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Title:

Clinical effectiveness of a patient decision aid to improve decision quality and glycaemic control in people with diabetes making treatment choices – a cluster randomised controlled trial (PANDAs) in General Practice.

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ARTICLE FOCUS:

- Does the use of the PANDAs decision aid in general practice improve decision quality and glycaemic control in people who are making treatment choices about their type 2 diabetes mellitus (T2DM) treatment, including whether or not to start insulin?

KEY MESSAGES:

- Patient decision aids provide evidence-based information about treatment options, help patients to clarify their values and guide them systematically to make an informed decision.
- The use of the PANDAs decision aid by doctors and nurses in usual NHS general practice with people who have T2DM and are making treatment choices reduces decision conflicts and improves knowledge, realistic expectations and patients' involvement in decision making.
- HbA1c levels were reduced in both groups at six months when compared to baseline (0.24% controls and 0.37% intervention) with a non-significant mean difference between the two groups of 0.351, p=0.117).

STRENGTHS AND LIMITATIONS

- This study was underpowered to detect a minimally, clinically important difference in glycaemic control between the two groups due to slow recruitment.
- There was no blinding in this study due to the nature of the intervention which may have influenced the outcome assessment.
- This was a pragmatic trial and there may have been variations in how the decision aid was used in different General Practices which may have diluted the effect of the study.

Abstract

Objective

To determine the effectiveness of a patient decision aid (PDA) to improve decision quality and glycaemic control in people with diabetes making treatment choices using a cluster RCT.

Design

A cluster randomised controlled trial.

Setting

49 general practices in UK randomised into intervention (n=25) and control (n=24).

Participants

General Practices: Inclusion criteria: > 4 medical partners; list size > 7000; and a diabetes register with > 1% of practice population. 191 Practices assessed for eligibility, 49 Practices randomised and completed the study.

Patients: People with T2DM taking at least two oral glucose-lowering drugs with maximum tolerated dose with an HbA1c greater than 7.4% (IFCC HbA1c >57mmol/mol) or advised in the preceeding six months to add or consider changing to insulin therapy. Exclusion criteria: currently using insulin therapy; difficulty reading or understanding English; difficulty in understanding the purpose of the study; visual or cognitive impairment or mentally ill. 182 assessed for eligibility, 175 randomised to 95 intervention and 80 controls, 167 completion and anlaysis.

Intervention

Brief training of clinicians and use of PDA with patients in single consultation.

Primary Outcomes

Decision quality (decisional conflict scores, knowledge, realistic expectations and autonomy) and glycaemic control (glycosolated haemoglobin, HbA1c).

Secondary Outcomes

Knowledge and realistic expectations of the risks and benefits of insulin therapy and diabetic complications.

Results

Intervention Group: lower total decisional conflict scores (17.4 v 25.2, p<0.001); better knowledge (51.6% v 28.8%, p<0.001); realistic expectations (risk of 'hypo', 'weight gain', 'complications'; 81.0% v 5.2%, 70.5% v 5.3%, 26.3% v 5.0% respectively, p<0.001); and were more autonomous in decision making (64.1% v 42.9%, p=0.012).

No significant difference in the glycaemic control between the two groups.

Conclusions

Use of the PANDAs decision aid reduces decisional conflict, improves knowledge, promotes realistic expectations and autonomy in people with diabetes making treatment choices in general practice.

ISRCTN Trials Register Number 14842077

Data sharing statement: There are no additional data available

Introduction

Diabetes mellitus is a growing health problem in England with a total of 2.4 million people (5.5% of population) living with the disease in 2011.[1] Diabetes currently accounts for 10% of all NHS expenditure.[2] However, overall diabetes control is less than satisfactory. In 2008/2009, 67% of people with T2DM achieved a glycosolated haemoglobin (HbA1c) of less than 7.5% (IFCC HbA1c 58 mmol/mol).[3]

The UK Prospective Diabetes Study (UKPDS) has established the importance of maintaining good blood glucose control in patients with T2DM. For every 1.0% increase in HbA1c, there is an increase, in risk, of 14% for myocardial infarction, 21% for diabetes-related deaths and 37% for micro-vascular complications.[4] In the same study, it was reported that only 25% were able to achieve good glycaemic control with monotherapy after 9 years of the trial. Most patients will require combination therapy, including insulin, 5-10 years after diagnosis.[5]

Currently, the NICE guidelines recommend a combination of metformin and insulin secretagogues in those who have inadequate blood glucose control with monotherapy. In those in whom dual therapy has been unsuccessful, either insulin or a thiozolidinedione should be added to optimise glycaemic control.[3] Frequently, this poses a clinical dilemma for both patients and healthcare providers; both parties need to agree which next treatment option to pursue and this includes whether or not to start insulin therapy. However, patients may be fearful of needles and the side effects of insulin (e.g. hypoglycaemia); they need to acquire new skills; change their daily routine and address the challenge of glucose monitoring.[6] Similarly, doctors may be hesitant to prescribe insulin due to their own lack of relevant skills, time pressures, and a fear of increasing the risk of side effects.[7 8] In this category of patients,

the decision making process is a complex one. Studies have shown that patients usually make decisions based on emotions such as trust, rather than on the information given by their healthcare providers.[9] For their part, doctors do not necessarily follow evidence-based guidelines[10] and it was in this context that the PANDAs decision aid was developed to facilitate shared decision making between clinicians and patients when making decisions about the treatment of their diabetes at this stage of their illness. The development of the PANDAs decision aid will be described elsewhere.

Patient decision aids are tools that provide evidence-based information about treatment options, help patients to clarify their values and guide them systematically to make an informed decision. Patient decision aids have been shown to improve knowledge, realistic expectations, value-decision concordance and patient involvement in decision making.[11]

The primary research question was “Does the use of the PANDAs decision aid improve decision quality in patients with T2DM who are making a decision whether or not to start insulin in general practice?”.

The study focussed on people with T2DM who had poor glycaemic control (HbA1c >7.4mmol/l or IFCC HbA1c >57 mmol/mol) and who, despite receiving optimal oral glucose lowering therapy, required "step-up" treatment. A cluster randomised controlled trial was carried out to evaluate the clinical effectiveness of the decision aid on decision quality and glycaemic control.

Methods

The setting for this study was general practices in Sheffield, Rotherham and Doncaster with recruitment being undertaken through the National Institute for Health Research Primary Care Research Network (PCRN) and the Cutler Group of South Yorkshire Research Practices. The recruitment of practices and patients began in 2008 and the data collection ended in 2011.

Practices were invited to take part by postal invitation following a publicity campaign using a modified viral marketing technique involving sequential non-specific PANDAs post cards ('PANDAs are coming') to 'pique' interest, followed by increasingly informative flyers (Figure 1).[12]

The inclusion criteria for general practices were: > 4 medical partners; list size > 7000; and a diabetes register with > 1% of practice population.The participating general practices were asked to screen their computerised diabetes register for eligible patients with T2DM (aged > 21 years). The inclusion criteria were: people with T2DM who were taking at least two oral glucose-lowering drugs with maximum tolerated dose and had a latest HbA1c greater than 7.4% (IFCC HbA1c >57mmol/mol) or had been advised in the preceeding six months to add or consider changing to insulin therapy. The exclusion criteria were: patients who were currently using insulin therapy; had difficulty reading or understanding English; had difficulty in understanding the purpose of the study; had visual or cognitive impairment and were mentally ill.

The patients were contacted by a letter from their general practitioners (GPs) and invited to participate in this study. If they agreed, they were sent details of the study (including the

information sheet) and asked to attend an appointment at their regular practice where consent to the study was obtained by the researchers. Practices were incentivised to take part in the trial, receiving a nominal payment to cover legitimate expenses.

Randomisation and concealment:

This was a pragmatic trial and all eligible and willing practices were randomly allocated by computer to two groups: the intervention group used the PANDAs decision aid when making the specified treatment choices and the control group delivered usual care. Each practice was considered a cluster and all patients within the cluster received either the intervention or usual care. The practices were the units of randomisation, since it would have been difficult to allocate two patients in the same practice to different arms of the trial. Blinding of the intervention and assessment of the process measures were not feasible in view of the nature of the intervention studied. A statistician generated the random allocation sequence while a secretary who was not involved in the research study assigned participants to either the intervention or control groups. A researcher and a research nurse enrolled the participants into the study.

Intervention and control groups

The doctors and/or the nurses who were primarily involved in the diabetes care of the practice attended a short training session lasting between one to two hours on how to use the PANDAs decision aid. The training topics covered included the principles of shared decision making, the importance and clinical effectiveness of decision aids, the evidence for various treatment options for poorly controlled T2DM and essential skills in risk communication.[13] The patient participants were given the PANDAs decision aid (Table 1) by the researcher to read and complete prior to the consultation in the waiting room. This was followed by the

consultation with the GP or the practice nurse facilitated by the use of the PANDAs decision aid.

In the control group, the GP and the practice nurse did not receive any training and the PANDAs decision aid was not used. The GPs or the nurses conducted a normal consultation with the patient.

Table 1: Content of the PANDAs decision aid

The PANDAs Decision Aid contains the following information in line with the International Patient Decision Aid Standards criteria:

1. Information about the insulin and other treatment options
   - Reasons for starting insulin
   - The procedure of insulin injection
   - Common concerns about insulin
   - Treatment options: Make no change; lifestyle modification; insulin therapy
2. Present probablities of outcomes
   - The advantages and disadvantages of each option were described in words, numbers and pictures ('smiley faces')
3. Patient value clarifications
   - A list of patients' values about the advantages and disadvantages of insulin therapy
4. Structured guidance

Outcome measures and follow-up

Primary outcome measure:

The primary outcome measures were decisional conflict based on the Decisional Conflict Scale score,[14 15] (immediate) used as an indicator of decision quality and glycaemic control (glycosolated haemoglobin, HbA1c) at six months.

Secondary outcome measures:

Knowledge and realistic expectations of the risks and benefits were assessed by asking the patients to indicate their perceived chance of experiencing the side effects of insulin therapy and diabetic complications.

Operational definitions of the secondary outcome measures were agreed as (1) knowledge: about the treatment option that is most effective in reducing blood glucose level and diabetic complications; (2) realistic expectations: a self-reported chance of experience hypoglycaemia, gaining weight and developing complications; (3) preference option: preferred treatment options of initiate insulin, adhere more to diabetes advice more regularly or make no change; (4) participation in decision making: using the Control Preference Scale scores and (5) regret: using the Regret Scale scores.

The secondary measures were other decision quality indicators (knowledge of treatment options, realistic expectation, preference option, proportion undecided, participation in decision making); duration of consultation; and outcome of decision making (regret and persistence with the chosen option).

The practice provided the baseline and six-month follow up data. Baseline data comprised: practice and clinician profile, patients' socio-demography, diabetes profile (duration, complication, prescription, glycaemic control), comorbidities (e.g. hypertension, coronary artery disease, dyslipidaemia, chronic kidney disease); and previous T2DM education. Immediate post-intervention data collected were: decision quality indicators and duration of consultation. Six-month data comprised: HbA1c, regret score and persistence with the decision.

Instruments:

Decisional conflict scale (DCS)

The DCS measures personal perceptions of (a) uncertainty in choosing options; (b) modifiable factors contributing to uncertainty such as feeling uninformed, unclear about personal values and unsupported in decision making; and (c) effective decision making such as feeling the choice is informed, value-based, likely to be implemented and expressing satisfaction with the choice. It was derived from the decisional conflict construct.[16] The traditional 16-item DCS with five response categories was used in this study. There are five subscales: 'uncertainty subscale'; 'informed subscale'; 'values clarity subscale'; 'support subscale'; and 'effective decision subscale'.[14] The DCS has been shown to be reliable and is correlated with the constructs of knowledge, regret and discontinuance, and has the ability to discriminate between those who make and delay decisions. Scores lower than 25 are associated with implementing decisions while scores exceeding 37.5 are associated with decisional delay or feeling unsure about implementation.[15]

Control preference scale (CPS)

The CPS measures the preferred or actual role in decision making.[17] It consists of five items: two represents active or patient controlled role; one a shared or collaborative role; and two items represent a passive or practitioner controlled role. It has proven validity and reliability in both general public and patients with medical conditions.[17 18] A recent study found a good inter-rater reliability and good agreement between self and researcher ratings on Control Preference Scale.[19]

Regret scale

This scale measures 'distress or remorse after a (health care) decision'. It is a five-item scale with five responses (1 strongly agree to 5 strongly disagree). Regret is measured at a point

where the respondent can reflect on the effects of the decision that has been made. A score of 0 means no regret while a score of 100 means high regret. The regret scale correlates with satisfaction with the decision, decisional conflict and overall quality of life.[20]

Sample size and statistical analysis (HbA1c)

Assuming an intracluster correlation coefficient of 0.047 for HbA1c[21] and a cluster sample size of 5 patients per practice, with 80% power and 5% (two-sided) significance, 160 patients in each group are required to allow the detection of 0.5% (SD 1.5%) difference in HbA1c.[22] The total number of Practices required, therefore, was estimated to be 64. When using the total DCS score as the primary outcome measure and using a similar method to calculate sample size, the total number of participants needed was 86 and the total cluster size was estimated to be 17. We aimed for the larger sample size for the design of this study.

The outcome variables, were treated as continuous and we used multiple regressions with generalised estimating equations (GEE) and exchangeable correlation to allow for clustering. Multiple logistic regression with GEE was used for binary outcomes in the secondary analysis. If a patient in the intervention arm refused to use the decision aid, they were still included in the intervention group for analysis and were analysed according to the intention-to-treat principle.

Results

Study practices profile (Table 2)

Forty-nine general practices were recruited into the study. The practices in both arms of the study were well matched in terms of mean list size, mean diabetes list size, mean number of partners and practice nurses and mean Index of Multiple Deprivation Scores.

