Author's response to reviews

Title: NHS Health Checks through general practice: randomised trial of population cardiovascular risk reduction

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Response to reviewers

Referee 1

Major Compulsory

Introduction

1. The research questions do not reflect your study. You did not evaluate the implementation (i.e. the uptake, reach, dose delivered, etc).

Response: We have changed the text to reflect the research questions, which now read as follows:
This paper evaluates the change in population cardiovascular disease (CVD) risk following implementation of NHS Health Checks in Stoke on Trent after one year of the programme. The question of whether there is added value of lifestyle support over and above the basic health check in reducing population CVD risk is also addressed.

Methods

2. Provide more detail about the lifestyle intervention as it is an important topic in the study. What was it based on/ how was it developed? How many sessions? Did it involve individual counselling or provision of information only?

Response: We have amended the text to give more detail of the lifestyle support provided and also moved reference [18] (the Primary Care Toolkit, which gives full details of the protocol used by the general practices) to here.

Discussion

adjust the last sentence of § 1 and/or discuss the statements:

Response: the last sentence of § 1 has been amended to read:
However, as shown in Figure 1 (Excluded box), overall uptake was low, indicating perhaps that population readiness to make change was not as good as it ought to have been, given that all patients screened and contacted had been identified from practice records as being at high risk of experiencing a CVD event.

3. ‘uptake was low’: how did you measure that?

Response: This finding relates to the data provided in Figure 1 and discussed in paragraph 1 of the Results section. To get 601 participants for the study, we had to screen/ contact 10046 individual high risk patients – an overall uptake of just 6%.

4. ‘apparent lack of effectiveness of lifestyle modification’. It is important to discuss why that would be. Mention that the lack of beneficial effect of the intervention could be due to the fact that the implementation of the intervention was suboptimal (e.g. lack of referral, lifestyle coach was inadequate), OR the participants attended only few sessions (they could choose whatever they desired, according to the methods). Apparently you did not have the resources to monitor every treatment. How would you handle this in the future? Could you possibly ask the lifestyle coaches to monitor the sessions that were chosen by the participants?
Response: We have added the following paragraph to the Discussion:
The apparent lack of effectiveness of the lifestyle support programme could be due
to the sub-optimal referral to the lifestyle coach, sub-optimal delivery of the services
referred to or poor compliance of patients with the support sessions offered. Our
data on referral to the lifestyle coaches and the personal health plan goals set by
participants (not reported here) indicated that referral to the lifestyle coach was good
and valued by participants. Thus, future research aimed at improving the contribution
of additional lifestyle support for the reduction of CVD risk should focus on the
delivery and compliance with treatment issues of the support services referred on to.

5. ‘Population readiness to make changes’: according to the reduction in risk
profile: they did make changes, didn’t they?

Response: These comments refer to the total population screened and or contacted
during the research and, to a certain extent, the readiness of community services to
provide the support required.

6. ‘cost-effective’ I wouldn’t use this term if you did not evaluate
cost-effectiveness.

Response: We have removed this term.

Minor essential

Introduction
1. §1: ‘the global burden of vascular diseases…’ Provide examples of vascular
diseases.

Response: We have added the following to the opening sentence:
, including heart disease and stroke and other disorders with a strong vascular
component such as diabetes and chronic kidney disease,

2. § 1-3 vs. § 4: Clarify whether you aim at ‘vascular diseases’ or ‘cardiovascular
diseases’.

Response: The NHS Health Check programme is aimed more generally at the so-
called major vascular risk disorders: stroke, heart disease, diabetes and chronic
kidney disease. In our specific study, we have focused on CVD risk but we prefer to
keep the text in the Background section as it stands to recognise that lifestyle
changes are expected to benefit not just cardiovascular diseases but other diseases
with a major vascular component more widely.

the Framingham risk equation actually measures: morbidity or mortality? CVD or
CHD?

Response: There are a number of Framingham equations, mostly predicting the risk
of major vascular disease events. Reference 13 contains equations for: CHD, MI,
CHD death, stroke, CVD and CVD death. We describe the actual risk estimator equation used in our study under Outcome measures.

Methods:
4. §3; In the intro you advocated a multifactorial approach including medication as a means of CVD prevention. Why is the intervention only aimed at lifestyle/ is medication still part of the multifactorial approach?

