PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Evaluating the Effectiveness of the NHS Health Check Programme in South England: a Quasi-Randomised Controlled Trial
AUTHORS	Kennedy, Oliver; Su, Fangzhong; Pears, Robert; Walmsley, Emily; Roderick, Paul

VERSION 1 - REVIEW

REVIEWER	Chris Kypridemos Lecturer in Public Health Department of Public Health & Policy University of Liverpool UK I am a co-investigator in the workHORSE NIHR grant that aims to build a prototype decision support tool for NHS Health Checks. Therefore, the results of this study are directly related to my research.
REVIEW RETURNED	24-Feb-2019

GENERAL COMMENTS	Many thanks for giving me the opportunity to review this very interesting and useful study. The authors report the results of a quasi-randomised trial of NHS Health Checks effectiveness. The results are potentially useful for policy-making, and they are a valuable addition to the existing empirical evidence on the effectiveness of NHS HC. Please find my comments and suggestions below: Major comments 1. It would be very useful if you could additionally stratify your analysis and results by IMD 2. Please justify why you used cohort 5 as your control. For example, why not comparing cohort 1 with all remaining cohorts in years 1, cohorts 1 and 2 with the remaining 3 cohorts etc. Or even in an analogy with a step-wedge design even include year 0 and 5 in your analysis. And of course, adjust for calendar time and possibly include the length of the period since the cohort/cluster has been invited for HC as an effect modifier. Minor comments: 1. P4L15-23. Both modelling exercises mentioned are likely to overestimate NHS HC effectiveness due to the modelling assumptions 2. P5L53. How many GP practices did not contribute data?

	3. P6L11. Please reword to make clearer that the control group was also eligible for NHS HC. I understand it was invited the year following the end of this study. 4. P6L50. Please clarify if the total proportion of the population that has been excluded. 5. P8L9. Please state R version for completeness. 6. P9 Table 1. Please clarify in the last line of the table “mean decile”. Is this decile of IMD? If so, please state if decile group 1 includes the most or least deprived areas. Also please clarify on the table or the caption that some in cohort 5 had an opportunistic HC to avoid confusion. 7. I couldn’t find a CONSORT checklist in my review pack.

REVIEWER	Michael Soljak Department of Primary Care & Public Health School of Public Health Imperial College London United Kingdom
REVIEW RETURNED	26-Feb-2019

GENERAL COMMENTS	This study reports on a large quasi-RCT (patients were randomised according to year of birth) of the implementation of NHS Health Checks (HCs) in SE England. The analysis was on an intention-to-treat basis. As such it adds to the existing evidence base, which used different methods, and warrants publication. I have had to respond to the review checklist more negatively than I wished, e.g. the objectives could have been stated more explicitly. I also considered that the conclusions ("there was little evidence of an associated increase in evidence based medical therapies"), were too negative, in that the ORs of CVD risk >10% plus statin or >20% plus statin, were 2.90 (2.36-3.57) and 2.60 (1.92-3.52) respectively, although they were lower than the ORs for other process measures. Other comments are as follows: - there is no detail about coding e.g. a code list should have been appended. I assume that the national HC minimum dataset was used e.g. for invitations and HCs performed, and CVD risk scores, but this is not stated - the HC MDS was not published until 2012, so, depending on implementation in SE England, data before this time will have few MDS codes and will underestimate HCs performed. We calculated risk scores ourselves using the raw data and the QRISK2 batch processor - ethnicity can be imputed using multiple imputation with chained equations if coding is >50% (which it is), so this could have been used -inexplicably there was adjustment for age and sex but not other covariates e.g. SES, practice... -we and others have also shown comparatively low uptake of some interventions in high risk groups. Patient refusal may be important. In summary, I suggest a significant revision to provide more coding information and adjust for more confounders.

VERSION 1 – AUTHOR RESPONSE

Reviewer(s)' Comments to Author:

We thank both reviewers for their very helpful and constructive comments.

