**Does information form matter when giving tailored risk information to patients in clinical settings? –**

 **a review of patients’ preferences and responses**

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**Running header: Role of information form in communicating risk to patients**

**Abstract (300 words)**

Neoliberal emphasis on ‘responsibility’ has colonised many aspects of public life, including how health care is provided. Clinical risk assessment of patients, based on a range of data concerned with lifestyle, behaviour and health status has assumed a growing importance in many health systems. It is a mechanism whereby responsibility for self (preventive) care can be shifted to patients, provided that risk assessment data is communicated to patients in a way which is engaging and motivates change. This study aimed to look at whether the form in which tailored risk information was presented in a clinical setting (for example, using photographs, online data, diagrams etc.), was associated with differences in patients’ responses and preferences to the material presented. We undertook a systematic review using electronic searching of 9 databases, along with hand-searching specialist journals and backwards and forwards citation searching. We identified 11 included studies (8 with a RCT design). Seven studies involved the use of computerised health risk assessments in primary care. Beneficial effects were relatively modest, even in studies merely aiming to enhance patient-clinician communication or to modify patients’ risk perceptions. In our paper we discuss the apparent importance of the accompanying discourse between patient and clinician which appears to be necessary in order to impart meaning to information on ‘risk’, irrespective of whether the material is personalised, or even presented in a vivid way. Thus while expanding computer technologies might be able to generate a highly personalised account of patients’ risk in a time efficient way, the need for face-to-face interactions to impart meaning to the data, means that these new technologies cannot fully address the resource issues which are attendant with this type of approach.

280 words

**Key words:**

risk; patient communication; personalisation; information; behaviour change; health education

**Introduction**

Risk communication is something that most clinicians do every day .1 This is because firstly patients’ risk perception (belief about the likelihood of personal harm from a behaviour), and how this balances with benefits, lies at the heart of helping patients make informed choices between treatment options; and secondly because self-care and self-management behaviour is underpinned by how patients perceive threats to their health .2,3 Risk communication is also the concern of public health practitioners, where it is seen as crucial to the prevention and cooperative management of health risks, and ‘at least equally essential to outbreak control as epidemiological training and laboratory analysis’.4 Literature on health risk communication is therefore, understandably prolific - embracing a range of disciplines and theories which explore the complexities of how individuals are influenced by such information.4

There is a general consensus that tailoring of information is beneficial,5-7 and so we set aside ‘mass’ programmes concerned with risk communication, and focus here on communicating individualised information. Individualised health communication can range from personalised generic communication (for example using some-one’s name to personalise the message), to targeted communication (composing the message with a particular group or segment of the population in mind – an approach which is the basis of many public health education and social marketing campaigns); through to truly personalised communication which provides information based on characteristics which are unique to a person (as in brief counselling interventions, for example). These latter approaches involve tailoring which is based on characteristics beyond broad demographic categories such as age or gender, and therefore depend on some sort of individual assessment; although with the advent of computer-based tailoring, their population reach can still be wide.8,9

A common aim of tailoring used in health education messages is to increase attention and therefore message comprehension - both cognitive preconditions for the processing of information which leads to a change in behaviour.6 It is also thought that tailoring works by way of peripheral or emotional processing; for example: ‘the sender understands me’; which enhances source credibility and the following of recommendations with little critical analysis.6 Some even argue that ‘patients’ assessment of risk is primarily determined not by facts but by emotions,10 for the more risk information evokes an emotional response, the greater perceived chance of the threat occurring.11

Studies show that visual displays enhance people’s understanding of risk, particularly holding attention when they are given in a vivid way;12,13 and emotional responses to information portrayed say in pictures or videos influence whether people increase or decrease certain health behaviours.12 So although much previous attention has been focused on the way risk messages are framed and presented (comparing gain-framed with lost-framed messages and various numerical and graphical formats;1,14 the actual form in which the risk information is presented (verbal, written leaflet with or without diagrams, video, computer, photograph) is an important additional feature which may influence people’s engagement and responses to the material. With current expansion in possibilities of tailored risk communication by means of intelligent interactive systems,15 it is important to consider both patients preferences and their responses to risk information when presented in different forms. Our aim was therefore to undertake a systematic review of patients’ preferences and responses to personally tailored information given in different forms, limiting this to clinical settings (‘patient communication’), although the work may inform wider public health education efforts too. After presenting the results of the review, we go on to discuss what this means in modern times, where computer and mobile phone capabilities make it possible to issue a wealth of feedback on lifestyle and clinical information to patients against a background where health policies increasingly advocate efficiencies of care delivery and patients’ responsibility for their own health.