Table 2 Study practice profile (mean and range)

	Intervention	Control
Number of Practices	25	24
List Size	7,510 (3,129-20,900)	7,325 (1,974-13,500)
People with diabetes	350(96-912)	356 (143-634)
No of partners	5 (1-13)	5 (2-10)
No of practice nurses	3 (1-6)	3 (1-5)
IMD* score	30.35 (range 8.9 - 59.5)	30.20 (range 6.5 - 55)

*Index of Multiple Deprivation

Participants

182 patients were assessed for eligibility, of whom seven were excluded for not meeting the inclusion criteria (n=5), or declined to participate (n=2). 175 patients were randomised, of whom 95 were allocated to the intervention group and 80 to the control group. Six participants in the intervention group were lost to follow-up (3 died, 1 moved away and 2 withdrew their consent), and 2 participants in the control group were also lost to follow-up (1 died and 1 moved away). The results from 167 participants were analysed (89 interventions and 78 controls) (Figure 2).

Table 3 compares the socio-demographic and clinical profiles of patients between intervention and control groups. The mean age of the patients was 64.6 years (range 39 – 87). The patients in the intervention group and control group were broadly similar except that the patients in the intervention group were older and more likely to have coronary heart disease. In both groups the patients were more likely to consult nurses for diabetes related conditions than a doctor (mean number of consultations with nurses and GPs were 2.03 and 1.15 respectively). The mean length of the initial consultation for patients, when entering the

study, in the intervention and control groups was 15.31 and 16.95 minutes respectively (mean difference 1.67min, 95% CI 0.93 to 4.27 mins).

Table 3. Baseline patient socio-demographic and clinical information of the intervention and control groups (mean and range unless otherwise stated)

	Intervention	Control
Socio-demographic profile		
Number	95	80
Demography		
Age (years)	66 (39 – 82)	62 (42 – 87)
Male (%)	50 (52%)	46 (57%)
Duration of education (years) (SD)	12.22 (4.83) (8 – 45*)	11.49 (2.74) (2 – 22)
Ethnicity white (%)	85 (89.5%)	71 (88.8%)
Clinical profile		
Duration of diabetes (years) (SD)	8.4(4.1)(1 – 25)	7.07(3.83) (1 – 16)
HbA1c (IFCC HbA1c mmol/mol) in past 12 months (%) (SD)	8.6 {70}(1.9) (7.4 – 13.1){57-120}	8.8 {73}(0.98) (7.5 – 11.5){58-102}
Number with diabetic complications (%)		
Coronary Heart Disease	29/93 (31.1)	13/80 (16.2)
Peripheral vascular disease	3/93 (3.22)	3/80 (3.75)
Stroke	8/93 (8.6)	5/80 (6.25)
Retinopathy	20/93 (21.5)	10/80 (12.5)
Nephropathy	5/93 (5.37)	10/80 (12.5)
Neuropathy	5/93 (5.37)	3/80 (3.75)
Number with co-morbidities (%)		
Hypertension	58/93 (62.3)	43/80 (53.75)
Dyslipidaemia	52/93 (55.9)	38/80 (47.5)
Health Service Utilisation		
Number of diabetes-related visits to the general practice in the past 6 months (SD)		
General Practitioners	0.92 (1.13)	1.41 (1.68) (0–11)
Nurse	2.15 (1.84)	1.89 (1.36)
Number of diabetes-related visits to the hospital in the past six months (SD)	0.51 (0.87)	0.45 (0.67)
Length of consultation (min)	15.31 (2 – 39)	16.95 (5 – 45)

*Self report (sic)

Decisional Conflict

The mean difference between the intervention and the control groups on the total score for decisional conflict was -7.72 (95% CI -12.5 to -2.97). The distribution of decisional conflict

sub-scores are shown in Table 4**.** The total and subscores for every decisional conflict domain, apart from the support sub-score, were significantly lower in the intervention group. The difference in uncertainty, informed, value clarity and effective decision subscores between the intervention and control groups remained statistically significant after adjusting for differences in age, education and gender.

Table 4: Comparison of decisional conflict scores between the intervention and control groups (0=no decisional conflict, 100=maximum decisional conflict).

Subscore	Intervention	Control	Mean difference unadjusted	Mean difference adjusted*	95% CI p value
Uncertainty	20.1 (16.6)	29.4 (20.8)	-9.29	-8.72	-14.9 to -2.53 p=0.006
Informed	18.1 (13.3)	26.0 (16.6)	-7.65	-8.69	-13.3 to -4.10 p<0.001
Values Clarity	16.7 (13.9)	26.7 (18.2)	-9.74	-9.84	-14.8 to -4.84 p<0.001
Support	17.4 (13.1)	20.8 (15.3)	-3.41	-3.66	-8.58 to 1.25 p=0.144
Effective Decision	16.1 (14.4)	23.3 (15.2)	-9.70	-9.80	-16.8 to 2.75 p=0.006
Total Score	17.4 (12.6)	25.2 (14.9)	-7.67	-7.72	-12.5 to –2.97 p<0.001

* adjusted for age, education and gender

Glycosolated Haemoglobin (HbA1c)

Table 5 shows the HbA1c levels for both the intervention and the control groups at six months. HbA1c levels reduced in both groups at six months compared to baseline (0.24% in the control group and 0.37% in the intervention group). The mean difference in the HbA1c level at 6 months between the two groups was 0.351 (95%CI -0.088 to 0.789, p=0.117) after adjusting for age, education, gender, baseline HbA1c, insulin status and clustering.

Table 5: The effect of the PANDAs decision aid on HbA1c at 6 months

Intervention	Control	Mean difference in HbA1c unadjusted	Mean difference in HbA1c adjusted*	95% CI
8.64 (SD 1.37)	8.40 (SD 1.31)	0.244	0.351	-0.088 to 0.789

* adjusted for age, education, gender, baseline HbA1c, insulin status and clustering. P=0.117

Secondary outcomes:

Knowledge

A comparison of the proportions of patients who answered the 'knowledge' questions correctly between the intervention and the control groups showed there were more patients in the intervention group who answered the questions correctly compared to those who received 'usual care'. (Table 6)

Table 6: Secondary outcomes: Knowledge and realistic expectations (Questions answered correctly)

	Intervention Decision Aid	Control Usual Care	Unadjusted Odds Ratio	Adjusted[+] Odds Ratio (95% CI)	ICC	p value
Knowledge						
Number	95	80				
Which choice has the greatest chance of lowering your blood sugar?	49 (51.6%)	23 (28.8%)	2.63	1.31 (1.14 to 1.50)	0.071	<0.001
Which choice has the greatest chance of lowering your complications?	29 (30.5%)	23 (28.8%)	1.09	1.20 (0.07 to 19.05)	0.202	0.90
Realistic expectations						
If you take insulin, about how many times might you experience 'hypos' in a year?	77/95 (81.0%)	4/75 (5.2%)	77	^	-	<0.001[*]
If you take insulin, about how much more weight might you gain in a year?	67/95 (70.5%)	4/75 (5.3%)	42.5		-	<0.001[*]
Out of 100 people like you	25/95 (26.3%)	4/80 (5%)	^		-	<0.001[*]

who take insulin, how many may get complications in five years?					

[+] adjusted for clustering, insulin initiation, age, gender and education level
[^] Numbers answering correctly in the control group were too few to control for clustering.
[*] Chi-squared p value

Realistic expectations

Patients who used the decision aid had significantly more realistic expectations about the side effects of insulin therapy compared to those who did not (Table 6). Almost all patients in the intervention group, compared to those of the control group, knew correctly their risk of hypoglycaemia (81.0% vs 5.2%, p<0.001) and weight gain (70.5% vs 5.3%, p<0.0010). More people knew their risk of complications in the intervention group if they were to take insulin, although most still got it wrong (26.3% vs 5.0%, p<0.001).

Preferred option

Table 7 shows that the preferred choices of patients in the intervention and control groups were similar after consultation.

Table 7: Preferred choices of patients in intervention and control groups post-consultation

	Make No Change	Follow the diabetes advice more regularly	Start insulin	I am not sure	Total
Control	33 (42.3.8%)	29 (37.1%)	9 (11.5%)	7 (9%)	78
Intervention	32 (34.7%)	38 (41.3 %)	17 (18.4%)	5 (5.4%)	92
Total	65	67	26	12	170

(X^2_3=2.88, p =0.410)

Proportion undecided

Table 8 shows that patients in the intervention group were over 3 times more likely to change from undecided to decided than in the control group, although, this was not statistically significant (P=0.15).

Table 8: Comparison of the proportion of patients who remained undecided between the intervention and control group immediately after intervention

	Intervention	Control	OR	95%CI
Undecided - preconsultation	23/95	14/80		
Undecided – post-consultation	8/95	9/80		
Odds in favour of changing: decided after and undecided before/undecided after and decided before	18/3*	11/6	3.27	0.69 to 16.3 (p=0.15)

*this means 18 patients changed from undecided to decided in the intervention group and 3 moved in the opposite direcntion. In the control group the corresponding numbers were 11 and 6

Participation in decision making

There were significant differences in patients' decision making role between the intervention and control groups (p=0.012 Chi square) (Table 9). It may be seen that a smaller proportion of patients in the intervention group described their decision about their diabetes treatment as "passive" or "collaborative".

Table 9: Decision making roles of patients in the intervention and control groups, post consultation with their doctor/nurse

	How did you make your decision about your diabetes treatment? (n = 169)			
	Passive	Collaborative	Autonomous	Total
Control	16 (21%)	28 (36%)	33 (43%)	77 (100%)
Intervention	8 (9%)	25 (27%)	59 (64%)	92 (100%)

(X^2=8.9, df=2, p=0.012)

However, patients in the intervention arm were more likely to demonstrate autonomy in their decision making about their treatment compared to the control group (64% compared to 43%). Further analysis showed that an individual patient was 1.23 (95% CI 1.05 to 1.44, p=0.008) times more likely to make an 'autonomous' decision using the PANDAs decision aid when the intervention and control groups are compared, allowing for age and gender.

Regret and persistence with decision

Table 10 shows that there was no difference at 6 months in the regret scale, but that patients in the intervention group were rather more likely to persist with their chosen option.

Table 10: Comparison of the decision Regret Score and persistence with chosen option between the intervention and usual care groups after six months

	Intervention	Control	Mean difference unadjusted	Mean difference adjusted*	p value
Regret Score	44.63	44.57	0.06	0.22 (-2.48 to 2.93)	0.872
Persistence with chosen option	68.1%	56.3%	1.65†	1.17^ (1.00 to 1.36)	0.041

* adjusted for age, education, gender, baseline HbA1c, insulin status and clustering
†Crude odds ratio
^Adjusted odds ratio

Discussion

The PANDAs decision aid was designed to facilitate decision making between clinicians and their patients with T2DM who were taking at least two oral glucose-lowering drugs at maximum tolerated dose, had a high HbA1c level and were considering future treatment options including the introduction of insulin. Its evaluation was based on the IPDAS recommendations [23] and the use of the ODSF Framework.[24] The PANDAs trial provides good

evidence not only for the clinical effectiveness of decision aids in usual NHS general practice but also for the utility and feasibility of use by both nurses and doctors. In addition, the PANDAs decision aid itself and its use were both effective and acceptable to people with diabetes making treatment choices during clinical consultations.

Decision quality

The findings from the PANDAs trial support the results of other studies which have evaluated the clinical effectiveness of decision aids[11 14] in demonstrating an improvement in decision quality when a decision aid is used in clinical consultations.

Decisional conflict scores, for example, when adjusted for age, education and gender were significantly lower in the intervention group post consultation when compared to the controls, apart from the support sub-score. It is interesting to note that the support sub-score in the intervention group was not significantly lower than the control group - this may be the result of a 'ceiling effect' since patients in both the intervention and control groups may already have been receiving very good diabetes care from their general practices.

Other indicators of decision quality used in the study also demonstrated an improvement when PANDAs was used in consultations – there was, for example, a highly significant difference in the knowledge of people which particular treatment choice had the greatest chance of lowering blood sugar in those who used the decision aid - although this was not the case when the chance of insulin in lowering complications was considered - here no difference in knowledge was observed. Some patients believe that insulin itself causes complications as a result of misperception [25 26] and this may explain why knowledge did not improve in the intervention group. However, highly significant differences were observed

between the intervention and control groups in all the three domains of realistic expectations ['hypos', weight gain and complications] supporting the notion that the PANDAs decision aid ensured that people were fully informed about the potential risks of each option when making their treatment choices.

As far as autonomy was concerned, patients in the intervention arm were more likely to make an autonomous decision using PANDAs when the intervention and control groups were compared allowing for both age and gender. This is consistent with the findings of other studies. [27 28]

These findings of an improvement in decision quality when a decision aid is used in clinical consultations in other conditions and contexts are also supported by a large number of other studies. [22,29]

Decisional Outcomes

The glycaemic control improved in both groups six months after the intervention although no significant difference in glycaemic control was observed between the two groups. Some GPs in the study expressed concern at the start of the trial that glycaemic control could deteriorate in some patients in the intervention group as a result of them choosing not to start insulin. However, this was clearly not the case as may be seen from these data.

Treatment decisions made using a decision aid should, of course, be ones that are both informed and value-based, and the PANDAs intervention was focussed on the process of decision making rather than the outcomes of those decisions. It is therefore important to note that PANDAs was not designed to persuade people to start treatment with insulin but to help

them make an informed treatment decision which was consistent with their values and wishes.

Indeed, there was reduced decisional conflict within the intervention group compared to the control and the decisions which were made were far more likely to be autonomous in nature rather than passive. Participants in the intervention group were also significantly more likely to persist with their chosen option at 6 months. This supports the hypothesis that people who use a decision aid such as PANDAs are more likely to make an informed and value-based decision and are therefore more likely to persist with their treatment choice. Concordance with agreed treatment is, in turn, more likely to lead to better health outcomes and quality of life.

