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RESEARCH

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

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Abstract

Objectives To evaluate the effect of training primary care health professionals in behaviour change counselling on the proportion of patients self reporting change in four risk behaviours (smoking, alcohol use, exercise, and healthy eating).

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

Setting General practices in Wales.

Participants 53 general practitioners and practice nurses from 27 general practices (one each at all but one practice) recruited 1827 patients who screened positive for at least one risky behaviour.

Intervention Behaviour change counselling was developed from motivational interviewing to enable clinicians to enhance patients' motivation to change health related behaviour. Clinicians were trained using a blended learning programme called Talking Lifestyles.

Main outcome measures Proportion of patients who reported making beneficial changes in at least one of the four risky behaviours at three months.

Results 1308 patients from 13 intervention and 1496 from 14 control practices were approached: 76% and 72% respectively agreed to participate, with 831 (84%) and 996 (92%) respectively screening eligible for an intervention. There was no effect on the primary outcome (beneficial change in behaviour) at three months (362 (44%) *v* 404 (41%), odds ratio 1.12 (95% CI 0.90 to 1.39)) or on biochemical or biometric measures at 12 months. More patients who had consulted with 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 (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. Training cost £1597 per practice.

Discussion Training primary care clinicians in behaviour change counselling using a brief blended learning programme did not increase patients reported beneficial behaviour change at three months or improve biometric and a biochemical measure at 12 months, but it did increase patients' recollection of discussing behaviour change with their clinicians, intentions to change, attempts to change, and perceptions of having made a lasting change at three months. Enduring behaviour change and improvements in biometric measures are unlikely after a single routine consultation with a clinician trained in behaviour change counselling without additional intervention.

Trial registration ISRCTN 22495456

Introduction

Making "every consultation count"[1] to help people adjust their lifestyles is part of current UK healthcare policy and of

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international recommendations for improving public health.[2 3] The rationale is clear: in 2006-07, for example, ill health related to poor diet cost the UK National Health Service £5.8bn; physical inactivity cost £0.9bn, smoking and alcohol consumption each cost £3.3bn, and overweight and obesity cost £5.1bn.[4] Smoking, excessive alcohol consumption, lack of exercise, and an unhealthy diet are the most important modifiable causes of premature morbidity, premature mortality, and healthcare expenditure in the developed world.[5 6] In the United States they are estimated to be responsible for around 900 000 deaths annually, close to 40% of total mortality.[5]

Providing access to effective, theoretically sound, clinical interventions for the whole population raises challenges.[2] In the UK, where over 80% of the population consult in general practice annually[7] with an average of 5.4 consultations per person per year,[8] the potential for opportunistic primary prevention is clear.[9] What the effective interventions might look like remains less clear.

A feature of research on lifestyle change has been its focus on single behaviours. This has produced evidence that opportunistic brief interventions aimed at smoking and drinking, for example, can be highly cost effective[10 11] and have small but important effects.[12 13] Offers of assistance to all patients facing a behaviour change (such as smoking) may be more effective than selective assistance to those who respond to advice to change.[14] However, optimum primary care prevention might need to be more holistic, because people often present with multiple, inter-related lifestyle patterns. Put another way, "If we continue to deal with risk factors in a piecemeal way then the results will be minor."[1] While the evidence supporting brief intervention has been available for some time, many patients with important risk factors do not seem to receive the interventions.[15] For their part, practitioners apparently do not routinely engage in prevention, citing lack of time, lack of a sense of effectiveness, inadequate training, and the impact on clinician-patient relationships.[16-19] Both practitioners and their patients face a challenge to change their behaviour.

Developing a holistic multi-behavioural complex intervention that practitioners learn, like, and can use, and which is effective and acceptable to patients, remains a challenge. Systematic reviews of primary prevention, through engagement with multiple risk factors in primary care, conclude that evidence for effectiveness is inadequate.[6 20] Studies such as the OXCHECK Study, and British Family Heart studies[21 22] relied on calling patients into the practice (that is, the approaches were not opportunistic), and gave little attention to practitioner training or to individual patient plans, both of which have been highlighted as necessary in a range of guidelines.[2 12]

Against this background, we set out to evaluate an intervention, behaviour change counselling, that emphasises engaging the patient, and patient and health professional together choosing which lifestyle behaviours the patient might focus on. It recognised also that many people were likely to feel ambivalent about change, and would not necessarily respond well to straightforward advice. Instead, people would be supported with information to make their own decisions about why and how they might change.

The intervention was derived from motivational interviewing, defined as "a person-centered counselling style for addressing the common problem of ambivalence about change,"[23] and refined over 15 years into a method for addressing the challenge of efficient, respectful, and effective consultations in primary care about multiple behaviours.[24] The final form of behaviour change counselling used in this study comprised a flexible, menu driven framework, with a definition and list of skills designed specifically for brief healthcare consultations.[25]

The intervention was developed with an awareness of the National Institute for Health and Clinical Excellence (NICE) guidelines for behaviour change interventions that are theoretically based, carefully constructed, sensitive to local and individual needs, and designed to motivate people to engage with and plan changes in health behaviour.[26] Adaptations of motivational interviewing are effective for a range of unhealthy behaviours, being superior to minimal or no treatment controls and as good as and much briefer than more intensive treatment interventions.[27] However, no study has evaluated and costed training members of primary healthcare teams in behaviour change counselling or examined effects in relation to a range of patient behaviours. This was the primary objective of this study.

A similar rationale informed the training programme for practitioners: simply advising them to change their way of consulting is ineffective.[28-30] Training should enhance their perceptions of the value of change and their ability to succeed.[31] This should ideally be an internally driven process,[32 33] linked to everyday clinical challenges,[34] adequately supported to ensure maintenance of change,[35] and properly evaluated.[36] Effective interventions are likely to be multifaceted, have a focused and active educational outreach component, include skills development, and be congruent with clinicians' values.[37-39]

Two broad training methods[34] were used to enable practitioners to move routinely between multiple, inter-related risk behaviours, while respecting patients' inevitable motivational struggles.[27 40] The "context-bound learning method" is an adult learning, experiential approach that relies on clinicians themselves evaluating the importance of the issue and then reflecting on authentic case scenarios.[34] Secondly, a self directed, blended electronic learning programme was developed to allow learners online access to video-rich clinical challenges before and after face-to-face training.

We hypothesised that more patients, after a single routine general practice consultation with a primary care clinician exposed to a blended learning programme in behaviour change counselling, would change their behaviour, and would recall a discussion about behaviour change, intend to change, and make more attempts and lasting changes in health related behaviour compared with patients who consulted clinicians who had not been exposed to behaviour change counselling training. We chose a cluster randomised design in order to minimise contamination.

Methods

Study design

The protocol for this cluster randomised, controlled trial with randomisation at the level of general practice has been published previously.[41] Behavioural outcomes were assessed for eligible participants who consulted with general practitioners and nurses exposed to training in behaviour change counselling (the Talking Lifestyle programme) and were compared with outcomes for participants consulting in practices where general practitioners and practice nurses had not been exposed to training in behaviour change counselling. After the training of the clinicians in the intervention practices, both intervention and control practices engaged in two intensive, one-week periods of patient recruitment. The first week was within one month of the behaviour change counselling training for intervention group clinicians. Five to seven months later, a second, similar period

of recruitment occurred in all practices. Two recruitment periods were included to examine whether any positive effects would be sustained after training. Data from both recruitment weeks were otherwise analysed together.

The study was funded by the National Research Prevention Initiative and approved by the Multicentre Research Ethics Committee and the relevant local health boards in Wales.

To facilitate smooth running of the study and minimise disruption to the practices during the recruitment phase, clinicians kept four consultation appointments per day free and were reimbursed for the cost of these consultation slots. As this time was necessary for making up for disruption from patient screening, discussions about trial participation, and data collection, these were considered research costs and not costs associated with the intervention.

Eligibility screening

All people who had an appointment with a general practitioner or practice nurse taking part in the study (intervention or control) underwent eligibility screening by a researcher. This ensured that participant identification differences could not account for differences in outcomes. Participants were consulting for a wide range of acute and chronic concerns. Potential participants were given a brief information sheet about the study by the practice receptionist and invited to speak to a researcher in the practice about participation before giving consent. It was made clear, in both the information sheet and verbally, that this was an intervention study looking at the effect of practitioner consulting style on their behaviour and lifestyle change. Once patients consented, they completed a short baseline questionnaire. Outcomes were measured with four questionnaires (see box 2 for ranges of scores):

1. A subset of the Dietary Instrument for Nutrition Evaluation (DINE), evaluated in a UK population[42] and measuring fat and fibre intake (four questions pertaining to fat; bacon or processed meats, fried foods, cakes, and biscuits) and the two item fruit and vegetable questionnaire[43]
2. The short form of the International Physical Activity Questionnaire (IPAQ), assessing overall physical activity over the past seven days in a self administered format[44]
3. The number of cigarettes smoked daily from the Heaviness of Smoking Index (HSI)[45]
4. The Alcohol Use Disorders Identification Test consumption subscale questionnaire (AUDIT-C) for risky drinking.[46]

On the basis of the outcomes of this eligibility questionnaire, a researcher present in the practice completed a screening sheet to indicate which behaviours the participants had screened as eligible for an intervention, if any. The thresholds for screening were:

Alcohol—Score >4 for men or >3 for women on AUDIT-C

Diet—Consumption of <5 fruit and vegetable items per day or ≥3 servings of any of the subset of DINE fat items

Exercise—<30 minutes for at least 5 days a week of vigorous or moderate exercise

Smoking—≥1 cigarettes smoked per day.