**Methods**

Literature searching was limited to all types of study design, including qualitative work and protocols, concerned with adult patients receiving tailored risk information as part of their care in clinical settings. Intervention studies were only included where the study involved comparing delivery of tailored risk information in one form, with either usual care, verbal risk messages, or with a different form of risk information - so that a comparison regarding differing information forms could be made (see Table 1 for full inclusion and exclusion criteria). Since studies show that lay concepts of ‘risk’ tend to be more aligned with a dichotomous model of risk presentation (“I am a likely/unlikely candidate for illness”), than a model involving graduations along a probability spectrum (“I am at a 30% higher risk of being ill than some-one else of my age”),16 we included studies involving giving tailored information about individuals’ levels of health with reference to likely negative consequences, as well as those involving ‘risk’ terminology and health outcome probabilities.

We adopted an iterative search strategy which involved electronic literature searching of 9 databases (including grey literature and dissertation databases) and hand searching 8 specialist journals (*details available in an online appendix*). To strike a balance between literature search sensitivity (finding all articles in the topic area) and precision (finding only relevant articles) we initially developed electronic search terms using Automatic Term Recognition software (TerMine), applying this to 35 papers previously retrieved through pilot searches undertaken in Google Scholar.17 We then broadened out the search strategy with general topic search terms (e.g. health education) as is customary to systematic review methods.18 We also used forward and backward citation searches, that is, reviewing references cited in articles identified earlier in the review process, and searching for publications which cited papers which met study inclusion criteria. Quality assessment of included Randomised Controlled Trials (RCTs) was undertaken using Cochrane risk of bias methodology.19

**Results**

Electronic and hand-searching identified 10,682 papers, of which 1,673 were duplicates. A further 100 papers were identified through backwards and forwards citation chasing. Screening by two independent reviewers identified 624 relevant papers. Full paper screening by two reviewers left 11 included papers,20-30 (Figure 1). The most common reason for paper exclusion (309) was because the risk information presented was not fully personalised as set out in our inclusion criteria (requiring a patient assessment prior to receiving the information, Table 1). In the majority of these excluded papers, risk information was formulated using broad population characteristics, such as age. Another 51 papers were excluded because they involved considering only one form of presenting information to patients, rather than a comparison between two different forms or comparing a certain form of information (e.g. photographs) with verbal information or usual care. Full reasons for exclusion are given in Figure 1.

Details of included papers indicate that this is a relatively new research area (Table 2). Eight of the 11 papers were published in the last 5 years. No studies were found which made comparisons between different information forms, with most included studies comparing particular forms of communicating risk information with usual care. Heterogeneity in study design and outcomes of included studies meant that meta-analysis was not undertaken. Where data from reviews are insufficient to merit pooling of included studies because of the very wide range of interventions covered, a ‘narrative synthesis’ is recommended.31 Narrative synthesis involves summarising the main features of different studies and important characteristics (such as similarities and differences between studies), and identifying patterns of results in the data.31

Summary of included studies

Five studies concerned cardio-vascular risk information;23,24,26-28 one concerned asthma risk information,29 and the rest covered broader ‘healthy life check’ information. Three studies involved information for Type 2 diabetes patients.24,28,30 Although 8 studies used an RCT design, two were feasibility studies,23,26 and two were pilot RCTs.25,27 Of the three remaining publications, one was an intervention description,30 one a protocol,27 and the other an uncontrolled prospective study.28 Quality assessment of included RCTs indicates that some of the RCTs had a low risk of bias in many domains, apart from intervention and outcome assessment blinding (Table 3).

