. There was no mention about who the nurses would contact if the resident ran into difficulties.

   We have provided additional details about delivery of care during the trial on page 5 of the paper.

3. In the methods it was stated that ramipril and bisoprolol were used as the standard. However it seems patients received other types of drugs from these groups. Especially in the usual care group. So it appears that it was fine to use any type of ACE-inhibitor and beta blocker.

   Ramipril and bisoprolol are both recommended and licensed for use in the treatment of heart failure in the UK and thus were recommended as first line drugs for both arms of the study. This was a pragmatic study, and we recognised that GPs’ views about the optimal drug and dose for individual patients would vary according to response and tolerability. We conducted secondary analysis on ‘any drug’ at ‘any dose’ with similar results (see pages 6-7 for addition).
4. Who was responsible for sending the letters to the GP, was it the nurse or the cardiologist? We have added to the section on page 5 details about the consultant cardiologist’s advice to the GP for the intervention group.

5. It seems in the routine care (usual care) group the residents received echocardiogram results and a letter was sent to the GP outlining a personalized HF management plan. However, it was never made clear who was responsible for sending the letter and more importantly who was responsible for the personalized HF management plan. We have added to the section on pages 5-6 details about the consultant cardiologist’s advice to the GP for the control group.

6. Patients were randomized rather than long term care facility being randomize. The issue with this is there could be GPs that have patients in both the groups and this could potentially lead to contamination between the two groups. We recognise the risk of contamination that this might have caused, however it was not logistically possible to ensure study access for all residents and to randomise at the level of the care facility or GP. While not by virtue of design, individual GPs did not have patients in both arms of the trial. We thank you for highlighting this as it is an issue we will need to deal with in the full trial. We have added this detail to page 8.

7. In the results they state 19 of the patients are NYHA I. In effect these patients were asymptomatic. However, they state that 3 of the patients were not eligible because they were not symptomatic. This really does not make sense because 19 of the patients were not symptomatic so why were they included? NYHA classification provided one of a number of diagnostic criteria including JVP, oedema, lung signs and orthopnoea, upon which symptoms of heart failure were assessed. The three patients who were classed as asymptomatic were judged to have none of the full range of symptoms and signs assessed. This pragmatic diagnosis reflects difficulties assessing NYHA class and other symptoms and signs in this sedentary population. In a nested diagnostic accuracy study we found a lack of correlation between NYHA classification and LVSD severity, and between LVSD and HfEF which raises questions about its utility in the study population.

8. In the Table the authors state 15 patients were NYHA I, whereas in the text of the results they state 19 were NYHA I. As well the number of patients who were NYHA II/III and IV listed in the text of the results does not match what is reported in the table. The text on page 8 refers to 19 patients with mild LVSD; these were identified from a group of 34 patients diagnosed with LVSD in the related prevalence study. Of the 34 patients 28 were included in this trial whose results are reported in Table 1.

9. It is interesting that I could not find any information about the average LVEF for this group of patients in the study. Details have been added to Table 1.
10. There seems to be little information about the usual care grouping regarding whether or not they could tolerate increases in drug therapy. Of course based on the design of the study one would assume the control group should tolerate up titration of therapy but this was never explicitly described to be the case. Given the small sample size it is possible by chance that a number of the patients in the control group may not have tolerated further up titration of therapy.

We used rigorous methods to limit selection bias but we acknowledge the important point raised about sample size. The point is that the groups should be able to achieve (on average) a similar percentage of the theoretical optimal titrated dose (accepted that individual patients vary). Given the small sample the actual achievable group averages might not be that similar: we have included this point in possible study limitations in the discussion on pages 10-11.

11. A comment was made in the results section that the diagnostic assessments were acceptable. However there is no description as to what type of diagnostic work up these patients were subjected to in order to make the diagnosis of heart failure.

We have added details of the assessment schedule which includes blood tests and other investigations completed on page 4.