Response: Medication is included as a part of usual primary care as is the opportunity to refer patients to a smoking cessation service. We have added the following to clarify this point:
, including medication and referral to smoking cessation services,

5. §4: Can you give any details about what the diet and physical activity categories were based on, or provide an example of e.g. poor diet or good diet?

Response: Details of good, average and poor diet are given in Appendix 1C of the Primary Care Toolkit. Physical activity was based on the GP Physical Activity Questionnaire

6. §5: What do you mean by ‘target 46 of 55’?

Response: There were 55 practices across the whole of Stoke on Trent but 9 of these did not have compatible software and so could not be included in the study. We have added the following clarification after 55 in the original to clarify:
practices – some practices did not have compatible software

7. §6: check whether the variables you mention in the first sentence are the ones necessary for the Framingham risk equation. I think that the variables diastolic BP and diabetes (y/n) are missing. Further, check whether Framingham calculates the risk of a ‘CVD event’ or ‘mortality due to coronary heart disease’.

Response: The variables mentioned in the first sentence are the ones necessary for the Framingham equation used. We had omitted the diabetes status variable (as this was an exclusion criterion for the study) but agree that it is better to keep this here for completeness. There is a diastolic BP version of the Framingham equation but this was not the one used in our study.

Results:
8. §3 Variables included in the equation # replace to methods section (in fact, you mentioned them there already).

Response: We have replaced the variables to the Methods section. The coding of the variables has been retained as this is important in interpreting Table 3.

9. §3 Why did you not correct for BMI (and pulse); sign different between groups at baseline?
**Response:** We did check this possible requirement. Neither of these variables had any association with the primary outcome measure in our sample so this was not necessary.

Discussion

10. §4 ‘what is already known’ and § 5: ‘what this study adds’: Check whether the text in these sections are in line with the headings. For example, in §5 you discuss limitations

**Response:** We are satisfied that these sections are in line with the headings. Whilst we agree that some of the points in §5 may be construed as limitations, these were points that only came to light during the conduct of this study and have not, as far as we are aware, been reported elsewhere.

Discretionary

Introduction

1. § 4: is the first national programme to attempt to develop….’. I would change it into: ‘is the first national programme aimed at/ consisting of….’

**Response:** We see little to be gained by either of these alternative ways of saying essentially the same thing. Text here has not been altered.

Methods

2. If possible, shorten the § about randomisation, recruitment and blinding and add it to the § 'setting and participants'.

**Response:** This § has been shortened and moved to Settings and participants

3. §6. ‘Researcher who was responsible for stat analysis was blinded to…’
Replace sentence to § Blinding.

**Response:** Separate § on Blinding has been added.

Discussion

4. § 2: ‘alternative modes of recruitment’. Provide examples

**Response:** The following examples have been added to this sentence:

, for example bespoke drop-in clinics, opportunistic health checks or partial health checks,
Referee 2

- Major Compulsory Revisions

1. Results: In order to truly be able to answer whether one intervention is better than another, I feel it is important to report whether the degree of change seen in the ‘Health check plus’ group was smaller or larger than the change seen in the ‘Health Check’ group. I may have missed it or misinterpreted some of the findings, but as yet it appears as if only separate comparisons between the groups at baseline, and at follow-up have been made. This only tells us whether they were significantly different at these two time points, and not whether one intervention was better at bringing about improvements than the other. I would recommend that this further analysis is added before publication.

Response: We did perform separate checks on the change in CVD risk and individual risk factors between the two groups and did not detect any significant differences. We have added the sentence: ‘This was confirmed in separate comparisons of change in CVD risk and individual risk factors between groups’ to §2 of the Results section to clarify this point. In fact this analysis of individual changes is included in the Results §2 in the sentence ‘In terms of the comparison of available follow-up data with baseline data, both groups showed similar beneficial reductions in risk factors: about 7 mmHg in systolic blood pressure, 4 mmHg in diastolic blood pressure, 0.65 mmol/l in total cholesterol level, 0.5 in total cholesterol/ HDL ratio and 2 cm in waist circumference.’