No significant difference was observed on the regret scale scores and although people in the intervention group were over three times more likely to change from undecided to decided [ie come to a treatment decision after their consultation] in the control group, this difference was not statistically significant.

Finally, no significant difference was observed in the preferred choices [ie the treatment decision they came to] of the two groups although a higher proportion of people in the intervention group did choose to initiate insulin. However it is important to note that the use of a decision aid is not intended to produce a particular outcome but to support the patient making a treatment choice based on their knowledge and values. These findings are also consistent with current understanding of the anticipated decisional outcomes when a decision aid such as PANDAs is used in clinical consultations to make treatment choices. [29]

Impact on Clinical Practice

The results of the PANDAs trial demonstrate that the use of the decision aid in usual general practice by both practice nurses and GPs, provided the patient has the opportunity to complete their individualised decision aid prior to their consultation, does not require significant additional consultation time**.** Given the potential benefits of improved adherence to treatment choices and an improved therapeutic relationship between clinicians and their patients, this is likely to make the use of the decision aid acceptable to all parties in general practice, although, its use may require some initial 'investment' in consultation time. In particular, both clinician and patient satisfaction with their consultations, as well as the healthcare provided and received, are both likely to be increased. A further potential advantage is that the decision aid could be used by other clinical members of the primary care team (eg healthcare assistants) potentially increasing the consultation time available to doctors and nurses for other patients. However, the efficient use of the decision aid in consultations may in part be attributed to the familiarity of the clinicians with the decision aid as a result of the brief training clinicians received at entry to the trial. In addition, this may also be due to the process by which the decision aid was developed with the active involvement of both clinicians and people with diabetes to ensure that it was as 'user friendly' as possible. This involvement of users in the development of the decision aid and a process evaluation of its use in the consultation by both parties will be described elsewhere.

Health service utilisation

The PANDAs trial was a pragmatic one reflecting the reality of primary care diabetes clinics which are mainly run by practice nurses. The mean number of consultations with the nurses,

for example, was greater than the mean number of consultations with the GPs and within the intervention group patients were more likely to use the PANDAs decision aid with the practice nurse than the GP. At baseline the distribution of the mean number of diabetes related general practice visits was different in the intervention and control groups with the practice nurses providing more clinical care to people with diabetes in the former reflecting different patterns of care in the different practices.

Patient decision aids

The PANDAs decision aid is one of the few decision aids which focus on decision making in chronic diseases, which take place over several consultations. According to the latest Cochrane Decision Aid Inventory, 10 decision aids have been developed for diabetes.[29] Four decision aids focus on insulin treatment, of which two are for children, one for adults deciding on premixed insulin and one for insulin initiation in T2DM (PANDAs decision aid). However, unlike PANDAs, none have been developed for making treatment decisions about glycaemic control.

Although decision aids have positive effects on many aspects of the decision making process, there remains a large gap in the literature on how decision aids fare "in the real world". O'Cathain and Thomas (2004) conducted a pragmatic trial of decision aid in a maternity ward and found that health professional were not making use of the available decision aids, although they reported that they approved of them. The reasons for not using them included 'disagreement' with the available decision aids, lack of resources, perceived patients' reluctance to participate and unwillingness to change their "routine care".[30] O'Donnell, Cranney et al, classified the barriers to the use of decision aids in the clinical situation under

three categories – the nature of the decision aid itself, the attitudes of patients and healthcare professionals and organisational barriers such as institutional culture and commitment, time constraint and costing. [31]

A number of authors have proposed various strategies to facilitate such use of decision aids in different clinical settings.[32] The effectiveness of these proposed strategies has not yet been formally evaluated. The PANDAs trial however found the decision aid to be highly acceptable to both clinicians and people with diabetes in NHS general practice – a detailed process evaluation of its use can be found elsewhere. This report identifies some of the key challenges to its widespread implementation in NHS general practice.

However, most studies of decision aids have not shown an increase in the level of satisfaction with the decision making process or the decision itself. This may be another example of the 'ceiling effect' whereby the satisfaction with the service or consultation was already high before the intervention. It has also been observed that people tend to report satisfaction after they have made the decisions because they tend to "rationalise" and adapt quickly to uncertain events.[33] Moreover, the effect of decision aids on quality of life and health outcomes indicators which are commonly used in health technology assessments, have yet to be proved. More plausible intermediate outcomes, such as concordance with treatment and health service utilisation, could be used as alternative indicators to evaluate the use of decision aids.

General practice is a unique healthcare setting where multidisciplinary teams provide holistic, comprehensive and continuity of care to people in the community. Practitioners usually have an established relationship with their patient and an appreciation of their medical and

psychosocial background as well as their associated multi-morbid conditions. This puts them in a very good position to advise patients on their treatment options. The use of decision aids to facilitate treatment choices in general practice fits well with the adoption of a Care Planning model for long-term conditions. This model of care, developed by the Diabetes UK Year of Care Programme and recently adopted as a professional standard by the RCGP, is a good way of ensuring that patients with diabetes are both fully informed and fully involved in decisions about their care by supporting their "empowerment" and facilitating the "activation" of people with long-term conditions. [34,35]

Implications for research and clinical practice

For the use of patient decision aids, such as PANDAs, in routine clinical practice to become the accepted norm, the new GP clinical commissioning groups will need to be aware of the benefits of the use of such aids to ensure that decision aids become a professional standard in, for example, newly commissioned pathways for a long-term condition such as diabetes. Investment will also be necessary for the development and the continuing evaluation of decision aid use, as well as for the training of all members of the multidisciplinary team in the importance and in the practical use of decision aids in primary care. Both the patient's experience and patient/clinician satisfaction with the care received and provided is likely to be much improved if this professional standard is adopted by commissioning groups.

Conclusions

The use of the PANDAs decision aid by health care professionals in usual NHS clinical practice with T2DM patients who are making treatment choices in general practice improves decision quality by reducing decisional conflict, improving knowledge and promoting realistic expectations but has no demonstrable effect on glycaemic control.

Patient autonomy however is strengthened by the use of the decision aid and longer term clinical outcomes are likely to be improved. A larger trial of the PANDAs decision aid will be necessary to determine if biomedical parameters are improved when the decision aid is used in normal NHS practice.

Strengths and limitations of this study

The study failed to achieve its planned sample size as a result of recruitment difficulties. The reasons for this were the increase in availability of new oral and injectable glucose lowering drugs which were not available at the start of the project, significant staff changes in 2008/9 and the reluctance of practices to participate in the study because of a potential H1N1 flu pandemic in summer 2009. As a result each practice was only able to identify 3-5 eligible patients for inclusion in the trial. It proved impossible to secure a funded time-extension to the study and as a result recruitment ceased at 175 participants. This meant that the study was underpowered to detect a difference of 0.5% in HbA1c between the two groups. The original recruitment period was 12 months but because of the problems surrounding recruitment outlined above, recruitment was extended to 20 months. There was also some evidence of inadvertent recruitment bias with 95 participants allocated to the intervention group and 80 to the control group. This is an important and well recognised consequence of a cluster RCT design and is probably the result of the PANDAs practices being more likely to recruit participants to the trial. There were some differences in baseline characteristics between the intervention and the control and these were included in an analysis which explored how the estimates of the treatment effect changed when baseline differences were controlled for.

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Substantial contribution to conception and design, acquisition of data or analysis and interpretation of data:

NM, CJN, MCJ, BC, AB, IB

Drafting the article or revising it critically for important intellectual content:

NM, CJN, MCJ

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CONFIDENTIAL

Starting Insulin

Your Choice

When your diabetes tablets are not controlling your blood sugar ...

Do you need to add insulin?

This decision aid is for you if:

- You have type 2 diabetes
- Your blood sugar is not well controlled with your diabetes tablets
- Your doctor or nurse has advised you to add insulin

The University Of Sheffield.

This decision aid will guide you through the decision whether or not to start insulin. It will:

- Give you information about the treatment choices you have when you blood sugar is not well controlled
- Give you information about the advantages and disadvantages of starting insulin
- Help you to think about what is important to you when making the decision
- Help you find out what support you will need when making the decision
- Help you to decide which treatment choice you prefer

Your doctor or nurse will discuss with you about your decision after you have completed this decision aid.

1. Is there a need to start insulin?

- People with type 2 diabetes usually need insulin when their blood sugar is high despite taking tablets and having a healthy lifestyle.
- This usually happens 5 to 10 years after the diagnosis when the body no longer produces enough insulin. The only way to have enough insulin in the body is to take insulin injections.
- There are reasons why the blood sugar should be kept under control:
  - High blood sugar can damage your eyes, heart, kidneys, nerves and blood vessels. Damage can lead to blindness, heart attacks, kidney failure, leg amputations and strokes.
  - High blood sugar may make you feel thirsty, tired, pass urine more often, lose weight, have blurry vision, or have skin and urine infections.
- Insulin can improve the blood sugar level and prevent the complications or stop them from getting worse. It also helps to reduce the symptoms of diabetes.

2. What happens when people take insulin?

- Insulin is added to your diabetes treatment while you continue with your tablets, diet and exercise. For most people, only one insulin injection at night is required.
- Insulin is given using an injection 'pen'. You can set the dose and press the pen to deliver the insulin through the needle into the skin of your abdomen or the outer part of your thigh.
- Every morning, you check your blood sugar with a meter.
- Your doctor or nurse will explain to you how and when to use the insulin pen and check your blood sugar. You will be followed up regularly by the doctor or nurse until you are confident in using the insulin. You can contact the nurse during working hours if you have any queries about the insulin injections.

3. What are people concerned about when they start insulin?

When people start insulin, they often worry about:

- making changes to their daily life
- the needles, the injections and the pain caused by the injections
- putting on weight
- "hypos" – hypos happens when the blood sugar is too low after taking insulin. It makes you feel dizzy, cold and sweaty. Hypos are treated with sugary drinks and food.

Your doctor or nurse will help to address your concerns.

4. How is diabetes affecting you?

Diabetes can affect people in many ways. Below are some common problems which people with type 2 diabetes may face.

Tick ☑ any that apply to you.

Have you had any of these symptoms OVER THE PAST WEEK?

- ☐ Thirsty
- ☐ Tired
- ☐ Infections
- ☐ Passing urine more often
- ☐ Blurry vision
- ☐ Weight changes (past month)

How would you feel if the symptoms you have now stay the same for the rest of your life?

- ☐ Delighted
- ☐ Pleased
- ☐ Mostly satisfied
- ☐ Mixed (neither satisfied nor dissatisfied)
- ☐ Mostly dissatisfied
- ☐ Unhappy
- ☐ Terrible

Which complications has your doctor or nurse diagnosed?

- ☐ Eye disease
- ☐ Stroke
- ☐ Numbness hands/feet
- ☐ Heart disease
- ☐ Kidney disease
- ☐ Poor leg circulation

Which of the following apply to you?

- ☐ High blood pressure
- ☐ High cholesterol
- ☐ Smoking

5. Do you find it difficult to follow the diabetes advice?

Many people with type 2 diabetes find it difficult to follow the medical advice.

How often have you been following the diabetes advice during the **PAST WEEK?**

How often did you control your **diet?**

☐ Not at all ☐ 1-2 days ☐ 3-4 days ☐ 5-6 days ☐ Daily

How often did you take your **diabetes tablets?**

☐ Not at all ☐ 1-2 days ☐ 3-4 days ☐ 5-6 days ☐ Daily

How often did you **exercise** (e.g. walking, cycling)?

☐ Not at all ☐ 1-2 days ☐ 3-4 days ☐ 5-6 days ☐ Daily

6. What are your choices?

When people with type 2 diabetes have high blood sugar despite taking tablets, they have the following choices:

- **Make no change** and continue with your tablets and present lifestyle. You will return for a review in 3 to 6 months' time.
- **Follow the diabetes advice more regularly (diet, exercise, taking tablets),** and wait 4 to 6 months to see if your blood sugar drops.

  (Your blood sugar is unlikely to improve if you are already careful with your tablets, diet and exercise)
- **Add insulin** and continue with your tablets.

Working through the next 4 steps of this decision aid helps you decide which option to choose.

Step 1: Learn about the choices.....

To make a decision, it is important to know the advantages and disadvantages of each choice.

Choice 1: Make no change

If you make no change, your average blood sugar (HbA1c) will remain at .....% or higher. This is higher than the normal level of 7.4%.

If you decide to make no change to your treatment,

The advantages are:

- You keep to your daily routine
- No insulin injections
- No side effects of insulin

The disadvantages are:

- Continue to have diabetic symptoms (feeling thirsty, tired, pass urine more often, blurry vision, infections and weight changes)

Your chance of getting complications in 5 years is:
(heart disease, stroke, kidney disease, eye disease, numbness, poor circulation)

Sticker to go here

symbols mean stronger study results. or symbols mean weaker study results.

Choice 2: Follow the diabetes advice more regularly (diet, exercise, taking tablets)

This choice is not useful to you if:

- you are already following the diabetes advice carefully
- you are unlikely to follow the diabetes advice more regularly

If you follow the diabetes advice more regularly, your average blood sugar (HbA1c) will be .....%.
This is the same as your best average blood sugar level (HbA1c) in the past one year.

If you decide to follow the diabetes advice more regularly,

The advantages are:

- No insulin injections
- No side effects of insulin
- Your diabetic symptoms may improve

The disadvantages are:

- have to make changes to your daily routine (diet, exercise, taking tablets)

Your chance of getting complications in 5 years is:
(heart disease, stroke, kidney disease, eye disease, numbness, poor circulation)

Sticker to go here

symbols mean stronger study results. or symbols mean weaker study results.

