Achieving involvement: process outcomes from a cluster randomized trial of shared decision making skill development and use of risk communication aids in general practice

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**Background.** A consulting method known as ‘shared decision making’ (SDM) has been described and operationalized in terms of several ‘competences’. One of these competences concerns the discussion of the risks and benefits of treatment or care options—‘risk communication’. Few data exist on clinicians’ ability to acquire skills and implement the competences of SDM or risk communication in consultations with patients.

**Objective.** The aims of this study were to evaluate the effects of skill development workshops for SDM and the use of risk communication aids on the process of consultations.

**Methods.** A cluster randomized trial with crossover was carried out with the participation of 20 recently qualified GPs in urban and rural general practices in Gwent, South Wales. A total of 747 patients with known atrial fibrillation, prostatism, menorrhagia or menopausal symptoms were invited to a consultation to review their condition or treatments. Half the consultations were randomly selected for audio-taping, of which 352 patients attended and were audio-taped successfully. After baseline, participating doctors were randomized to receive training in (i) SDM skills or (ii) the use of simple risk communication aids, using simulated patients. The alternative training was then provided for the final study phase. Patients were allocated randomly to a consultation during baseline or intervention 1 (SDM or risk communication aids) or intervention 2 phases. A randomly selected half of the consultations were audio-taped from each phase. Raters (independent, trained and blinded to study phase) assessed the audio-tapes using a validated scale to assess levels of patient involvement (OPTION: observing patient involvement), and to analyse the nature of risk information discussed. Clinicians completed questionnaires after each consultation, assessing perceived clinician–patient agreement and level of patient involvement in decisions. Multilevel modelling was carried out with the OPTION score as the dependent variable, and rater, consultation and clinician levels of data, standardized by rater within clinician.

**Results.** Following each of the interventions, the clinicians significantly increased their involvement of patients in decision making (OPTION score increased by 10.6 following risk communication training [95% confidence interval (CI) 7.9–13.3; \(P < 0.001\)] and by 12.9 after SDM skill development [95% CI 10–15.8, \(P < 0.001\)], a moderate effect size. The level of involvement achieved by the risk communication aids was significantly increased by the...
subsequent introduction of the skill development workshops (7.7 increase in OPTION score, 95% CI 3.4–12; \(P < 0.001\)). The alternative sequence (skills followed by risk communication aids) did not achieve this effect. The use of most risk information formats increased after the provision of specific risk communication aids \((P < 0.001)\). Clinicians using the risk communication tools perceived significantly higher patient and clinician agreement on treatment \((P < 0.001)\), patient satisfaction with information \((P < 0.01)\), clinician satisfaction with decision \((P < 0.01)\) and general overall satisfaction with the consultation \((P < 0.001)\) than those who were exposed to SDM skill development workshops.

**Conclusions.** These clinicians were able to acquire the skills to implement SDM competences and to use risk communication aids. Each intervention provided independent effects. Further progress towards greater patient involvement in health care decision making is possible, and skill development in this area should be incorporated into postgraduate professional development programmes.

**Keywords.** Primary care, randomized trial, risk communication, shared decision making.

**Introduction**

Shared decision making (SDM), a shorthand term used for the process of involving patients in clinical decisions, has been the subject of debate in the recent literature on interpersonal communication in health care.\(^1\)\(^2\) Although the principles of the method are described,\(^3\) the competences outlined\(^4\)\(^5\) and a measure proposed,\(^6\) there is uncertainty about the proposal\(^7\)\(^8\) and some doubt that the concept can be applied in clinical settings.\(^9\)\(^10\) Although there are feasibility studies reported,\(^11\) there is little agreement, or evidence, about how to implement SDM. In essence, the ethos of shared decision making is one where professionals should work to define problems with sufficient clarity and openness so that patients can comprehend the options and uncertainties that surround most decisions in health care and therefore appreciate that choices have to be made between competing options. A part of this process includes the discussion of the harms and benefits relating to these options\(^9\)—a stage of ‘risk communication’. SDM is only one stage of the consultation, which must be viewed holistically, but it is a stage that has, until recently, received relatively little attention, particularly in professional skill development.\(^12\)\(^13\)\(^14\) Such consideration should also not be divorced from evidence about what patients value most from consultations, including doctors’ ability to listen, empathize and support, be interested in the effect of problems on patients’ lives and to maintain a positive approach.\(^15\)\(^16\)

