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What evidence is required to justify the NHS Health Check programme?



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Abstract

Authors of a matched cohort study claimed the NHS Health Check programme reduced total mortality 23% and liver cirrhosis incidence 44%. Such impressive results require critical scrutiny, especially as the intervention targets a large, predominantly healthy population, and as it has harms and costs. Eleven high-quality randomised trials containing varying combinations of the elements constituting the NHS Health Check assessed total mortality. They included 233,298 participants and 21,535 deaths, with a risk ratio for total mortality of 1.00 (95% CI 0.97 to 1.03) and little or no effect on mortality from targeted diseases, including cardiovascular disease. However, the observational study did not reference any of those trials. No harms, though well-known, were assessed or mentioned. While some limitations were discussed, others were not and central questions regarding the likelihood of their results were not asked. A burden of proof must be met before interventions are introduced, especially those directed towards healthy citizens that divert resources away from medical and non-medical interventions of known benefit. In our opinion, the NHS Health Check programme does not meet UK National Screening Committee requirements that high-quality randomized trials show benefits outweigh harms. Emphasizing evidence from observational studies while disregarding randomised trials that contradict their findings and failing to assess or mention harms of interventions directed at healthy citizens, are contrary to sound scientific principles, and to evidence-based medicine. This apparently guides policies which burden an already stressed health system. A review of the NHS Health Check programme by the UK National Screening Committee seems timely.

Keywords Regular health checks, Evidence-based medicine, Sustainable healthcare, General health checks, Screening interventions

*Correspondence: Karsten Juhl Jørgensen kj@cochrane.dk Whether regular health checks for the general population, in addition to usual care, and how to best improve patient-relevant outcomes through prevention, has been discussed for a long time

A matched cohort study by McCracken et al."(...) demonstrates that proactive, well-designed preventive programmes such as the NHS Health Check can be effective in reducing longer-term disease outcomes, across multiple organ systems" and that it"(...) is an important addition to a growing body of work supporting the long-term benefits of a programme such as NHS Health Check and its effectiveness for potential multimorbidity prevention" [1].

The apparent effects are impressive. Total mortality was reduced 23%, as was cardiovascular mortality. Liver cirrhosis was reduced 44%, and all-cause dementia 19%



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[1]. They were quoted in the press release and by media [2]. But history has shown observational studies can indicate large benefits later dismissed by randomised trials.

Even the best observational studies must be interpreted cautiously because they are prone to important biases. To their credit, McCracken et al. acknowledge several. Their UK Biobank population is not representative, and self-selection bias is important. Self-selection bias means screening attenders are healthier than others. Observational studies that compare attenders with non-attenders in breast screening find a 50% lower risk of dying from all causes combined, an 'effect' that is caused by self-selection bias as only 2–3% of women die from breast cancer over a lifetime [3]. The study by McCracken et al. [1] aims to correct for this, but one can only correct for known confounders, their effects are uncertain, and self-selection bias is linked to important health behaviours.

Given the limitations of observational studies, researchers may test important interventions in randomized trials, particularly when there are trade-offs. While the benefit of screening may appear intuitive, the programs are expensive, labour intensive both directly and indirectly, and they cause harms. For health checks, such trials have been done, and an objective with a study such as that by McCracken et al. [1] would therefore be to assess if benefits in randomised trials appear in practice and if they are financially feasible.

A meta-analysis of 15 trials assessing health checks, including a quarter of a million participants, found little or no effect on important health outcomes [4]. Further, if anything, these trials likely overestimated benefits due to their high intensity of health scrutiny and use of preventive interventions impossible in a real-life setting with limited resources [4].

Eleven of the trials reported on total mortality. These trials included 233,298 participants and 21,535 deaths. They had a low risk of bias and negligeable heterogeneity (I²=0%). The risk ratio (RR) was 1.00 (95% CI 0.97 to 1.03) and much the same was found for other outcomes in relevant trials: cardiovascular mortality (RR 1.05, 95% CI 0.94 to 1.16); fatal and non-fatal ischaemic heart disease (RR 0.98, 95% CI 0.94 to 1.03); and fatal and non-fatal stroke (RR 1.05 95% CI 0.95 to 1.17) [4]. While the trials were powered to detect these effects individually, they did not, even collectively. If this is not enough to consider evidence-based de-implementation in health care, nothing will be.

What should be done when observational studies and randomized trials fundamentally disagree? The appropriate approach is to trust the trials and conclude that observational findings likely reflect bias that was not accounted for, for example residual confounding.

