

Psychological impact of screening for type 2 diabetes: controlled trial and comparative study embedded in the ADDITION (Cambridge) randomised controlled trial

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ABSTRACT

Objective To quantify the psychological impact of primary care based stepwise screening for type 2 diabetes.

Design Controlled trial and comparative study embedded in a randomised controlled trial.

Setting 15 practices (10 screening, five control) in the ADDITION (Cambridge) trial in the east of England.

Participants 7380 adults (aged 40-69) in the top fourth for risk of having undiagnosed type 2 diabetes (6416 invited for screening, 964 controls).

Interventions Invited for screening for type 2 diabetes or not invited (controls), incorporating a comparative study of subgroups of screening attenders. Attenders completed questionnaires after a random blood glucose test and at 3-6 months and 12-15 months later. Controls were sent questionnaires at corresponding time points. Non-attenders were sent questionnaires at 3-6 months and 12-15 months.

Main outcome measures State anxiety (Spielberger state anxiety inventory), anxiety and depression (hospital anxiety and depression scale), worry about diabetes, and self rated health.

Results No significant differences were found between the screening and control participants at any time—for example, difference in means (95% confidence intervals) for state anxiety after the initial blood glucose test was -0.53, -2.60 to 1.54, at 3-6 months was 1.51 (-0.17 to 3.20), and at 12-15 months was 0.57, -1.11 to 2.24. After the initial test, compared with participants who screened negative, those who screened positive reported significantly poorer general health (difference in means -0.19, -0.25 to -0.13), higher state anxiety (0.93, -0.02 to 1.88), higher depression (0.32, 0.08 to 0.56), and higher worry about diabetes (0.25, 0.09 to 0.41), although effect sizes were small. Small but significant trends were found for self rated health across the screening subgroups at 3-6 months (P=0.047) and for worry about diabetes across the screen negative groups at 3-6 months and 12-15 months (P=0.001).

Conclusions Screening for type 2 diabetes has limited psychological impact on patients. Implementing a national screening programme based on the stepwise screening procedure used in the ADDITION (Cambridge)

trial is unlikely to have significant consequences for patients' psychological health.

Trial registration Current Controlled Trials
ISRCTN99175498.

INTRODUCTION

Type 2 diabetes mellitus, the fourth leading cause of death in the United Kingdom,¹ fulfils many of the criteria for screening yet important uncertainties remain.² As with any screening programme the overall benefits should outweigh any physical and psychological harm associated with the programme. Consequently it is important to quantify possible adverse psychological effects of screening, and the consequent diagnosis and treatment. Given that a small adverse effect for most participants who will screen negative may outweigh a large benefit to the few diagnosed as having the condition, it is important to assess potential harms among all those invited to participate in screening.

Evidence from studies of screening for other conditions shows that people who screen positive can show reactions such as reduced perceptions of health and have increased absenteeism from work.³ A systematic review of prospective studies of the psychological harms that can arise from screening across various conditions found that anxiety is often raised, at least in the short term, when a positive result is received, although it is unlikely to be raised by receiving a negative result.⁴ However, few controlled trials of the psychological effects of screening have been published that would enable the psychological impact of being invited to screening and subsequent participation to be estimated.⁴ Furthermore, there are few evaluations of screening procedures that involve people undergoing a series of tests over time.³ These multistage screening programmes have the potential to cause increased distress because of prolonged uncertainty in the screening process.⁵

A recent review concluded that the psychological impact of screening for type 2 diabetes is limited⁶; slightly increased short term levels of anxiety were reported in two studies.^{7,8} A further study has reported

Box 1 | Screening procedure used in ADDITION (Cambridge) trial

Fifty four general practices in the east of England were randomly allocated to control, screening followed by routine care of screen detected cases according to national recommendations,¹⁶ and screening followed by intensive multifactorial intervention. Automated searches of computerised general practice records were carried out to identify those in the top fourth of risk of having prevalent but undiagnosed type 2 diabetes.¹⁷

Screening arms

- Individuals at high risk were invited by letter to attend their local general practice for capillary blood tests for random blood glucose (HemoCue glucometer; HemoCue, Angelholm, Sweden) and glycated haemoglobin
- Patients were excluded if they already had type 2 diabetes, were pregnant or lactating, or had a psychotic illness or an illness with a prognosis of less than one year
- Patients with a blood glucose level of 5.5 mmol/l or more were invited to return for a fasting (capillary) blood glucose test
- Patients with a fasting blood glucose level of 6.1 mmol/l or more or 5.5-6.1 mmol/l and a glycated haemoglobin of 6.1% or more were invited to attend an outpatient centre for a standard 75 g oral glucose tolerance test¹⁷ and clinical, anthropometric, and biochemical measures
- Diagnosis of type 2 diabetes was made according to World Health Organization criteria¹⁸
- Results were faxed to the patient's doctor for discussion with patients in consultations