Consultation

Once the patient was in the consultation, the clinician countersigned the form unless they felt it was inappropriate for that patient to participate. The research team did not follow ineligible patients or those considered inappropriate for participation by their clinician any further.

Participants were seen again by a researcher after the consultation with a study clinician to complete a post consultation questionnaire that covered intention to change behaviour, recall of and satisfaction with the consultation, and the patient enablement instrument.[47] Demographic information (age, marital status, and socioeconomic status) and presenting health concerns were also recorded.

Follow-up

At three and 12 months after recruitment, outcomes were measured using instruments specific to the four behaviours (DINE and the fruit and vegetable questionnaire for diet,[43] the short form IPAQ for physical activity,[44] HSI for smoking,[45] and AUDIT for alcohol intake) in self completed postal questionnaires. Single questions, each assessing quality of life and general health,[48 49] were included in the baseline, and the follow-up questionnaires. The three month questionnaire asked about the number of times participants had attempted to change any of the four health behaviours and whether they felt they had made a lasting change. The 12 month questionnaire used the Perceived Health Competence Scale (PHCS) to assess self efficacy for health behaviour change.[50]

Participants who did not respond to the questionnaires were sent a reminder and another questionnaire two weeks later. If there was still no response after four weeks from the initial questionnaire, the participant was contacted by telephone and invited to either return the questionnaire by post or to complete it over the phone. An unconditional £5 gift voucher was sent out with each questionnaire.[51]

Shortly after replying to the 12 month questionnaire, participants were invited to attend a follow-up appointment at their practice at a mutually convenient time and date. A £10 voucher was given in recognition of any travel expenses incurred and the time dedicated to attend the appointment. Waist to hip ratio, body mass index, and blood pressure were assessed with practice scales and sphygmomanometers. High density lipoprotein and total cholesterol concentrations were measured in finger prick samples with the Cholestech LDX system.[52] Salivary cotinine was tested with a SmokeScreen device.[53]

The primary outcome was a composite measure of beneficial change across four behaviours reported by patients three months after consulting with participating clinicians. This measure was based on the proportion of participants who reported one or more of the following potentially beneficial changes:

- 20% decrease in AUDIT-C score of alcohol intake
- 20% decrease in the number of cigarettes smoked per day
- 20% decrease in the subset of DINE score for dietary fat
- Increase of 120 metabolic equivalent (MET) minutes per week in IPAQ score of physical activity.

A 20% change was considered clinically important and potentially beneficial to health. Given that the change in exercise for many people was expected to be from very low levels or zero, a change that related to 20% of the recommended weekly exercise was chosen.

The secondary objectives of this study were to evaluate the effect of training primary care health professionals in behaviour change counselling on patients'

- Perception of having been engaged about health behaviour during the consultations

- Satisfaction, enablement, and intention to change immediately after consultation
- Perceptions of lasting behaviour change and having tried to change at three months after consultation
- Self reported behaviour change at three and 12 months after consultation for individual behaviours in addition to the composite
- Total and high density lipoprotein cholesterol concentrations, salivary cotinine levels in individuals reporting quitting smoking, waist to hip ratio, body mass index, and blood pressure at 12 months

Clinician competence in using behaviour change counselling was assessed in the intervention cluster practices through rating the transcripts of the simulated consultations with the Behaviour Change Counselling Index (BECCI) scale.[54]

Participants

General practices

We aimed for participating practices to have one general practitioner and one practice nurse available to participate in the study for the duration of the intervention and evaluation, with adequate internet links for accessing the training. General practices in Wales, UK, were recruited over a five month period from November 2007. We wrote to, and subsequently telephoned as necessary, general practices in South East Wales that were not engaged in any of our other related trials, explained the study, and invited participation and consent to the study. In the UK, patients are registered on a practice list and consult for all their routine care with that practice in usual consulting hours.

Patients

The patient inclusion criteria were:

- Ability to provide informed consent
- Aged ≥18 years
- Attending general practice to see one of the study clinicians (general practitioner or practice nurse)
- Screened above a designated risk threshold on at least one of the four behaviours (smoking, risky drinking, unhealthy eating, and inactive lifestyle)
- The clinician (in both intervention and control practices) thought the potential participant to be eligible and appropriate for the trial.

There were no specific exclusion criteria, other than inability to understand and comply with the study protocol. We therefore excluded people who were unable to complete the questionnaires in English. While we did not aim to exclude any patient who might benefit from the intervention offered, in some cases (112 in the intervention clusters; 29 in the control clusters; see figure⇓), after a brief discussion, clinicians were able to withdraw the patient from further involvement in the study if they perceived that the research process was inappropriate for the individual patient—for example, in the case of terminal or severe mental illness.

Experimental intervention

The intervention group received a behaviour change counselling training programme called the Talking Lifestyle learning programme that took practitioners through a portfolio-driven set of learning activities. Precise details of both intervention content and the training programme can be found in www.3trials.net: login = guest10@cf.ac.uk, password = guest10, then click on the PRE-EMPT icon. The goal of training was not to ensure complete clinical competence in the use of a guiding style for talking about behaviour change, but rather to start this process. As such, it was an introduction to a set of skills that learners could practise and improve as they refined their efforts in everyday practice. Box 1 provides a more detailed description of the components of the training programme. Less visible to a reader is the architecture of this programme. It was developed over many years to allow specific online content to be "dropped into" relevant sections to make up a sequence of portfolio-driven learning activities to be carried out both online (such as commenting on recorded video consultations) and in the practice setting itself (such as seminars and simulated consultations).

Practitioners were trained to shift their consulting style away from directing to a guiding style when talking about lifestyle change, to use an agenda setting strategy to negotiate what change to focus on, and to use a range of other strategies to encourage patients to clarify why and how they might change. We have previously provided a full description of all the skills and strategies involved,[24] and a description of the rationale for defining behaviour change counselling as a method with a specific set of skills.[25]

The theoretical base and mechanism of action of behaviour change counselling was strongly linked to research on the process of motivational interviewing,[55] where it has been confirmed in a number of studies that a less confrontational style is more likely to evoke "change talk," which in turn predicts a better outcome. A broader theoretical base came from psychological treatment research in general, in which interventions for behaviour change contain both interpersonal skills (such as using listening to draw out solutions from patients, rather than providing them) and specific content (such as discussing topics like reasons for change and improving self efficacy).[56 57] In our study, for practical reasons, clinicians were not specifically trained in the listening skills that lie at the heart of motivational interviewing, and we focused on the more general adoption of a guiding style. As such, it would be inappropriate to describe this as a study of motivational interviewing.

Training costs

All resources used in training were monitored prospectively. These included trainer and learner time, including time online, as well as materials, travel, etc. Training involved two seminars at each intervention practice attended by one general practitioner and one practice nurse, two rounds of simulated consultations with feedback from a facilitator and a web based e-learning programme and forum. Timings of simulated consultations were from audio recordings and e-learning times from clinicians' login and logout times that the online programme recorded automatically.

Sample size

To show an increase in the proportion of patients reporting beneficial change on one or more of the four health behaviours from 50% (the most conservative estimate for sample size calculation purposes) to 65% at three months, an individually randomised study would require 340 patients. To account for clustering effects from randomised practices, with a moderate intracluster correlation coefficient of 0.05, this was inflated to 1104 patients, with 24 practices recruiting 46 patients each. There was little specific evidence on which to base an intracluster correlation coefficient, so we chose one based on

Box 1: Content and learning methods of the Talking Lifestyle training programme

Part 1: Practice based seminar—Face-to-face, one hour programme induction from a facilitator trained in behaviour change counselling (BCC)

Part 2: E-learning—Introduction to the programme, up to date summary of research evidence, and elicitation of participants' judgments and views about behaviour change

Parts 3 and 4: E-learning—Introduction to the core elements of BCC and the value of flexible shifting between styles, using video consultations with actors

Part 5: Practice based seminar—Meeting with facilitator to review progress and prepare for the forthcoming simulated consultation

Part 6: Simulated consultation in practice setting—Simulated consultation with a standardised patient during a normal surgery session. Transcription of audio recording used to provide feedback by telephone or follow-up email

Part 7: E-learning—Reflection about everyday practice experience and the use of the BCC consulting strategies

Part 8: E-learning—Access to Talking Lifestyle forum to share experiences and questions with colleagues and facilitators

Part 9: Simulated consultation in practice setting—At about six months after rest of training programme, simulated consultation with a standardised patient during a normal surgery session. Transcription of audio recording used to provide feedback by telephone or follow-up email

previous findings on what might reasonably be expected in general practice.[58]

We initially planned to recruit 60 patients per practice, 30 during each recruitment week, making 1440 in total, to allow for loss to follow-up of 30%. However, after a poor three month follow-up rate in the pilot study, we revised our recruitment and retention methods and recruited and randomised 29 practices (to allow for practice drop-out) and continued recruitment beyond the 30 participants during each recruitment week. We implemented an early recruitment closure strategy in practices where the number of participants enrolled reached 40 in any recruitment week.[59]

Practice randomisation and data analysis

Randomisation was undertaken by the trial statistician using an optimal allocation approach[60] after all practices allocated to a pre-specified block had provided consent. Once a block of practices had provided consent, all potential allocations to two groups were generated, and a balance statistic calculated based on practice list size and modified Townsend scores.[61] Allocations that showed the greatest degree of balance (1% with the smallest imbalance) were then passed blind to an independent statistician to randomly select one allocation, and randomly allocate groups to intervention and control. Blocks of practices were randomised in this way, rather than all practices being randomised together, to allow for phased practice set-up and patient recruitment over time. Subsequent blocks incorporated the degree of imbalance from previous ones to maintain balance across the study. The first block consisted of 14 practices, and subsequent block sizes were determined by the rate at which further practices were recruited (though no block was smaller than six).