Computer generated individualised written feedback on health risk

Seven articles concerned personalised risk information presented on computer.20-23,25,29,30 Developments in information technology have made it possible to combine health behaviour change theory, communication theory, social marketing principles and computer-based programmes and algorithms to produce personally relevant health messages for individuals. Information from participants’ survey data can be assembled to generate customised messages, to the extent which includes elements such as an individuals’ health literacy, locus of control, internet experience, attitude to self-care, decision preferences and current health knowledge.30 Computer technology allows incorporation of several hundred text files, graphics, and photographs which can potentially correspond with each survey question selected for tailoring and its possible response option combinations.32 By personalising messages and the language in the interactive dialogue (for example, contextualising according to the user’s viewpoint e.g. ‘as you said before…’), attention and impact is thought to be increased.

Most of the randomised controlled trials within our included studies involved computer-generated health risk appraisals (HRA), although results were generally disappointing. A RCT of a web-based intervention delivering personalised cardiovascular risk information to patients was found to be ineffective; with no significant differences in health outcomes or behaviour between intervention and control groups after 3 months.23 Even a study of computerised HRA where the outcome of interest was set relatively modestly at changes in risk perception; found that adjustments in optimistic and pessimistic bias only occurred in some of the disease domains studied22 (Table 2).

Two included studies reported randomised controlled trials of computerised health risk appraisals (HRA) administered in a general medical practice setting.20,21 Both involved older adults. The earliest of these integrated computerised HRAs into practice-based information technology systems, and generated individualised feedback to both patients and general practitioners who had been trained on current care and behaviour recommendations relating to the risk domains covered. It was, however, left to the discretion of doctors and patients as to how any issues identified were addressed in consultations, if at all.21 Results were relatively disappointing, with minimal improvement in patients’ health behaviour or uptake of preventive care across the domains studied,21 (Table 2). Intervention group participants reported slightly higher pneumococcal vaccination uptake (Odds ratio 1.7, CI 1.4-2.1) and some improvement in physical activity levels compared with controls (Odds ratio 2.0, CI 1.6-2.6). However, no significant differences were observed for any other of the 14 categories of health behaviour or types of preventive health service use at the 12 month follow up.21

The later study, this time undertaken in medical practices in Hamburg, Germany offered additional message reinforcement, as well as the HRA information for patients and practitioners (again with a training of the general practitioners involved).20 Overall, results were slightly better (Table 2). While there were still no differences between intervention and controls in mortality, hospital admissions and the frequency of visits to a doctor; there were small, but statistically significant shifts in self-reported health behaviours.20 After one year, the proportion of 9 types preventive service use (such as dental check-ups) was an average of 75% in the intervention group, and 68% in controls (Odds ratio 6.1, CI 4.3-7.9).20 Likewise, out of 6 possible health behaviours (such as three or more moderate to strenuous physical activities per week), 64% of these behaviours were reported by the intervention group, versus 60% in the controls (Odds ratio 3.7, CI 2.0 -5.4).20  Of the 804 participants in the HRA intervention group, 503 opted to take up some group session reinforcement, 77 opted for home visit reinforcement, and 224 did not take up the reinforcement offer. This allowed a sub-group analysis to explore the efficacy of the reinforcement component within this complex intervention. Findings indicate that a reinforcement component is needed if the intervention is to be effective. The *difference* in reported preventive service use between intervention and controls was 7.1% (CI 5.2% - 9.0%; p<0.001) for those receiving the full HRA intervention, including some kind of reinforcement; but 2.0% (CI -2.2- 6.3, p> 0.1), where intervention participants received the HRA only.20 The same pattern was seen in other self-reported health behaviour outcomes.20