Choice 3: Add insulin

If you take insulin, your average blood sugar (HbA1c) will drop from .....% to .....%

If you decide to take insulin,

The advantages are:

- Your diabetic symptoms will improve

The disadvantages are:

- Have to make changes to your daily routine
- May feel slight discomfort with the insulin injection
- Have to check your blood sugar regularly
- May put on 6 to 8 pounds in the first year
- May have 'hypos' 3 to 5 times a year

Your chance of getting complications in 5 years is:
(heart disease, stroke, kidney disease, eye disease, numbness, poor circulation)

Sticker to go here

symbols mean stronger study results. or symbols mean weaker study results.

Summary of the 3 choices

Choice 1: Make no change	Choice 2: Follow the diabetes advice more regularly	Choice 3: Add insulin
Average blood sugar (HbA1c) is .....%.	**Average blood sugar (HbA1c) is .....%.**	**Average blood sugar (HbA1c) is .....%.**
Advantages: • Keep to your daily routine • No insulin injections • No side effects of insulin	**Advantages:** • No insulin injections • No side effects of insulin • Your diabetic symptoms may improve	**Advantages:** • Your diabetic symptoms will improve
Disadvantages: • Continue to have diabetic symptoms	**Disadvantages:** • Have to make changes to your daily routine and follow the diabetic advice more regularly	**Disadvantages:** • Have to make changes to your daily routine • Slight discomfort with the insulin injection • Have to check your blood sugar regularly • May put on 6 to 8 pounds in the first year • May have 'hypos' 3 to 5 times a year
Your chance of getting complications in 5 years is:	**Your chance of getting complications in 5 years is:**	**Your chance of getting complications in 5 years is:**
Sticker to go here	Sticker to go here	Sticker to go here

Step 2. Thinking about what is important to you .....

Now you have to consider whether the advantages and disadvantages of these choices are IMPORTANT TO YOU.

Tick ☑ whether each statement is important to you.

Reasons for choosing insulin:	**Yes**	**No**
Is it important to you to reduce your blood sugar?	☐	☐
Is it important to you to reduce your chance of getting complications?	☐	☐
Is it important to you to reduce your diabetic symptoms?	☐	☐
Reasons for not choosing insulin:	**Yes**	**No**
Is it important to you not to have injections?	☐	☐
Is it important to you not to have to check your blood sugar everyday?	☐	☐
Is it important to you not to put on weight?	☐	☐
Is it important to you not to have "hypos" (low blood sugar)?	☐	☐
Is it important to you to keep to your daily routine?	☐	☐
Other reason that is important to you?	**Yes**	**No**
.....	☐	☐

Now, think about which choice has the advantages and disadvantages that are important to you.

Which choice do you prefer? Tick ☑ one

☐ Make no change
☐ Follow the diabetes advice more regularly
☐ Add insulin
☐ Unsure

Step 3: What else do you need to help you make a decision?

Knowledge

Find out how this decision aid has helped you learn the key facts.

Tick ☑ the best answer.

	Make no change	Follow the diabetes advice more regularly	Add insulin
a) Which choice has the greatest chance of lowering your blood sugar?	☐	☐	☐
b) Which choice has the greatest chance of lowering your complications?	☐	☐	☐

If you are unsure about the answer, you can go back to the summary at page 10.

c) If you take insulin, about how many times might you experience 'hypos' in a year?	☐ 3 to 5	☐ 6 to 8	☐ 9 to 11
d) If you take insulin, about how much more weight might you gain in a year?	☐ 3 to 5 pounds	☐ 6 to 8 pounds	☐ 9 to 11 pounds

Check your answers at the bottom of page 14.

Facts

Do you know enough about the **advantages** and **disadvantages** of each choice? ☐ Yes ☐ No

Values

Are you clear about which advantages and disadvantages **matter most** to you? ☐ Yes ☐ No

Support

Have you had enough **support and advice from others** to make a choice? ☐ Yes ☐ No

Uncertainty

Do you feel sure about the **best choice for you**? ☐ Yes ☐ No

Please discuss with your doctor or nurse, if you are still unsure about the decision.

Step 4: What are the next steps?

Are you ready to make a decision? Tick ☑ one.

☐ No, I am not ready ☐ Yes, I am ready

If you are ready to make a decision, which choice do you prefer? Tick ☑ one.

☐ Make no change

☐ Follow the diabetes advice more regularly

☐ Add insulin

If you decide to add insulin,

How motivated are you to do this? Not Motivated ① ② ③ ④ ⑤ Very Motivated

How confident are you that you can do this? Not Confident ① ② ③ ④ ⑤ Very Confident

List the things that might get in the way of doing this:

.....

.....

List the things that will help you to do this:

.....

.....

Answers for the key facts: a. insulin b. insulin c. 3 to 5 times d. 6 to 8 pounds

Notes

You may want to write down:

- Your concerns about starting insulin
- Things that you would like to discuss with your doctor, nurse and family.

This decision aid is not intended to replace the advice of your doctor or nurse.

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Figure 1:

Figure 2:

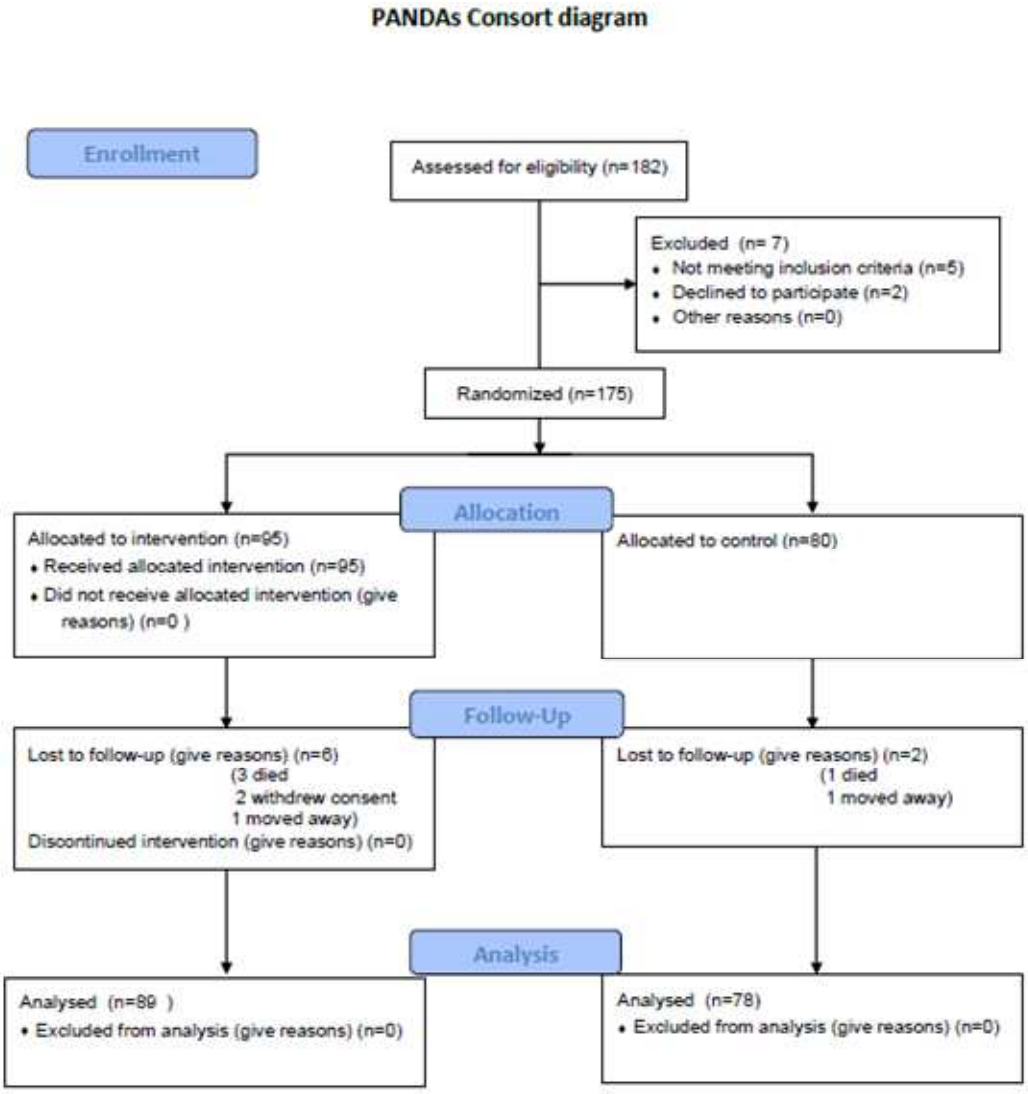
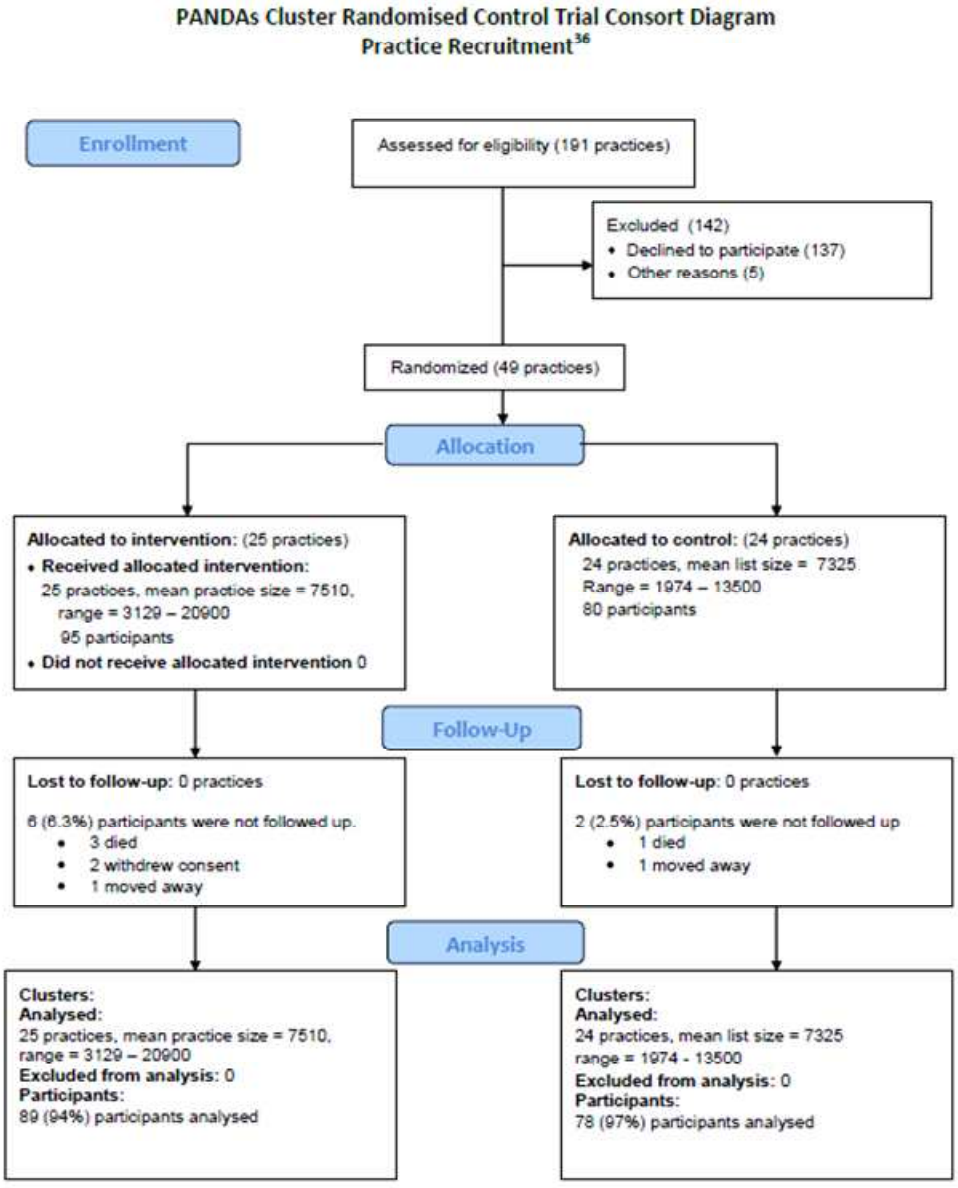


Figure 3:


PANDAs Cluster Randomised Control Trial Consort Diagram
Practice Recruitment[36]
Enrollment
Assessed for eligibility (191 practices)
Excluded (142)
• Declined to participate (137)
• Other reasons (5)
Randomized (49 practices)
Allocation
Allocated to intervention: (25 practices)
• Received allocated intervention:
25 practices, mean practice size = 7510,
range = 3129 – 20900
95 participants
• Did not receive allocated intervention 0
Allocated to control: (24 practices)
24 practices, mean list size = 7325
Range = 1974 – 13500
80 participants
Follow-Up
Lost to follow-up: 0 practices
6 (6.3%) participants were not followed up.
• 3 died
• 2 withdrew consent
• 1 moved away
Lost to follow-up: 0 practices
2 (2.5%) participants were not followed up
• 1 died
• 1 moved away
Analysis
Clusters:
Analysed:
25 practices, mean practice size = 7510,
range = 3129 – 20900
Excluded from analysis: 0
Participants:
89 (94%) participants analysed
Clusters:
Analysed:
24 practices, mean list size = 7325
range = 1974 - 13500
Excluded from analysis: 0
Participants:
78 (97%) participants analysed

The University Of Sheffield.

School Of Medicine & Biomedical Sciences.

Practice Information Sheet

Study Title: ***'PANDAs':*** **Patient Decision Aids for Type 2 Diabetes**
Protocol Ref: **ZH25**
Version: **V6-06-08-2009**

Part 1 tells you the purpose of this study and how your practice will be involved if you take part.

Part 2 gives you more detailed information about the conduct of the study.