Analysis

Unless specifically indicated, all analyses were pre-planned in accordance with our statistical analysis plan and were intention to treat.[41] Analysis of the primary outcome used a three level logistic (2nd order penalised quasi-likelihood extra binomial) regression model to account for clustering at the level of practice, clinician, and patient to produce an odds ratio and associated 95% confidence interval. A conservative approach assumed non-responders made no positive change (intention to treat population).

Secondary outcomes were analysed using similar three level models, linear (to produce a difference in means) or logistic (to produce an odds ratio) as appropriate. These included patient reports of having been engaged by their clinicians for each risky behaviour. This was tested in a number of ways: firstly, in a similar fashion to the primary outcome, with individual behaviours combined into a composite measure of beneficial change on one or more behaviours. Participants' intention (or likelihood) to change on the four behaviours were analysed in the same way. When individual behaviours were analysed, this was undertaken on the population who had screened positive at baseline for that behaviour (for example, change in exercise behaviour was analysed for those who screened positive for not undertaking enough exercise).

Sensitivity analyses of the primary and secondary outcomes were undertaken on those followed up to assess the impact of assuming that a non-responder had no change in behaviour (complete case population).

The post consultation enablement and satisfaction assessments required some unplanned alteration for analysis. Although the full, six item enablement score was distributed reasonably to allow for linear regression analysis, the short, three item score was dichotomised because of the distribution of scores. Hence, participants either showed "no enablement" (scored 0) or "some enablement" (scored 1 to 6). Similarly, the satisfaction score was dichotomised into "less than very satisfied" (score 0–3) and "very satisfied" (scored 4). These were then analysed using logistic regression.

The three month questionnaire asked participants how many times (if any) they had attempted to make change on each of the four behaviours. Because of the distribution of responses, this was analysed as a dichotomous variable categorised as "tried to change" (tried ≥1 times) or "did not try to change." Participants were also asked whether they had made a lasting change on each of the four behaviours. These were analysed in the same way as the post consultation questionnaire and likelihood to change assessments.

The primary outcome, derived from the three month questionnaire data, was repeated using the 12 month questionnaire data. A subgroup analysis was conducted for both the three and 12 month questionnaires among patients in the intervention cluster who indicated they had discussed all the behaviours they had screened eligible for with their clinician during the consultation. Further subgroup analyses were performed on the primary outcome to explore whether the week of recruitment or the clinician type (general practitioner or practice nurse) affected the result.

Analyses were also undertaken on the four individual continuous variables from which the beneficial change outcome was created (DINE subset for dietary fat and fruit and vegetable intake, IPAQ score for physical activity, number of cigarettes smoked daily, and AUDIT-C score for alcohol intake). These, as well as the absolute decreases in AUDIT-C, number of cigarettes smoked, and subset of DINE, were analysed using linear

regression as these results were approximately normally distributed. Also analysed at both three and 12 months were DINE healthy eating, fat and fibres scores; fruit and vegetable consumption; full, 10 item AUDIT score; Heaviness of Smoking Index; the number of minutes spent sitting; self reported general health; and quality of life. Where necessary, items underwent transformation to be analysed using linear regression. Lastly, the Perceived Health Competence Scale was analysed at 12 months. Table 1⇓ provides the range of scores for each measure.

Data from the 12 month consultation, (such as hip to waist ratio, body mass index, and total, low density lipoprotein, and high density lipoprotein cholesterol concentrations) were analysed using linear regression. Blood pressure values were dichotomised (for systolic, ≤120 and >120 mm Hg; diastolic, ≤80 and >80 mm Hg). These, along with the levels of those who had quit smoking (confirmed by a cotinine test), were analysed using logistic regression.

Response rates to questionnaires and also to items within the questionnaires were assessed for bias in terms of the cluster and phase of patient recruitment.

Sensitivity analyses were performed assuming those people that the clinician deemed not eligible or appropriate for study participation, and were therefore not followed up, responded in a similar way to the control group participants. Values were imputed based on distributional parameters of the control group for that outcome, regardless of whether the participant was from a control or intervention practice. This explores the potential impact of intervention clinicians "selecting" who was eligible for the study.

Study of the fidelity of intervention delivery comprised evaluation of practitioner competence (not performance) in simulated consultations before the onset of the study and again five to seven months later. Simulated patients provided audio recordings of the simulated consultations that took place before each of the recruitment weeks. The Behaviour Change Counselling Index (BECCI),[54] developed for assessing competence during training in behaviour change counselling, comprised 11 items, each being rated as 0 (not at all), 1 (minimally), 2 (to some extent), 3 (a good deal), or 4 (a great extent). Recordings were analysed by trained raters, who doubled coded 17% to ensure reliability.

Data entry was by scanning using Cardiff Teleform. Data cleaning and descriptive analysis were undertaken using SPSS 18.0, and multilevel modelling was done with MLwiN 2.17.

Training costs

Resources were valued using standard methods[62] and are in 2009 prices. All learning was valued at work time unit costs which reflect what costs would be if all training occurred during working hours as is likely to be the case if the intervention is rolled out.

Results

Practice recruitment and training

We recruited 29 general practices and randomised 14 to the control cluster and 15 to the intervention cluster, although two practices in the intervention cluster withdrew before patient recruitment began (figure⇓). General practices in the intervention and control clusters were similar in terms of practitioner sex and type. As expected, the balancing variables of list size and modified Townsend score were similar across intervention and control clusters (table 2⇓).

All 25 clinicians in the intervention cluster completed the first six parts of the learning programme that included training in the behaviour change counselling skills and the first simulated patient consultation and feedback. Thirteen (52%) started Part 7 and completed the first section (where they entered accounts of cases), but only seven (28%) completed the whole of Part 7. Seven clinicians used the web forum (Part 8), and all but three (12%) completed the second simulated patient task with feedback (Part 9).

There was no difference in mean scores on the 11 item BECCI scale for intervention cluster clinicians between the two recruitment periods, phase 1 (mean 1.196) and phase 2 (mean 1.566) (paired samples *t* test, P=0.140). Half of the clinicians (11/22) produced competence scores indicating that they had used the skills "to some extent," "a good deal," or to "a great extent."

Patient recruitment

A total of 2067 (1078 control and 989 intervention) patients completed the baseline questionnaire (figure⇓). Of these, 1827 were eligible and recruited (996 control and 831 intervention) and thus formed the intention to treat population screening positive for at least one risky behaviour. Patients from the two clusters were similar in terms of screening levels (table 3⇓) and baseline characteristics (table 4⇓). There were, however, slightly more men in the intervention group (39.8% *v* 36.4%). There was also reasonable balance on those lost to follow-up at three months (table 5⇓).

Post consultation outcomes

At this stage, 1761 (96.4%) of participants completed the post consultation questionnaire. There was no significant difference between clusters, with 795 (95.7%) and 966 (97.0%) providing data in the intervention and control groups respectively: 724 (91.1%) of patients in the intervention cluster reported having discussed behaviour change with their clinician, compared with 531 (55.0%) in the control cluster (odds ratio 12.44 (95% confidence interval 5.85 to 26.46)). Analysing each risky behaviour separately produced similar significant differences in reported discussions.

There were no significant differences in satisfaction or enablement between the two clusters (table 6⇓). Regarding likelihood to change behaviour, there was a significant difference in favour of the intervention cluster for all behaviours combined (72.1% *v* 49.3%, odds ratio 2.88 (2.05 to 4.05)), and individually (except alcohol) (table 7⇓).

Three month outcomes

In total, 1470 (80.5%) participants responded to the three month questionnaire. There was no significant difference in response between clusters, with 668 (80.4%) and 802 (80.5%) responding in the intervention and control clusters respectively.

The composite measure of behaviour change (beneficial change on one or more behaviours), the primary outcome, marginally favoured the intervention group but the difference was not statistically significant (table 8⇓). The success rates were 43.6% in the intervention clusters and 40.6% in the control clusters, which produces an odds ratio of 1.12. However, the 95% confidence interval (0.90 to 1.39) is wide enough to encompass no difference (value of 1.00). The intracluster correlation coefficients here are 0.021 for the centre level and <0.001 for the clinician level. The intracluster correlation coefficients are minimal throughout all analyses and are therefore not reported.