Although authors suggest that computerised HRAs in clinical settings are best used to complement face-to-face consultations with clinicians; making them ‘more efficient and satisfying for both sides’ by ‘increasing patients knowledge and power to enable them to be active partners in their care;30 a RCT using computer-generated risk information on tablet PCs just prior to a doctor’s appointment does not support this.25 Little increase in both patients and doctors reports of discussion on various health topics for patients with prior access to their HRA was found.25 Harari et al (2008),21 also reported no HRA effect on patients’ self-efficacy related to patient/doctor interactions (Table 2). In summary therefore, several studies come to the same conclusion: that although computerisation makes tailoring of risk information possible, and enables simple and visual representation of complex risk information, additional input is needed to interpret and discuss the feedback – in other words some sort of face-to-face component to HRA interventions appears to be needed if beneficial effects are to be seen.20-23

Risk information presented by way of diagrams, charts and photographs

These small or non-significant findings are not limited to risk information presented on computers. Studies in the clinical setting presenting risk information by way of population diagram,24,28 coloured charts26 or photographs,27 come to similar conclusions – that risk information presented in this way alone is insufficient to prompt patients to adopt healthier lifestyles, or to enhance clinical communication, (Table 2). The only effect found was a short term increase in risk perception.24,27 Welschen24 concludes that risk communication is insufficient on its own, but should be a first stage in a more complex lifestyle intervention.

The RCT by Shabab et al27 using ultrasound scans showing the extent of blockage in carotid arteries allows some insight into the processes involved. They theorised that visual imagery such as scans of partially blocked carotid arteries span the conscious-unconscious continuum more readily than language, with the result that patients experience less filtering out of the information by the ‘conscious critical apparatus’ which usually serves to disengage the individual from beliefs which derogate the threat message. Their study collected behaviour mediator variables based on the Extended Parallel Process model, and was able to offer an explanation as to why some individuals were able to ignore the threat message even when it was presented in such a vivid way. Results showed that positive responses to the threat message presented were dependant on individuals having high self-efficacy beliefs (feeling able to make positive changes in the necessary behaviour), .27 A more recent study by Saver et al,28 supports the hypothesis that individuals are able to distance themselves from computer generated risk information, even when it is presented in an personally tailored way. Participants professed that ‘*the computer model is wrong about me…I know my health better …than some statistics*’. Almost 80% reported that they felt the data did not apply to them personally. Instead, 75% described ‘*knowing myself*’ as an important way they understood their risks: ‘*because I know myself better than I think some statistics show…*’. Embodiment of risk was described, although interestingly, the doctor was identified as someone who was the next best placed person to make risk judgements: *‘….that’s why I go by my body experiences, besides the doctor, you are the one who knows how your body functions*’.28

**Discussion**

As is the case in all systematic reviews, despite carefully constructing electronic search strategies, some literature may have been missed if articles were poorly indexed. We recognise this as a possible limitation of the review. Systematic review search term filters are usually determined in a trade-off between sensitivity (ability to detect all possible publications on the topic, knowing that this will throw up a lot of papers not meeting inclusion criteria) and precision (ability to deliver a search identifying a high proportion of relevant papers).33 We attempted to balance these two considerations by undertaking text mining of sample papers, and then subsequently broadening the search to increase sensitivity; supplementing this with hand-searching of specialist journals. However, it is possible that by using text mining to design a precise search, we may have limited its sensitivity somewhat, and some relevant publications were missed.

Nevertheless, it is striking how little literature there is on how tailored risk information is received by patients in clinical settings; bearing in mind the emphasis on personal responsibility for health and providing personal health and lifestyle risk factor advice to patients which is the basis of current health policy in many countries.34 For example, in both medical and dental care in the UK, growing attention is paid to collecting a range of ‘life check’ information, in personal health and lifestyle risk assessment tools with the intention that this is linked to personalised advice to patients.34,35 This is in contrast to a wealth of studies contrasting whether people’s risk perception is best informed using various different types of numerical and diagrammatical representations.14 The expansion of technology which allows extensive personalisation of risk information, makes translation into the clinical setting tempting. Certainly, computer technology which allows a range of information to be incorporated into patients’ assessments on the face of it appears to offer some assistance to clinicians. However, our study indicates these approaches may be insufficiently meaningful for patients, to make this worthwhile on their own.