In particular, few studies have investigated SDM and risk communication to great depth in actual clinical settings.\(^12\)\(^13\)\(^14\) Hulsman and Bensing’s review noted the inadequacy of research designs reported to date.\(^17\) Some evidence is emerging about the benefits of SDM in practice,\(^14\) but most reviews have been more general in their scope, addressing the effects of ‘patient-centred approaches’.\(^18\)\(^19\)\(^20\) The potential problems of taking a ‘shared approach’ to decision making have also been highlighted.\(^9\)\(^21\) As yet, for SDM, the unanswered questions are 2-fold: first, it is not clear whether clinicians working in everyday settings can improve their skills to involve patients in decisions. Secondly, we need to know whether the model for developing SDM should be based on information provision or interpersonal communication skill development.

This study sought to operationalize SDM and risk communication aids as specific and comparable interventions to clinicians. These were not viewed as mutually exclusive interventions. The aim was to investigate whether each intervention, first separately and then combined with the other, would increase clinicians’ ability to involve patients in decision-making processes. If this was found to be the case, the secondary aim was to evaluate whether acquiring skills in SDM should happen before or after exposure to the risk communication aids.

**Methods**

**Setting and subjects**

The study took place in Gwent, South Wales, which includes urban, suburban and rural areas that cross a range of socio-economic levels,\(^22\) and had ethical approval from the Gwent Health Authority Local Research Ethical Committee. GPs were approached for consent to participate in the study. Eligibility for the trial was restricted to those who had been principals in general practice for between 1 and 10 years at the start. Participants also had to be tape-recorded for a surgery session (~10 patients). Both this and the former criterion (through exposure to recent training methods) were adopted to achieve a group of participants who were likely to be familiar with the data collection methods intended. Only one practitioner per practice would be recruited. Three practitioners were excluded from the potential sample pool of 104 practitioners because of
prior exposure to the training content during developmental work conducted earlier in other areas. In all, 101 practitioners from 49 practices were approached, initially by letter (followed by telephone contact), and asked to participate.

Patients were approached by the practices for consent to participate in the study if they were known to have one of the following conditions: non-valvular atrial fibrillation; prostatism; menorrhagia; or menopausal symptoms. These conditions were selected because they are characterized by having more than one treatment option available, and about which the professionals as a group are likely to have no clear preference—‘equipoise’. This is not the only context for SDM in practice, but it is a context in which the opportunity for SDM is greater than if equipoise is not present.4 Although patients with these problems can be found in all practices, the incidence of patients presenting with these problems de novo is low. The trial therefore proactively identified previous attenders, avoiding the problems associated with clinician-based patient recruitment. These patients were identified from Read Codes on electronic practice databases by staff from the practices using a standard protocol, assisted by a research officer (CA). If Read Code searches were insufficient, then specific treatments were identified (such as digoxin for atrial fibrillation). For this stage, patient records were then checked to ensure eligibility. Inclusion and exclusion criteria are listed in Table 1. Patient recruitment and allocation are described in more detail in the accompanying paper.24

The interventions
Separate interventions to enhance clinician skills in either SDM or the use of risk communication aids were devised (see Box 1 and related figures) and piloted;11,25 they were provided to the clinicians before each active trial phase (see below).

Design
A cluster randomized design with crossover was chosen (Fig. 1). The ‘cluster’ was each participating clinician and the patients who consulted them. This method offered the greatest potential to gain understanding about the effects of the training interventions alone and in combination, and whether the sequence of skill acquisition was important. The latter evidence would be important in applying the results of this trial to continuing professional development initiatives.