More participants in the intervention group reported having tried to change a behaviour, for the different behaviours and the behaviours combined. However, analyses of the drinking and smoking behaviours here were not statistically significant (table 7⇓), with particularly wide 95% confidence intervals due to the smaller number of patients screening for these behaviours. Overall, 39.5% in the intervention cluster and 31.8% in the control cluster reported having tried to change one or more risky behaviour (odds ratio 1.40 (95% CI 1.15 to 1.70)). Those reporting making a lasting change followed a similar pattern (combined behaviours 34.7% *v* 28.1%, odds ratio 1.36 (1.11 to 1.65)), with all odds ratios favouring the intervention clusters, and non-significant results for alcohol and smoking behaviours (also a non-significant result for diet when analysed conservatively), again due to wide confidence intervals in these analyses.

When the primary outcome was re-analysed including only those in the intervention cluster who reported having relevant discussions with their clinician about behaviour change (and therefore could be considered to have received the intervention), there was no statistically significant difference in the primary outcome (table 8⇓). It did favour the intervention clusters to a greater extent than the original analysis, but the 95% confidence interval just approaches 1.00 (46.0% *v* 40.6%, odds ratio 1.25 (1.00 to 1.56)). A complete case analysis of the primary outcome was also undertaken. This excludes those who were lost to follow-up at three months and those who did not provide enough data to calculate an answer for this outcome (whereas the primary analysis uses all of the intention to treat population and assumes these people to be intervention failures). The odds ratio again favours the intervention clusters, but the confidence interval contains 1 and hence this is not significant (69.6% *v* 65.5%, odds ratio 1.21 (0.94 to 1.55)).

Levels of reported successful change in behaviour were higher in the intervention cluster for all behaviours and for the composite measure. The largest difference between clusters (1.82 percentage points) was seen for smoking behaviour.

Secondary outcome are also presented in table 8⇓. The DINE healthy eating score (for those screened for any behaviour and for those just screened for diet behaviour) was significantly better for the intervention cluster.

Subgroup analyses were undertaken for the composite measure of behaviour change by consulting clinician (general practitioner or practice nurse) and phase recruitment (immediately after training or six months later). There were no significant differences associated with either of these two factors.

12 month outcomes

In total, 1401 (76.7%) participants responded to the 12 month questionnaire. There was no significant difference in response rate between clusters, with 624 (75.1%) and 777 (78.0%) responding in the intervention and control clusters respectively. As with the three month results, the composite measure of behaviour change favoured the intervention cluster, but the difference was not significant (40.6% *v* 39.8%, odds ratio 1.03 (0.83 to 1.28)). However, there were significant differences in the absolute change from baseline for the absolute increase in IPAQ score for physical activity, the DINE healthy eating score, and the DINE fibre score (for those with a healthy eating score who screened for diet) in favour of the intervention cluster (table 8⇓).

Among the 969 (53.0%) patients who attended the 12 month clinical assessment, there was no significant difference between clusters, with 425 (51.1%) and 544 (54.6%) attending in the intervention and control clusters respectively. Two biometric measures, hip to waist ratio and body mass index, and three cholesterol measures (high and low density lipoprotein and total cholesterol) were not significantly different between groups (table 9⇓). Continuous and discrete measures of blood pressure (systolic pressure dichotomised around 120 mm Hg, diastolic dichotomised around 80 mm Hg) were also not significantly different (table 9⇓). Cotinine test results were compared against smoking questions at baseline to confirm patients' reported smoking cessation. The numbers available for this test (173) were small, and the number shown to have quit smoking was even smaller. There was no significant difference between clusters (table 9⇓).

Sensitivity analyses

We repeated statistically significant analyses, but this time assumed that those patients who clinicians deemed not eligible or appropriate for an intervention would have responded as if in the control group—in order to explore whether significant differences could have arisen from selective exclusion of patients in the intervention cluster. The differences in those indicating they were likely to change behaviour, those who had tried to change behaviour, and the improvement in the DINE fibre score at 12 months (for those who were screened for diet and had a DINE healthy eating score) remained statistically significant (table 10⇓). The lasting change outcome, the absolute increase in IPAQ score (physical exercise) at three months, and all outcomes based on the DINE healthy eating score were found to be non-significant in these analyses. It is therefore possible that the analyses of these outcomes on the intention to treat population may have been biased by the level of exclusions made by clinicians.

Training costs

The total cost of delivering the Talking Lifestyle training to 15 intervention practices was £9136 (table 11⇓). The total mean cost to the practices in terms of practitioner time was £988 (SD £310). The e-learning programme represented the largest time commitment, with a mean time of 316 (SD 150) minutes for general practitioners and 332 (190) minutes for practice nurses. Adding apportioned costs of delivering the training brought the total cost per practice to £1597.40 (€1833, $2384).

Discussion

Summary of main findings

This cluster randomised trial is the first to evaluate the effects of training primary care clinicians in a blended learning programme dedicated to patient lifestyle behaviour change on patients' self reported measures of change and selected differences in biological measures for a range of risky behaviours, with outcomes assessed immediately after and at three and 12 months after a single routine general practice consultation. We did not find a significant effect on our primary outcome, a composite measure of beneficial behaviour change across four behaviours, three months after patients consulted with clinicians trained in the intervention. We found no effect at 12 months on biometric or biological measures related to risky behaviours.

However, after their consultation with study clinicians, more patients seen by the clinicians who had been trained in behaviour change counselling reported that they had been engaged about one of the risky behaviours (91.1% *v* 55.0%) and more stated that they intended to change behaviour (72.1% *v* 49.3%). At

three months, more of these patients reported having made an attempt to change (39.5% *v* 31.8%) and more reported having made a sustained change (34.7% *v* 28.1%) in one of the behavioural domains. The DINE healthy eating score was also significantly different in favour of the intervention group. At 12 months we found a significant difference in the absolute change in IPAQ score for physical exercise, the DINE healthy eating score, and the DINE fibre score (for those with a healthy eating score who were screened for diet) in favour of the intervention. These differences in scores at three and 12 months were small and of unknown clinical importance.

There were no important differences in outcome among patients by recruitment week (shortly after clinician training or about six months after) or by whether general practitioners or practice nurses delivered the intervention.

At a total cost of £1597 per practice, the Talking Lifestyle training programme does not represent a high cost. Costs associated with the trial (such as keeping some appointment slots open to ensure smooth patient flow because of waiting room recruitment and other trial related activities) are not included in this figure. Moreover, training represents an investment that may yield continuing benefits over time. However, training costs represent a small fraction of the total costs associated with delivering the intervention in primary care.

Strengths and weaknesses of study

The study design of randomising by cluster at the level of general practice (and not at the level of patient or clinician) was appropriate to the research question in that this was a study of the effects of training practitioners from the same general medical practice on their patients. Once clinicians are trained in new consultation skills, they are not able to revert back to their previous untrained state according to individual patient randomisation. Diffusion of the acquisition of new skills and knowledge within practices is desirable, and randomising by practitioner would have increased the risk of contamination, especially if practitioners from the same practice were randomised to be trained and not trained. We were not able to assess such diffusion within practices. Appropriate adjustments for clustering were made. Clinicians who agreed to participate in our study may have been more interested in behaviour change consultation skills, and thus intervention and control clinicians may have already been more skilful than the general population of general practitioners and practice nurses, thus potentially underestimating the effects of training if it were generalised. However, we do not know whether the skill levels or interest in behaviour change counselling differed between those agreeing to participate and those who did not agree, as we were not able to collect such data from those who did not agree to participate. However, as randomisation occurred after clinicians had agreed to participate, it is likely that control and intervention groups were balanced for initial interest and skill levels.

Researchers in the practices attempted to screen all patients consulting with participating clinicians, thus eliminating bias that may arise from clinician initiated recruitment.[63] Independent identification and recruitment of eligible participants was intended to remove from the research question the challenge of identification of risky behaviour, therefore making this a clean assessment of the impact of the training and intervention in the consultation, not the clinicians identifying (or failing to identify) people at risk. This makes the trial less pragmatic in nature, but was necessary to answer the research question. This eligibility screening could have acted as a co-intervention, masking any differences between groups as the control group did not represent usual care (as this would not include identification). However, given the reported differences immediately after consultation on the levels of discussion of behaviour change received by the two groups and on intentions to change, it unlikely that the lack of significant difference in other outcomes can be attributed to the screening. The number of patients recalling a discussion with their clinicians about behaviour change and intending to change after the consultation was high in both groups, suggesting that the research process may have affected this. The differences in recall between the two groups are nevertheless dramatic, suggesting training had an important effect on this outcome.

Clinicians in the intervention group excluded more patients during the consultation. We had asked clinicians to exclude patients only if the research process was deemed inappropriate for the patient—such as in the event of terminal illness or major psychiatric disorder (also requested by the ethics committee). When we analysed all of those who were excluded by their clinician as not eligible or not appropriate—assuming that they had responded similarly to the control group—the differences in intending to change risky behaviour, having made an attempt to change, and the DINE fibre score at 12 months (for those who screened for diet and had a DINE healthy eating score) remained statistically significant.

Patient eligibility criteria were deliberately wide to ensure generalisability of findings to the broad range of general practice patients. Patient recruitment differed slightly between groups. Fewer patients were recruited during the second recruitment week in practices (927 *v* 1148), and this was more pronounced in the intervention group (144 *v* 77 fewer patients in phase 2 compared with phase 1). Key characteristics of practices, clinicians, and patients were reasonably well balanced between groups. Questionnaire return rates were good (over 96%, over 80%, and over 75% for the post consultation, three month, and 12 month questionnaires respectively). Over 53% of patients were followed up in a clinical assessment at 12 months, and there was no significant difference between intervention and control groups, or recruitment phase, for the levels of non-response to these questionnaires or specific items within them.