Reviewer: 1

Reviewer Name: Chris Kypridemos

Institution and Country: Lecturer in Public Health, Department of Public Health & Policy, University of Liverpool, UK

Please state any competing interests or state ‘None declared’: I am a co-investigator in the workHORSE NIHR grant that aims to build a prototype decision support tool for NHS Health Checks. Therefore, the results of this study are directly related to my research.

Please leave your comments for the authors below Many thanks for giving me the opportunity to review this very interesting and useful study. The authors report the results of a quasi-randomised trial of NHS Health Checks effectiveness. The results are potentially useful for policy-making, and they are a valuable addition to the existing empirical evidence on the effectiveness of NHS HC. Please find my comments and suggestions below:

We thank Dr Kypridemos for these comments.

Major comments

1. It would be very useful if you could additionally stratify your analysis and results by IMD

We now include table 4, which shows the numbers of participants, % attendance and % male for cohort 4, which is the most recently invited cohort, stratified according to index of multiple deprivation (IMD) quintiles. We also include additional regression analyses for cohort 4 with an interaction term for IMD, and discuss outcomes where the interaction is significant. Finally, we include table 5, which shows odds ratios for the outcomes stratified according to national IMD quintiles.

2. Please justify why you used cohort 5 as your control. For example, why not comparing cohort 1 with all remaining cohorts in years 1, cohorts 1 and 2 with the remaining 3 cohorts etc. Or even in an analogy with a step-wedge design even include year 0 and 5 in your analysis. And of course, adjust for calendar time and possibly include the length of the period since the cohort/cluster has been invited for HC as an effect modifier.

We now state in the text that: “We calculated ORs for each invited cohort (i.e. cohorts 1-4) separately, with the reference being uninvited cohort 5. The rationale for this approach was to capture changes in performance over a time period when awareness and experience among patients and providers was increasing. Evaluation of earlier years (e.g. cohort 1) is still of interest because of longer follow-up, but the most recently invited cohort (i.e. cohort 4) may be most reflective of current practice”.

Minor comments:

1. P4L15-23. Both modelling exercises mentioned are likely to overestimate NHS HC effectiveness due to the modelling assumptions

We now state in the text that: “Modelling by the UK Department of Health suggested that the NHS HC programme could prevent 1,600 strokes and heart attacks each year, although the modelling assumptions, particularly with regard to uptake, may have overestimated effectiveness.[5]”

2. P5L53. How many GP practices did not contribute data?

We now state that: “There were 151 General Practices that contributed data to this study, around 80% of the total in the region.”

3. P6L11. Please reword to make clearer that the control group was also eligible for NHS HC. I understand it was invited the year following the end of this study.

We have amended the text to clarify that: “Cohort 5 was eligible for a HC but not invited (i.e. until after the follow-up period ended) and was our control group.”

4. P6L50. Please clarify if the total proportion of the population that has been excluded.

We have amended the text to state that: “In total, we excluded around 35% of the population.”

5. P8L9. Please state R version for completeness.

We have amended the text to state that we used “R (Version 3.5.1, R Foundation for Statistical Computing, Vienna, Austria).”

6. P9 Table 1. Please clarify in the last line of the table “mean decile”. Is this decile of IMD? If so, please state if decile group 1 includes the most or least deprived areas. Also please clarify on the table or the caption that some in cohort 5 had an opportunistic HC to avoid confusion.

This is clarified in the table, which now states: “Index of Multiple Deprivation (IMD - 1 = most deprived, 10 = least deprived), *some participants in cohort 5 attended a HC opportunistically (i.e. without receiving a formal invitation)”

7. I couldn’t find a CONSORT checklist in my review pack.

We have not included a CONSORT checklist since application of many of the criteria would be unclear or not possible given our study design (e.g. method of randomisation, concealment etc.).