All patients consulted the participating clinician only once for the study. This ‘review type’ consultation was allocated randomly to one of the three trial phases (baseline, risk communication or SDM only, or combined interventions). In each of these phases, the consultations were allocated randomly to occur alongside routine surgery consultations or in a ‘research clinic’. This clinic was also held at the participating clinician’s own health centre but was protected so that other interruptions and time constraints could be minimized and the required assessments (audio-taping and patient interviews) could be achieved. If required, locum payments were provided. Although the clinicians were advised to conduct consultations in their usual way, the encounters in the research clinics had the potential to take ~50% more time than usual. By evaluating the effect of the interventions, and the added element of protected time, the trial sought to be explanatory in nature.26 Patients unable to attend an allocated appointment were offered an alternative appointment (or excluded from the study and replaced by other patients if alternatives were inconvenient or if they did not attend).

All randomizations were undertaken by random number generation, and allocations by the trial statistician (KH) were concealed from those implementing the interventions or assessments. Both clinicians and patients were informed that the trial was investigating

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
<th>Exclusion criteria</th>
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<tbody>
<tr>
<td><strong>General</strong></td>
<td></td>
</tr>
<tr>
<td>Consultation within previous 3 years</td>
<td>&gt;75 years of age</td>
</tr>
<tr>
<td>Identification by computer codes or repeat medications</td>
<td></td>
</tr>
<tr>
<td><strong>Specific</strong></td>
<td></td>
</tr>
<tr>
<td>Non-valvular atrial fibrillation</td>
<td>Valvular heart disease</td>
</tr>
<tr>
<td>Lower urinary tract obstruction: diagnosis of ‘prostatism’ (range of synonyms)</td>
<td>History of prostate cancer</td>
</tr>
<tr>
<td>Diagnosis of ‘menorrhagia’ (range of synonyms)</td>
<td>Previous prostate surgery</td>
</tr>
<tr>
<td></td>
<td>Raised prostatic-specific antigen level</td>
</tr>
<tr>
<td></td>
<td>Hysterectomy</td>
</tr>
<tr>
<td></td>
<td>Diagnosis of ‘menopause’-related problems (range of synonyms)</td>
</tr>
<tr>
<td></td>
<td>Ages 45–55 current or previous users of HRT</td>
</tr>
</tbody>
</table>
Box 1 Trial interventions

The theoretical basis underlying both these skill developments
was the extended model of interpersonal interaction outlined by
Hargie, which proposes that as skill 'perceptions' are translated
into motor responses (speech and actions), a sequence of
feedback loops ensures that performance is modified. Repeated
cycles lead to fluent skill acquisition. This is a widely accepted
basis for communication skill development in clinical contexts.
The simulated patients involved in each intervention
were non-medical people with considerable experience as
simulators from undergraduate medical education.

Shared decision making

Practitioners randomized to this intervention attended two
workshops where a standardized and previously piloted skill
development process was undertaken using presentations,
discussions and participation in consultations with simulated
patients (facilitated by GE). The background literature on
discussions and participation in consultations with simulated
patients (facilitated by GE). The background literature on
the development process was undertaken using presentations,
workshops, where a standardized and previously piloted skill
simulators from undergraduate medical education.

Risk communication aids

Similar workshops addressing risk communication were
facilitated by AE. The risk communication aids consisted of
tabulated data and visual displays of risk estimates (histograms
and bar charts) for the four study conditions. The risk data were
based on systematic reviews and (other publications, see
below) and presented as the best evidence available at the time
of the trial. Risk communication was defined in order to
distinguish it from other terms in common use, such as risk
management and risk analysis. Recent research in this area
was summarized, including evidence of effectiveness
of interventions and the expressed needs of clinicians and
patients. The participants were provided with treatment
outcome information for the study conditions in the following
range of formats: summary statements, bar charts, numerical
statistical information and source publications. Examples are
shown in the figures. Participants were asked about the derivation
of the risk aids, advised on how they might be incorporated in
consultation discussions and then asked to use them in simulated
patient consultations. Participants were directed first to conduct
a simulated consultation using only numerical data, followed by
a consultation in which they would use only graphical data
displays. They then conducted further consultations in which
they chose the most appropriate format to use with the individual
patients—the recommended strategy to apply in the trial setting
itself. The consultations were conducted in pairs, where
colleagues alternated between clinician and observer roles. This
was repeated until each participant had received feedback after
conducting two or three consultations using the risk
communication aids across a range of conditions. A plenary
group discussion, which included the patient simulators, allowed
the group to share learning points and consider the application of
the materials in clinical practice.