Clinicians in the intervention group generally responded well to the behaviour change counselling intervention and training. They all engaged fully with the first six of the seven parts of the learning programme, which included online activity, on-site training, and the gathering of the first simulated consultation recording. A minority failed to complete the final simulated recording. In this pragmatic study, compromises were made around the behaviour change counselling training and fidelity assessment. Listening skills, a central feature of interventions known to predict good outcome,[53] were not targeted for training. This might have reduced the effect of the intervention and could be included in future training without necessarily increasing the length of the training. We might have improved the intervention effectiveness by ensuring that clinicians reached a specific level of competence before recruiting any patients. The training programme may have been more effective if the clinicians had received more training and support to deliver behaviour change counselling to a higher standard. The fidelity assessment of intervention was indirect. Simulated consultations were part of the clinicians' learning programme. Clinicians' skills in delivering behaviour change counselling in these simulated consultations as assessed by the Behaviour Change Counselling Index[54] indicated the level of skill acquisition was suboptimal. Direct assessment of behaviour change counselling fidelity in real consultations would have provided a better indication of

competence. However, this would have increased the burden of participation for clinicians, perhaps limiting participation and making the study less pragmatic. Studies where understanding mechanism of effect is a major focus clearly require more direct assessments of intervention fidelity, whereas those studies whose main question is "does the intervention work under usual conditions?" may limit their generalisability by more intensive assessment of study processes.[64]

We were unable to identify in advance an existing and suitable composite outcome measure of change across the four risky behaviours we assessed. We thus developed one for the purposes of this study using components of established self report measures of the behaviours. We do not know how effectively this measure distinguishes overall change between groups, and so suboptimal performance of our primary outcome measure may have meant that important differences could have been underestimated at the group level.

Self reported change at three months differed from results obtained by scales to measure behaviours. Scales may be less prone to bias arising from perceptions of social desirability. Alternatively, perceptions of having made a lasting change and scale scores may be measuring different constructs.

Comparison with existing literature

The objective of our study was to evaluate the effect of training clinicians on patient behaviour, regardless of patient interest or readiness to change. A major strength of the intervention is its flexibility and applicability to most consultations where there is an opportunity to address health behaviour issues. Most other research has focused on interventions for single risky behaviours.[10 11] Not many studies of clinician training have shown an effect on patients' recall of having received a behaviour change intervention and their intentions to change risky behaviours or perceptions of having made lasting changes at three months after a single consultation. Training healthcare professionals in addressing risky behaviours is important, as those who receive training are more likely to give smoking cessation advice than untrained controls.[65] A study of patient and physician interventions to modify patient lifestyle found a small effect on blood pressure at six months that did not persist at 18 months.[66] A systematic review of seven randomised controlled trials[21 67-72] of lifestyle counselling in primary care for the primary prevention of cardiovascular disease found that four[21 69-71] had a significant positive effect, mainly on blood pressure and blood lipid levels, and only two showed consistent effects across several outcomes. All effects were small.[20] No study, including ours, has yet shown an effect of an intervention in a routine consultation on a range of biological measures related to health behaviours one year after patients consulted with clinicians trained in behaviour change counselling.

We found no significant difference in risky drinking, smoking, exercise, or weight loss at 12 months. A systematic review of 22 trials enrolling 7619 patients found "brief interventions" resulted in lower alcohol consumption after one year.[73] A systematic review of interventions aimed at changing either the behaviour of professionals or the organisation of care to promote weight reduction in overweight or obese adults included six trials (246 health professionals and 1324 patients). Meta-analysis of the three trials that evaluated educational interventions aimed at general practitioners found that such interventions could reduce average weight after a year by just over 1 kg.[74] As smoking declines, those who continue to smoke may be less influenced by a brief intervention in primary care. However, inactive lifestyle and unhealthy diet, which are far commoner than smoking and have received medical and media attention for a shorter time, may benefit more from brief intervention in primary care. More intensive interventions in primary care with planned engagement over a longer period may be required to achieve a difference in biological measures relevant to behaviour change.[75]

There were differences between intervention and control group patients in reports of having received an intervention and in intention to change. Exposure to trained clinicians may have increased patients' sense of the importance of change and ability to achieve change, in keeping with the underlying theory of behaviour change counselling, or these may be reporting artefacts. A systematic review of 47 studies suggested that intentions do predict behaviour, though there are of course gaps between the two.[76] Behaviour change is a complex process within and across individuals, and this study evaluated efforts to alter the behaviour of both clinicians and patients. It is possible that the intervention may have had a greater effect on those more ready to change, though this is difficult to measure and thus evaluate.[77] It is also possible that the outcome measures were not sufficiently sensitive to detect clinically important changes in behaviour. Measuring diet and physical activity is particularly challenging.

Patients may also require more specific[78] or intensive engagement and follow-up to produce an effect on biological parameters. Ongoing professional support enhances behaviour change maintenance.[79] Maintaining both a sense of the importance of change and the confidence to attain change requires more successful engagement than has been achieved here.

Implications for policy and practice

Training clinicians in behaviour change counselling resulted in more patients perceiving that their clinician had engaged them about health behaviour change, in the context of a trial evaluating the effects of clinician training, and had an effect on their intentions to change and perception of having made a lasting health behaviour change. At three and 12 months, there were small changes in scales measuring key behaviours that favoured the intervention. This is encouraging, after exposure to a trained clinician in possibly just one consultation and during which many other clinical needs would have required attention.

Behaviour change counselling is a generic consultation skills approach, applicable to a wide range of behaviours beyond those assessed in this study. As some forms of lifestyle advice can be counterproductive,[80] many clinicians may wish to increase their repertoire of consultation skills through programmes such as the one evaluated in this study. With these skills, clinicians may be more inclined to engage patients about behaviour change, increasing the numbers exposed to behaviour change counselling and thus increasing the importance of any small beneficial changes that may arise from clinician engagement. The approach to training and skills acquisition, with its flexible and diverse learning methods, may also fit in well with modern continuing professional development needs of clinicians.

Given that more patients in the intervention group recalled a discussion about behaviour change and intended to change, the lack of lasting change is likely to arise from patient difficulties with adherence to intended plan, suggesting that behaviour change counselling in a single consultation on its own is insufficient to achieve lasting change for important numbers. Additional intervention, such as greater exposure to trained clinicians and structured follow-up or referral of patients, may

be required to achieve lasting, measureable changes in behaviour and biometric and biochemical effects.

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Data sharing: please contact Chris Butler (bultercc@cf.ac.uk) to discuss requests

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What is already known on this subject

Unhealthy lifestyle accounts for most preventable illness and early death in resource-rich countries

Health care practitioners are being encouraged to engage in opportunistic primary prevention and to "make every consultation count" by promoting healthier lifestyle at every appropriate opportunity

Efforts to develop multi-behavioural interventions have focused on specific diseases, and the evidence base is currently inadequate

What this study adds

Training primary care clinicians in behaviour change counselling using a brief blended learning programme did not increase patients' reported beneficial behaviour change at three months or improve biometric and a biochemical measures at 12 months

The training did increase patients' recollection after a single consultation of a discussion with their clinicians about behaviour change, intention to change, self reported attempts to change, and perceptions of having made a lasting change at three months, and some differences in improvement in healthy eating at three and 12 months and physical activity at 12 months

Lasting behaviour change and improvements on biochemical and biometric measures are unlikely after a single routine consultation with a clinician trained in behaviour change counselling without additional intervention

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Tables

Table 1| Range of scores for measures of patient characteristics and risk behaviours

Name of measure	Range of scores
Modified Townsend deprivation index	−10 to 10
Self enablement score (full)	0 to 12
Alcohol intake:	
AUDIT-C score	0 to 12
AUDIT score	0 to 40
Diet:	
Subset of DINE	4 to 31
DINE healthy eating	−119 to 156
DINE fat	8 to 122
DINE fibre	3 to 164
Fruit and vegetable consumption	0 upwards
Physical activity:	
IPAQ	0 upwards
Minutes spent sitting	0 upwards
Smoking:	
HSI	0 to 6
No of cigarettes smoked daily	0 upwards
Self reported general health	0 to 4
Quality of life	0 to 100
Perceived health competence score	1 to 5

AUDIT-C = Alcohol Use Disorders Identification Test consumption subscale. DINE = Dietary Instrument for Nutrition Evaluation. IPAQ = International Physical Activity Questionnaire. HSI = Heaviness of Smoking Index.

Table 2| Characteristics of participating clinicians by control and intervention clusters. Values are numbers (percentages) unless stated otherwise

Characteristic	Control cluster (n=28)	Intervention cluster (n=25)	Overall percentage or median
Men	8 (28.6)	10 (40.0)	34.0
Women	20 (71.4)	15 (60.0)	66.0
Nurses	14 (50.0)	12 (48.0)	49.1
General practitioners	14 (50.0)	13 (52.0)	50.9
Median (IQR) practice list size	6050.5 (4984.0)	6776.0 (5267.0)	6266.0 (4842.0)
Median (IQR) modified Townsend score	1.985 (4.390)	0.990 (6.040)	1.630 (4.890)

IQR = interquartile range.