Part 1

We would like to invite your practice to take part in a research study. This study will find out whether a patient decision booklet is useful for people with type 2 diabetes who need to make decisions about their diabetes treatment.

Before you decide whether your practice should participate, you need to understand why the research is being done and what it would involve. Please take time to read the following information carefully; talk to others about the study if you wish.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

---

1. What is the purpose of the study?

It is sometimes difficult for patients with Type 2 diabetes to make decisions about the treatment of their illness, especially when it involves taking additional medications or changing to another medication. Informed decision-making not only requires them to know the risks and benefits of the treatment, it also depends on how they feel and think about the treatment. Sometimes, they may not have had opportunity to discuss this information in detail with their doctor or nurse.

A Patient Decision Aid is a simple booklet which contains useful information on diabetes and its treatment. It also explores what patients feel and think about these treatments. It has been used widely to help people to make decisions about their specific illnesses, for example the menopause or a prostate problem.

So the purpose of this study is to find out whether using a patient decision aid before the GP's/Nurse's consultation will improve the quality of patients' decision-making and, eventually, their blood sugar control.

2. Why have I been invited?

Your practice is thought to have at least 1% of its practice population on a practice diabetes register.

3. Do I have to take part?

The participation of your practice is entirely voluntary and it is up to you to decide. We will describe the study and go through this information sheet with you when we visit your surgery if you invite us to do so. We will then ask you to sign a consent form to show you have agreed to take part.

4. What type of study is this?

This is a "Cluster Randomised Trial" in which practices which have consented to participate will be randomly allocated for their participating patients to be given the Patient Decision Aid or to the control group of practices in which normal diabetic practice will be followed.

5. What will happen to my practice if I take part?

If you agree to take part in this study, all GPs and one or two nurses in your practice will be given a *PANDAs* Training Package and the nurses will receive a brief training session at your practice, based on the package. If your practice has been randomised to the Patient Decision Aid, the package will be distributed immediately and this training will take place straightaway. Otherwise the package and training will be offered to your practice at the end of the study, if you wish to opt for this.

However the researchers will, before randomisation, have assisted the practice manager and nurses in how to identify eligible patients based on the following inclusion and exclusion criteria:

Inclusion criteria:
Patients with type 2 DM aged ≥ 21who
- are taking the maximally tolerated doseof oral glucose-lowering drugs at AND have a latest HbA1c ≥ 7.5% throughout the last six months
OR
- have been advised to add or change to insulin therapy but declined previously AND have a latest HbA1c ≥ 7.5%.

Exclusion criteria:
Patients who:
- have a latest HbA1c ≥ 11% unless they have previously declined insulin
- are currently using insulin therapy
- have chronic debilitating illness (including mental illness, visual or cognitive impairment)
- have difficulty understanding English or are unable to read or are without essential reading glasses at the time of consent

Your eligible patients will need to attend your normal clinic twice within six months for the purposes of the study.

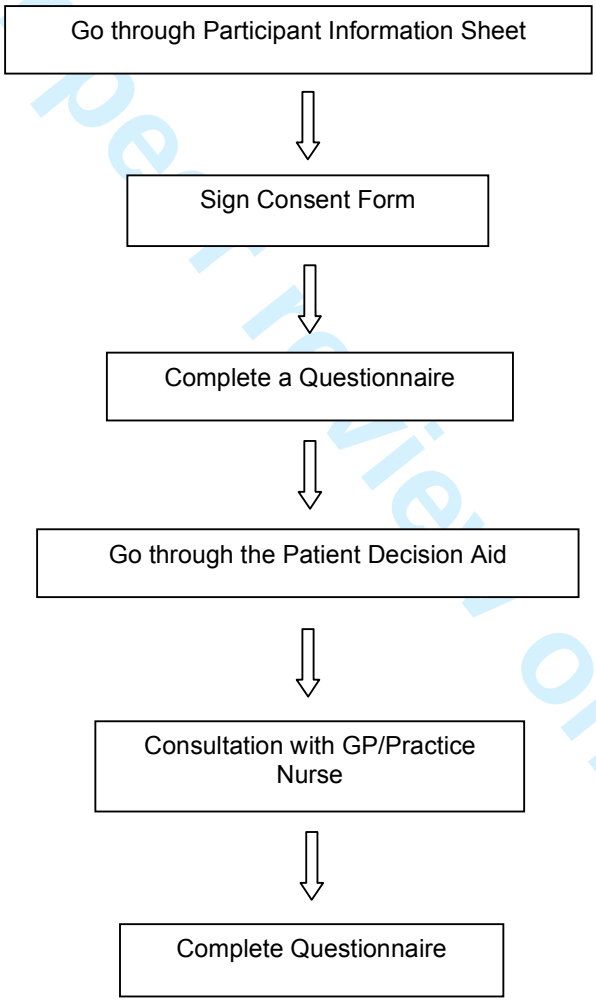
A total of 446 people with type 2 diabetes will be invited to participate in the study and up to 15 would be recruited from your practice until May 2009.

During the first visit, the researcher will go through the Participant Information Sheet with patients. If they agree to participate, the researcher will ask them to sign a consent form, and then to answer a questionnaire (10 minutes).

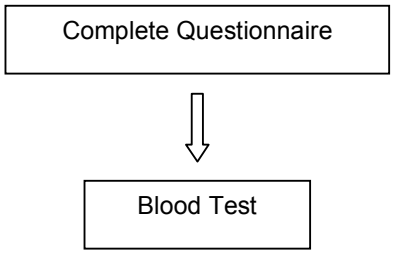
Depending on which treatment group your practice is put into, they will either receive the Patient Decision Aid followed by a consultation with their GP/Practice Nurse or just the consultation without the Patient Decision Aid. Going through the Patient Decision Aid will take 15 minutes. After the consultation, all patients will be asked to fill in another questionnaire (10 minutes).

During the second visit six months later, patients will be asked to answer a questionnaire and a blood sample will be taken to assess their blood sugar level (5 minutes).

Visit 1



Visit 2



6. Expenses and payment

The practice will receive £1,700 for set-up costs, including recruitment of the first consenting patient and then £50 per consenting patient thereafter, to compensate for costs of the time of all practice staff involved (practice manager, GPs, nurses and clerical officers)

At the end of the second visit, your patients will be given a £15 shopping voucher to compensate for the time they have taken to participate in this research.

7. What will the practice have to do?

A one-hour training session will be held at your practice for nurses (and GPs if they wish) on how to use the Patient Decision Aid. For practices in the intervention group this will be given immediately after the practice consents. For practices in the Control group this training will be available on request at the end of the trial.

Each practice will identify 15 eligible participants from the diabetes register and invite them to participate by telephone or mail.

Patients will attend a normal scheduled appointment at a diabetes clinic or a specially allocated appointment if the practice is willing. This appointment will, for practices in the intervention group, be after the proposed date for practice training and no later than 30 June 2009, the proposed closing date for recruitment of patients.

In the intervention group, the participants will use the Patient Decision Aid with the Nurse's assistance.

A questionnaire will be completed for each patient, but the researchers will administer that at your practice.

The GP or Nurse will then counsel the participants as in usual practice.

There will be a follow-up visit at 6-months to check the participants' HbA1c.

Your patients will be required to attend your clinic twice in six months during the study.

During their first visit, they will have to read the Patient Decision Aid, and answer a questionnaire before and after their routine consultation with the Doctor/Nurse. During the second visit, they will have to answer a questionnaire and a blood sample will be taken.

8. What is the procedure that is being tested?

We are testing the use of the Patient Decision Aid, which is a booklet containing evidence-based information about diabetes and its treatment options. It also contains questions which explore their ideas, concerns and values regarding the treatment. So far, more than 500 Patient Decision Aids have been developed in the world for various medical conditions to help patients with their decision-making. It is used to supplement GP- or nurse-led consultations .

9. What are the possible disadvantages and risks of taking part?

The Patient Decision Aid contains information about the possible side effects of different treatment options. Some people may feel anxious after reading this information. However, practice staff and/or the researchers will be able to answer any queries or concerns patients may have during and after the study.

10. What are the possible benefits of taking part?

Previous research on other medical conditions has shown that the use of Patient Decision Aids has helped people to make better-informed decisions about their treatments.

11. What happens when the research study stops?

The practice will continue to provide usual medical care.

12. What if there is a problem?

Any complaint about the way patients have been dealt with during the study or any possible harm they might suffer will be investigated. The detailed information on this is given in Part 2.

13. Will participation of patients in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about patients will be handled in confidence. The details are included in Part 2.

14. Is the purpose of this study educational?

Yes. Part of the data from this research will be used for a PhD study.

This completes Part 1.
If the information in Part 1 has interested your practice and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2

15. What if relevant new information becomes available?

Sometimes we get new information about the intervention being studied. If this happens, the researcher will tell the practice and then the study patients and discuss with them whether they should continue in the study. If patients decide not to carry on, they will be told that their care will be continued by your practice. If they decide to continue in the study, the researcher may ask them to sign an updated consent form.

If the study is stopped for any other reason, we will tell the practice and study patients. The practice will then continue the care of the study patients. The researchers will also keep practices and study patients informed of any new alternative treatment available for their diabetes care.

16. What will happen if patients don't want to carry on with the study?

Patients can withdraw from the study without giving a reason and without it affecting their care. The practice and its patients are also welcome to keep in contact with us to let us know of progress. Information already collected may still be used. Any stored blood samples that can still be identified as yours will be destroyed if you wish.

17. What if there is a problem?

If patients have a concern about any aspect of this study, they should ask to speak to the researchers who will do their best to answer their questions (Contact Brigitte Colwell/Rachel Dwyer at: 0114 271 5824/0114 226 9773 OR Professor Nigel Mathers at: 0114 271 5922). If they remain unhappy and wish to complain formally, they can do this through the NHS Complaints Procedure. Details can be obtained from the GP or the local Primary Care Trust.

In the event that something does go wrong and patients are harmed during the research and this is due to someone's negligence, then patients may have grounds for a legal action for compensation against the NHS but may have to pay their legal costs. The normal National Health Service complaints mechanisms will still be available to study patients.

18. Will patients' participation in this study be kept confidential?

Only the GP/Practice Nurse will have access to patients' medical records. All information collected will be coded and anonymised. The information we have collected as paper copies will be stored under lock and key, while the electronic data can only be accessed with a secure password. Only the researchers, sponsors, regulatory authorities and Research & Development auditors will have access to the identifiable data.

The data we collect will be used only for the purpose of this research; if data were to be used for future studies, further Research Ethics Committee approval will be sought. The data will be kept for 20 years according to the Medical Research Council guidelines.

All information which is collected about patients during the course of the research will be kept strictly confidential, and any information about patients which leaves the surgery will have their name, telephone and address removed so that they cannot be recognised.

19. Involvement of the practice

Patients will be told that the practice has been informed about their participation in this study.

20. What will happen to any samples patients give?

The blood sample patients give will be used to check their HbA1c as part of their routine care.

The blood sample will be collected and sent to a standard laboratory through the surgery. Only the researchers, GPs/Practice Nurse and the laboratory staff will have access to the blood results. An appointment will be arranged by the practice to provide feedback regarding patients' blood results.

21. What will happen to the results of the research study?

The results of this study will be published in medical journals. A summary of the results will be sent to the practice and to study patients by post and you and they will be invited to attend a public seminar.

Patients will not be identified in any report, publications or presentation without seeking their full consent.

22. Who is organising and funding the research?

Sheffield Health and Social Research Consortium is the sponsor of this study and the Department of Health will be funding it. Patients will be told that the practice will be compensated for its costs of including them in this study.

23. Who has reviewed the study?

This study has been reviewed and given favourable opinion by North Sheffield NHS Research Ethics Committee and scientifically reviewed by Sheffield Health and Social Research Consortium as well as the Research for Patient Benefit funding stream of the National Institute for Health Research. Research governance approval on behalf of Sheffield Primary Care Trust has been given by Sheffield Health and Social Research Consortium.

24. Further information and contact details.

General Information about research

Patients and the practice can visit the following web site to obtain more general information about research:

INVOLVE – Promotes public involvement in the NHS: http://www.invo.org.uk

National Electronic Library for Health:

http://www.library.nhs.uk/trials

Specific information about this research project

Ms Brigitte Colwell
Academic Unit of Primary Medical Care
University of Sheffield
Sam Fox House
Northern General Hospital
Herries Road
Sheffield
S5 7AU

Tel: 0114 2715824
Fax: 0114 2422136
Email: b.colwell@sheffield.ac.uk

Advice to your patients as to whether they should participate

Rachel Dwyer
Academic Unit of Primary Medical Care
University of Sheffield
Sam Fox House
Northern General Hospital
Herries Road
Sheffield
S5 7AU

Tel: 0114 2269773
Fax: 0114 2422136
Email: rachel.dwyer@sheffield.ac.uk

Who should patients approach if unhappy with the study

The Chief Investigator:
Professor Nigel Mathers
Academic Unit of Primary Medical Care
University of Sheffield
Sam Fox House
Northern General Hospital
Herries Road
Sheffield
S5 7AU

Tel: 0114 2715922
Fax: 0114 2422136
Email: n.mathers@sheffield.ac.uk

OR

Using the NHS Complaint Procedures, which you can obtain from the surgery or your local NHS Primary Care Trust. You can visit the following web site for more details: http://www.nhs.uk/England/AboutTheNhs/ComplainCompliment.cmsx

The University Of Sheffield.

School Of Medicine & Biomedical Sciences.

Participant Information Sheet

Study Title: **Patient Decision Aid for Type 2 Diabetes**
Protocol Ref: **ZH25**
Version: **V3-22/04/07**

Part 1 tells you the purpose of this study and what will happen to you if you take part.

Part 2 gives you more detailed information about the conduct of the study.

