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Evaluation of an informed choice invitation for type 2 diabetes screening

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Abstract

Objective: To evaluate an innovative invitation designed to facilitate informed choices for undergoing screening for type 2 diabetes.

Methods: Four hundred and seventeen people aged 40–69 years (sex: F 53%/M 47%), without known diabetes, recruited from street locations. Participants were randomised to receive one of two hypothetical invitations for screening for type 2 diabetes; one based on General Medical Council guidelines and combined with a decisional balance sheet, the other a brief traditional invitation. Informed choice was assessed immediately after the invitation and 3 weeks later using measures of knowledge, attitudes and intentions.

Results: Two weeks after receipt of the invitation, the proportion of informed choices was significantly higher among participants who received the informed choice invitation compared with those who received the traditional invitation (42.9% versus 11.2%; difference = 31.7%, 95% CI: 22.5–40.5%; $p < 0.001$). Mean knowledge scores were significantly higher after the receipt of the invitation designed to facilitate informed choices than after the traditional invitation (5.49 versus 3.90; $t(405) = 10.106$, $p < 0.001$). Intentions to participate in screening were unaffected by receipt of the informed choice invitation.

Conclusion: Compared with a traditional invitation, receipt of the invitation designed to facilitate informed choices increased the proportion of informed choices about type 2 diabetes screening attendance.

Practice implications: : Although the new invitation was associated with better knowledge of screening it had no differential effect on intention and its effect on attendance still requires evaluation.

Keywords: Informed choice; Decision-making; Screening; Diabetes; Knowledge

1. Introduction

The importance of informed consent is enshrined within UK health policy [1]. There is a strong emphasis on the need for an individual to be provided with sufficient information regarding possible risks, and the lack of certainty with respect to benefits, prior to agreeing to treatment. The General Medical Council (GMC) makes similar recommendations [2], advocating provision of the following information relevant to screening programmes: details of possible diagnosis; uncertainty around diagnosis; treatment options; the purpose of the investigation, and details of the likely experience including side effects; details of benefits and harms, including potential lifestyle changes; the nature of ongoing assessment; and an unambiguous statement regarding freedom of choice to proceed or not.

These recommendations have yet to be implemented in practice. Invitations to attend for screening traditionally provide information about its population benefits, aimed at achieving high rates of uptake [3]. Indeed, a recent Cochrane Review of interventions that communicated individuals' risk of disease in screening programmes found that they generally increase screening uptake [4,5]. However, the review noted that insufficient data were available to examine effects on informed choice and related outcomes, mirroring the typical lack of mention of possible adverse effects in screening programmes. This approach reflects a greater concern with potential public health benefits than with individual autonomy. This may reflect a reluctance of those organising screening programmes to

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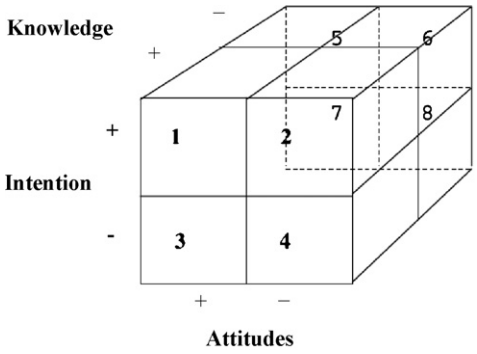

Legend

Cell	Meaning	Informed choice	Congruent choice
1	Positive attitudes and intentions, high knowledge	Yes	Yes
2	Negative attitudes, positive intentions, high knowledge	No	No
3	Positive attitudes, negative intentions, high knowledge	No	No
4	Negative attitudes, negative intentions, high knowledge	Yes	Yes
5	Positive attitudes and intentions, low knowledge	No	Yes
6	Negative attitudes, positive intentions, low knowledge	No	No
7	Positive attitudes, negative intentions, low knowledge	No	No
8	Negative attitudes, negative intentions, low knowledge	No	Yes

Fig. 1. Classification of choices, based on the three dimensions of attitudes (*x*-axis: positive, negative), intentions (*y*-axis: positive, negative), and knowledge (*z*-axis: low, high). Adapted from [17].