Table 3| Numbers of patients in control and intervention general practices who screened as eligible for behaviour change counselling for four risky behaviours. Values are numbers (percentages) unless stated otherwise

	Control cluster (n=1078)	Intervention cluster (n=989)	Overall percentage
Behaviour screened for:			
Alcohol	389 (36.1)	386 (39.1)	37.5
Diet	750 (70.9)	716 (73.2)	72.0
Exercise	738 (68.5)	707 (71.5)	69.9
Smoking	249 (23.1)	200 (20.2)	21.8
No of behaviours:			
0	53 (4.9)	46 (4.7)	4.8
1	278 (25.8)	217 (21.9)	23.9
2	449 (41.7)	452 (45.7)	43.6
3	242 (22.4)	208 (21.0)	21.8
4	56 (5.2)	66 (6.7)	5.9

Table 4| Characteristics of patients from control and intervention general practices. Values are numbers (percentages) unless stated otherwise

	Control cluster	Intervention cluster	Overall percentage or mean
Male sex	363/996 (36.4)	331/831 (39.8)	38.0
Mean (SD) age (years)*	51.4 (35.49) (n=961)	50.3 (62.23) (n=791)	50.9 (49.55)
Marital status:	(n=966)	(n=793)	
Single	159 (16.5)	177 (22.3)	19.1
Married or cohabiting	624 (64.6)	489 (61.7)	63.3
Divorced	89 (9.2)	66 (8.3)	8.8
Widowed	94 (9.7)	61 (7.7)	8.8
Socioeconomic classification†:	(n=840)	(n=682)	
Managerial and professional occupations	351 (41.8)	304 (44.6)	43.0
Intermediate occupations	106 (12.6)	103 (15.1)	13.7
Small employers and own account workers	102 (12.1)	88 (12.9)	12.5
Lower supervisory and technical occupations	97 (11.5)	69 (10.1)	10.9
Semi-routine and routine occupations	184 (21.9)	118 (17.3)	19.8
Self reported health concerns‡:	(n=966)	(n=795)	
Heart disease	135 (14.0)	108 (13.6)	13.8
Diabetes	110 (11.4)	103 (13.0)	12.1
Depression	171 (17.7)	133 (16.7)	17.3
Stroke	40 (4.1)	33 (4.2)	4.1
Arthritis	248 (25.7)	171 (21.5)	23.8
Hypertension	212 (21.9)	161 (20.3)	21.2
High blood cholesterol levels	202 (20.9)	161 (20.3)	20.6
Asthma	140 (14.5)	125 (15.7)	15.0
COPD	34 (3.5)	23 (2.9)	3.2
Backache	282 (29.2)	225 (28.3)	28.8
Other	281 (29.1)	230 (28.9)	29.0

COPD = chronic obstructive pulmonary disease.

*Standard deviations inflated using cluster inflation factors and intracluster correlation coefficients.

†As defined by Office of National Statistics (www.ons.gov.uk/about-statistics/classifications/current/ns-sec/index.html).

‡In response to question “Do you have any of the following health concerns?”

Table 5| Characteristics of patients who were lost to 3 month follow-up from control and intervention general practices Values are numbers (percentages) unless stated otherwise

	Control cluster	Intervention cluster	Overall percentage or mean
Male sex	81/194 (41.8)	71/163 (43.6)	42.6
Mean (SD) age (years)*	42.0 (19.62) (n=189)	39.2 (28.53) (n=148)	40.7 (24.44)
Marital status:	(n=190)	(n=149)	
Single	56 (29.5)	65 (43.6)	35.7
Married or cohabiting	106 (55.8)	68 (45.6)	51.3
Divorced	21 (11.1)	9 (6.0)	8.8
Widowed	7 (3.7)	7 (4.7)	4.1
Socioeconomic classification†:	(n=160)	(n=119)	
Managerial and professional occupations	63 (39.4)	37 (31.1)	35.8
Intermediate occupations	14 (8.8)	19 (16.0)	11.8
Small employers and own account workers	18 (11.2)	19 (16.0)	13.3
Lower supervisory and technical occupations	21 (13.1)	14 (11.8)	12.5
Semi-routine and routine occupations	44 (27.5)	30 (25.2)	26.5
Self reported health concerns‡:	(n=190)	(n=149)	
Heart disease	15 (7.9)	15 (10.1)	8.8
Diabetes	21 (11.1)	13 (8.7)	10.0
Depression	45 (23.7)	26 (17.4)	20.9
Stroke	4 (2.1)	4 (2.7)	2.4
Arthritis	34 (17.9)	15 (10.1)	14.5
Hypertension	28 (14.7)	17 (11.4)	13.2
High blood cholesterol levels	25 (13.2)	15 (10.1)	11.8
Asthma	33 (17.4)	23 (15.4)	16.5
COPD	5 (2.6)	5 (3.4)	2.9
Backache	56 (29.5)	34 (22.8)	26.5
Other	47 (24.7)	29 (19.5)	22.4

COPD = chronic obstructive pulmonary disease.

*Standard deviations inflated using cluster inflation factors and intracluster correlation coefficients.

†As defined by Office of National Statistics (www.ons.gov.uk/about-statistics/classifications/current/ns-sec/index.html).

‡In response to question “Do you have any of the following health concerns?”

Table 6| Patients' perceived enablement and satisfaction with regard to behaviour change counselling after index consultation for control and intervention practices. Values are numbers (percentages) unless stated otherwise

Outcome measure*	Control cluster	Intervention cluster	Overall percentage	Odds ratio or difference in means (95% CI)
Mean self enablement score (full, 6 item)†	5.41 (n=896)	5.35 (n=725)	—	−0.04 (−0.29 to 0.20)
Dichotomised self enablement score (3 item)‡:				1.37 (0.95 to 1.98)
No enablement	353 (39.9)	247 (34.1)	37.3	
Some enablement	532 (60.1)	478 (65.9)	62.7	
Dichotomised satisfaction score§:				1.06 (0.73 to 1.55)
Less than very satisfied	274 (28.5)	208 (26.3)	27.5	
Very satisfied	688 (71.5)	582 (73.7)	72.5	

*Complete case analysis: we analysed only those who responded to enough items to form the score.

†Screened for any behaviour.

‡Because of skewed nature of this outcome measure, we created a dichotomous variable of those who displayed no enablement (score 0) and those who displayed some enablement (scores 1–6).

§Because of skewed nature of this outcome measure, we created a dichotomous variable of those who were very satisfied (score 4) and those who were less than very satisfied (scores 0–3).

Table 7| **Number of patients who reported that they were likely to change, had tried to change, or had made a lasting change to four risky behaviours at three months for control and intervention practices. Values are numbers (percentages) unless stated otherwise**

Outcome measure		Control cluster	Intervention cluster	Overall percentage	Odds ratio (95% CI)
Likely to change behaviour					
ITT population:					
Any behaviour	No	505 (50.7)	232 (27.9)	40.3	2.88 (2.05 to 4.05)
	Yes	491 (49.3)	599 (72.1)	59.7	
Alcohol intake	No	256 (67.0)	226 (63.1)	65.1	1.21 (0.79 to 1.85)
	Yes	126 (33.0)	132 (36.9)	34.9	
Cigarette smoking	No	134 (55.1)	79 (44.6)	50.7	1.53 (1.03 to 2.25)
	Yes	109 (44.9)	98 (55.4)	49.3	
Diet	No	446 (61.3)	263 (41.2)	51.9	2.30 (1.70 to 3.12)
	Yes	281 (38.7)	376 (58.8)	48.1	
Physical exercise	No	432 (60.4)	268 (43.6)	52.7	2.03 (1.52 to 2.72)
	Yes	283 (39.6)	346 (56.4)	47.3	
Complete case population*:					
Any behaviour	No	458 (48.3)	186 (23.7)	37.1	3.21 (2.30 to4.49)
	Yes	491 (51.7)	599 (76.3)	62.9	
Alcohol intake	No	241 (65.7)	201 (60.4)	63.1	1.28 (0.84 to 1.96)
	Yes	126 (34.3)	132 (39.6)	36.9	
Cigarette smoking	No	121 (52.6)	65 (39.9)	47.3	1.67 (1.12 to 2.51)
	Yes	109 (47.4)	98 (60.1)	52.7	
Diet	No	405 (59.0)	224 (37.3)	48.9	2.44 (1.80 to 3.30)
	Yes	281 (41.0)	376 (62.7)	51.1	
Physical exercise	No	388 (57.8)	230 (39.9)	49.6	2.11 (1.58 to 2.82)
	Yes	283 (42.2)	346 (60.1)	50.4	
Tried to change behaviour					
ITT population:					
Any behaviour	No	679 (68.2)	503 (60.5)	64.7	1.40 (1.15 to 1.70)
	Yes	317 (31.8)	328 (39.5)	35.3	
Alcohol intake	No	336 (88.0)	302 (84.4)	86.2	1.35 (0.89 to 2.06)
	Yes	46 (12.0)	56 (15.6)	13.8	
Cigarette smoking	No	186 (76.5)	127 (71.8)	74.5	1.28 (0.81 to 2.01)
	Yes	57 (23.5)	50 (28.2)	25.5	
Diet	No	529 (72.8)	421 (65.9)	69.5	1.38 (1.08 to 1.76)
	Yes	198 (27.2)	218 (34.1)	30.5	
Physical exercise	No	545 (76.2)	427 (69.5)	73.1	1.40 (1.08 to 1.80)
	Yes	170 (23.8)	187 (30.5)	26.9	
Complete case population*:					
Any behaviour	No	375 (54.2)	254 (43.6)	49.4	1.52 (1.19 to 1.95)
	Yes	317 (45.8)	328 (56.4)	50.6	
Alcohol intake	No	220 (82.7)	174 (75.7)	79.4	1.54 (0.95 to 2.51)
	Yes	46 (17.3)	56 (24.3)	20.6	
Cigarette smoking	No	85 (59.9)	65 (56.5)	58.4	1.11 (0.66 to 1.87)
	Yes	57 (40.1)	50 (43.5)	25.5	
Diet	No	321 (61.8)	222 (50.5)	56.6	1.59 (1.16 to 2.18)
	Yes	198 (38.2)	218 (49.5)	43.4	
Physical exercise	No	328 (65.9)	240 (56.2)	61.4	1.50 (1.12 to 2.00)
	Yes	170 (34.1)	187 (43.8)	38.6	
Lasting change made to behaviour					
ITT population:					