Part 1

We would like to invite you to take part in a research study. This study will find out whether a patient decision booklet is useful for people with type 2 diabetes who need to make decisions about their diabetes treatment.

Before you decide whether to participate, you need to understand why the research is being done and what it would involve. Please take time to read the following information carefully; talk to others about the study if you wish.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

---

1. What is the purpose of the study?

It is sometimes difficult to make decisions about the treatment of your illness, especially when it involves taking additional medications or changing to another medication. Informed decision-making not only requires you to know the risks and benefits of the treatment, it also depends on how you feel and think about the treatment. Sometimes, you may not have had opportunity to discuss this information in detail with your doctor or nurse.

A Patient Decision Aid is a simple booklet which contains useful information on diabetes and its treatment. It also explores what you feel and think about these treatments. It has been used widely to help people to make decisions about their specific illnesses, for example menopause or prostate problem.

Therefore, the purpose of this study is to find out whether using a patient decision aid before the GP's/Nurse's consultation will improve the quality of your decision-making and, eventually, your blood sugar control.

2. Why have I been invited?

Your GP/Practice Nurse has read through your medical notes and they found that your blood sugar is not well controlled. You might need a change in your treatment and this will involve you making a decision what you want to do to improve your blood sugar control.

A total of 446 people with type 2 diabetes will be invited to participate in the study.

3. Do I have to take part?

Your participation is entirely voluntary and it is up to you to decide. We will describe the study and go through this information sheet with you when you attend the clinic. We will then ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason. This would not affect your treatment or the standard of care you receive.

4. What type of study is this?

This is a "Randomised Trial". Sometimes we don't know which way of treating patients is best. To find out, we need to complete different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same to start with, patients from each practice are put into a group by chance.

5. What will happen to me if I take part?

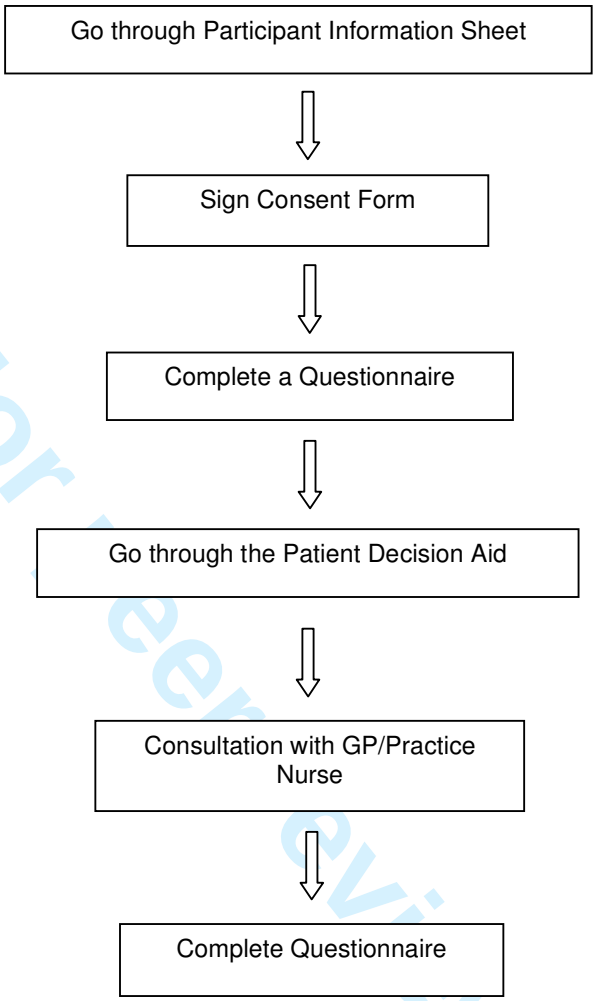
If you agree to take part in this study, you will attend your normal clinic twice within six months. These visits, as far as possible, will coincide with your routine follow-up.

During the first visit, the researcher will go through the Participant Information Sheet with you. If you agree to participate, the researcher will ask you to sign a consent form, followed by answering a questionnaire (10 minutes).

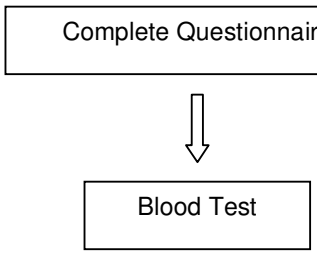
Depending on which treatment group you are put into, you will either receive the Patient Decision Aid followed by a consultation with your GP/Practice Nurse or just the consultation without the Patient Decision Aid. Going through the Patient Decision Aid will take 15 minutes. After the consultation, you will be asked to fill in another questionnaire (10 minutes).

Six months later you will be contacted by a member of the PANDAs research team, prior to being sent a postal questionnaire for you to complete and return to us. We will also need a recent blood sugar level reading, which might mean that you will need to visit your practice to have this done.

Visit 1



Visit 2



6. Expenses and payment

When we have received your completed questionnaire, you will be sent a £15 shopping voucher to compensate for the time you have taken to participate in this research.

7. What will I have to do?

You are required to attend your clinic twice in six months during the study.

During the first visit, you will have to read the Patient Decision Aid, and answer a questionnaire before and after your routine consultation with the Doctor/Nurse. During the second visit, you will have to answer a questionnaire and a blood sample will be taken.

You should not participate in this research if you are currently involved in other drug studies, or have been in the past one-year.

8. What is the procedure that is being tested?

We are testing the use of the Patient Decision Aid, which is a booklet containing evidence-based information about diabetes and its treatment options. It also contains questions which explore your ideas, concerns and values regarding the treatment. So far, more than 500 Patient Decision Aids have been developed in the world for various medical conditions to help patients with their decision-making. It is used to supplement consultations with the doctors and nurses.

9. What are the possible disadvantages and risks of taking part?

The Patient Decision Aid contains information about the possible side effects of different treatment options. Some people may feel anxious after reading this information. However, your GP or nurse as well as the researchers will be able to answer any queries or concerns you may have during and after the study.

10. What are the possible benefits of taking part?

Previous research on other medical conditions has shown that the use of Patient Decision Aids has helped people to make better-informed decisions about their treatments.

11. What happens when the research study stops?

Your GP/Practice Nurse will continue to provide medical care for you.

12. What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be looked into. The detailed information on this is given in Part 2.

13. Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

14. Is the purpose of this study educational?

Yes. Part of the data from this research will be used for a PhD study.

This completes Part 1.
If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2

15. What if relevant new information becomes available?

Sometimes we get new information about the intervention being studied. If this happens, the researcher will tell you and discuss whether you should continue in the study. If you decide not to carry on, your care will be continued by your GP. If you decide to continue in the study, the researcher may ask you to sign an updated consent form.

If the study is stopped for any other reason, we will tell you and your GP will continue your care. We will also keep you informed of any new alternative treatment available for your diabetes care.

16. What will happen if I don't want to carry on with the study?

You can withdraw from the study without giving a reason and without affecting your care. You are also welcome to keep in contact with us to let us know your progress. Information already collected may still be used. Any stored blood samples that can still be identified as yours will be destroyed if you wish.

17. What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (Contact Ms Brigitte Colwell at: 0114 2715824 OR Professor Nigel Mathers at: 0114 2715922). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the GP or the local Primary Care Trust.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence, then you may have grounds for a legal action for compensation against the NHS but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

18. Will my taking part in this study be kept confidential?

Only your GP/Practice Nurse will have access to your medical records. All information will be coded and anonymised. The information we have collected as paper copies will be stored under lock and key, while the electronic data can only be accessed with a secure password. Only the researchers, sponsors, regulatory authorities and Research & Development auditors will have access to the identifiable data.

The data we collect will be used only for the purpose of this research; if data were to be used for future studies, further Research Ethics Committee approval will be sought. The data will be kept for 20 years according to the Medical Research Council guidelines.

All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you which leaves the surgery will have your name, telephone and address removed so that you cannot be recognised.

19. Involvement of the General Practitioner/Family doctor (GP)

Your GP has been informed about your participation in this study.

20. What will happen to any samples I give?

The blood sample you give will be used to check for your sugar control (HbA1c). This is part of your normal routine care.

The blood sample will be collected and sent to a standard laboratory through the surgery. Only the researchers, GPs/Practice Nurse and the laboratory staff will have access to the blood results. An appointment will be arranged by the practice to provide feedback regarding your blood results.

21. What will happen to the results of the research study?

The results of this study will be published in medical journals. A summary of the results will be sent to you by post and you will be invited to attend a public seminar.

You will not be identified in any report, publications or presentation without seeking your full consent.

22. Who is organising and funding the research?

The Sheffield Health and Social Research Consortium is the sponsor of this study and the Department of Health will be funding the research. Your healthcare providers will be paid for including you in this study.

23. Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, well-being and dignity. This study has been reviewed and given favourable opinion by North Sheffield Local Research Ethics Committee.

24. Further information and contact details.

General Information about research

You can visit the following web site to obtain more general information about research:

INVOLVE – Promotes public involvement in the NHS: http://www.invo.org.uk

National Electronic Library for Health:
http://www.library.nhs.uk/trials

Specific information about this research project

Ms Brigitte Colwell
Academic Unit of Primary Medical Care
University of Sheffield
Sam Fox House
Northern General Hospital
Herries Road Sheffield
S5 7AU

Tel: 0114 2715824
Fax: 0114 2715915
Email: b.colwell@sheffield.ac.uk

Advice as to whether you should participate

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Academic Unit of Primary Medical Care
University of Sheffield
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Northern General Hospital
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Fax: 0114 2715915
Email: b.colwell@sheffield.ac.uk

Who you should approach if unhappy with the study

Professor Nigel Mathers
Academic Unit of Primary Medical Care
University of Sheffield
Sam Fox House
Northern General Hospital
Herries Road Sheffield
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OR

Using the NHS Complaint Procedures, which you can obtain from the surgery or your local NHS Primary Care Trust. You can visit the following web site for more details: http://www.nhs.uk/England/AboutTheNhs/ComplainCompliment.cmsx

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For more assistance with Adobe Reader visit http://www.adobe.com/go/acrreader.

Checklist of items to include when reporting a cluster randomised trial

* = addition to CONSORT *Modifications to checklist in italics*			
PAPER SECTION and topic	Item	Descriptor	Reported on Page No.
TITLE & ABSTRACT	1*	How participants were allocated to interventions (e.g., "random allocation", "randomised", or "randomly assigned"), *specifying that allocation was based on clusters*	P1
INTRODUCTION Background	2*	Scientific background and explanation of rationale, *including the rationale for using a cluster design.*	P6
METHODS Participants	3*	Eligibility criteria for participants *and clusters* and the settings and locations where the data were collected.	P7
Interventions	4*	Precise details of the interventions intended for each group, *whether they pertain to the individual level, the cluster level or both,* and how and when they were actually administered.	P8
Objectives	5*	Specific objectives and hypotheses, *and whether they pertain to the individual level, the cluster level or both*.	P6
Outcomes	6*	Report clearly defined primary and secondary outcome measures, *whether they pertain to the individual level, the cluster level or both*, and, when applicable, any methods used to enhance the quality of measurements (e.g., multiple observations, training of assessors).	P9-10
Sample size	7*	How *total* sample size was determined *(including method of calculation, number of clusters, cluster size, a coefficient of intracluster correlation (ICC or k), and an indication of its uncertainty*) and, when applicable, explanation of any interim analyses and stopping rules.	P11-13
Randomisation.			
Sequence generation	8*	Method used to generate the random allocation sequence, including details of any restriction (e.g., blocking, stratification, *matching*).	P7
Allocation concealment	9*	Method used to implement the random allocation sequence, *specifying that allocation was based on clusters rather than individuals and* clarifying whether the sequence was concealed until interventions were assigned.	P7
Implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.	P7
Blinding (Masking)	11	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. If done, how the success of blinding was evaluated.	P7
Statistical methods	12*	Statistical methods used to compare groups for primary outcome(s) *indicating how clustering was taken into account*; methods for additional analyses, such as subgroup analyses and adjusted analyses.	P11
RESULTS Participant flow	13*	Flow of *clusters and* individual participants through each stage (a diagram is strongly recommended). Specifically, for each group report the numbers of *clusters and* participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. Describe protocol deviations from study as planned, together with reasons.	P31-32
Recruitment	14	Dates defining the periods of recruitment and follow-up.	Practices: Aug 2008-Jul 2010; Patients Nov 2008-Sept 2010; Follow-up March 2011
Baseline data	15*	Baseline information for each group *for the individual and cluster levels as applicable*	P34-35
Numbers analyzed	16*	Number of *clusters and* participants (denominator) in each group included in each analysis and whether the analysis was by "intention-to-treat". State the results in absolute numbers when feasible (e.g., 10/20, not 50%).	P35

Outcomes and Estimation	17*	For each primary and secondary outcome, a summary of results for each group measures *for the individual or cluster level as applicable*, and the estimated effect size and its precision (e.g., 95% confidence interval) *and a coefficient of intracluster correlation (ICC or k) for each primary outcome.*	P36-7
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory.	n/a
Adverse events	19	All important adverse events or side effects in each intervention group.	n/a
DISCUSSION Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision and the dangers associated with multiplicity of analyses and outcomes.	21-22
Generalisability	21*	Generalisability (external validity) *to individuals and/or clusters (as relevant)* of the trial findings.	23
Overall evidence	22	General interpretation of the results in the context of current evidence.	22

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Clinical effectiveness of a patient decision aid to improve decision quality and glycaemic control in people with diabetes making treatment choices – a cluster randomised controlled trial (PANDAs) in General Practice

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Clinical effectiveness of a patient decision aid to improve decision quality and glycaemic control in people with diabetes making treatment choices – a cluster randomised controlled trial (PANDAs) in General Practice.