implement a policy change that is unevaluated in practice and is feared may privilege concern for informed choice to the neglect of achieving the public health benefits of screening [3]. In relation to screening for diabetes, there is increasing evidence that psychological consequences are limited in terms of anxiety in the short-term [6], and in the long term with respect to health-related quality of life [7], perceived health status and well-being [8]. However, whilst the psychological effects of screening do appear to be minimal, there are burdens associated with diagnosis following screen detection [9,10]. It is possible that information about the type and likelihood of the burdens associated with the screening procedure as well as the possible treatment, when presented alongside the type and likelihood of the benefits, could deter some people from participating in screening programmes [11–14].

In preparation for a trial to test the impact of an informed choice invitation for screening for type 2 diabetes on attendance and subsequent motivation to adopt recommended preventive actions (the DICISION trial), we have developed an invitation designed to foster informed choices. This paper reports an evaluation of the effect of this invitation on the proportion of participants who make an informed choice compared with a traditional invitation in an experimental analogue study in which participants were asked to imagine that they had received an invitation for screening for type 2 diabetes.

Type 2 diabetes is a chronic condition that meets many of the criteria for screening [15]. Undiagnosed diabetes is common and typically asymptomatic, but is associated with significant consequent morbidity and premature mortality. Between one-third and one-half of people with type 2 diabetes are undiagnosed, and at diagnosis up to 30% exhibit evidence of diabetic complications [16]. However, there is continuing uncertainty over the extent to which the benefits of early detection outweigh the harms and whether screening is a cost-effective use of limited health service resources [15].

1.1. Conceptualising informed choices

An informed choice can be defined as a behaviour with two core characteristics: first, it is based upon knowledge of relevant information; and second, it reflects the decision-maker's values [17–20]. This conceptualisation of informed choice is consistent with a multidimensional measure of informed choice [17,21], which categorises behavioural choices as either uninformed or informed based on measures of knowledge and attitudes (Fig. 1). In this operationalisation, uninformed choices are those in which knowledge is poor, or in which knowledge is good but the decision-maker's behaviour does not reflect their attitudes. Intention is specified as the most proximal determinant of behaviour by several theories, including the theory of planned behaviour, and protection motivation theory [22–24], and is used as a proxy for behaviour in this study.

Based on this model of informed choice, we developed an invitation for screening for type 2 diabetes that was designed to provide good quality information to increase knowledge of the relevant aspects of the screening test and that included a decision aid to increase participants' awareness of their attitudes and thereby to increase attitude–intention congruence.

1.2. Aim and hypotheses

This study aimed to evaluate an innovative invitation to increase informed choice in relation to screening for type 2 diabetes. The following hypotheses were tested:

H1. The proportion of informed choices will be higher following an informed choice invitation compared with a traditional appointment invitation.

H2. The proportion of choices in which attitudes and intentions are congruent will be higher following an informed choice invitation compared with a traditional appointment invitation.

H3. Knowledge about screening will be higher following an informed choice invitation compared with a traditional appointment invitation.

To reflect the likely gap between receipt of an invitation and attending for screening, and therefore the need for choices to be sustained over this period, the study assessed choice 2 weeks later.[1]

[1] Identical data were collected immediately following presentation of the invitations, and a similar pattern to the results presented here was observed.

2. Methods

2.1. Participants

Eligible participants were volunteer members of the public aged between 40 and 69 years, with no previous diagnosis of diabetes, who agreed to provide demographic details and accept a follow-up visit at their place of residence 2 weeks later. Additionally, a quota was set of 50% of participants having finished full-time education at 16 or before.

2.2. Study materials

2.2.1. Traditional invitation

The traditional invitation was based on previous invitations to attend for screening tests for diabetes and coronary heart disease [25,26]. It contained information (200 words) regarding the seriousness of diabetes, the nature of the screening test, and details of how the appointment would be arranged. Readability scores indicated that it could be comprehended by 11-year-olds (Flesch–Kincaid Grade level = 6.34; Flesch Reading Ease score = 71.51[2]).