Control arm

- Neither practitioners nor patients were informed of the risk score

similarly low distress levels after diagnosis in screen detected patients but noted that a significant number had clinically relevant anxiety and depression.⁹ Previous studies have been limited by non-randomised designs comparing just two groups: people with newly diagnosed type 2 diabetes and those who screen negative.^{7 10 11} Only one study reported distress levels for participants, grouped according to their level of risk.⁸ Another limitation of previous studies is the use of general anxiety measures. Studies on the impact of cancer screening suggest no detectable effect on measures of general anxiety but a substantial effect on disease specific measures.¹²⁻¹⁴ The review of screening for type 2 diabetes identified the need for controlled trials on large samples.⁶

The Anglo-Danish-Dutch study of intensive treatment in people with screen detected diabetes in primary care¹⁵ (the ADDITION trial) is evaluating

the cost effectiveness of screening and intensive treatment of screen detected cases, with 54 general practices being included in the Cambridge arm. The current study was embedded in the ADDITION (Cambridge) trial and used validated measures to assess the short term and long term psychological effects of screening in a large well defined cohort of people at high risk of developing type 2 diabetes. More specifically it investigated the psychological impact of being invited to attend screening for type 2 diabetes at a general practice and of the screening tests and results. We formulated the following hypotheses for one of the outcome measures, anxiety. Similar hypotheses were specified for the other outcomes (depression, diabetes specific worry, self rated health): participants invited to screening would report higher anxiety than those not invited; participants who screen positive at the first test (and thus are invited to return for further tests) would report higher anxiety than those who screen negative; and within the screening group there would be a dose-response effect of level of risk (from number of tests and results) on anxiety—each stage of the screening process would be associated with an increase in anxiety.

METHODS

The study design was a controlled trial comparing those invited for screening with non-invited controls, incorporating additional comparisons between subgroups of screening attenders, embedded in the ADDITION (Cambridge) trial. In that trial, practices were randomly allocated to screening or control arms. The psychological impact substudy included all five control practices in the main trial and a sample of 10 of the screening practices. It was not possible to randomly select the screening practices because the substudy started later than the main trial and by this time many of the practices had finished screening; three of the 10 screening practices included in the substudy were part way through screening.

The screening procedure is summarised in box 1. The figure shows the design of the psychological impact study and the flow of participants through the screening programme, with response rates.

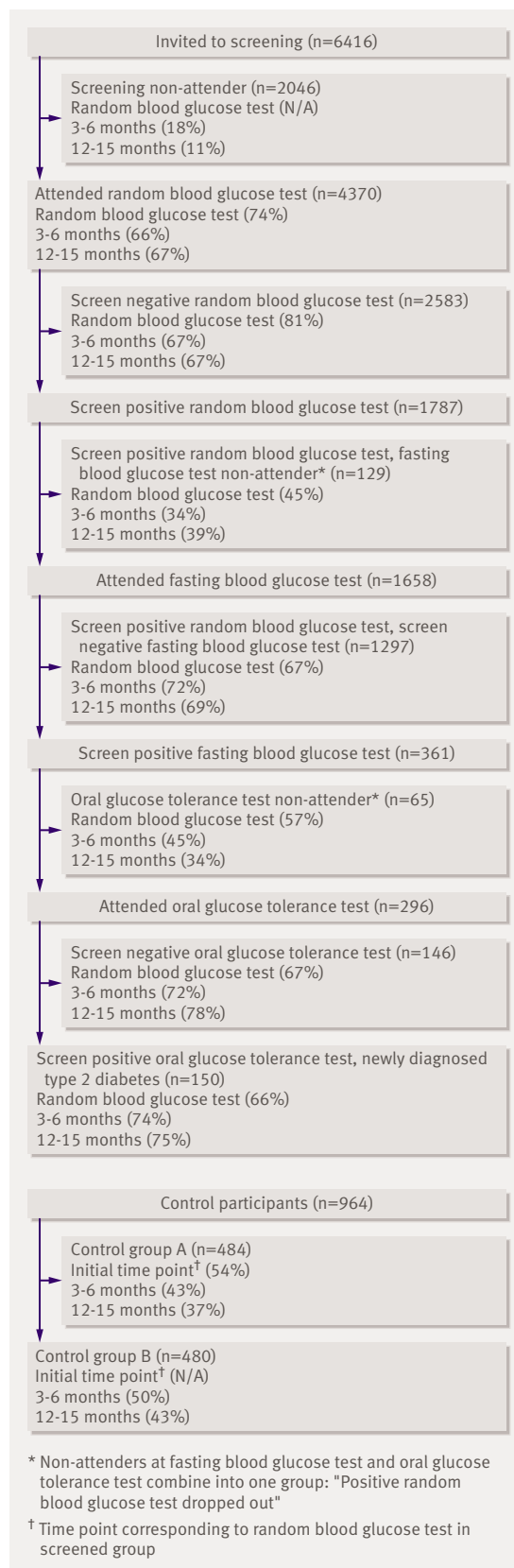
Participants in the 10 screening practices who attended the initial glucose test (n=4370) were given a questionnaire to complete and return by post to the study centre; subsequent questionnaires were sent at 3-6 months and 12-15 months after this initial appointment. Screening non-attenders in these practices (n=2046) were sent the questionnaire at 3-6 months and 12-15 months after the date of their scheduled random blood glucose test. Postal questionnaires were sent from the practices and returned to the study centre.

