Training practitioners to deliver opportunistic multiple behaviour change counselling in primary care: a cluster randomised trial

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Research: Effectiveness of screening and brief alcohol intervention in primary care (SIPS trial) (*BMJ* 2013;346:e8501)
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STUDY QUESTION

What is the effect of training primary care health professionals in behaviour change counselling on patients self reported changes in smoking, risky drinking, unhealthy eating, or inactive lifestyle?

SUMMARY ANSWER

There was no significant change in behaviour at three months or on biochemical or biometric measures at 12 months, but after consultation with the trained clinicians, more patients recalled discussing health behaviour and reported intending to change. They also reported having attempted to change, and having made a sustained change in behaviour more often at three months.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Unhealthy lifestyle accounts for most preventable illness and early death in resource rich countries, and healthcare practitioners are encouraged to promote healthier lifestyles. Lasting behaviour change and improvements on biochemical and biometric measures are unlikely after a single routine consultation with a primary care clinician trained in behaviour change counselling.

Design

Cluster randomised trial with general practices as the unit of randomisation.

Participants and setting

Fifty three general practitioners and practice nurses from 27 general practices in Wales (one each at all but one practice) recruited 1827 patients who screened positive for at least one of four risky behaviours (smoking, risky drinking, unhealthy eating, or inactive lifestyle). The 25 clinicians at the 13 intervention practices were trained in behaviour change counselling to enhance patients' motivation to change health related behaviour.

Primary outcome(s)

The primary outcome was the proportion of patients who reported making beneficial changes in at least one of the four risky behaviours at three months.

Main results and the role of chance

Of the 1306 patients from the intervention practices and 1496 from the control practices who were approached, 831 and 996 respectively agreed to participate and screened positive for a risky behaviour. There was no effect on the primary outcome (beneficial change in behaviour) at three months (44% *v* 41%, odds ratio 1.12 (95% CI 0.90 to 1.39)) (table), or on biochemical or biometric measures at 12 months. More patients who had consulted trained clinicians recalled consultation discussion about a health behaviour (724/795 (91%) *v* 531/966 (55%), odds ratio 12.44 (5.85 to 26.46)) and intended to change behaviour (599/831 (72%) *v* 491/996 (49%), odds ratio 2.88 (2.05 to 4.05)). More intervention practice patients reported making an attempt to change (328 (39%) *v* 317 (32%), odds ratio 1.40 (1.15 to 1.70)), a sustained behaviour change at three months (288 (35%) *v* 280 (28%), odds ratio 1.36 (1.11 to 1.65)), and reported slightly greater improvements in healthy eating at three and 12 months, plus improved activity at 12 months.

Harms

Patients from intervention practices did not do worse on any outcomes.

Bias, confounding, and other reasons for caution

Cluster randomisation reduced the risk of bias from contamination. Clinicians agreeing to participate may have been more interested in behaviour change consultation skills and thus may have already been more skilful than healthcare professionals generally, potentially underestimating the effects of the intervention. Researchers in the practices attempted to screen all patients consulting participating clinicians to eliminate bias that may have arisen from clinician initiated recruitment. This eligibility screening could have acted as a co-intervention, so the control group did not fully represent usual care. Clinicians in the intervention group excluded more patients during the consultation, but sensitivity analysis showed this did not meaningfully affect the results. Key characteristics of practices, clinicians, and patients were reasonably well balanced, but patient recruitment differed slightly between study groups. Questionnaire return rates were high, and there was no significant difference between intervention and control groups in the proportion of patients followed up.

Generalisability to other populations

Patient eligibility criteria were deliberately wide to ensure generalisability of findings to the broad range of general practice patients. Behaviour change counselling is a generic consultation skills approach, applicable to a wide range of behaviour change situations beyond those assessed in this study.

Study funding/potential competing interests

The study was funded by the National Prevention Research Initiative.

Patients' composite change in any of four risky behaviours at three months after consultation

	No (%) of patients			
Change in behaviour	Control practices	Intervention practices	Overall percentage	Odds ratio (95% CI)
Failure	592 (59.4)	469 (56.4)	58.1	1.12 (0.90 to 1.39)
Success	404 (40.6)	362 (43.6)	41.9	

Overdiagnosis in screening mammography in Denmark: population based cohort study

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STUDY QUESTION

What is the amount of overdiagnosis in population based service mammography screening programmes?