Outcome measurement

This paper reports the evaluation of process in the
consultations, and the results of questionnaires completed by clinicians after each study consultation. Patient outcomes are reported elsewhere. The principal process measure was the OPTION (observing patient involvement) scale. Audio-tapes were recorded on the randomly selected half of study consultations that were scheduled for the 'research clinics'. Two post-doctoral social science researchers were trained to score audio-tapes independently using the OPTION scale and manual. This scale requires raters to listen to audio-tapes of consultations, and make judgements regarding the demonstration of 12 behaviours that cover the competences of SDM. All consultation recordings were intended to be rated by two raters and ratings were undertaken blind to study group allocation of clinicians or patients. Inter-rater differences for OPTION scores for consultations (clusters in clinicians) were assessed. An example of the first items in the OPTION scale is shown in Box S1 available at Family Practice Online.

In addition, observations were made about the nature of risk information used in these research clinic consultations. The raters recorded whether or not the discourse included (at any time in the consultation) general risk statements, descriptives (such as 'likely', 'rare'), comparisons with everyday risks, numerical information, absolute risk information, relative risk information, numbers-needed-to-treat formats or visual depiction of risks. These different methods of communicating risk were all covered in the intervention workshops, with emphasis on clinicians using what they felt was most appropriate with individual patients.

The participating clinicians also completed questionnaires after every study consultation ('research clinic and routine surgery study consultations'). These addressed clinician perceptions of the level of clinician–patient agreement, the patient's satisfaction with information provided and the clinician's satisfaction with the decision and overall consultation.

Sample size

Sample size calculations were based on patient outcomes and on providing 80% power (5% significance levels) to detect a change of 20 percentage points in either direction from a baseline of 50% for binary variables, and full details are given in the accompanying paper. The sample size requirements were for 240 in each phase, 960 for the whole trial. Each doctor would consult with 48 patients (see Fig. 1). However, only half the consultations were to be audio-taped (six patients per clinician at baseline, 12 at the risk communication or SDM phase, and six at the final phase). Complete patient
attendance would therefore have resulted in 480 consultations being available for tape-recording and OPTION ratings. This gave 80% power to detect (at 5% significance levels) a change of 6.6 points on the OPTION scale (from earlier work, this amounts to a ‘moderate’ effect size\(^6,27\)).

Data processing and analysis

Data from the questionnaires were entered into SPSS files (error rate of items <0.5% in a 10% random sample). Further data cleaning included correction of out-of-range values. Scores were calculated from the mean of other valid items for up to two missing item ratings out of the 12.

The primary outcome (OPTION) was assessed with multilevel modelling with MLwiN software.\(^{28,29}\) Explanatory variables were entered as fixed effects in a regression model with the OPTION score as the dependent variable. The improvement of fit from allowing the effect to be random was also assessed. A three-level model was fitted with rater at level 1, consultation at level 2 and clinician at level 3 to the data standardized by rater within clinician (i.e. adjusting for consistent scoring differences between raters). The model assessed the extent to which variability in OPTION could be explained by practitioner variables (age, gender and membership of the Royal College of General Practitioners), patient variables (age, condition). The sequence effect was entered as the last explanatory variable. Improvements in the model were assessed using reductions in the log likelihood. The mean OPTION scores [and 95% confidence intervals (CIs)] for each GP during the phases of the trial were calculated.

Secondary outcomes were assessed at the cluster level using \(t\)-tests weighted for cluster size. These outcomes included the types of risk information used in consultations, and clinician perceptions of doctor–patient agreement, patient’s satisfaction with information and clinician satisfaction ratings.