In each of the five control practices 25% (n=964) of those with a high risk score were randomly sampled to be sent questionnaires at equivalent times to 3-6 months and 12-15 months. (Four hundred and eighty four of these were randomly assigned to also

Table 1 | Baseline characteristics of screening and control participants. Values are percentages (numbers) of participants unless stated otherwise

Variables	Screening group (n=6416)	Control group (n=964)	P value
No of practices	10	5	
Mean (SD) practice list size	7810 (3026)	7160 (2527)	0.68
Women	34.6 (2220)	35.6 (343)	0.57
Mean (SD) age (years)	57.6 (7.9)	58.6 (7.8)	0.25
Mean (SD) body mass index*	30.5 (4.7)	30.6 (4.9)	0.39
Body mass index >30*	47.0 (2747)	48.5 (430)	0.38
Prescribed steroids	6.1 (390)	4.4 (42)	0.42
Prescribed antihypertensives	46.6 (2992)	49.0 (472)	0.33

*Data not available from general practice records for 9% screening and 8% control participants.



Flow of participants through screening programme, with questionnaire response rates at each time point

Box 2 | Participant groups in study sample

Initial random blood glucose test

- Screen negative at first test
- Screen positive at first test: invited for further tests
- Control participant

3-6 months and 12-15 months

- Screen negative at first (random blood glucose) test
- Screen negative at second (fasting blood glucose) test
- Screen negative at oral glucose tolerance test
- Screen positive at oral glucose tolerance test: newly diagnosed as having type 2 diabetes
- Screening non-attender
- Screening dropout (attended at least one test but did not complete tests required for diagnosis)
- Control participant

being sent a questionnaire at the initial time point for a substudy on measurement effects.)

For the screening attenders, consent for participation in the psychological impact study was obtained during attendance at the initial test. Control participants and non-attenders received an information sheet, consent form, and covering letter from their surgery with their first questionnaire.

At each wave, participants who had not returned a questionnaire after about three weeks were sent one reminder (including a copy of the questionnaire). Control participants and non-attenders who did not return their questionnaire after one reminder were not sent questionnaires at subsequent waves for ethical reasons.

At the initial time point screening attenders were classified according to their random blood glucose test result. At 3-6 months and 12-15 months participants were classified according to the point at which they had tested negative or positive or failed to attend (box 2).

Measures

We studied five main outcome measures. State anxiety was measured using the six item short form state scale of the Spielberger state anxiety inventory¹⁹; scores of 6-24 were prorated to range from 20-80 to correspond with the full form of the scale. General anxiety and depression were measured with the 14 item hospital anxiety and depression scale,²⁰ comprising two subscales resulting in scores of 0-21 each for anxiety and depression. Disease specific worry was measured using a six item scale for worry about developing diabetes, adapted from the Lerman cancer worry scale²¹; sum scores result in scores of 6-24. A single item was used to measure self reported general health; response options were excellent⁵, very good⁴, good³, fair², and poor.¹⁻²² The questionnaire also included basic demographic information and further measures not directly relevant to the current study.