Reviewer: 2

Reviewer Name: Michael Soljak

Institution and Country: Department of Primary Care & Public Health, School of Public Health, Imperial College London, United Kingdom

Please state any competing interests or state ‘None declared’: None declared

Please leave your comments for the authors below This study reports on a large quasi-RCT (patients were randomised according to year of birth) of the implementation of NHS Health Checks (HCs) in SE England. The analysis was on an intention-to-treat basis. As such it adds to the existing evidence base, which used different methods, and warrants publication.

We thank Dr Soljak for these comments.

I have had to respond to the review checklist more negatively than I wished, e.g. the objectives could have been stated more explicitly.

We have amended the end of the introduction to state: “This study aims to evaluate the effect of invitation for a HC (i.e. not just attendance) in terms of uptake and risk factor detection and management in eligible participants”.

We have also amended the title to “Evaluating the Effectiveness of the NHS Health Check Programme in South England: a Quasi-Randomised Controlled Trial”.

I also considered that the conclusions ("there was little evidence of an associated increase in evidence based medical therapies"), were too negative, in that the ORs of CVD risk >10% plus statin or >20% plus statin, were 2.90 (2.36-3.57) and 2.60 (1.92-3.52) respectively, although they were lower than the ORs for other process measures.

We have amended the passage quoted, which now reads: “The HC programme resulted in large increases in the detection of patients with CVD risk factors, particularly raised cholesterol and 10-year CVD risk scores >10%. There were corresponding, albeit smaller, increases in certain evidence based medical therapies, most notably statins”.

Other comments are as follows:

- there is no detail about coding e.g. a code list should have been appended. I assume that the national HC minimum dataset was used e.g. for invitations and HCs performed, and CVD risk scores, but this is not stated

We have now included a list of Read Codes as supplementary information.

- the HC MDS was not published until 2012, so, depending on implementation in SE England, data before this time will have few MDS codes and will underestimate HCs performed. We calculated risk scores ourselves using the raw data and the QRISK2 batch processor

We thank the reviewer for pointing out this fact, which in part explains why uptake in cohort 1 was lower than the other cohorts. We have added this important information to the discussion.

We appreciate that in other studies the completion of a HC, where not formally coded, has been inferred by, for example, the calculation of a 10-year CVD risk score. However, our intervention is HC invitation, rather than completion, and our control group is usual care (e.g. opportunistic screening), so there would be no clear benefit in taking this approach.

- ethnicity can be imputed using multiple imputation with chained equations if coding is >50% (which it is), so this could have been used -inexplicably there was adjustment for age and sex but not other covariates e.g. SES, practice...

Unfortunately, the Care and Health Information Exchange, who govern access to the data used in this study, did not make participant ethnicity available to us due to concerns about identifiability. The manuscript has been amended to reflect this.

We appreciate the suggestion regarding further adjustments for covariates. This has been an important step in previous HC studies that use matched case-control designs. However, our method "randomises" participants to an intervention or control group based on birth year. Birth year is unlikely to effect the distribution of covariates other than age and gender (through its effect on life-expectancy). This is reflected in table 1 by the identical means and standard deviations of the deprivation deciles across cohorts 1-5. Thus, extensive adjustment for confounders is neither necessary nor desirable.

-we and others have also shown comparatively low uptake of some interventions in high risk groups. Patient refusal may be important.

We thank the reviewer for this insight and we have amended the manuscript to mention this.

VERSION 2 – REVIEW

REVIEWER	Chris Kypridemos University of Liverpool, UK I am a co-investigator in the workHORSE NIHR grant that aims to build a prototype decision support tool for NHS Health Checks. Therefore, the results of this study are directly related to my research.
REVIEW RETURNED	06-Jun-2019

GENERAL COMMENTS	The authors have addressed all my comments and I particularly applaud their effort to include effect sizes by QIMD.