Results

Recruitment and participant flow

Twenty-one out of 49 practices (42.8%) had a doctor who agreed to participate, had a surgery session audio-taped, and had sufficient practice computerization to enable identification of a patient sample. One doctor dropped out after the baseline phase. The remaining practitioners, 12 men and eight women, had an average age of 38 years. These characteristics did not differ from the eligible sample frame (101 practitioners with average age of 41 years, 62% male). Eighty percent of the participating doctors had Membership of the Royal College of General Practitioners, compared with 54% in the overall sample approached.
A total of 2585 patients were approached and 1135 (43.9%) consented to take part in the trial. The full flow chart for patients in the study and analysis of bias from non-consent or participation are given in the accompanying paper. Patients were selected randomly from those consenting to be invited to attend study appointments with their doctor. The mean age of patients recruited was as follows: those with prostatic symptoms 63 years, atrial fibrillation 65 years, menorrhagia 45 years, and hormone replacement therapy 56 years. Audio-tape recording was scheduled for 480 of the study consultations. Some patients could not attend and were replaced by other patients. In all, 566 patients were invited; 391 attended. Audio-taping was successful for 352 consultations (92%; see Fig. 2 and Table S1).

There was no difference in the mean consultation lengths at baseline, phase 1 and phase 2 (overall consultation mean duration was 12.5 min).

OPTION (patient involvement in decision making) scores
A total of 698 completed OPTION ratings entered the multilevel analysis. Six hundred and forty-three ratings had corresponding complete data on patient age and condition, but these showed no association with OPTION score, so the full sample was used. No clinician or ‘condition’ variables resulted in a significant improvement in the model presented by a random effect. The intra-cluster correlation coefficient (ICC) was 0.18 in the baseline phase. The final model is given in Table 2.
TABLE 2  Effects of risk communication (RC) or shared decision making (SDM) training or both on OPTION scores

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Coefficient</th>
<th>95% CI</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>RC training</td>
<td>10.6</td>
<td>(7.9 to 13.3)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>SDM training</td>
<td>12.9</td>
<td>(10.0 to 15.8)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Both</td>
<td>−10.6b</td>
<td>(−15.1 to −6.1)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Order of training</td>
<td>7.7c</td>
<td>(3.4 to 12.0)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

*a* Regression coefficients from three-level model.

*b* Indicates that OPTION scores in the combined intervention group were 10.6 less than the sum of the individual effects.

*c* Indicates that doctors receiving RC before SDM had OPTION scores 7.7 higher than the reverse order.

Chi-square statistic = 152.2; df = 4; P < 0.001; final −2 log likelihood = 5200.8.

![Figure 3](image-url)  
**Figure 3** Mean OPTION scores (standardized) across trial phases for the participating doctors, numbered 1–20

Mean scores for each participant are shown in Figure 3 and Table S2. Consistent inter-rater differences for OPTION scores were identified. Analyses therefore used standardized scores within clinicians, and the results remained significant after this adjustment.

Table 2 shows that there were significant increases in patient involvement as a result of both the risk communication (OPTION score increased by 10.6, 95% CI 7.9–13.3; P < 0.001) and SDM skill development workshops (12.9 increase, 95% CI 10–15.8, P < 0.001). A significant addition in patient involvement as a result of receiving both interventions was only seen in those who received risk communication intervention first then SDM skill development second (`RC then SDM': 7.7 increase, 95% CI 3.4–12; P < 0.001).

**Use of risk information in consultations**

The use of risk information across the phases of the study is shown in Table 3. The content of risk information discussed in consultations changed dramatically in association with the risk communication intervention, including the provision of the packs with information in different formats. The changes were noted across all categories (formats) of risk information, but were most evident in the use of visual formats (charts).

Taking the group randomized to receive risk communication first, most categories of risk information increased between baseline and phase 1, with generally little further change into phase 2 (P < 0.001). The exceptions (`comparisons drawn' and using individualized risk estimates) did not increase, offering validation of the rating exercise, as these were not made available to doctors as part of the training.

In the doctors receiving SDM training first, few changes were seen between baseline and phase 1. After receiving the risk communication intervention, large changes in the use of risk information were seen, mirroring those in the other group after their risk communication intervention. Again, the `comparisons drawn' category showed no change, and the individualized risk estimates remained at low levels.

In summary, clinicians increased the proportion of consultations in which they used several categories of risk information after the risk communication training intervention. This was not shown when the groups received SDM training. Statistically significant changes were shown for all of the numerical information items, and were largest for the visual formats of risk information.