SUMMARY ANSWER

Overdiagnosis most likely amounted to 0.7-3.4% in women targeted for screening and 1-5% among participants.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Most studies on overdiagnosis have methodological limitations. On the basis of a natural experiment in Denmark, the amount of overdiagnosis was limited; women should be followed for at least eight years after the end of screening to give a reliable estimate of overdiagnosis.

Participants and setting

In Denmark, Copenhagen and Funen, covering 20% of the female population aged 50-69 years, had population based mammography screening for more than 14 years before screening was implemented nationally. In these regions, 57 763 women targeted by organised screening and aged 56-69 at the start of the programme formed the study group. Women in the same birth cohorts and age groups in the rest of Denmark formed the control groups.

Design, size, and duration

We followed the study groups (32 931 women in Copenhagen and 24 832 in Funen) and control groups (27 000 to 281 000 women) for invasive breast cancer and ductal carcinoma in situ from the programme start in 1991-93 until the end of 2009. We compared incidences of breast cancer and calculated relative risks.

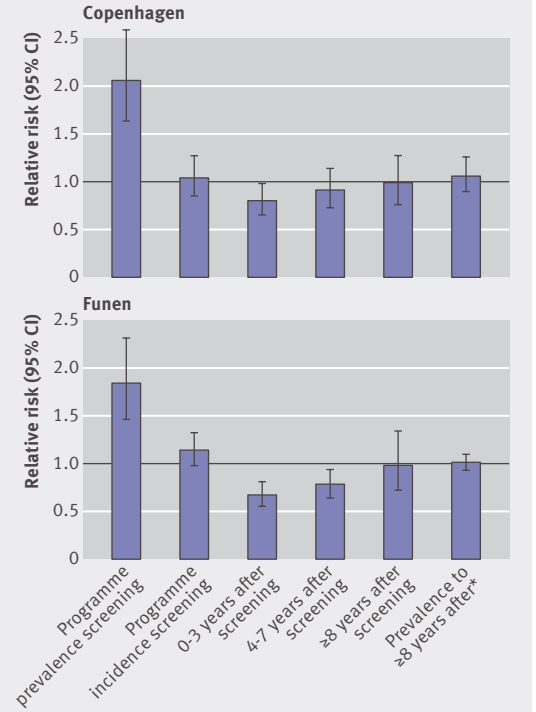
Main results and the role of chance

The incidence of breast cancer (invasive carcinoma and ductal carcinoma in situ) doubled during the programme prevalence peak (Copenhagen: relative risk 2.06, 95% confidence interval 1.64 to 2.59; and Funen: 1.84, 1.46 to 2.32) and was non-significantly increased during programme incidence screening rounds (1.04, 0.85 to 1.27; and 1.14, 0.98 to 1.32). We saw a clear deficit 0-3 years after the end of screening (0.80, 0.65 to 0.98; and 0.67, 0.55 to 0.81), after which the incidence gradually approached the level expected in the absence of screening. The cumulative incidence was increased by 5% in Copenhagen (1.05, 0.88 to 1.24) and 1% in Funen (1.01, 0.92 to 1.10); in women who could be followed for at least eight years after the end of screening, the increases were 3.4% and 0.7%.

Bias, confounding, and other reasons for caution

Differences between regions can be taken into account by estimating the differences between regions from historical data before the start of screening. A bias would emerge if differences between regions have changed over time. We investigated this and found that this was likely for Copenhagen but not for Funen. The effect is that the overdiagnosis estimate for Copenhagen is based on an extra assumption (the change found over time in the pre-study period equalled the change over time in the study period) and is more uncertain than the estimate for Funen.

Incidence of invasive breast carcinoma and ductal carcinoma in situ by time during and after end of invitation to screening



* Starting with prevalence round and including follow-up 8 years and more after end of invitation to screening

Generalisability to other populations

To ensure sufficient follow-up time after the end of screening, we included only women aged 56-69 years when the programmes started. We would, however, expect our overdiagnosis estimate to be fairly representative also for women aged 50-69. Overdiagnosis is likely to be affected by the detection rate of ductal carcinoma in situ; programmes with detection rates different from those of the Danish programmes might therefore have different amounts of overdiagnosis.