McCracken et al. [1] makes no mention of the randomized trials. Likewise, the NHS medical director for primary care did not mention the trials and recommended participation without reservations based on this observational study [2].

It is an unfortunate scientific limitation that an effect can never be disproved and confidence intervals will inevitably include a small benefit and a small harm, even when the true risk ratio is 1.00. But rarely can we say with such conviction that, if a benefit of regular health checks exists, it must be very small. The large effects claimed by McCracken et al. appear unrealistic and should have raised questions regarding their robustness. But these were apparently never considered as the trials that speak against them were not cited [1].

No previous trial perfectly mirrored the NHS Health Check package (Table 1), but targeted conditions and interventions were represented across trials and McCracken et al.'s claims cover 'a programme such as NHS Health Check' [1]. It is generally required that new results are discussed in the light of existing evidence.

It is a valid concern that some trials are older. But the largest trial was also the latest, reported in 2014, and included preventive medications such as statins [5]. It, too, came out negative for patient relevant outcomes, despite effectively identifying and reducing risk factors [5]. The DANCAVAS trial, which investigated much more comprehensive screening for cardiovascular disease than the NHS Health Check, including CT scans, published results in 2022, and included statins. It, too, came out negative [6] and so did a large, randomised trial of type 2 diabetes screening performed in the UK and published in 2012 [7]. We appreciate that McCracken et al. assess patient relevant outcomes and do not assume surrogate outcomes necessarily translate [1].

Screening of healthy populations generally have modest absolute benefits. This places increased requirements on the quality of the evidence as small effects are easily erased or created by bias. That screening targets healthy citizens rather than people with medical problems increase this requirement for ethical reasons. There is good reason that the UK National Screening Committee require evidence from randomised trials that benefits outweigh harms [8]. Clearly, this requirement has not been met for health checks. McCracken et al. state that NHS Health Checks are screening [1] and we agree.

A premise of evidence-based medicine is that harms of interventions are inevitable and at least as important as benefits. McCracken et al. do not quantify or mention any harms [1]. It appears a benefit is considered sufficient justification.

Harms of prevention are unintuitive. But many identified risk factors will never develop into disease and thus

 Table 1
 According to the NHS Health Check web site (https://www.nhs.uk/conditions/nhs-health-check/), the Check takes'about 20 to 30 min'

Criteria for eligibility	Content	Follow-up
–40 to 74 years No pre-existing heart disease, chronic kidney disease, diabetes, hypertension, atrial fibrillation, transient ischaemic attack, inherited hypercholesterolaemia, heart failure, peripheral artery disease, stroke, statin prescription, previous check has found > 20% risk of heart disease over next 20 years -People with these conditions should have specific, regular checks	-Weight and height (BMI) -Blood pressure -Cholesterol -Questions about alcohol use, smoking, exercise, age, gender, and ethnicity -Those over 65 years will be informed about symptoms of dementia	-A risk score for CVD, diabetes II, stroke, and kidney disease over 10 years -Alcohol use score; physical activity assessment; diabetes risk assessment -Discussion about results and how to improve scores through lifestyle changes -Referal to local services such as for for smoking cessation and physical activity

Jørgensen et al. BMC Medicine (2025) 23:242 Page 4 of 4

people cannot benefit from their detection. But it may impact their perceived health and quality of life; necessitate follow-up tests which may be invasive and risky; and lead to preventive interventions carrying a risk of harm.

But perhaps the most important harms from preventive interventions are indirect. Follow-up will take place in an over-burdened health system, taking up clinician's time and resources from those in need. Most follow-up resulting from health checks will be performed in people who do not need it. To factor in such costs is urgently needed and assessing the Time Needed to Treat (TNT) in guidelines has been suggested to ensure distributive justice [9].

Screening may also serve as an excuse not to take unpopular political action with benefits of a magnitude far beyond screening. These include structural changes to diminish poverty and poor living conditions, particularly for children, and unhealthy behaviours, i.e. taxes on tobacco, sugar, and alcohol.

Evidence requirements for the NHS Health Check should be kept to accepted standards and all screening needs regular, independent re-evaluation [10]. A review of the NHS Health Check by the UK National Screening Committee seems timely.

Abbreviations

RR Risk ratio

TNT Time Needed to Treat

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Authors' contributions

KJJ conceived of the manuscript and wrote the first draft. Intellectual content was discussed thoroughly within the author group; MJ and SW provided extensive comments and revised the manuscript. All authors read and approved the final manuscript.

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 $\ensuremath{\mathsf{KJJ}}$ is a co-author of the Cochrane review that assess the evidence for general health checks.

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Data availability

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Not applicable

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Not applicable.

Competing interests

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