2.2.2. Informed choice invitation

The information contained in both informed choice invitation was based upon the GMC guidelines [2] described above. The draft invitation text was developed iteratively using ''think-aloud'' methods with volunteers [27]. The method requires respondents to verbalise their thoughts whilst reading the invitation and has typically been to examine decision-making [28,29]. In this case the verbal reports were used to ascertain where information was not being understood as intended, and readability tools [30] were then used to refine the text. The final invitation comprised 857 words and retained an equivalent reading comprehension score to the traditional invitation (Flesch–Kincaid Grade level = 5.76; Flesch Reading Ease score = 72.88). Additionally, two pie charts were used to represent data described in the text regarding the likelihood of a positive screening result and the likelihood of health benefits from early detection.

A decision balance sheet decision aid followed the informed choice text. This required participants to write down the anticipated consequences for themselves of undergoing screening in terms of pros and cons, prompted by the instruction:

> *When making your decision, it might help you to think about the good and bad things that could happen if you are screened for diabetes. Spend a few minutes thinking about having screening for diabetes. Please list all the good and bad things that go through your mind. Please underline the things that are most important to you.*

This text was followed by two open text boxes, entitled ''Good things from screening for diabetes'' and ''Bad things from screening for diabetes''.[3]

2.3. Measures

Knowledge about screening for type 2 diabetes was measured using eight multiple-choice items derived from the GMC guidelines, with between three and six response options (e.g. ''the screening test for diabetes is... [a finger prick test; a test where blood is taken from a vein in the arm; a urine test; a fitness test; I don't know]''). The number of correct items was used as the knowledge score, with a potential range of 0–8. Attitude regarding undergoing screening for type 2 diabetes were measured by six items (e.g. ''For me, having the screening test for diabetes would be... [beneficial–not beneficial], each scored on 7-point scales scored from 1 to 7. The mean of the six items was used as the score. Cronbach's alpha was 0.89 at time 1 and 0.92 at time 2. Intention regarding undergoing screening for type 2 diabetes was measured by a five-item scale (Would you have the diabetes screening test? [definitely yes; probably yes; do not know; probably not; definitely not]) and a 7-point scale (''Would you have the diabetes screening test?'' [extremely likely–extremely unlikely]). Both scores were converted to z-scores. The mean of the two items was used as the score. Cronbach's alpha was 0.72 at time 1 and 0.84 at time 2.

2.4. Procedure

Data were collected by a market research company (Cambridge Market Research) from members of the public across the UK between February and April 2006. Participants were recruited from street locations by trained interviewers. Participants were invited to immediately complete a brief questionnaire containing demographic measures that were used to ensure that the inclusion criteria (see Section 2.1) were satisfied. Those who met the criteria were then asked to read either a traditional invitation, an instrumental-informed choice invitation or an affective-informed choice invitation from a pile of invitations that were randomly ordered using a random number generator, and were told ''[it is] an invitation to attend a diabetes screening appointment. The appointment will not take place, but please VIVIDLY IMAGINE that you have received this from your GP regarding a REAL appointment''. Two weeks later, participants were visited at their homes by interviewers, and completed a questionnaire. Participants received £5 immediately on completion of the follow-up questionnaire. The Cambridge University Psychology Research Ethics Committee granted ethical approval for the research.

[2] Approximates to a reading age of around 11 years.

[3] We developed 2 versions of the invitation; identical except that in the first, the decision aid referred to ''good things'' and ''bad things'' about screening for diabetes, whereas the other referred to ''good feelings'' and ''bad feelings''. However, this instrumental/affective manipulation had no significant effects on any outcome. Subsequently, we have treated the two invitations as a single group.