Sample size

The study size was based on the Spielberger state anxiety inventory, informed by a pilot study²³ providing a standard deviation of 12, an intrapractice correlation coefficient of 0.048, and plausible effect differences of 3 to 7 units from state anxiety scores of 34.1 (control), 37.6 (screening), 33.1 (negative at first test), and 41.7 (after further testing). With samples of 2500 patients from those eligible for screening in 24 screening practices and 500 patients from four control practices, and allowing for 20-40% of dropouts depending on group and wave, the study had 80% power, with two sided tests at the 5% level of significance, to detect a difference in mean state anxiety between screening and control (hypothesis 1) of 4.3 units ($n=1800$ v $n=350$, design effect 4), between screen negative and screen positive groups (hypothesis 2) of 1.6 units ($n=900$ v $n=900$), and between the two smallest fully screened groups of 5.0 units ($n=80$ v $n=120$) at 3-6 months and 5.5 units ($n=64$ and $n=96$) at 12-15 months (hypothesis 3). To coincide with the timing of the main screening study, for the practicality of involving all rather than a sample of eligible patients in the screening practices, and because the prevalence of undiagnosed diabetes was lower than expected, we altered the study size to five control practices and 10 screening practices, with 964 and 6416 eligible patients. The study numbers and measure variability provided 80% power to detect effect differences of 3.2 units, 1.4 units, 5.7 units, and 5.4 units, respectively (3.2 units equates to a difference between adjacent response categories—for example, “not at all” and “somewhat”—on three of the 20 items on the full form of the scale).

Analyses

We assessed cross sectional comparisons between groups and dose-response trends across testing groups using a linear mixed effects model, with practice as random effect to account for clustering. Effect sizes were summarised with 95% confidence intervals, and we assessed hypotheses using two sided tests at the 5% level of significance. These were adjusted for clustering and for age and comorbidity (use of antihypertensives) to allow psychological effects to be attributed to

screening rather than to pre-existing comorbidity or age differences that might arise from the practices being selected or being part way through screening (in the event the effect of covariate adjustment made no difference to the overall conclusions). The size of the difference in means between groups was interpreted in terms of the response categories of the scale and by comparison with the standard deviation, using Cohen's guidelines for interpreting standardised differences in means (0.2 is small; 0.5 is medium, 0.8 is large).²⁴ Analysis was primarily by intention to treat although we followed the explanatory nature of the hypotheses by excluding those who did not return a questionnaire until after their subsequent test in the screening programme.

RESULTS

At the time of the initial random blood glucose test 82% of 1787 patients who screened positive for type 2 diabetes, 81% of 2583 patients who screened negative, and 54% of 484 control participants responded. To ensure that data at this time captured the impact of the random test only, 310 questionnaires from screen positive patients that were completed or returned after the date of the second test were excluded, providing amended response rates of 65% for the patients who screened positive and 74% for the screened group (participants who screened positive plus participants who screened negative).

Response rates at 3-6 months were 66% among screening attenders, 18% among non-attenders, and 47% among controls. At 12-15 months response rates were 67%, 11%, and 40%. To ensure that analysis at these times captured the impact of the oral glucose tolerance test result, questionnaires received from attenders of this test before they had received their result (3-6 months, $n=10$; 12-15 months, $n=4$) were excluded.

The screening and control groups were comparable at baseline on the measures used to calculate the diabetes risk score¹⁷ and for practice size (table 1).

Impact of being invited to screening

At the time of the random test no significant differences were found between the screening attenders and

Table 2 | Differences in outcome between screening attenders and control participants, and between participants who screened positive and those who screened negative (random blood glucose test), at initial time point*. Values are means (standard deviations) unless stated otherwise

Variables	Control, non-screening	Screening attenders	Difference† (95% CI), P value‡	Screen negative at RBG	Screen positive at RBG	Difference§ (95% CI), P value‡
Self reported health	3.14 (0.85), n=253	3.10 (0.88), n=3199	-0.02 (-0.18 to 0.14), 0.81	3.17 (0.87), n=2057	2.97 (0.89), n=1142	-0.19 (-0.25 to -0.13), <0.001
State anxiety	32.7 (11.5), n=199	32.7 (11.6), n=2468	-0.53 (-2.60 to 1.54), 0.62	32.4 (11.4), n=1594	33.1 (11.9), n=874	0.93 (-0.02 to 1.88), 0.05
HADS anxiety	6.42 (4.39), n=255	6.04 (3.79), n=3140	-0.46 (-0.99 to 0.07), 0.12	6.07 (3.75), n=2016	5.97 (3.87), n=1124	-0.00 (-0.28 to 0.27), 0.99
HADS depression	4.52 (3.48), n=256	4.24 (3.31), n=3161	-0.37 (-0.93 to 0.18), 0.21	4.14 (3.24), n=2032	4.41 (3.43), n=1129	0.32 (0.08 to 0.56), 0.01
Worry about diabetes	7.95 (2.44), n=255	8.04 (2.20), n=3127	0.03 (-0.36 to 0.42), 0.90	7.97 (2.19), n=2019	8.18 (2.21), n=1108	0.25 (0.09 to 0.41), 0.002

HADS=hospital anxiety and depression scale; RBG=random blood glucose test.