12. In the discussion the statement is made that the intervention group attained a higher level of evidence-based treatment of optimal doses of ACE-inhibitor and beta blocker. However statistically this is not true so I think they are over stating the case. This is a very small study so if the numbers were larger this trend could potentially disappear.

We acknowledge this, and we are simply underpowered to know either way. This is included possible study limitations and the statement: ‘although results were non-significant due to the sample size’ in the discussion on page 10.

13. It seems that a number of patients were not taking bisoprolol and there is no mention of the other types of beta blockers used. This is an important omission because not all beta blockers are recommended for the treatment of HF. Although looking at the tables it may be that there were not many on beta blocker other than bisoprolol. Given the small number of patients I think it is worth reporting the other types of beta blockers used in the study.

We agree that this is an important part of the study and have added the following to the paper:
At baseline, 46% of patients were receiving an ACEi (of these 77% were prescribed ramipril, 15% lisinopril, and 8% perindopril), 50% were receiving a β-blocker (of these 42% were prescribed bisopropol, 36% metoprolol and 22% atenolol); (page 8)

Prescribing trends in the usual care group remained largely stable although at 12 months all β blocker prescriptions were for bisoprolol and 90% of ACEi prescriptions were for ramipril, with the remainder being for lisinopril and perindopril. (page 9)

14. In the discussion the statement is made that the magnitude of change over 6 months might have been even higher if existing cases of LVSD were excluded... I am not sure if this is true because drug therapy was not great at the beginning of the study even for people with existing LVSD.

We agree and have revised the sentence on page 10 to reflect this: ‘It is possible that the magnitude of change over 6 months might have been even higher if existing cases of LVSD had been excluded in the trial, although drug therapy was already limited in this group’.
15. The comment in the discussion was made that the low numbers of hospitalisations for both groups was reassuring and that the intervention did not increase hospitalizations. However this may have been a lower risk population because 19 of the patients were NYHA I, there was no mention of previous hospitalizations; however as mentioned previously there was no documentation of the LVEF. In order to better define the population there should be some mention of previous hospitalizations etc.

We have clarified the issue of the NYHA classification and LVEF above. We acknowledge the importance of clarifying baseline characteristics of this cohort and have included details of the number of other prescribed medications, hospitalisations and renal function; cognition and quality of life are reported in table 3 as MMSE and EQ5D respectively (this table also shows changes in these characteristics over time). We collected data on co-morbidities and other outcomes relevant to the frail elderly but were limited by the prospective nature of data collection which required the cooperation and not-insignificant time of residents, carers and GPs.

16. The observation that treatment levels don’t seem to be maintained is interesting and it is unfortunate there is not more information about the possible reasons for this reduction in therapy. One possibility may be there was not good knowledge translation to the GPs. In other words they were not provided with effective plans to keep the patients on the more intensive therapies.

We recognised the importance of effectively communicating recommendations for the management of heart failure to GPs throughout the study. These plans were sent to GPs by the research team cardiologist who wrote these in consultation with a GP with specialist interest in heart failure.

We agree that a stand-alone intervention raises important questions about sustainability and capacity building in general practice. Fuat (2003), mentioned above, is a colleague and co-author and his paper and our more recent work with him (in press) has provided some of the impetus for this research: ostensibly to assess the feasibility of a different model of care in primary care. We acknowledge that additional steps might have been taken to improve GP knowledge about heart failure; however the purpose of this study was to assess baseline practices from which to inform the development of a subsequent structured interventional study. We have added the points above to the paper (pages 5-6 and 11).

Discretionary Revisions
1. It might be reasonable to divide table 2 into 2 tables with one of them dealing with 6 month follow up and the other with 12 month follow up.

We have submitted these data in one table to reduce space requirements but would be happy to amend these if requested.

Quality of written English: Acceptable
Statistical review: No, the manuscript does not need to be seen by a statistician.
Declaration of competing interests: I have no competing interests.