Study funding/potential competing interests

This study was financially supported by the Esper and Olga Boel Foundation.

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- Research: Women's views on overdiagnosis in breast cancer screening (*BMJ* 2013;346:f158)
- Research: Possible net harms of breast cancer screening (*BMJ* 2011;343:d7627)
- Research: Overdiagnosis from non-progressive cancer detected by screening mammography (*BMJ* 2011;343:d7017)
- Feature: Preventing overdiagnosis: how to stop harming the healthy (*BMJ* 2012;344:e3502)

Cemented, cementless, and hybrid prostheses for total hip replacement: cost effectiveness analysis

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STUDY QUESTION

What is the relative cost effectiveness of cemented, cementless, and hybrid prostheses for primary total hip replacement in adults with osteoarthritis aged 60, 70, and 80 in the English National Health Service?

SUMMARY ANSWER

On average, hybrid prostheses (prosthesis with cemented femoral stems and cementless acetabular cups) are most cost effective in all patients, except women aged 80, for whom cemented prostheses are most cost effective.

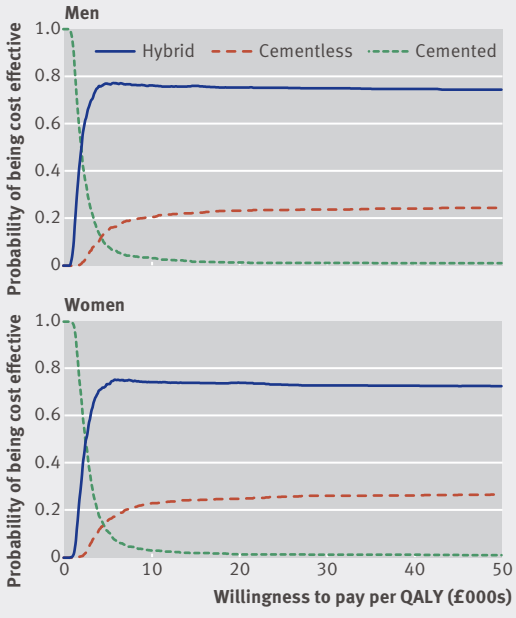
WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Cemented prostheses are cheaper and are associated with lower revision rates than cementless and hybrid prostheses, but cementless prostheses have become the most commonly used prosthesis type in many countries. We found that, on average, hybrid prostheses are the most cost effective type of prosthesis and that cementless prostheses do not provide sufficient gain in health outcomes to justify their extra costs.

Main results

For all subgroups apart from women aged 80, hybrid prostheses were associated with higher mean postoperative quality of life than cemented or cementless prostheses and therefore higher lifetime quality adjusted life years (QALY). For 70 year old patients, for example, we found that the incremental costs per QALY for hybrid prostheses compared with cemented prostheses was about £2100 ($3400; €2500) for men and £2500 for women. If the societal willingness to pay for a QALY gain exceeded £10 000, the probability that hybrid prostheses were most cost effective was about 70%. For patients aged 60 and 80, the cost effectiveness results were less clear cut.

Cost effectiveness acceptability curves for cemented, cementless, and hybrid prostheses for total hip replacement in adults aged 70



Design

Markov model with parameters derived from individual patient data from three national databases.

Sources of effectiveness

Non-randomised cohort studies including patients undergoing hip replacement with different prosthesis type in the English NHS. Multivariable matching technique and regression were used to adjust for differences in case mix.

Data sources

Data on case mix and postoperative quality of life were obtained from an English national programme that collected patient reported outcome measures immediately before and six months after elective surgery in all patients who had a total hip replacement in the NHS between July 2008 and December 2010. Revision rates were derived from patients who had a hip replacement between 2003 and 2009 according to the National Joint Register for England and Wales linked to the English hospital episode statistics. Costs of each prosthesis type were calculated from the prices paid by a typical NHS provider. Costs of the operation theatre and hospital stay were based on national data.

Results of sensitivity analysis

The results were robust to alternative assumptions about the long term revision rates and whether or not patients with a metal-on-metal prosthesis were included. The results were sensitive to assumptions about the duration of observed differences in postoperative quality of life.