*Immediately after initial (random blood glucose) test for screening attenders, first contact for control participants.

†Screening attenders minus controls.

‡Adjusted for age and comorbidity (use of antihypertensives).

§Participants who screened positive minus participants who screened negative.

control participants on any of the five outcome measures—for example, for state anxiety, difference in means -0.53 (95% confidence interval -2.60 to 1.54), $P=0.62$; table 2: no data were available on non-attenders at this time. At 3-6 months and 12-15 months no significant differences were found between those invited for screening (attenders and non-attenders) and control participants—for example, for state anxiety, difference in means at 3-6 months 1.51 (-0.17 to 3.20 ; $P=0.10$) and at 12-15 months 0.57 (-1.11 to 2.24 ; $P=0.52$, table 3). Thus the hypothesis that being invited to a screening programme has an adverse psychological impact was not supported.

Immediate impact of initial screening test results

After the initial test the participants who screened positive reported significantly poorer general health (difference in means -0.19 , -0.25 to -0.13 ; $P<0.001$), higher state anxiety (0.93 , -0.02 to 1.88 ; $P=0.05$), higher depression (0.32 , 0.08 to 0.56 ; $P=0.01$), and higher diabetes specific worry (0.25 , 0.09 to 0.41 ; $P=0.002$) than participants who screened negative (table 2). No significant difference was found on general anxiety. Thus, the second hypothesis, that participants who screened positive would have worse outcomes than those who screened negative, was supported for four of the five outcome measures. The effect sizes were, however, small.

Impact of a recent diagnosis of type 2 diabetes

A significant linear trend across the subgroups of screening attenders was found on two measures (table 4). At 3-6 months self reported health declined across groups according to the number of tests before testing negative, with the poorest general health

reported by those testing positive at the final test—that is, those with newly diagnosed type 2 diabetes ($P=0.047$). The effect was no longer evident at 12-15 months. Secondly, the more screening tests that a participant underwent before testing negative, the higher the diabetes specific worry reported at 3-6 months and 12-15 months ($P=0.001$ in both cases). No significant trend was found across groups for the anxiety and depression measures. Thus, support was limited for the hypothesis of a dose-response effect of length of involvement with the screening programme on psychological costs.

Non-attenders

Those invited for screening included two further groups (table 5): screening non-attenders (for the initial test) and dropouts (participants who tested positive at the initial test but did not attend for further tests and so never received their final result). Both had poor response rates (18% and 38% at 3-6 months, 11% and 37% at 12-15 months). Compared with screening attenders, non-attenders had significantly higher scores on diabetes specific worry at 3-6 months (difference in means 0.26 , 0.01 to 0.50 ; $P=0.04$) and 12-15 months (0.35 , 0.03 to 0.66 ; $P=0.03$), but the effect sizes were small. Participants who screened positive at the initial test but who dropped out were compared with those who screened positive at the initial test but attended for subsequent tests. Dropouts had significantly poorer self reported health at 12-15 months (-0.26 , -0.46 to -0.06 ; $P=0.01$) and significantly higher diabetes specific worry at 12-15 months (1.25 , 0.66 to 1.83 ; $P<0.001$), a medium sized effect.

Table 3 | Differences in outcome between screening and control participants at 3-6 months* and 12-15 months†. Values are means (standard deviations) unless stated otherwise