Results remind us that the very notion of ‘risk’ itself differs substantially when approached from different standpoints. Scientific medicine defines ‘risk’ in terms of an objective reality which can be measured, controlled and managed.36 Although this approach tends to dominate thinking in this area of health care, and leads on to approaches which quantify risk, for example, with elaborate computer modelling of lifestyle data, our results indicate these may lack sufficient meaning for patients. In other words: ‘risk’ is something of a ‘trans-scientific’ topic in the issues can be raised but not completely answered by science.37

Lindell et al38 identify that there important differences exist when communicating risk information to individuals (in clinical settings) as opposed to populations. Science-based notions of risk which are based on mathematically expressed probabilities are only meaningful at the level of a population. Although this type of data represents objective, anonymised knowledge, at the level of individuals, the information becomes potentially emotionally charged and anxiety inducing.38 Lindell et al38 also observe that when talking to individuals about ‘risk’, it becomes concretized, almost ‘reified’, as if it was something ‘carried’ by the patient in her own body – a conclusion which resonates with the qualitative data reported in Saver’s study.28

And so it is up to clinicians to ‘re-contextualise’ the information to make it meaningful at a truly personal level.38 Often data involving percentages are recast into an ‘all or nothing’ scenario (‘*Will I get sick or not?*’).16 And so we observe that clinicians naturally simplify risk information when talking to patients to a relatively dichotomous model through the use of verbal qualifiers ("*Your risk is high*" or "*This is not good for your health*").39 Misselbrook and Armstrong agree, that when talking to individuals rather than populations, a high/low risk model is a better fit because it ‘provides the patient with a map to enable them to function and cope in an uncertain world’.40

A common theme across our included studies, which limited to those undertaken in a clinical setting, is that *discourse* (in some sort of face-to-face interaction) is a necessary way in which meaning is imparted to risk information, making it possible to move from scientifically-based risk representations relevant at a population level, to notions of risk which are relevant to individuals. Our results indicate that this is still necessary with scientific data even where this has been ‘personally tailored’ to individuals. Faisal et al (2013), terms the process as ‘internalisation’ of information of ‘externalised’ data (externalised data such as visual representations of data on computer-supported tools),41 and argue that ‘sense-making’ is a necessary process of finding meaning from information. So while risk information may be helpful in assisting people to perceive and make sense of their health status and medical condition, the process of sense-making concerns not just the data, but their own life experiences.42 The study by Dapp et al20 is particularly interesting because discourse on HRA data took place in groups or at home, and not in the medical practice with a doctor. These discursive practices help to define ‘who and what is normal, standard, and acceptable’.43 They help to challenge what was once ‘taken for granted’. It is after destabilising current meaning, that the information forms a basis for change.

**Conclusion**

Although presenting personalised information on health risk to patients is increasingly expected as part of a general health policy approach which emphasises patients’ contribution for their health by adhering to health education advice, our review reveals that relatively little empirical work has been done which compares

the relative impact of communicating information on risk to patients using different forms. Most work has been done in the growing field of presenting computerised health risk appraisals to patients. Findings suggest however that the impact of this information format is limited because there remains a need for discourse between patient and clinician (or even between patients) in order to impart personal meaning to the information sufficient to prompt a change in behaviour. More work is needed to explore this further.

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**List of captions for tables and figures**

Appendix (online): Table of electronic databases and journals searched

Table 1 Inclusion and exclusion criteria

Table 2: Included papers: study design and main findings

Table 3: Risk of bias of included Randomised Controlled Trials

Figure 1: Preferred Reporting Items for Systematic Reviews (PRISMA) diagram

**Appendix (online) Electronic databases and journals searched**

|  |
| --- |
| MEDLINE (Ovid MEDLINE and MEDLINE in process & Other Non-Indexed Citations) |
| Web of Science: Social Sciences Citation Index  |
| Web of Science: Conference Proceedings Citation Index- Social Science & Humanities  |
| PsycINFO  |
| PsycArticle  |
| Communication and Mass Media complete |
| Proquest Dissertations and Theses |
| Cochrane Library Cochrane Reviews (reviews and protocols) |
| Open Grey |
| Health Informatics Journal |
| Patient Preference and Adherence |
| Patient Education and Counselling |
| Health Communication |
| Journal of the American Medical Informatics Association |
| Preventive Medicine |
| Journal of Health Communication |
| BMC Medical Informatics and Decision Making |