**Clinicians’ views on the consultations**

Clinicians showed significant differences between the RC and SDM arms (see Table S3). Doctors receiving the risk communication tools and training first perceived significantly higher doctor–patient agreement on treatment (P < 0.001), patient satisfaction with information (P < 0.01), doctor satisfaction with decision (P < 0.01) and general overall satisfaction (P < 0.001) with the consultation than those who were exposed to SDM training. The latter group of doctors showed lower scores after the interventions. The differences were largely maintained in the second intervention phase, i.e. even when provided with the risk communication training and tools, the group of doctors who had received SDM training first still reported lower levels of satisfaction, agreement, etc. In contrast, doctors who had received risk communication training first maintained their higher levels of satisfactions and agreement, even when later given the SDM training which appeared less beneficial (to doctors) in the first phase.

**Discussion**

**Principal findings**

The clinicians in this study demonstrated greater involvement of patients in treatment decision making after skill development workshops. They also integrated the risk communication aids by using the graphical illustrations in scheduled review consultations with real
patients after the training intervention. Both interventions independently increased patient involvement levels. It appears that the most effective way to increase clinicians’ abilities to involve patients is to familiarize them with detailed information before discussing skill development techniques. Patient involvement in decisions did not vary significantly between the four clinical conditions or for patient age differences. The clinicians also perceived higher levels of patient involvement, improved clinician–patient agreement and increased patient satisfaction with the consultations. These findings should be taken in conjunction with those of the accompanying paper on patient-based outcomes.24

Strengths and weaknesses of the study
The strength of this study is that it operationalized SDM by using a rigorously developed competences framework4,5 and that it used a specific and validated scale (OPTION) as its principal outcome measure.6 This study focuses on practitioners in settings that were as near as possible to normal service conditions given the data collection requirements. At patient level, the comparison was randomized between all comparison groups. At clinician level, the crossover design allowed assessment of the differential effects of acquiring the skills and competences for SDM and risk communication in different sequences.

Weaknesses of the study include a degree of bias from participant representativeness and data captured. It is likely that the GPs were motivated clinicians with higher than average confidence and ability regarding interpersonal communication skills. A pure control group was not included in the design, due to the issues of control group disengagement from a complex study protocol occurring over a number of months.30 Thus some of the changes demonstrated may represent Hawthorne effects.

Patient non-attendance was more likely among younger and female patients. Nearly 30% fewer consultations were audio-taped than intended. Thus bias or reduced power in the study to detect intervention effects was possible. The ‘review’ nature of the study consultations may have hindered discussions about treatment choices, although the trial maximized its chances of showing effects by using conditions characterized by clinician Equipolice.4,31 The assessment of risk information used in the audio-taped consultations was restricted to frequency of using information and did not address skills with which the information was discussed.

The multilevel modelling could not test a period (referred to in this design as ‘phase’) effect separately. Period and carry-over effects are confounded here, so we have tested for carry-over (interaction between the two types of training), attributing changes between period (‘phases’) 1 and 2 as the combined effect of the training. This is justified on the grounds that the

### Table 3
Consultations where types of risk information were used between clinician groups

<table>
<thead>
<tr>
<th></th>
<th>Risk (n = 11 doctors)</th>
<th>SDM (n = 9 doctors)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline (%)</td>
<td>Phase 1a (%)</td>
</tr>
<tr>
<td>General statements**</td>
<td>40</td>
<td>65</td>
</tr>
<tr>
<td>Likely/rare*</td>
<td>15</td>
<td>35</td>
</tr>
<tr>
<td>Comparisons drawn</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Individualized risk</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Numerical information**</td>
<td>4</td>
<td>78</td>
</tr>
<tr>
<td>Absolute risk**</td>
<td>2</td>
<td>34</td>
</tr>
<tr>
<td>Relative risk**</td>
<td>2</td>
<td>32</td>
</tr>
<tr>
<td>Number needed to treat**</td>
<td>0</td>
<td>12</td>
</tr>
<tr>
<td>Visual format**</td>
<td>6</td>
<td>77</td>
</tr>
</tbody>
</table>

Results are weighted mean percentage of consultations in which the types of information were used and t-tests between clinician groups (weighted for cluster size, 18 degrees of freedom, critical \( t = 2.1 \)).