2. Results: Final paragraph. Mean scores seem to have been given for diet and physical activity. Given that these are categorical variables, I’d have thought that means would not be appropriate. It also seems inappropriate to give mean scores to one or two decimal places when participants would only have been allocated scores with whole numbers. Please check with a statistician and amend if necessary.

Response: We have compared the ordinal scores on exercise grade and diet grade using the appropriate statistical test (Wilcoxon signed ranks test). We use mean grade score here as a succinct way of indicating direction and extent of shift for the groups as a whole, requiring two decimal places to capture the latter. Median scores do not differ between baseline and follow-up in either group.

3. Conclusions: Whilst the statement ‘there was no further reduction in risk measure from the additional lifestyle support package offered to patients” may well be true, I don’t think it can be made without carrying out the analyses recommended in point 1.

Response: See point 1 above.

- Minor Essential Revisions

4. Abstract: It is stated that there were ‘601 (365, 236)’ patients – please state what the two numbers in brackets relate to.

Response: We have added group identifiers to the Abstract
5. Methods: Outcome measures - A relatively crude method has been used to categorise the lifestyle variables, particularly diet, and I have doubts that it would not be sensitive enough to pick up on some of the changes that may have occurred. For example, improvements to one or two aspects within a category may be insufficient to move someone from e.g. ‘poor’ to ‘average’, yet they would still be considered improvements. I think it is important to acknowledge this.

Response: We accept this point and have acknowledged so at the end of the section on Outcome measures by adding the sentences:
It is acknowledged that both the diet grade and exercise grade measures are relatively crude and lack the sensitivity to detect subtle changes in either diet or physical activity that may benefit health. On the other hand, they are simple to use measures that capture the importance of lifestyle to cardiovascular health and serve as a focus for discussion and change within the context of a busy general practice.

6. Methods: Randomisation and recruitment - I found the recruitment of participants to the trial is a little confusing and although it is possible to refer back to Davey et al. (2010), it would be helpful to briefly summarise the recruitment process as this would also bring clarity to the reason as to how some were excluded as they were already seeing their GP or receiving treatment. If there were any changes to the protocol for selection and recruitment of participants (prior to randomisation), please also specify this.

Response: We have added the following explanatory sentence to the Settings and participants section:
Practice nurses or project support workers in each practice went through their list, systematically contacting patients in batches of 20-50 depending on practice size, until either the recruitment target for the practice had been reached or all eligible patients had been invited.

7. Methods: Intervention compared - although I realise the detail can be found in the previous publication (ref 17), it would still be helpful to provide a brief summary of the structure and content of the intervention. For example, the format (telephone or face to face, individual or group sessions), how often they were seen and how many times.

Response: This was also requested by Referee 1 and has been added to §3 of the Methods.

8. Results: A large proportion of potentially eligible patients were excluded on the basis that they had already been seen by their GP and were receiving some sort of treatment. Was there any potential to modify the recruitment process to avoid this and could this have affected the representativeness of the sample? If so, this may be something that could be picked up in the discussion.

Response: This was caused in the main by unavoidable delay between initial data screening and eventual follow-up contact. This point is discussed in §1 under What this study adds in the Discussion and also to some extent in the final § of Limitations section.
9. Table 1: Please define the cut-offs used to define ‘deprived’, ‘intermediate’ and ‘affluent’.

Response: Definition of socio-economic status cut-offs has been added to the footnote to Table 1.

10. Results: Para 2 – it is noted that ‘Changes in HDL, weight and BMI were negligible, though a small significant reduction in BMI of 0.25kg/m2 was noted’. Technically a reduction in BMI was only found for the ‘Health check plus’ group so this should be clarified, particularly as the Health check group’s BMI had actually increased marginally. As a minor point, it is also noted that the units in this sentence are to two decimal places whereas the table is only given to one decimal place.

Response: Actually, the 0.25 kgm$^2$ refers to a change in the BMI for the overall population for whom full BMI measures were available. We have rounded the units in the text to 1 decimal place.

11. Table 4: The formatting of this table is quite confusing. Please amend it to make the distinction between which values are the means and which are the 95% confidence interval values clearer e.g. by using brackets.

Response: The Table has been reformatted with brackets.