Time	Control, non-screening	Screening group (attenders and non-attenders)	Difference ‡ (95% CI), P value §
Self-reported health:			
3-6 months	3.14 (0.80), n=443	3.13 (0.88), n=3211	0.02 (-0.13 to 0.18), 0.78
12-15 months	3.21 (0.81), n=383	3.15 (0.87), n=3093	-0.03 (-0.20 to 0.13), 0.70
State anxiety:			
3-6 months	31.8 (11.4), n=358	33.5 (12.0), n=2504	1.51 (-0.17 to 3.20), 0.10
12-15 months	32.8 (11.8), n=304	33.5 (12.2), n=2377	0.57 (-1.11 to 2.24), 0.52
HADS anxiety:			
3-6 months	5.97 (3.86), n=442	5.91 (3.89), n=3159	-0.12 (-0.55 to 0.32), 0.61
12-15 months	5.81 (3.87), n=377	5.85 (3.87), n=3034	-0.01 (-0.47 to 0.45), 0.98
HADS depression:			
3-6 months	4.18 (3.38), n=444	4.24 (3.40), n=3177	0.01 (-0.51 to 0.54), 0.96
12-15 months	4.03 (3.35), n=378	4.28 (3.40), n=3049	0.22 (-0.31 to 0.74), 0.44
Worry about diabetes:			
3-6 months	7.87 (2.35), n=428	7.79 (2.15), n=3041	-0.11 (-0.42 to 0.19), 0.48
12-15 months	8.08 (2.30), n=365	7.75 (2.21), n=2889	-0.33 (-0.67 to 0.01), 0.08

HADS=hospital anxiety and depression scale.

*Time since initial or scheduled (random blood glucose) test for screening group, 3-6 months since first contact or equivalent for control group.

†Time since initial or scheduled (random blood glucose) test for screening group, 12-15 months since first contact or equivalent for control group.

‡Screening group minus control group.

§Adjusted for age and comorbidity (use of antihypertensives).

Sensitivity to missing data

The analysis at the initial test included only those participants who had screened positive and who had completed or returned their questionnaire before the second test, but included all responders who screened negative at the initial test. To mirror the exclusion criterion applied to the screen positive group, the analysis was repeated with a reduced screen negative group, excluding those who took a long time to return the questionnaire (matching the mean return time of the screen positive group). The only change in conclusion from this further analysis was that participants who screened positive scored higher than those who screened negative on state anxiety (difference in means 1.22, 0.25 to 2.18; $P=0.01$). The effect size remained small.

Completion rates for all items constituting the hospital anxiety and depression scale and measures for worry about developing diabetes were high (97%, 98%, 94%), but only 76% of participants completed all items constituting the state anxiety measure. At the initial test non-completers of the state anxiety measure had higher mean general anxiety (hospital anxiety scale) than completers, by 1.36 units in controls and by 0.79 units in participants who screened negative and 0.62 units in those who screened positive, with the same completion rate across groups. Inclusion of non-completers for state anxiety would therefore be expected to reduce the difference in scores between the group who screened positive and those who screened negative (table 2).

To investigate bias arising from dropout between the initial test and 3-6 months, non-responders to the questionnaire at 3-6 months were compared with responders at the initial test. For each outcome measure non-response rates were similar across the three main groups from the initial test to 3-6 months

(within 7%). Non-responders had a mean outcome worse than responders; this was greater in the control group and at a similar level in the groups who screened negative or positive (data not shown). If non-responders had responded similarly at 3-6 months the effect would be relatively to worsen the outcomes in the control group and reduce the evidence in favour of a psychological impact of screening.

DISCUSSION

Our finding that the psychological impact of screening for type 2 diabetes seems to be limited is in line with previous research.⁶⁻¹¹ Firstly, no significant differences were found on any of the five outcome measures (state anxiety, anxiety, depression, diabetes specific worry, and self rated health) between the screening attenders and control participants at the initial random blood glucose test or between those invited for screening and controls at 3-6 months and 12-15 months. This was important to address, as previous studies have not included such a control group at similar risk of having undiagnosed type 2 diabetes.

Previous studies have also not dealt with the immediate impact of patients screening negative at a first random blood glucose test compared with screening positive and thus being required to return for further tests. Those who screened positive at this initial test did report significantly poorer general health and higher state anxiety and depression and worry about developing type 2 diabetes than those who screened negative. These effects were, however, small and the mean scores were not clinically relevant (anxiety and depression)^{19,20} or relatively high (diabetes specific worry).^{14,21} It can be concluded that being required to return for further tests after an initial positive test result has a small negative psychological impact that is unlikely to be of clinical significance.