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ARTICLE FOCUS:

- Does the use of the PANDAs decision aid in general practice improve decision quality and glycaemic control in people who are making treatment choices about their type 2 diabetes mellitus (T2DM) treatment, including whether or not to start insulin?

KEY MESSAGES:

- Patient decision aids provide evidence-based information about treatment options, help patients to clarify their values and guide them systematically to make an informed decision.
- The use of the PANDAs decision aid by doctors and nurses in usual NHS general practice with people who have T2DM and are making treatment choices reduces decision conflicts and improves knowledge, realistic expectations and patients' involvement in decision making.
- HbA1c levels were reduced in both groups at six months when compared to baseline (0.24% controls and 0.37% intervention) with a non-significant mean difference between the two groups of 0.351, p=0.117).

STRENGTHS AND LIMITATIONS

- This study was underpowered to detect a minimally, clinically important difference in glycaemic control between the two groups due to slow recruitment.
- There was no blinding in this study due to the nature of the intervention which may have influenced the outcome assessment.
- This was a pragmatic trial and there may have been variations in how the decision aid was used in different General Practices which may have diluted the effect of the study.

Abstract

Objective

To determine the effectiveness of a patient decision aid (PDA) to improve decision quality and glycaemic control in people with diabetes making treatment choices using a cluster RCT.

Design

A cluster randomised controlled trial.

Setting

49 general practices in UK randomised into intervention (n=25) and control (n=24).

Participants

General Practices: Inclusion criteria: > 4 medical partners; list size > 7000; and a diabetes register with > 1% of practice population. 191 Practices assessed for eligibility, 49 Practices randomised and completed the study.

Patients: People with T2DM taking at least two oral glucose-lowering drugs with maximum tolerated dose with an HbA1c greater than 7.4% (IFCC HbA1c >57mmol/mol) or advised in the preceeding six months to add or consider changing to insulin therapy. Exclusion criteria: currently using insulin therapy; difficulty reading or understanding English; difficulty in understanding the purpose of the study; visual or cognitive impairment or mentally ill. 182 assessed for eligibility, 175 randomised to 95 intervention and 80 controls, 167 completion and anlaysis.

Intervention

Brief training of clinicians and use of PDA with patients in single consultation.

Primary Outcomes

Decision quality (decisional conflict scores, knowledge, realistic expectations and autonomy) and glycaemic control (glycosolated haemoglobin, HbA1c).

Secondary Outcomes

Knowledge and realistic expectations of the risks and benefits of insulin therapy and diabetic complications.

Results

Intervention Group: lower total decisional conflict scores (17.4 v 25.2, p<0.001); better knowledge (51.6% v 28.8%, p<0.001); realistic expectations (risk of 'hypo', 'weight gain', 'complications'; 81.0% v 5.2%, 70.5% v 5.3%, 26.3% v 5.0% respectively, p<0.001); and were more autonomous in decision making (64.1% v 42.9%, p=0.012).

No significant difference in the glycaemic control between the two groups.

Conclusions

Use of the PANDAs decision aid reduces decisional conflict, improves knowledge, promotes realistic expectations and autonomy in people with diabetes making treatment choices in general practice.

ISRCTN Trials Register Number 14842077

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Introduction

Diabetes mellitus is a growing health problem in England with a total of 2.4 million people (5.5% of population) living with the disease in 2011.[1] Diabetes currently accounts for 10% of all NHS expenditure.[2] However, overall diabetes control is less than satisfactory. In 2008/2009, 67% of people with T2DM achieved a glycosolated haemoglobin (HbA1c) of less than 7.5% (IFCC HbA1c 58 mmol/mol).[3]

The UK Prospective Diabetes Study (UKPDS) has established the importance of maintaining good blood glucose control in patients with T2DM. For every 1.0% increase in HbA1c, there is an increase, in risk, of 14% for myocardial infarction, 21% for diabetes-related deaths and 37% for micro-vascular complications.[4] In the same study, it was reported that only 25% were able to achieve good glycaemic control with monotherapy after 9 years of the trial. Most patients will require combination therapy, including insulin, 5-10 years after diagnosis.[5]

Currently, the NICE guidelines recommend a combination of metformin and insulin secretagogues in those who have inadequate blood glucose control with monotherapy. In those in whom dual therapy has been unsuccessful, either insulin or a thiozolidinedione should be added to optimise glycaemic control.[3] Frequently, this poses a clinical dilemma for both patients and healthcare providers; both parties need to agree which next treatment option to pursue and this includes whether or not to start insulin therapy. However, patients may be fearful of needles and the side effects of insulin (e.g. hypoglycaemia); they need to acquire new skills; change their daily routine and address the challenge of glucose monitoring.[6] Similarly, doctors may be hesitant to prescribe insulin due to their own lack of relevant skills, time pressures, and a fear of increasing the risk of side effects.[7 8] In this category of patients,

the decision making process is a complex one. Studies have shown that patients usually make decisions based on emotions such as trust, rather than on the information given by their healthcare providers.[9] For their part, doctors do not necessarily follow evidence-based guidelines[10] and it was in this context that the PANDAs decision aid was developed to facilitate shared decision making between clinicians and patients when making decisions about the treatment of their diabetes at this stage of their illness. The development of the PANDAs decision aid will be described elsewhere.

Patient decision aids are tools that provide evidence-based information about treatment options, help patients to clarify their values and guide them systematically to make an informed decision. Patient decision aids have been shown to improve knowledge, realistic expectations, value-decision concordance and patient involvement in decision making.[11]

The primary research question was “Does the use of the PANDAs decision aid improve decision quality in patients with T2DM who are making a decision whether or not to start insulin in general practice?”.

The study focussed on people with T2DM who had poor glycaemic control (HbA1c >7.4mmol/l or IFCC HbA1c >57 mmol/mol) and who, despite receiving optimal oral glucose lowering therapy, required "step-up" treatment. A cluster randomised controlled trial was carried out to evaluate the clinical effectiveness of the decision aid on decision quality and glycaemic control.

Methods

The setting for this study was general practices in Sheffield, Rotherham and Doncaster with recruitment being undertaken through the National Institute for Health Research Primary Care Research Network (PCRN) and the Cutler Group of South Yorkshire Research Practices. The recruitment of practices and patients began in 2008 and the data collection ended in 2011.

Practices were invited to take part by postal invitation following a publicity campaign using a modified viral marketing technique involving sequential non-specific PANDAs post cards ('PANDAs are coming') to 'pique' interest, followed by increasingly informative flyers (Figure 1). [12]

The inclusion criteria for general practices were: > 4 medical partners; list size > 7000; and a diabetes register with > 1% of practice population.The participating general practices were asked to screen their computerised diabetes register for eligible patients with T2DM (aged > 21 years). The inclusion criteria were: people with T2DM who were taking at least two oral glucose-lowering drugs with maximum tolerated dose and had a latest HbA1c greater than 7.4% (IFCC HbA1c >57mmol/mol) or had been advised in the preceeding six months to add or consider changing to insulin therapy. The exclusion criteria were: patients who were currently using insulin therapy; had difficulty reading or understanding English; had difficulty in understanding the purpose of the study; had visual or cognitive impairment and were mentally ill.

The patients were contacted by a letter from their general practitioners (GPs) and invited to participate in this study. If they agreed, they were sent details of the study (including the information sheet) and asked to attend an appointment at their regular practice where consent to the study was obtained by the researchers. Practices were incentivised to take part in the trial, receiving a nominal payment to cover legitimate expenses.

Randomisation and concealment:

This was a pragmatic trial and all eligible and willing practices were randomly allocated by computer to two groups: the intervention group used the PANDAs decision aid when making the specified treatment choices and the control group delivered usual care. We stratified the practices according to the Practice list size. Each practice was considered a cluster and all patients within the cluster received either the intervention or usual care. The practices were the units of randomisation, since it would have been difficult to allocate two patients in the same practice to different arms of the trial. Blinding of the intervention and assessment of the process measures were not feasible in view of the nature of the intervention studied. A statistician generated the random allocation sequence while a secretary who was not involved in the research study assigned participants to either the intervention or control groups. A researcher and a research nurse enrolled the participants into the study.

Intervention and control groups

This was a complex intervention comprised three components: PDA; healthcare professional training workshop; and use of the PDA in a consultation. The development of the intervention was based on the UKMRC framework for the development and evaluation of complex interventions [13] and this will be reported in another study. The doctors and/or the nurses who were primarily involved in the diabetes care of the practice attended a short

training session lasting between one to two hours on how to use the PANDAs decision aid. The training topics covered included the principles of shared decision making, the importance and clinical effectiveness of decision aids, the evidence for various treatment options for poorly controlled T2DM and essential skills in risk communication.[14]

The patient participants were given the PANDAs decision aid (Table 1) by the researcher to read and complete prior to the consultation in the waiting room. This was followed by the consultation with the GP or the practice nurse facilitated by the use of the PANDAs decision aid. In the control group, the GP and the practice nurse did not receive any training and the PANDAs decision aid was not used. The GPs or the nurses conducted a normal consultation with the patient.

Table 1: Content of the PANDAs decision aid

The PANDAs Decision Aid contains the following information in line with the International Patient Decision Aid Standards criteria:

1. Information about the insulin and other treatment options
- Reasons for starting insulin
- The procedure of insulin injection
- Common concerns about insulin
- Treatment options: Make no change; lifestyle modification; insulin therapy

2. Present probablities of outcomes
- The advantages and disadvantages of each option were described in words, numbers and pictures ('smiley faces')

3. Patient value clarifications
- A list of patients' values about the advantages and disadvantages of insulin therapy

4. Structured guidance

Outcome measures and follow-up

Primary outcome measure:

The primary outcome measures were decisional conflict based on the Decisional Conflict Scale score,[15 16] (immediate) used as an indicator of decision quality and glycaemic control (glycosolated haemoglobin, HbA1c) at six months.

Secondary outcome measures:

Knowledge and realistic expectations of the risks and benefits were assessed by asking the patients to indicate their perceived chance of experiencing the side effects of insulin therapy and diabetic complications.

Operational definitions of the secondary outcome measures were agreed as (1) knowledge: about the treatment option that is most effective in reducing blood glucose level and diabetic complications; (2) realistic expectations: a self-reported chance of experience hypoglycaemia, gaining weight and developing complications; (3) preference option: preferred treatment options of initiate insulin, adhere more to diabetes advice more regularly or make no change; (4) participation in decision making: using the Control Preference Scale scores and (5) regret: using the Regret Scale scores.

The secondary measures were other decision quality indicators (knowledge of treatment options, realistic expectation, preference option, proportion undecided, participation in decision making); duration of consultation; and outcome of decision making (regret and persistence with the chosen option). Persistence with the chosen option is a single self-reported item which the participant was asked what their treatment was six months after the intervention. They were considered to be persistent with their decision if there was no change in the treatment in the past six months.

The practice provided the baseline and six-month follow up data. Baseline data comprised: practice and clinician profile, patients' socio-demography, diabetes profile (duration, complication, prescription, glycaemic control), comorbidities (e.g. hypertension, coronary artery disease, dyslipidaemia, chronic kidney disease); and previous T2DM education. Immediate post-intervention data collected were: decision quality indicators and duration of consultation. Six-month data comprised: HbA1c, regret score and persistence with the decision.

Instruments:

Decisional conflict scale (DCS)

The DCS measures personal perceptions of (a) uncertainty in choosing options; (b) modifiable factors contributing to uncertainty such as feeling uninformed, unclear about personal values and unsupported in decision making; and (c) effective decision making such as feeling the choice is informed, value-based, likely to be implemented and expressing satisfaction with the choice. It was derived from the decisional conflict construct.[17] The traditional 16-item DCS with five response categories was used in this study. There are five subscales: 'uncertainty subscale'; 'informed subscale'; 'values clarity subscale'; 'support subscale'; and 'effective decision subscale'.[15] The DCS has been shown to be reliable and is correlated with the constructs of knowledge, regret and discontinuance, and has the ability to discriminate between those who make and delay decisions. Scores lower than 25 are associated with implementing decisions while scores exceeding 37.5 are associated with decisional delay or feeling unsure about implementation.[16]

Control preference scale (CPS)

The CPS aims to measure the extent to which patients prefer or are involved in decision

making during a clinical consultation. It measures the preferred or actual role in decision making by asking a single question which contains five items: two represents active or patient controlled role; one a shared or collaborative role; and two items represent a passive or practitioner controlled role.[18] It has proven validity and reliability in both general public and patients with medical conditions.[18 19] A recent study found a good inter-rater reliability and good agreement between self and researcher ratings on Control Preference Scale.[20]

Regret scale

This scale measures 'distress or remorse after a (health care) decision'. It is a five-item scale with five responses (1 strongly agree to 5 strongly disagree). Regret is measured at a point where the respondent can reflect on the effects of the decision that has been made. A score of 0 means no regret while a score of 100 means high regret. The regret scale correlates with satisfaction with the decision, decisional conflict and overall quality of life.[21]

Sample size and statistical analysis (HbA1c)

Assuming an intracluster correlation coefficient of 0.047 for HbA1c[22] and a cluster sample size of 5 patients per practice, with 80% power and 5% (two-sided) significance, 160 patients in each group are required to allow the detection of 0.5% (SD 1.5%) difference in HbA1c.[23] The total number of Practices required, therefore, was estimated to be 64. When using the total DCS score as the primary outcome measure and using a similar method to calculate sample size, the total number of participants needed was 86 and the total cluster size was estimated to be 17. We aimed for the larger sample size for the design of this study.

The outcome variables, were treated as continuous and we used multiple regressions with generalised estimating equations (GEE) and exchangeable correlation to allow for clustering. Multiple logistic regression with GEE was used for binary outcomes in the secondary

analysis. If a patient in the intervention arm refused to use the decision aid, they were still included in the intervention group for analysis and were analysed according to the intention-to-treat principle.