**Table 1 Inclusion and exclusion criteria**

|  |
| --- |
| **Inclusion:**1. Personalised (tailored) information given to patients which is reliant on a pre-assessment of the patient rather than information which is targeted according to population characteristics such as age and gender
2. Studies concerned with information aimed at increasing patients’ perception of health risk. These include studies involving tailored information about an individual’s level of health with reference to likely negative consequences; as well as those involving ‘risk’ terminology or health outcome probabilities
3. Studies reporting delivery of information in a certain form (e.g. written, video, online, photograph) versus no intervention/usual care controls, or comparing information in different forms. In the control group ‘usual care’ information may or may not be tailored. Studies involving multi-component interventions which had a control group components such as motivational interviewing, or education which was also part of the intervention group, were included.
4. Outcome measures including one or more of: behaviour mediators including risk perception, health behaviour, health outcomes
5. Adults aged 18 yrs +
6. Patients receiving information as part of their care
7. Any health system
8. English language only
9. Date 1980 to present
10. All types of study design including qualitative studies and protocols
 |
| **Exclusion:**1. Studies concerned with giving information in a verbal form compared to a control
2. Outcomes concerned with decision making in relation to treatment options only.
 |

**Table 2: Included papers: study design and main findings**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Study** | **Participants** | **Intervention** | **Control** | **Follow up**  | **Outcome measures**  | **Results summary** |
| **Dapp et al (2011) (20)***RCT*Patientsrandomised by computer | Non-disabledAged 60 yrs+21 medical practicesHamburg | N=878 (14 practices)Written risk reports Multiple risk factorComputer-generated Health Risk Appraisal (HRA) individualised written reports + personal reinforcement (choice of group session/home visit), + physician training | N=1,702 (14 practices)Usual care (with physician training and checklists with preventive recommendations)N= 746An additional 7 concurrent ‘comparison’ practices with untrained GPs | 1 year | Behaviour10 preventive care use behaviours (PCUB) e.g. dental check-up 6 preventive health behaviours (PHB) e.g. consumption of fruit or fibreHealth Outcomes 5 measures e.g. hospital admissions | Adherence↑ in PCUB (OR 1.7, CI 1.4 - 2.1) and ↑ PHB (OR 2.0, CI 1.6 – 2.6) but subgroup analyses suggest a favourable effect only with personal reinforcement.**NS** health outcomesPreferencesMajority selected group rather than home visit reinforcement*Group reinforcement is promising* |
| **Harari et al (2008) (21)***RCT*Patientsrandomised by computer | Aged 65 yrs +4 general practices UK(26 general practitioners, GPs) | N= 940 patients (18 GPs)Written risk reports Computer-generated HRA individualised written reports + letter encouraging discussion with Dr or practice nurse (PN) + information on e.g. exercise schemes + GP/PN training + GP summary report  | N= 1,066Usual care (18 GPs)Concurrent comparison group (1 practice, 8 GPs) | 1 year | Behaviour10 PCUB 4 PHBHealth outcomesNo. hospital admissionsNo. GP visitsCommunicationPatient (pt) reported self-efficacy of patient/ physician interaction | Adherence↑ in 1 PCUB (OR 1.2, CI 1.01 – 1.5) and ↑1 PHB (OR 1.4, CI 1.0 – 2.0)**NS** health outcomes or patient self-efficacy*Lower than expected effect attributed to lack of face-to-face reinforcement* |
| **Kreuter and Strecher (1995) (22)***RCT*Randomis-ation unreported | 1, 317 adult patients aged 18-75 yrs from 8 US medical practices | N= not reportedGraphical and numerical presentation of patients 10-year mortality riskGroup 1: HRA feedbackGroup 2: HRA feedback plus behaviour change informationResults combined groups 1 and 2 and only given for participants recalling the intervention | N= not reportedUsual care | 6 months | Risk perception of mortalityHeart attack, Stroke, CancerMotor cycle Results reported for each mortality risk as perceived optimistic risk perception (un-realistically optimistic) and pessimistic risk perception (worried well) | **↓** optimistic bias for risk perception of stroke mortality only (OR 1.27, CI 1.02 – 1.60) i.e. intervention gps were 27% more likely to have ↑ risk perception at follow up↓ pessimistic bias for cancer risk perception only (OR 1.36, CI 1.07 – 1.73) i.e. intervention gps 36% more likely to ↓ risk perception at follow up |
| **Study** | **Participants** | **Intervention** | **Control** | **Follow up**  | **Outcome measures** | **Results summary** |
| **Zullig et al (2014) (23)***Feasibility study*Block randomis-ation | US pts with Cardiovascular disease (CVD) + a modifiable risk factorMean age 65 yrs | N= 96Web-based interventionGiven individual CVD risk face-to-face + link to self-directed online modules to adjust scores in areas where willing to change behaviour | N= 49Usual care with general health education information | 3 months | BehaviourMedication adherenceHealth outcomes10 year CVD risk scoreBMI, smokingBlood pressure | * **NS**