* \( P < 0.01 \); ** \( P < 0.001 \).

a Phase 1 for these clinicians comprised only training for risk communication aids; phase 2 comprised SDM skills in addition to the previous risk communication aids.
b Phase 1 for these clinicians comprised only training for SDM skills; phase 2 comprised risk communication aids in addition to the previous risk communication aids.
c Numerical information includes absolute and relative risk and number needed to treat formats.
randomization of patients to period minimized case mix differences in the periods. The potential reduction in power from assessing both sequence effects of training and the individual effects via the crossover design is acknowledged.

Interpretation in context of setting and intervention
There are very few data examining the effect of providing interventions such as these with real patients in UK general practice. The results demonstrate that the interventions led to significant changes in the process of consultations, as detected by the OPTION scale and analysis of the types of risk information discussed, and to changes in clinicians’ perceptions of the consultation. These findings must be taken in the context of a lack of change in patient-based outcomes.24

The increased involvement levels after both interventions, with an additive effect when SDM skills are provided after the introduction of risk communication aids, indicates that skill development and information provision can lead to changes in the clinical interaction. One explanation for the sequential enhancement of OPTION scores is that clinicians may have used the risk communication aids to reinforce professional decisions after the risk communication workshops.25 Doing this in the consultation led clinicians also to demonstrate a number of the competences of SDM—and hence increased scores on OPTION. However, some of the (perhaps finer) competences were only covered by the SDM intervention, e.g. portraying equipoise and inviting patient choice. However, the converse was not found: the doctors who received the SDM skills intervention first then showed no further enhancement in OPTION scores after risk communication training. This statistically significant difference is likely to be important in practice. This finding informs how continuing professional development initiatives can take forward efforts to enhance patient involvement in health care decisions. Risk communication training and provision of (decision) aids should precede skill development in SDM. This is not only because the levels of involvement were highest among doctors following this sequence, but also because doctors’ confidence and satisfaction with the process and decisions appeared greater with this sequence.

Further work is needed in this area. In particular, this should assess the sustainability of SDM skills and evaluate whether clinicians can apply these skills to ‘new’ decisions over an increased range of conditions. This trial was also explanatory in nature.26 It used an idealized setting and subjects to evaluate the efficacy of the interventions. The participating clinicians reported that the interventions were highly acceptable. Having demonstrated that it is possible to achieve change in the consultation process, a pragmatic trial is desirable to assess the generalizability to routine service settings. Only in the light of such further evidence would it be valid to suggest that all GPs should receive specific training on risk communication and SDM. We recognize that in reality education and training should be part of a process rather than the single interventions evaluated here, and might be expected to achieve greater or longer-lasting effects as a result. In the meantime, the efficacy of these interventions to affect consultation processes indicates the potential for improvements in clinical practice and the value of further postgraduate communication skills development for those keen to progress in this area. The efficacy of these interventions to date also indicates the value of developing decision support materials and technologies that offer easily utilized information for both clinicians and patients. Further research should address practitioner skills for using such decision aids and the discussion of the information in ways that are flexible to meet the needs of individual patients.

Conclusion
The skills and steps of SDM (including the need for risk communication) are valid competences that can be operationalized. Experienced and motivated practitioners are willing to develop skills in this area. As a result of the trial interventions, the clinicians significantly increased their involvement of patients in decision making, as measured by the OPTION scale, and the frequency of discussing risk information with patients. Greatest effects were evident among the doctors receiving SDM training after risk communication training and provision of decision aids. This could be the basis for continuing professional development initiatives in this area.

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AE and GE designed and managed the study and were responsible for the interventions. CA was the principal research officer on the study, KH was the principal statistician. MR managed the trial data. IR also designed the trial and evaluation. MW and RG contributed to the development and use of OPTION as an outcome measure for the trial. In addition the members of the trial steering group were as follows: Paul Kinnersley, David Cohen, Mirella Longo, Ruth Davis, Ian Russell, Helen Houston, Hazel Thornton, Sue Thomas and Roisin Pill. For their contributions to the study and the drafting of this paper, joint authorship is attributed to all. AE and GE are the guarantors of the study.

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