Table 4 | Trends across four subgroups of screening attenders, at 3-6 months and 12-15 months since initial random blood glucose test. Values are means (standard deviations) unless stated otherwise

Time	Screen negative RBG	Screen positive RBG, screen negative FBG	Screen positive RBG, screen negative OGTT	Screen positive RBG, screen positive OGTT	Test for trend P value*
Self reported health:					
3-6 months	3.16 (0.87), n=1718	3.11 (0.87), n=865	3.08 (0.87), n=103	2.99 (0.82), n=103	0.047
12-15 months	3.18 (0.87), n=1701	3.13 (0.87), n=880	3.16 (0.83), n=111	3.17 (0.78), n=110	0.77
State anxiety:					
3-6 months	33.6 (11.9), n=1341	33.0 (11.8), n=666	32.4 (12.6), n=85	34.4 (13.8), n=85	0.94
12-15 months	33.5 (12.0), n=1297	33.2 (11.9), n=682	32.3 (11.7), n=86	32.9 (13.5), n=90	0.72
HADS anxiety:					
3-6 months	5.90 (3.82), n=1687	5.76 (3.93), n=851	6.07 (3.86), n=100	5.64 (3.95), n=103	0.89
12-15 months	5.89 (3.90), n=1673	5.76 (3.79), n=862	5.94 (3.91), n=107	5.32 (4.18), n=109	0.46
HADS depression:					
3-6 months	4.14 (3.36), n=1695	4.28 (3.31), n=859	4.50 (3.66), n=100	3.99 (3.63), n=104	0.47
12-15 months	4.20 (3.33), n=1678	4.26 (3.36), n=866	4.80 (3.86), n=110	3.92 (3.86), n=111	0.44
Worry about diabetes:					
3-6 months	7.69 (2.02), n=1678	7.68 (2.06), n=858	8.75 (3.09), n=101	—	0.001
12-15 months	7.61 (2.07), n=1654	7.79 (2.26), n=856	8.07 (2.35), n=110	—	0.001

RBG=random blood glucose; FBG=fasting blood glucose; OGTT=oral glucose tolerance test.

*Adjusted for age and comorbidity (use of antihypertensives).

At 3-6 months rather than comparing those with and without screen detected type 2 diabetes we compared participants according to the point in the screening process at which they screened negative or positive, to examine the impact of the tests as well as the diagnosis. A marginally significant dose-response effect was found on self reported health in the hypothesised direction—those screening negative at the initial test reported the best health and those with a diagnosis of diabetes reported the poorest health; the trend was, however, no longer evident at 12-15 months. Within the screen negative group the more screening tests that participants had before screening negative the higher was their worry at 3-6 months about developing type 2 diabetes; this trend was maintained at 12-15 months. Although this trend is in the direction hypothesised the level of worry was relatively low^{14,12}; the mean score for those screening negative after three tests equated to being “sometimes” worried on three items and “not at all or rarely” worried on the other three items on the scale. No trends were found for the anxiety and depression measures. Thus the hypothesis of a dose-response effect across the screening groups was only partially supported.

Only a small proportion of non-attenders for the initial test returned questionnaires but those who did had higher scores on diabetes specific worry than the attenders. The non-attender group comprised 32% of those invited for screening, so an adverse impact in this group is a potential concern. The effect size was, however, small. Another important group of non-attenders was the 11% of participants who screened positive at the initial test but who failed to attend for further tests. These dropouts were more worried about

diabetes at 12-15 months than those who completed subsequent tests. The findings for non-attenders should be interpreted with caution because of the poor response rates in these groups.

Most comparisons in this study provided no statistically significant differences between groups. As a consequence of the large sample size, the estimates of differences in means had narrow confidence intervals and these can be interpreted as robust negative findings. When significant differences between groups were observed, in almost every case the effect size was small, as judged both for standard deviation of the measure and for response categories of the scale. The largest effect we observed was for diabetes specific worry at 12-15 months in the comparison between participants who screened positive at the initial test who dropped out of the screening programmes and those who attended for subsequent tests (table 5).

The current study had several limitations. Firstly, the screening practices were not randomly selected from those in the Cambridge arm of the Anglo-Danish-Dutch study of intensive treatment in people with screen detected diabetes in primary care (ADDITION) trial. Nevertheless, the screening and control groups were comparable on the baseline measures used to calculate the diabetes risk score and for practice size. Secondly, the study did not include a true baseline measure of anxiety and other psychological measures assessed before participants were invited for screening. This was a deliberate decision to avoid the possibility that the uptake of screening would be influenced by sending patients a questionnaire. It means, however, that to attribute the observed differences between groups to differences in their screening experience (number of tests, test

Table 5 | Differences in outcome between screening attenders and non-attenders (for random blood glucose test) and, within screen positive group (random blood glucose), between those who attended all subsequent tests and dropouts, at 3-6 months and 12-15 months since initial or scheduled random blood glucose test. Values are means (standard deviations) unless stated otherwise