Table 1
Demographic characteristics of study participants (%(*n*))

Variable	Total sample % (*n* = 417)	Traditional % (*n* = 139)	Informed % (*n* = 278)
Social grade C2, D and E	32.4 (135)	37.4 (52)	29.9 (83)
Home owner	86.1 (359)	79.9 (111)	89.2 (248)
Sex (male)	47.0 (196)	50.4 (70)	45.3 (126)
Over 50 years	50.6 (211)	52.5 (73)	49.6 (138)
Left school at or before 16 years	61.6 (257)	66.2 (92)	59.4 (165)
Highest formal qualification at or below NQF[a] level 2	69.7 (232)	74.3 (84)	67.3 (148)
Not working	26.6 (111)	23.7 (33)	28.1 (78)

[a] Education was represented by National Qualifications Framework level 35. QCA. The structure of the Nqf: QCA, 2007.

2.5. Analyses

The study was designed with 140 participants per invitation, providing 90% power to detect an absolute increase of 20% in the percentage of participants making an informed choice when comparing the invitations using a chi-squared test at the 5% level of significance.

2.5.1. Defining criteria for informed choices

Drawing upon the multidimensional measure of informed choice [17], participants were categorised as having made an informed choice using the knowledge, attitude, and intention measures. Participants were assigned as having made an informed choice if they scored above the median on knowledge and were jointly above or below the median on attitude and intention (see Fig. 1: cells 1 and 4, respectively). Participants were assigned as having made a congruent choice if they scored jointly above or below the median on attitude and intention (see Fig. 1: cells 1 & 5 and 4 & 8, respectively).

Chi-square tests were used to compare groups on categorical variables (e.g. whether or not the choice was congruent) and *t*-tests for variables that could be treated as continuous (e.g. knowledge score); for the latter, the standardised mean difference (*d*) was used as the measure of effect size. To maximise precision of results, rather than deleting a case that had any missing data, we retained such cases for analysis if they had available data. Analyses were carried out using SPSS 12 for Windows.

3. Results

Four hundred and seventeen people completed demographic measures at time 1 and, of these, 407 (97.6%) completed the questionnaire 2 weeks later, of whom 53% were female and 47% were male. There were no missing data for demographic items at time 1, and of the responses to the questionnaire 2 weeks later, 2.4% (range 1.9–3.4%) were missing.

3.1. Randomisation checks

Table 1 shows demographic characteristics of study participants, which were not significantly different between study groups.

3.2. Informed and congruent choices

The proportions of informed and congruent choice and chi-square statistics for tests of difference between participants assigned the traditional and informed invitations are given in Table 2. Two weeks after presentation of the invitation, the informed choice invitation resulted in a significantly higher proportion of informed choices compared with the traditional invitation (42.9% and 11.2%, respectively; difference = 31.7%, 95% CI: 22.5–40.5%; $\chi^2 = 41.1$ (1), $p < 0.001$). Thus, the hypothesis (H1) that the proportion of informed choices is higher following an informed choice invitation was supported. The proportion of attitude–intention congruent choices was uniformly high, with no differences between the traditional and the informed choice invitations (76.1% and 74.0%, respectively). Thus, the hypothesis that the proportion of choices in which attitudes and intentions are congruent is higher following an informed choice invitation (H2) was not supported. To further investigate the lack of effect on congruence, post hoc tests were performed on the attitude and intention measures (see Table 3). There were no significant differences between the informed and traditional invitation recipients on attitudes or intentions.

Table 2
Rates of choice (%(*n*)) categorised by MMIC by invitation type

Category	Invitation		χ^2 (d.f.)
	Traditional (*n* = 134)	Informed (*n* = 273)	
Informed choice (cells 1 and 4)	11.2 (15)	42.9 (117)	41.1 (1)***
High knowledge, incongruent choice (cells 2 and 3)	0.7 (1)	15.4 (42)	20.4 (1)***
Low knowledge, congruent choice (cells 5 and 8)	64.9 (87)	31.1 (85)	42.1 (1)***
Low knowledge, incongruent choice (cells 6 and 7)	23.1 (31)	10.6 (29)	11.2 (1)***
Congruent choice (cells 1, 4, 5 and 8)	76.1 (102)	74.0 (202)	0.6 (1)

***$p < 0.001$.

Table 3
Knowledge, attitudes and intentions by invitation type

Variables	Invitation		*t*-Test
	Traditional ($n = 134$)	Informed ($n = 273$)	
Knowledge	3.90 (1.47)	5.49 (1.53)	10.1 (405)***
Attitude	6.15 (0.98)	6.25 (0.89)	1.0 (405)
Intention (*z*-score)	−0.11 (0.99)	0.06 (0.88)	1.7 (404)

***$p < 0.001$. The intention scale *z*-scores rescaled to a 7-point scale are 6.0 and 6.2 for the traditional and informed groups, respectively.