Table 7 (continued)

Outcome measure		Control cluster	Intervention cluster	Overall percentage	Odds ratio (95% CI)
Any behaviour	No	716 (71.9)	543 (65.3)	68.9	1.36 (1.11 to 1.65)
	Yes	280 (28.1)	288 (34.7)	31.1	
Alcohol intake	No	334 (87.4)	306 (85.5)	86.5	1.18 (0.78 to 1.80)
	Yes	48 (12.6)	52 (14.5)	13.5	
Cigarette smoking	No	202 (83.1)	144 (81.4)	82.4	1.13 (0.68 to 1.87)
	Yes	41 (16.9)	33 (18.6)	17.6	
Diet	No	553 (76.1)	452 (70.7)	73.6	1.32 (0.99 to 1.76)
	Yes	174 (23.9)	187 (29.3)	26.4	
Physical exercise	No	576 (80.6)	465 (75.7)	78.3	1.33 (1.02 to 1.72)
	Yes	139 (19.4)	149 (24.3)	21.7	
Complete case population*:					
Any behaviour	No	464 (62.4)	341 (54.2)	58.6	1.40 (1.13 to 1.74)
	Yes	280 (37.6)	288 (45.8)	41.4	
Alcohol intake	No	220 (82.1)	192 (78.7)	80.5	1.24 (0.80 to 1.92)
	Yes	48 (17.9)	52 (21.3)	19.5	
Cigarette smoking	No	110 (72.8)	85 (72.0)	72.5	1.04 (0.61 to 1.79)
	Yes	41 (27.2)	33 (28.0)	27.5	
Diet	No	369 (68.0)	292 (61.0)	64.7	1.37 (1.01 to 1.87)
	Yes	174 (32.0)	187(39.0)	35.3	
Physical exercise	No	393 (73.9)	307 (67.3)	70.9	1.37 (1.04 to 1.80)
	Yes	139 (26.1)	149 (32.7)	29.1	

ITT=intention to treat.

*"Complete case population" considered only those who responded (rather than assuming non-response = No as for the ITT population).

Table 8| **Three and 12 month questionnaire outcomes: changes in four risky behaviours, composite change in any behaviour, and measures of quality of life and general health by control and intervention practices. Values are numbers (percentages) unless stated otherwise**

	Outcomes at 3 months				Outcomes at 12 months			
Outcome measure	Control cluster	Intervention cluster	Overall percentage	Odds ratio or difference in means (95% CI)	Control cluster	Intervention cluster	Overall percentage	Odds ratio or difference in means (95% CI)
Composite change in any behaviour*								
All participants in ITT population:								
Failure	592 (59.4)	469 (56.4)	58.1	1.12 (0.90 to 1.39)	600 (60.2)	495 (59.4)	59.9	1.03 (0.83 to 1.28)
Success	404 (40.6)	362 (43.6)	41.9		396 (39.8)	337 (40.6)	40.1	
Those who recalled counselling about behaviour change:								
Failure	592 (59.4)	256 (54.0)	57.7	1.25 (1.00 to 1.56)	600 (60.2)	281 (59.3)	59.9	1.04 (0.82 to 1.31)
Success	404 (40.6)	218 (46.0)	42.3		396 (39.8)	193 (40.7)	40.1	
Complete case population†:								
Failure	213 (34.5)	158 (30.5)	32.6	1.21 (0.94 to 1.55)	201 (33.7)	139 (29.2)	31.7	1.23 (0.95 to 1.60)
Success	404 (65.5)	362 (69.6)	67.4		396 (66.3)	337 (70.8)	68.3	
Change in alcohol intake‡								
Mean decrease in AUDIT-C:								
Percentage decrease	4.10 (n=277)	5.33 (n=243)		1.24 (−3.49 to 6.00)	9.98 (n=269)	6.86 (n=227)		−2.12 (−7.59 to 3.35)
Absolute decrease	0.35 (n=277)	0.34 (n=243)		−0.01 (−0.29 to 0.27)	0.56 (n=267)	0.48 (n=227)		−0.08 (−0.41 to 0.25)
Mean AUDIT score	7.43 (n=271)	7.74 (n=229)		0.31§ 0.04 (−0.07 to 0.15)¶	6.79 (n=255)	7.25 (n=217)		0.46§ 0.11 (−0.04 to 0.26)**
Change in diet								
Mean decrease in subset of DINE††:								
Percentage decrease	9.02 (n=513)	10.51 (n=453)		1.26 (−4.43 to 7.00)	9.39 (n=490)	9.78 (n=424)		0.19 (−5.28 to 5.66)
Absolute decrease	1.69 (n=513)	1.57 (n=453)		−0.16 (−0.81 to 0.50)	1.69 (n=490)	1.57 (n=424)		−0.16 (−0.78 to 0.46)
Mean DINE healthy eating score††:	3.69 (n=265)	6.87 (n=235)		3.18 (0.49 to 5.87)	1.46 (n=268)	4.93 (n=225)		3.47 (1.00 to 5.93)
DINE fat score	29.39 (n=265)	27.46 (n=235)		−1.93§ −0.07 (−0.14 to 0.00)¶	29.46 (n=268)	28.63 (n=225)		−0.83§ −0.03 (−0.10 to 0.05)¶
DINE fibre score	33.08 (n=265)	34.34 (n=235)		1.28 (−0.89 to 3.44)	30.93 (n=268)	33.56 (n=225)		2.71 (0.56 to 4.87)
Mean DINE healthy eating score*	6.24 (n=353)	8.61 (n=310)		2.36 (0.13 to 4.59)	4.22 (n=357)	6.94 (n=294)		2.71 (0.46 to 5.00)
Fruit and vegetable consumption††	5.17 (n=565)	5.22 (n=489)		0.01 (−0.40 to 0.42)	5.09 (n=550)	5.14 (n=461)		0.05§ 0.01 (−0.02 to 0.04)‡‡
Change in cigarette smoking§§								
Mean decrease in No of cigarettes/day:								
Percentage decrease	−1.64 (n=149)	0.18 (n=120)		1.82 (−9.93 to 13.56)	4.11 (n=151)	10.26 (n=114)		4.14 (−15.78 to 24.06)
Absolute decrease	0.12 (n=149)	1.35 (n=120)		1.23 (−0.17 to 2.62)	1.42 (n=151)	2.74 (n=114)		1.37 (−0.74 to 3.47)

Table 8 (continued)

Outcome measure	Outcomes at 3 months				Outcomes at 12 months			
	Control cluster	Intervention cluster	Overall percentage	Odds ratio or difference in means (95% CI)	Control cluster	Intervention cluster	Overall percentage	Odds ratio or difference in means (95% CI)
Mean Heaviness of Smoking Index	2.30 (n=152)	2.07 (n=119)		−0.17 (−0.73 to 0.40)	2.16 (n=153)	1.94 (n=115)		−0.10 (−0.67 to 0.47)
Change in physical exercise								
Mean absolute increase in IPAQ¶¶	245.26 (n=349)	456.74 (n=309)		201.23 (−239.94 to 642.41)	234.08 (n=332)	775.84 (n=286)		541.77 (45.39 to 1038.15)
Mean No of minutes spent sitting/day¶¶	348.74 (n=409)	349.08 (n=364)		0.32§ 0.08 (−0.67 to 0.82)**	396.40 (n=417)	374.96 (n=245)		−21.45§ 0.00 (−0.11 to 0.12)¶
Mean No of minutes spent sitting/day*	334.00 (n=570)	336.00 (n=503)		2.00§ 0.13 (−0.62 to 0.88)**	377.32 (n=575)	355.24 (n=474)		−22.08§ 0.03 (−0.07 to 0.13)¶
Self reported quality of life and general health								
Mean general health score*	1.85 (n=791)	1.94 (n=660)		0.06 (−0.09 to 0.21)	1.78 (n=766)	1.93 (n=616)		0.14 (−0.01 to 0.29)
Mean quality of life score*	59.08 (n=761)	60.71 (n=645)		1.63§ 0.01 (0.00 to 0.02)‡‡	59.21 (n=736)	62.02 (n=601)		2.52 (−0.80 to 5.83)
Mean Perceived Health Competence Scale	—	—			3.41 (n=728)	3.48 (n=592)		0.05 (−0.09 to 0.20)

ITT = intention to treat. AUDIT-C = Alcohol Use Disorders Identification Test consumption subscale. DINE = Dietary Instrument for Nutrition Evaluation. IPAQ = International Physical Activity Questionnaire.