Time	Screening attenders	Screening, non-attenders	Difference* (95% CI), P value†	Screen positive RBG, attended all	Screen positive RBG, dropped out	Difference‡ (95% CI), P value†
Self reported health:						
3-6 months	3.13 (0.87), n=2860	3.09 (0.94), n=351	-0.05 (-0.15 to 0.05) 0.32	3.10 (0.87), n=1071	2.93 (0.93), n=71	-0.18 (-0.39 to 0.02), 0.08
12-15 months	3.16 (0.86), n=2874	3.08 (0.94), n=219	-0.07 (-0.19 to 0.05) 0.24	3.14 (0.86), n=1101	2.88 (0.90), n=72	-0.26 (-0.46 to -0.06), 0.01
State anxiety:						
3-6 months	33.2 (11.9), n=2225	34.5 (12.7), n=279	0.30 (-1.20 to 1.81) 0.69	33.1 (12.1), n=836	36.3 (10.9), n=48	2.55 (-0.94 to 6.04), 0.15
12-15 months	33.3 (12.0), n=2210	35.3 (13.8), n=167	1.33 (-0.58 to 3.25) 0.17	33.1 (12.1), n=858	34.9 (11.3), n=55	1.72 (-1.54 to 4.97), 0.30
HADS anxiety:						
3-6 months	5.87 (3.85), n=2813	6.29 (4.19), n=346	0.16 (-0.28 to 0.59) 0.48	5.78 (3.92), n=1054	6.23 (3.73), n=72	0.26 (-0.66 to 1.19), 0.57
12-15 months	5.83 (3.86), n=2833	5.94 (3.91), n=211	-0.17 (-0.71 to 0.37) 0.53	5.74 (3.84), n=1078	6.19 (3.41), n=72	0.40 (-0.49 to 1.30), 0.38
HADS depression:						
3-6 months	4.20 (3.36), n=2828	4.59 (3.63), n=349	0.28 (-0.10 to 0.66) 0.14	4.27 (3.37), n=1063	4.67 (3.19), n=70	0.33 (-0.49 to 1.14), 0.43
12-15 months	4.22 (3.39), n=2833	4.68 (3.53), n=216	0.27 (-0.20 to 0.74) 0.26	4.28 (3.47), n=1087	5.06 (3.38), n=68	0.71 (-0.13 to 1.55), 0.10
Worry about diabetes:						
3-6 months	7.76 (2.10), n=2701	8.08 (2.45), n=340	0.26 (0.01 to 0.50) 0.04	7.79 (2.22), n=959	8.31 (2.39), n=64	0.42 (-0.15 to 0.98), 0.15
12-15 months	7.76 (2.18), n=2683	8.16 (2.52), n=206	0.35 (0.03 to 0.66) 0.03	7.83 (2.27), n=966	9.08 (2.80), n=63	1.25 (0.66 to 1.83), <0.001

RBG=random blood glucose; HADS=hospital anxiety and depression scale.

*Attenders minus non-attenders.

†Adjusted for age and comorbidity (use of antihypertensives).

‡Dropped out minus attended all subsequent tests.

WHAT IS ALREADY KNOWN ON THE TOPIC

Observational studies suggest that the psychological impact of screening for type 2 diabetes is limited

No evidence is available from controlled trials

WHAT THIS STUDY ADDS

Screening for type 2 diabetes does not seem to have an adverse psychological impact
A national screening programme based on the ADDITION (Cambridge) model is unlikely to have important psychological costs

results), it is necessary to assume that they were similar at baseline for anxiety and the other psychological measures. Even without a true baseline, however, the findings are informative. For example, that attenders for screening are no more anxious immediately after their first test than non-invited controls is an important finding, even if we do not know how anxious the attenders were before receiving their invitation for screening.

A third limitation is the low questionnaire response rates among the screening non-attenders, an almost universal finding in the literature on screening participation.²⁵ This affects the comparison between those invited for screening and controls. If screening non-attenders who do not return questionnaires are more anxious (as a result of receiving an invitation) than those who do, we may be underestimating the adverse impact of being invited for screening.

Despite these limitations this study provides strong evidence on the psychological impact of screening for type 2 diabetes. The findings confirm the emerging position that screening for type 2 diabetes does not cause psychological costs.⁶⁻¹¹ Implementing a national screening programme based on the stepwise screening procedure used in the ADDITION (Cambridge) trial is unlikely to have significant consequences for patients' psychological health. A prospective qualitative study²⁶ with ADDITION (Cambridge) trial participants helps to illuminate the findings from this quantitative study by showing how participants' perceptions changed as they progressed through the stepwise screening process.

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