3.3. Knowledge

Table 3 presents the group means and tests of between group differences on the component constructs of the informed choice measure. There was a significant difference in knowledge when comparing the informed with the traditional invitation recipients (informed $M = 5.49$, traditional $M = 3.90$; $t(405) = 10.1$, $p < 0.001$; $d = 0.95$). Thus, the hypothesis that knowledge about screening is higher following an informed choice invitation (H3) was supported.

To further investigate the effect of the informed choice invitation on knowledge, post hoc tests were performed upon the responses to the eight multiple-choice knowledge items (see Table 4). Where significant differences were found, these were in the expected direction, with proportions of correct answers uniformly associated with receipt of the informed choice invitation. High proportions of correct answers in both groups on items relating to the seriousness of diabetes and the nature of the screening test indicate either that this knowledge is available in both the traditional and informed choice invitations or that the majority of participants already knew this information. Low proportions of correct answers on the meaning of a positive test result in both groups indicate that this information was not adequately conveyed. Additionally, despite higher proportions of correct scores on the item relating to the efficacy of early treatment to reduce the consequences of diabetes being significantly associated with receipt of the informed choice invitation, only 19.6% were correct on this item. This proportion of correct answers was markedly lower than where other significant associations occurred, with proportions higher than 75% on those items.

4. Discussion and conclusion

4.1. Discussion

Compared with the traditional invitation, the informed choice invitation resulted in a significantly higher proportion of informed choices as defined by our conceptualisation. This increase reflected increased type 2 diabetes screening-related knowledge but not increased attitude–intention congruence.

Inspection of the knowledge items revealed that whilst the written materials effectively conveyed the consequences of diabetes, the likely results of screening, the meaning of a negative screening result, and the likely harms of screening, only around one-third of recipients understood that a positive type 2 diabetes screening test result was not diagnostic or that following early treatment following the diagnosis of diabetes from screening tests, a minority will benefit but there will be costs for all.

Compared with the information that was successfully conveyed, explaining the meaning of a positive screening result and the effectiveness of early treatment involved the presentation of more complicated numerically based information. We drew upon review findings suggesting the effectiveness of using graphs to present complex outcomes [31], and used pie charts as well as text that had been subjected to ''think-aloud'' testing. However, the information conveyed required comparison of the probabilities of more than a single potential outcome. In the case of those receiving positive screening test results, subsequent diagnostic testing would either confirm a diagnosis of diabetes or not. Concerning the effectiveness of early treatment following the diagnosis of diabetes from screening tests, a minority will benefit but there will be costs for all. The failure to benefit the majority may be due to treatment failure, or to treatment being unnecessary (i.e. the individual would not have developed long-term complications of diabetes). A recent study comparing comprehension of different types of risk information indicates that comprehension may be lower when individuals are asked to compare multiple outcomes [32]. We elected to convey the benefits and harms of a procedure within the same graphical and textual elements of the information provided so as to reduce the amount of text and number of graphical representations presented. Further

Table 4
Correct responses (%(n)) to each of the eight knowledge items by invitation type

Question	Invitation		Test
	Traditional ($n = 134$)	Informed ($n = 273$)	
Seriousness of diabetes	89.7 (122)	93.7 (254)	2.1 (0.149)
Common long-term problems	42.1 (56)	81.5 (220)	64.0 (0.000)***
Nature of screening test	86.8 (118)	93.0 (252)	4.2 (0.039)*
Most likely test result	52.9 (72)	84.1 (228)	45.5 (0.000)***
Meaning of negative screening result	40.4 (55)	78.2 (212)	57.3 (0.000)***
Meaning of positive screening result	27.9 (38)	27.1 (74)	0.0 (0.858)
Efficacy of early treatment to reduce consequences of diabetes	3.7 (5)	19.6 (53)	18.7 (0.000)***
Possible harms of screening	47.1 (64)	76.1 (207)	34.3 (0.000)***

*$p < 0.05$.
***$p < 0.001$.

research is needed to develop effective ways of conveying such complex information. Rather than attempting to convey all of the information suggested by the GMC [2], focusing upon the information that is harder to convey may result in greater levels of knowledge.