*Web interventions may be ineffective without guidance and accountability from clinician interactions* |
| **Welschen et al (2012) (24)***RCT*Patientsrandomised by computer | Referred Type 2 Diabetes (T2D) pts Netherlands | N= 131Verbal + pictorialNurse gave a figure (%) for relative risk of CVD + visual risk card + population diagram + gather patient response through open questions + pt asked to ‘think aloud’ explaining risk to themselves | N=130Usual care  | 12 weeks | Risk perceptionDifference in actual and perceived CVD riskAnxiety & worry about CVD riskBehaviour6 attitudes and intention to change (ICB) diet, smoking, exerciseCommunication Communication satisfaction | Risk perception ↑ (β between group difference 0.48, CI 0.02-0.95) after 2 weeks, but not at 12 weeks (β between group difference -0.03, CI -0.43 - 0.37) **NS** risk anxiety / worry **NS** ICB*There is no evidence that risk communication, besides an improved risk perception will motivate patients to adopt a healthier lifestyle* |
| **Hess et al (2013) (25)***Pilot RCT*Cluster randomised by Dr,  | Attending single US general practiceMean age 29 yrs | N= 51 (16 Drs)Computer generated immediate feedback of risk: tobacco use, physical activity, health related Quality of Life (HRQoL) before clinical appointment to prompt initiation of discussion | N= 48 (14 Drs)Usual care (completing health questionnaire without feedback) | At the end of the visit  | CommunicationPatient initiation of health related discussion (PID) reported by patient and DrPatients reported to find the discussion useful(Unit of analysis = patients) | **NS** Patient initiation of health-related discussion but ↑ Dr reports of PID on physical HRQoL only for pts with low physical HRQoL (OR 4.6, CI 1.3 -16.3).Preference: **NS** patient perceived discussion to be useful |
| **Neuner-Jehle et al** **(2013) (26)***Feasibility RCT*Cluster randomised by Dr | Swiss general practiceMedian age 47 yrsTotal 27 GPs114 patients | Verbal + numbers + pictorial risk messageGPs using ‘quit smoking tool’+ individualised CVD risk calculation training presented in numbers and coloured charts + training + guidelines including Motivational Interviewing  | VerbalGPs using a ‘quit smoking tool’+ training + guidelines including Motivational Interviewing (MI) | Not reported | Behaviour: Before & after motivation using a 10 point Visual Analogue scale Preference: satisfaction,Comprehensiveness, Communication: GP counselling frequency and duration, self-confidence | **NS** Patients estimated motivation**NS** Comprehensiveness, satisfaction**NS** Counselling duration, self-confidence*Feasibility & acceptability of adding a visual element is ‘equally high’* |
| **Study** | **Participants** | **Intervention** | **Control** | **Follow up**  | **Outcome measures** | **Main results** |
| **Shahab et al (2007) (27)***Pilot RCT*Patientsrandomised by computer | 23 cardiovascular disease (CVD) outpatients UK | N=11Print of ultra-sound image of their carotid artery alongside a disease-free artery + leaflet linking smoking and CVD | N=12Routine verbal feedback | Immediately afterand at4 weeks | BehaviourIntention to stop smoking (7 point Likert scale)Perceived susceptibilityPerceived seriousness Perceived response efficacy from smoking cessationPerceived self-efficacySmoking cessation Qualitative – interviews with patients | All outcomes **NS** except Perceived susceptibilityMean difference high perceived susceptibility = 8.04 (CI 5.58 – 10.50)Interviews: Only patients in the intervention group reported the visit made them think seriously about giving up smoking*High self-efficacy may be necessary to translate higher risk perception into intention to change behaviour*  |