12. Table 4: It would be useful to specify that the follow up values were subtracted from the baseline values to clarify why positive values refer to a reduction and negative values refer to an increase.

Response: Specification of the change has been added to Table header.

13. Table 4: It may be a misinterpretation on my part, but please check the values for weight and BMI. Table 2 suggests that for both of these, the ‘health check’ group increased whilst the ‘health check plus’ group decreased, whereas Table 4 suggests both groups reduced their weight and BMI.

Response: In Table 2 comparisons have been carried out on the basis of available data only (best estimates of ‘on treatment’ effect) whereas those in Table 4 have been carried out on the basis of intention to treat (best estimates of whole population effect). We accept that this may cause confusion and have added an explanatory footnote to both Tables and qualifying comment to the text.

14. Table 5: Given the different numbers of participants in each group, it would be helpful to show the percentage of patients with the risk factors at each time point. This would allow an easier visual comparison of the two interventions. Removing the numbers without the risk factor would also simplify the table.

Response: This Table has been set up specifically to show the changes in the repeated measures of the dichotomous risk factors between baseline and follow-up (which are then tested formally using the McNemar test). For each two by two cell, patients in the right upper position got worse i.e. did not have the risk factor at
baseline but had it at follow-up, whereas patients in the left lower position got better i.e. had the risk factor at baseline but did not have it at follow-up. Patients in the other two positions stayed the same. We do not believe that adding percentages to the Table in this case would help with interpretation of the Table.

15. References: Reference 19 is no longer available and should be updated.

Response: Reference 19 has been updated and also moved to earlier section on Interventions, now reference# [18].

- Discretionary Revisions

16. Abstract: If possible within the word limit, it would be helpful to add some more detail on the ‘health check plus’ intervention, e.g. in terms of format (telephone vs. face to face, individual vs. group), duration, frequency and number of sessions.

Response: Further detail has been added to the Background section of the Abstract.

17. Methods: Outcome measures. References to cut-offs used for high cholesterol, blood pressure and BMI would be beneficial.

Response: These are widely accepted standards not requiring further referencing.

18. Figure 1: Since a relatively large proportion of potential participants were excluded for ‘other reasons’, it would be helpful to break this down according to the reasons listed in the text. This would also save the reader having to refer to the text for further information.

Response: Details have been added to Figure and Figure has been reformatted slightly.

19. Table 3: To ensure the tables stand-alone without the need to refer to the text, I’d suggest a footnote is added whereby the factor abbreviations are defined, as they are in the text. Alternatively, rather than give the abbreviations in the ‘Factor’ column, the full titles could be given removing the need to have any of these abbreviations in the paper. The coding, particularly where it isn’t obvious e.g. for gender, should also be added as a footnote.

Response: We have added footnotes to the Table but prefer to keep the detail in the text as it is unwieldy to cover all this in footnote. Coding has been added to the text.

20. Statistical analysis para 1, Results and Table 3: Two ways of expressing the levels used in the model appear to be used interchangeably - Levels 1, 2 and 3 or practice level, individual level and identifier variables. For clarity, it would help the reader if only one system was used, preferably the latter which is more meaningful.

Response: We have modified the text and the Table to remove this confusion.

21. Discussion: The last sentence in paragraph 1 seems quite negative to the
programme overall whereas I’d have thought the question over cost-effectiveness would relate more to the lifestyle intervention aspect. Should it be revised to read “… population readiness to make changes is not as good as it may need to be to make the NHS Health Check plus programme cost effective as a national policy’?

**Response:** This point was also picked up by referee 1 (point 6). We have removed this reference to the cost-effectiveness of national policy.

22. References: The General Practice Physical Activity questionnaire reference refers to the report, which is fine, but it would be useful to also add a reference to the questionnaire itself.

**Response:** We have updated the reference to the GPPAQ.

Copyediting comments

1. Written English

Response: We are satisfied with the quality of the written English and have reviewed the text in line with the reviewers’ comments

2. Email addresses

Response: We have added email addresses as requested

3. Abstract – aims of study

Response: Aims have been amended in the Background section

4. Trial registration

Response: This will be done at manuscript upload

5. Change Introduction to Background

Response: This has been done

6. Figure cropping

Response: Figure 1 has been cropped as pdf