4.1.1. Rates of congruence

Failure to generate a greater proportion of congruent choices was unexpected given our use of a decisional balance sheet. Such decision aids are expected to enhance motivation to pursue a chosen goal [33] and have been shown to raise awareness of the consequences of a decision [34]. Given this, one might expect that their use would generate stronger attitudes and therefore stronger intentions. It is possible that the hypothetical nature of the decision may have reduced the level of engagement with the materials.

The failure of the informed choice invitation to increase attitude–intention congruence reflects other findings in this area. In a recent review of RCTs of leaflets designed to promote informed choices in type 2 diabetes screening, most trials found that leaflets increased knowledge but there was little evidence that the leaflets facilitated the making of informed choices [35]. In a review of decision aids, which frequently include decisional balance sheets, there is little evidence that their use increases the value consistency of decisions [36]. Recent research on unconscious processing of information suggests that rational decision-making approaches may be less likely to elicit value-consistent decisions than approaches that facilitate the use of unconscious processes in making a decision, such as encouraging those facing decisions to engage in distraction rather than deliberating on the pros and cons of different decision options [37].

Intentions to participate in screening were unaffected by receipt of either of the informed choice invitations. While there is limited evidence to suggest that such invitations could reduce interest in screening [11], other studies do not support this hypothesis [38,39].

4.1.2. Strengths and weaknesses

This study presents a novel application of the multidimensional measure of informed choice in operationalising informed choice in the context of screening. A recent review of communication of risk in screening [4] recommended the development of the multidimensional measure of informed choice [17] for a range of screening choices. Six studies have reported using variants of this measure and all relate to prenatal screening [17,40–43]. All used correlational designs. As such, this is the first time that any form of the MMIC has been used in the randomised evaluation of materials to promote informed choice or in the context of screening for type 2 diabetes. The study has limitations. Firstly, the external validity of findings from analogue studies in which volunteer individuals are presented with an imaginary situation may be questioned. The invitation was however for a screening test that is familiar and widely available [9]. There is also, evidence from laboratory decision studies that provided the simulated decision mimics the choice it is designed to reflect, lab based responses and their consequences mirror those outside the laboratory [44,45]. Finally, the use of intention as a proxy for behaviour begs future studies that should seek to replicate the findings reported here. Still, in terms of the component constructs used to index the decision, a recent meta-analysis of studies that applied the theory of planned behaviour to screening [46] found that the correlation between screening intentions and screening behaviour was 0.42 ($k = 19$, $n = 8148$, 95% CI = 0.40–0.44). As such, whilst this study may not provide a full account of the potential impact of the invitation, it is likely to be a reliable account [47,48].

4.2. Conclusion

Compared with the traditional invitation, the informed choice invitation resulted in a significantly higher proportion of informed choices as defined by our conceptualisation. This was achieved by increasing knowledge from a low level rather than improving attitude–intention congruence. Participants appeared to find it difficult to understand the implications of attending for type 2 diabetes screening, with over 50% of those receiving informed choice invitations classified as making uninformed choices, around half of these because of low levels of knowledge. Methods for increasing attitude–intention congruence need further development based on greater theoretical understanding.

4.3. Practice implications

This study demonstrated that careful development of materials, combining a ''think aloud'' protocol and efforts to enhance readability, can be used to generate invitations for type 2 diabetes screening that increase knowledge. However, it also shows that informed choice is a complex concept that depends on more than knowledge alone. Although the new invitation was associated with better knowledge of screening it had no differential effect on intention and its effect on attendance still requires evaluation.

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