| **Saver et al (2014) (28)***Before and after study* | English/Spanish speaking adults with T2D and at least one CVD risk factor2 general practices in 1 US city | N=56 patientsVerbal + Pictorial risk messageFirst 38 pts randomised to receive bar chart/crowd chart, final 18 pts receive bar chart/crowd chart sequentially | N/A | N/A | Risk perceptionChange in ranking using 6 cards of health risks including mortalityQualitative data on reasons for changing/ not changing, motivations for change, incongruence in perceptions | **NS** change in risk rankingAlthough 80% felt some/all of the data applied to them personally, < 40% felt it motivate changes; 75%report‘their own body experiences’ as their motivator. 20% report a ‘warning shot’ event or an instance where the provider urges, as prompting change.*Personalised risk estimates have limited salience* |
| **Ahmed et al (2011) (29)***RCT* protocolBlock randomis-ation | 18-69 yrsAsthma patients from tertiary care pulmonary clinics, CanadaN=80 | Web-based self-management system (with asthma status presented as Red (be careful), Amber (needs improvement), green (keep up the good work) + links to online educational resources tailored to patients gaps in knowledge and clinical information | Usual care | 3, 6, 9 months | BehaviourChronic disease self-efficacyMedication adherenceHealth care useHealth outcomesPrescription broncho-dilatorsAsthma Quality of life |  |
| **Study** | **Participants** | **Intervention** | **Control** | **Follow up**  | **Outcome measures** | **Main results** |
| **Weymann et al (2013)****(30)***Outline of an intervent-**ion* | T2D patients | Tailored web-based interactive health communication application. Personalisation involves mirroring what the user says, conveying esteem and empathy, building individualised bridges, content matching and presenting users with information on themselves | N/A | N/A | N/A |  |

**Table 3. Risk of bias of included Randomised Controlled Trials**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Risk domain** | **Dapp et al (2011)** (20) | **Harari et al (2008)** (21) | **Kreuter & Strecher (1995)** (22) | **Zullig et al (2014)** (23) | **Welschen et al (2012)** (24) | **Hess et al (2013)** (25) | **Neuner-Jehle et al (2013),** (26) | **Shahab et al (2007)** (27) |
| **Selection bias** |  |
| Random sequence generation | Low | Low | Unclear | Medium | Low | Low | Unclear | Low |
| Allocation concealment | Low | Low | Unclear | Medium | Low | Low | Unclear | Low |
| **Performance bias** |  |
| Blinding of participant and personnel | High | High | High | High | High | High | High | High |
| **Detection bias** |  |
| Blinding of outcome assessment | High | High | Unclear | Unclear | High | High | High | High |
| **Attrition bias** |  |
| Incomplete outcome data | Low | Low | Low | Unclear | Low | Low | Low | Low |
| **Reporting bias** |  |
| Selective reporting | Low | Low | High | Low | Unclear | Low | Low | Low |
| **Other bias** |  |
| Bias other than those above | N/A | N/A | N/A | N/A | N/A | N/A | N/A |  |

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