Limitations

The study used observational data and it is possible that we did not completely eliminate the impact of differences in preoperative characteristics. In addition, the only available data for postoperative quality of life was observed at six months after the hip replacement, and the maximum follow-up to identify revisions was six years in the national joint registry and 13 years in hospital episode statistics.

Study funding /potential competing interests

This study was funded by the English Department of Health. We have no competing interests.

Sample size determinations in original research protocols for randomised clinical trials submitted to UK research ethics committees: review

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STUDY QUESTION

How are sample size calculations reported in research protocols for randomised clinical trials?

SUMMARY ANSWER

Most research protocols did not contain sufficient information to allow the sample size to be reproduced or the plausibility of the design assumptions to be assessed. Greater transparency in the reporting of the determination of the sample size and more focus on study design during the ethical review process would allow deficiencies to be resolved before the trial begins.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Sample size determination is an accepted and important part of the planning process for randomised controlled trials. Sample size reporting in original research protocols is often incomplete and in many instances the reliability of the design assumptions and hence the validity of the sample size determination cannot be judged.

Selection criteria for studies

All unpublished research protocols for phase IIb, III, and IV randomised clinical trials of investigational medicinal products submitted to research ethics committees in the United Kingdom during 1 January to 31 December 2009.

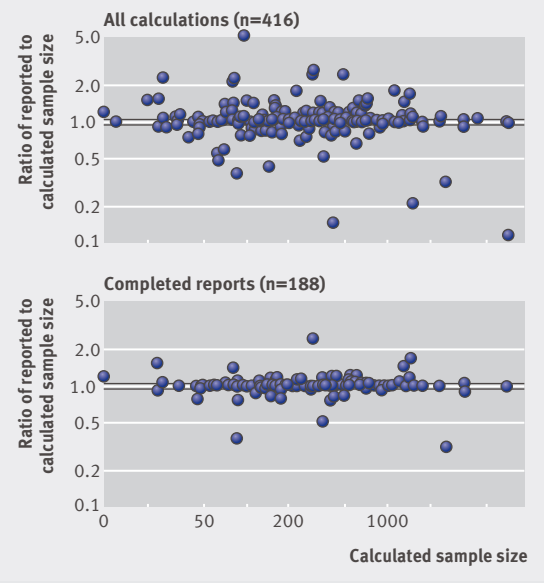
Primary outcomes

Completeness of reporting of the sample size determination, including the justification of design assumptions, and disagreement between reported and recalculated sample size.

Main results and role of chance

446 study protocols were reviewed. Of these, 190 (43%) justified the treatment effect and 213 (48%) the population variability or survival experience. Only 55 (12%) discussed the clinical importance of the treatment effect sought. Few protocols provided a reasoned explanation as to why the design assumptions were plausible for the planned study. Overall, 416 (93%) protocols could be recalculated by imputing missing information and 262 (59%) could be reproduced. Only 188 (42%) protocols reported all of the information to enable the sample size to be recalculated with no data imputation; the assumed withdrawal or dropout rate was not given in 177 (40%) studies. Only 134 of the 446 (30%) sample size calculations could be accurately reproduced. Study size tended to be overestimated rather than underestimated. Studies with non-commercial sponsors justified the design assumptions used in the calculation more often than studies with commercial sponsors, but less often reported all the components needed to reproduce the sample size calculation. Sample sizes for studies with non-commercial sponsors were less often reproduced.

Modified Bland-Altman plot of reported to calculated sample size by calculated sample size, separated by all calculations (with imputation) and complete reports (no imputation). Lines at 0.95 and 1.05 mark limits of underestimation and overestimation, respectively Data are presented on a log transformed scale



Bias, confounding, and other reasons for caution

We only reviewed research protocols submitted to research ethics committees in the United Kingdom and had no access to any other documents. The review was completely independent of the ethical review process. Our analysis was descriptive since it was not clear how to generalise quantitative statements to a wider population of protocols or to changes that the UK research ethics committees will face in the coming years.

Study funding/potential competing interests

This study received no funding. TC received support for travel from the National Research Ethics Service and has worked as a consultant for the clinical research organisation ICON in the previous three years.

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- Research: Reporting of sample size calculation in randomised controlled trials (*BMJ* 2009;338:b1732)
- Research methods and reporting
- Sample size calculations: should the emperor's clothes be off the peg or made to measure? (*BMJ* 2012;345:e5278)