REVIEWER	Michael Soljak Imperial College London, United Kingdom
REVIEW RETURNED	04-Jul-2019

GENERAL COMMENTS	This study aimed to evaluate the effect of invitation for an NHS Health Check (HC, i.e. not just attendance) in terms of uptake and risk factor detection and management in eligible participants. Previous studies have been unable to include data on invitation with electronic health record (EHR) analyses of attendances. Abstract: HC attendance could also be considered an (intermediate) outcome. In the Results, the first list of results presumably show significant increases presumably using hypothesis tests, but there are no p values or CIs. In the conclusions, I would not call a 2-3 fold increase in appropriate intervention "modest".

	Methods: "HC attendance" was documented by Read codes released in 2011-12 by HSCIC as it was then, these and other HC-specific codes may have been underused at the start of the study, underestimating uptake. Statistical analyses were appropriate. Results: low uptake of statins in high risk groups has been documented in other studies. Hampshire apparently did not target deprived populations as uptake of the HC was highest among participants in the least deprived national IMD quintile. This is a deficiency of the programme which should have been discussed. In summary, this is a useful contribution to the literature on HCs which provides new information about uptake.

VERSION 2 – AUTHOR RESPONSE

Reviewer: 1
Reviewer Name: Chris Kypridemos

Institution and Country: University of Liverpool, UK

The authors have addressed all my comments and I particularly applaud their effort to include effect sizes by QIMD.

We thank Reviewer 1 again for his constructive and helpful comments on our work.

Reviewer: 2
Reviewer Name: Michael Soljak

Institution and Country: Imperial College London, United Kingdom

This study aimed to evaluate the effect of invitation for an NHS Health Check (HC, i.e. not just attendance) in terms of uptake and risk factor detection and management in eligible participants. Previous studies have been unable to include data on invitation with electronic health record (EHR) analyses of attendances.

Abstract:
HC attendance could also be considered an (intermediate) outcome. In the Results, the first list of results presumably show significant increases presumably using hypothesis tests, but there are no p values or CIs.

We have specified HC attendance as an outcome in the abstract and methods sections.

We understand that Reviewer 2 is referring to the differences in proportions (e.g. the absolute differences in the percentages having blood pressure measured in the cohorts invited for health checks compared to the cohort that was not). We now specify p-values for the absolute differences in the abstract and in a table provided as supplementary information. We note that the absolute differences previously specified were calculated from the rounded proportions in table 2. However, we have recalculated these differences using unrounded proportions, which we also used for hypothesis testing. As a result, a minority of the absolute differences differ from those stated previously (but not more than by 0.1%), as seen in the marked-up manuscript.

In the conclusions, I would not call a 2-3 fold increase in appropriate intervention "modest".

We agree that a 2-3 fold increase is significant, but use of the word “modest” is appropriate given that the increases are small in real terms and less than that considered necessary by the Department of Health to make the programme cost effective.

Methods: "HC attendance" was documented by Read codes released in 2011-12 by HSCIC as it was then, these and other HC-specific codes may have been underused at the start of the study, underestimating uptake. Statistical analyses were appropriate.

We thank Reviewer 2 again for pointing out this limitation, which was previously incorporated into the discussion section ("…there were potential coding errors or omissions by GPs in recording attendance, measurements, diagnoses and interventions. This may have been particularly problematic for cohort 1 because Read Codes for HC completion were only released in 2012, after the start of the invitation year…"). We thank Reviewer 2 for his comments on our statistical analysis.

Results: low uptake of statins in high risk groups has been documented in other studies. Hampshire apparently did not target deprived populations as uptake of the HC was highest among participants in the least deprived national IMD quintile. This is a deficiency of the programme which should have been discussed.

The lack of targeting of deprived populations in the present study is now discussed in the revised manuscript.

In summary, this is a useful contribution to the literature on HCs which provides new information about uptake.

We thank Reviewer 1 again for his constructive and helpful comments on our work