*Participants screened for any behaviour.

†"Complete case population" considered only those who responded (rather than assuming non-response = No as for the ITT population).

‡Participants screened for alcohol intake.

§Actual difference.

¶Difference in means (95% CI) from model using transformation ln(x+1) as the response.

**Difference in means (95% CI) from model using transformation x^(1/2) as the response.

††Participants screened for diet.

‡‡ Difference in means (95% CI) from model using transformation x^(1/27) as the response.

§§Participants screened for smoking.

¶¶Participants screened for exercise.

Table 9| 12 month clinical assessment outcomes: biometric measures, blood pressure, and cholesterol levels by control and intervention practices. Values are numbers (percentages) unless stated otherwise

Outcome measure	Control cluster	Intervention cluster	Overall percentage	Odds ratio or difference in means (95% CI)
Quit smoking*†:				
No	93 (93.0)	67 (91.8)	92.5	1.14 (0.30 to 4.28)
Yes	7 (7.0)	6 (8.2)	7.5	
Systolic blood pressure (mm Hg):				
≤120	204 (37.7)	131 (31.1)	34.8	1.32 (0.78 to 2.22)
>120	337 (62.3)	290 (68.9)	65.2	
Diastolic blood pressure (mm Hg):				
≤80	384 (71.1)	316 (75.1)	72.8	0.70 (0.37 to 1.33)
>80	156 (28.9)	105 (24.9)	27.2	
Mean systolic blood pressure (mm Hg)	128.65 (n=541)	130.57 (n=421)	—	1.61 (−2.48 to 5.70)
Mean diastolic blood pressure (mm Hg)	76.78 (n=540)	76.00 (n=421)	—	−0.99 (−3.76 to 1.79)
Mean hip to waist ratio	0.89 (n=537)	0.91 (n=397)	—	0.01 (−0.01 to 0.03)
Mean body mass index (kg/m^2)	29.33 (n=526)	29.57 (n=416)	—	0.24* 0.01 (−0.02 to 0.04)‡
Mean serum cholesterol concentration (mg/dL):				
High density lipoprotein	1.24 (n=503)	1.30 (n=398)	—	0.06* 0.02 (−0.01 to 0.06)‡
Low density lipoprotein	3.49 (n=464)	3.31 (n=382)	—	−0.17 (−0.40 to 0.07)
Total	4.79 (n=509)	4.71 (n=405)	—	−0.08* −0.01 (−0.04 to 0.03)‡

*Participants screened for smoking behaviour.

†Smoking status confirmed via cotinine test. Results analysed by order MQL extra binomial model.

‡Difference in means (95% CI) from model using transformation ln(x+1) as the response.

Table 10 Results of sensitivity analyses for evaluations of behaviour change counselling effects on patients reporting change in risky behaviours for control and intervention practices. Values are numbers (percentages) unless stated otherwise. (These are example results: numerous simulations were run with the same outcomes in terms of significance each time)

	Control cluster	Intervention cluster	Overall percentage	Odds ratio or difference in means (95% CI)
Likelihood to change behaviour*				
Likely to change:				
No	520 (50.7)	297 (31.5)	41.5	2.28 (1.66 to 3.12)
Yes	505 (49.3)	646 (68.5)	58.5	
Tried to change:				
No	697 (68.0)	582 (61.7)	65.0	1.32 (1.09 to 1.59)
Yes	328 (32.0)	361 (38.3)	35.0	
Lasting change made:				
No	745 (72.7)	655 (69.5)	71.1	1.17 (0.96 to 1.42)
Yes	280 (27.3)	288 (30.5)	28.9	
Measures of behaviour change				
Mean absolute increase in IPAQ score†¶	270.50 (n=355)	622.07 (n=379)	—	355.20 (−98.45 to 808.85)
Mean DINE healthy eating score‡:				
Assessed at 3 months	3.86 (n=288)	5.70 (n=312)	—	1.87 (−0.79 to 4.53)
Assessed at 12 months:	1.93 (n=291)	4.11 (n=302)	—	2.18 (−0.05 to 4.41)
DINE fibre score§	30.89 (n=291)	32.94 (n=302)	—	2.05 (0.25 to 3.84)
Mean DINE healthy eating score*:				
Assessed at 3 months	6.16 (n=382)	8.01 (n=422)	—	1.84 (−0.34 to 4.02)
Assessed at 12 months	4.20 (n=386)	5.85 (n=406)	—	1.65 (−0.39 to 3.69)

*Participants screened for any behaviour.
†Participants screened for exercise behaviour.
‡Participants screened for diet behaviour.
§Only for participants with a DINE healthy eating score

Table 11| Cost of delivering training in behaviour change counselling to 15 practices (29 health professionals) and cost per practice of receiving training

	Time (minutes)	Cost (£)
Providing training	**Total time**	**Total cost**
Administrators	1800	375.60
Actors for simulated consultations*	N/A	4600.00
Trainers (training, travel time, other costs)	6895	4160.53
Total:	—	9136.13
Cost per practice (apportioned)	—	609.08
Receiving training	**Mean (SD) time/practice**	**Mean (SD) cost/practice**
Seminar:	209 (43)	235.00 (35.92)
GP	109 (14)	186.85 (24.32)
Practice nurse†	100 (33)	48.15 (15.92)
Simulated consultations:	42 (10)	49.83 (14.49)
GP	24 (9)	41.41 (14.64)
Practice nurse	18 (6)	8.42 (3.07)
e-learning:	648 (259)	703.86 (286.49)
GP	316 (150)	543.92 (258.63)
Nurse	332 (190)	159.94 (91.07)
Total cost/practice:	899 (287)	988.32 (309.83)
GP	449 (160)	772.54 (274.83)
Practice nurse	450 (211)	215.78 (101.40)
Total cost/practice including apportioned cost of delivering training	—	1597.40

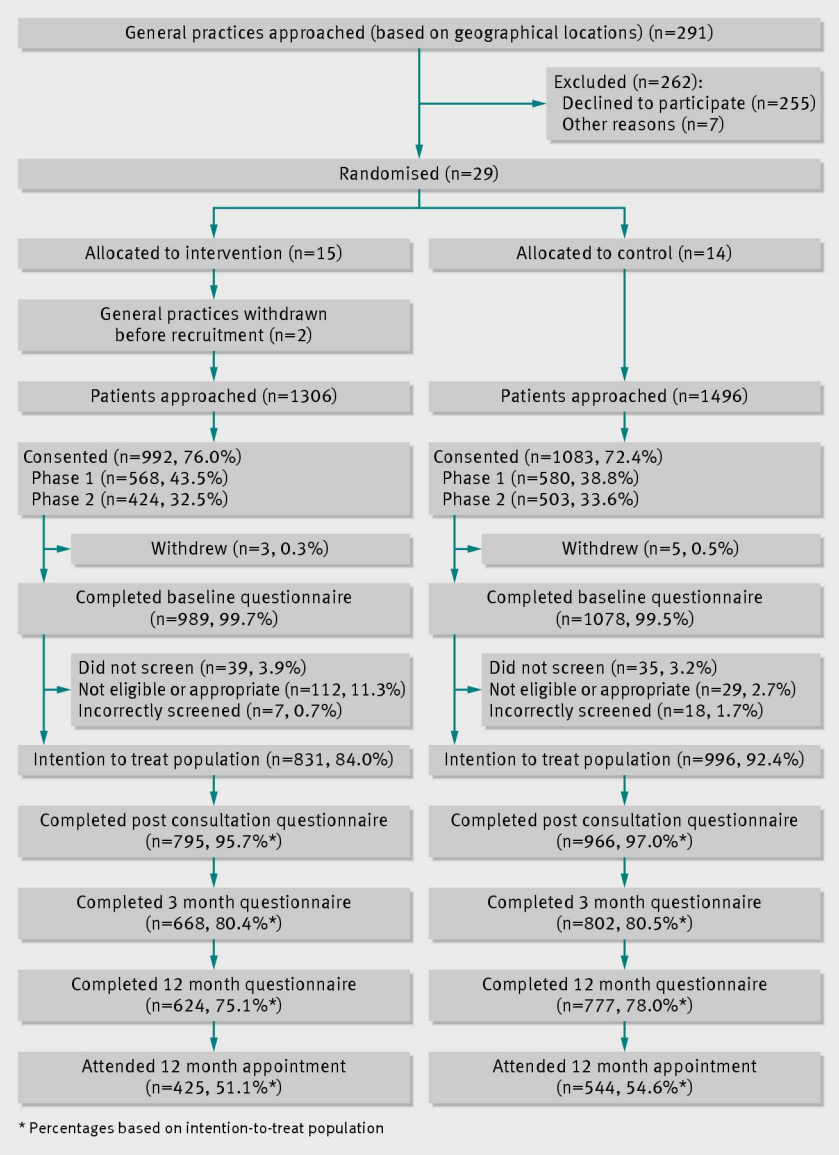
GP training time cost= £103/hour. Practice nurse training time cost= £29/hour.[81]

Administrator and trainer time = salaries + on-costs at 22%.

*Actors paid fixed fee per simulated consultation.

†Only GP trained at 1 practice.

Figure



Flow diagram of general practices and patients participation in study