Results

Study practices profile (Table 2)

Forty-nine general practices were recruited into the study. The practices in both arms of the study were well matched in terms of mean list size, mean diabetes list size, mean number of partners and practice nurses and mean Index of Multiple Deprivation Scores.

Table 2 Study practice profile (mean and range)

	Intervention	Control
Number of Practices	25	24
List Size	7,510 (3,129-20,900)	7,325 (1,974-13,500)
People with diabetes	350(96-912)	356 (143-634)
No of partners	5 (1-13)	5 (2-10)
No of practice nurses	3 (1-6)	3 (1-5)
IMD* score	30.35 (range 8.9 - 59.5)	30.20 (range 6.5 - 55)

*Index of Multiple Deprivation

Participants

182 patients were assessed for eligibility, of whom seven were excluded for not meeting the inclusion criteria (n=5), or declined to participate (n=2). 175 patients were randomised, of whom 95 were allocated to the intervention group and 80 to the control group. Six participants in the intervention group were lost to follow-up (3 died, 1 moved away and 2 withdrew their consent), and 2 participants in the control group were also lost to follow-up (1 died and 1 moved away). The results from 167 participants were analysed (89 interventions and 78 controls) (Figure 2). [24]

Table 3 compares the socio-demographic and clinical profiles of patients between intervention and control groups. The mean age of the patients was 64.6 years (range 39 – 87). The patients in the intervention group and control group were broadly similar except that the patients in the intervention group were older and more likely to have coronary heart disease. In both groups the patients were more likely to consult nurses for diabetes related conditions than a doctor (mean number of consultations with nurses and GPs were 2.03 and 1.15 respectively). The mean length of the initial consultation for patients, when entering the study, in the intervention and control groups was 15.31 and 16.95 minutes respectively (mean difference 1.67min, 95% CI 0.93 to 4.27 mins).

Table 3. Baseline patient socio-demographic and clinical information of the intervention and control groups (mean and range unless otherwise stated)

	Intervention	Control
Socio-demographic profile		
Number	95	80
Demography		
Age (years)	66 (39 – 82)	62 (42 – 87)
Male (%)	50 (52%)	46 (57%)
Duration of education (years) (SD)	12.22 (4.83) (8 – 45*)	11.49 (2.74) (2 – 22)
Ethnicity white (%)	85 (89.5%)	71 (88.8%)
Clinical profile		
Duration of diabetes (years) (SD)	8.4(4.1)(1 – 25)	7.07(3.83) (1 – 16)
HbA1c (IFCC HbA1c mmol/mol) in past 12 months (%) (SD)	8.6 {70}(1.9) (7.4 – 13.1){57-120}	8.8 {73}(0.98) (7.5 – 11.5){58-102}
Number with diabetic complications (%)		
Coronary Heart Disease	29/93 (31.1)	13/80 (16.2)
Peripheral vascular disease	3/93 (3.22)	3/80 (3.75)
Stroke	8/93 (8.6)	5/80 (6.25)
Retinopathy	20/93 (21.5)	10/80 (12.5)
Nephropathy	5/93 (5.37)	10/80 (12.5)
Neuropathy	5/93 (5.37)	3/80 (3.75)
Number with co-morbidities (%)		
Hypertension	58/93 (62.3)	43/80 (53.75)
Dyslipidaemia	52/93 (55.9)	38/80 (47.5)
Health Service Utilisation		
Number of diabetes-related visits to the general practice in the past 6 months (SD)		
General Practitioners	0.92 (1.13) (0-5)	1.41 (1.68) (0–11)
Nurse	2.15 (1.84)	1.89 (1.36)
Number of diabetes-related visits to the hospital in the past six months (SD)	0.51 (0.87)	0.45 (0.67)
Length of consultation (min)	15.31 (2 – 39)	16.95 (5 – 45)

** Self-report (this figure includes self taught continuing education outwith a formal educational programme).

Decisional Conflict

The mean difference between the intervention and the control groups on the total score for decisional conflict was -7.72 (95% CI -12.5 to -2.97). The distribution of decisional conflict sub-scores are shown in Table 4**.** The total and subscores for every decisional conflict domain, apart from the support sub-score, were significantly lower in the intervention group.

The difference in uncertainty, informed, value clarity and effective decision subscores between the intervention and control groups remained statistically significant after adjusting for differences in age, education and gender.

Table 4: Comparison of decisional conflict scores between the intervention and control groups (0=no decisional conflict, 100=maximum decisional conflict).

Subscore	Intervention	Control	Mean difference unadjusted	Mean difference adjusted*	95% CI p value
Uncertainty	20.1 (16.6)	29.4 (20.8)	-9.29	-8.72	-14.9 to -2.53 p=0.006
Informed	18.1 (13.3)	26.0 (16.6)	-7.65	-8.69	-13.3 to -4.10 p<0.001
Values Clarity	16.7 (13.9)	26.7 (18.2)	-9.74	-9.84	-14.8 to -4.84 p<0.001
Support	17.4 (13.1)	20.8 (15.3)	-3.41	-3.66	-8.58 to 1.25 p=0.144
Effective Decision	16.1 (14.4)	23.3 (15.2)	-9.70	-9.80	-16.8 to 2.75 p=0.006
Total Score	17.4 (12.6)	25.2 (14.9)	-7.67	-7.72	-12.5 to –2.97 p<0.001

* adjusted for clustering, insulin initiation, age, gender and education level

Glycosolated Haemoglobin (HbA1c)

Table 5 shows the HbA1c levels for both the intervention and the control groups at six months. HbA1c levels reduced in both groups at six months compared to baseline (0.24% in the control group and 0.37% in the intervention group). The mean difference in the HbA1c level at 6 months between the two groups was 0.351 (95%CI -0.088 to 0.789, p=0.117) after adjusting for age, education, gender, baseline HbA1c, insulin status and clustering.

Table 5: The effect of the PANDAs decision aid on HbA1c at 6 months

Intervention	Control	Mean difference in HbA1c unadjusted	Mean difference in HbA1c adjusted*	95% CI
8.64 (SD 1.37)	8.40 (SD 1.31)	0.244	0.351	-0.088 to 0.789

* adjusted for age, education, gender, baseline HbA1c, insulin status and clustering. P=0.117

Secondary outcomes:

Knowledge

A comparison of the proportions of patients who answered the 'knowledge' questions correctly between the intervention and the control groups showed there were more patients in the intervention group who answered the questions correctly compared to those who received 'usual care'. (Table 6)

Table 6: Secondary outcomes: Knowledge and realistic expectations (Questions answered correctly)

	Intervention Decision Aid	Control Usual Care	Unadjusted Odds Ratio	Adjusted[+] Odds Ratio (95% CI)	ICC	p value
Knowledge						
Number	95	80				
Which choice has the greatest chance of lowering	49 (51.6%)	23 (28.8%)	2.63	1.31 (1.14 to 1.50)	0.071	<0.001

your blood sugar?						
Which choice has the greatest chance of lowering your complications?	29 (30.5%)	23 (28.8%)	1.09	1.20 (0.07 to 19.05)	0.202	0.90
Realistic expectations						
If you take insulin, about how many times might you experience 'hypos' in a year?	77/95 (81.0%)	4/75 (5.2%)	75.9	^	-	<0.001*
If you take insulin, about how much more weight might you gain in a year?	67/95 (70.5%)	4/75 (5.3%)	42.5	^	-	<0.001*
Out of 100 people like you who take insulin, how many may get complications in five years?	25/95 (26.3%)	4/80 (5%)	6.8	^	-	<0.001*

+ adjusted for clustering, insulin initiation, age, gender and education level

^ Numbers answering correctly in the control group were too few to control for clustering.

* Chi-squared p value

Realistic expectations

Patients who used the decision aid had significantly more realistic expectations about the side effects of insulin therapy compared to those who did not (Table 6). Almost all patients in the intervention group, compared to those of the control group, knew correctly their risk of hypoglycaemia (81.0% vs 5.2%, p<0.001) and weight gain (70.5% vs 5.3%, p<0.0010). More

people knew their risk of complications in the intervention group if they were to take insulin, although most still got it wrong (26.3% vs 5.0%, p<0.001).

Preferred option

Table 7 shows that the preferred choices of patients in the intervention and control groups were similar after consultation.

Table 7: Preferred choices of patients in intervention and control groups post-consultation

	Make No Change	Follow the diabetes advice more regularly	Start insulin	I am not sure	Total
Control	33 (42.3.8%)	29 (37.1%)	9 (11.5%)	7 (9%)	78
Intervention	32 (34.7%)	38 (41.3 %)	17 (18.4%)	5 (5.4%)	92
Total	65	67	26	12	170

(X^2_3=2.88, p =0.410)

Proportion undecided

Table 8 shows that patients in the intervention group were over 3 times more likely to change from undecided to decided than in the control group, although, this was not statistically significant (P=0.15).

Table 8: Comparison of the proportion of patients who remained undecided between the intervention and control group immediately after intervention

	Intervention	Control	OR	95%CI
Undecided (pre-consultation)	23	14		
Undecided (post-consultation)	8*	9*		

Odds in favour of changing: undecided (pre) to decided (post)/ decided (pre) to undecided (post)	18/3**	11/6**	3.27	0.69 to 16.3 (p=0.15)

* This figure of 8 patients includes 5 who remained 'undecided' post consultation and includes 3 patients who moved from 'decided' pre consultation to 'undecided' post consultation. Similarly for the 9 'undecided' post consultation patients in the control group, 3 remained 'undecided' and 6 had moved from 'decided' to 'undecided'.

**This ratio means that a total of 18 patients changed from 'undecided' to 'decided' in the intervention group and that 3 moved in the opposite direction (ie a net total of 15 patients [18 – 3] had 'decided' post consultation). In the control group the corresponding numbers were 11 and 6 (ie a net total of 5 patients [11 – 6] had 'decided' post-consultation).

Participation in decision making

There were significant differences in patients' decision making role between the intervention and control groups (p=0.012 Chi square) (Table 9). It may be seen that a smaller proportion of patients in the intervention group described their decision about their diabetes treatment as "passive" or "collaborative".

Table 9: Decision making roles of patients in the intervention and control groups, post consultation with their doctor/nurse

	How did you make your decision about your diabetes treatment? (n = 169)			
	Passive	Collaborative	Autonomous	Total
Control	16 (21%)	28 (36%)	33 (43%)	77 (100%)
Intervention	8 (9%)	25 (27%)	59 (64%)	92 (100%)

(X^2=8.9, df=2, p=0.012)

However, patients in the intervention arm were more likely to demonstrate autonomy in their decision making about their treatment compared to the control group (64% compared to 43%). Further analysis showed that an individual patient was 1.23 (95% CI 1.05 to 1.44, p=0.008) times more likely to make an 'autonomous' decision using the PANDAs decision aid when the intervention and control groups are compared, allowing for age and gender.

Regret and persistence with decision

Table 10 shows that there was no difference at 6 months in the regret scale, but that patients in the intervention group were rather more likely to persist with their chosen option.

Table 10: Comparison of the decision Regret Score and persistence with chosen option between the intervention and usual care groups after six months

	Intervention	Control	Mean difference unadjusted	Mean difference adjusted*	p value
Regret Score	44.63	44.57	0.06	0.22 (-2.48 to 2.93)	0.872
Persistence with chosen option	68.1%	56.3%	1.65†	1.17^ (1.00 to 1.36)	0.041

* adjusted for age, education, gender, baseline HbA1c, insulin status and clustering
†Crude odds ratio
^Adjusted odds ratio

Acceptability

Most of the PDA users found the PDA useful. When asked about their opinion of the PDA, 83.2% (n=88), 86.3% (n=89), 86.3% (n=89) and 88.4%(n=90) thought that the PDA had helped them: to recognize that a decision needs to be made; know that the decision depends on what matters most to them; think about how involved they wanted to be in the decision; and prepare to talk to the nurse or doctor about what mattered most to them', respectively.

Discussion

The PANDAs decision aid was designed to facilitate decision making between clinicians and their patients with T2DM who were taking at least two oral glucose-lowering drugs at maximum tolerated dose, had a high HbA1c level and were considering future treatment options including the introduction of insulin. Its evaluation was based on the IPDAS recommendations [25] and the use of the ODSF Framework.[26] The PANDAs trial provides good

evidence not only for the clinical effectiveness of decision aids in usual NHS general practice but also for the utility and feasibility of use by both nurses and doctors. In addition, the PANDAs decision aid itself and its use were both effective and acceptable to people with diabetes making treatment choices during clinical consultations.

Decision quality

The findings from the PANDAs trial support the results of other studies which have evaluated the clinical effectiveness of decision aids[11 15] in demonstrating an improvement in decision quality when a decision aid is used in clinical consultations.

Decisional conflict scores, for example, when adjusted for age, education and gender were significantly lower in the intervention group post consultation when compared to the controls, apart from the support sub-score. It is interesting to note that the support sub-score in the intervention group was not significantly lower than the control group - this may be the result of a 'ceiling effect' since patients in both the intervention and control groups may already have been receiving very good diabetes care from their general practices.

Other indicators of decision quality used in the study also demonstrated an improvement when PANDAs was used in consultations – there was, for example, a highly significant difference in the knowledge of people which particular treatment choice had the greatest chance of lowering blood sugar in those who used the decision aid - although this was not the case when the chance of insulin in lowering complications was considered - here no difference in knowledge was observed. Some patients believe that insulin itself causes complications as a result of misperception [27 28] and this may explain why knowledge did not improve in the intervention group. However, highly significant differences were observed

between the intervention and control groups in all the three domains of realistic expectations ['hypos', weight gain and complications] supporting the notion that the PANDAs decision aid ensured that people were fully informed about the potential risks of each option when making their treatment choices.

As far as autonomy was concerned, patients in the intervention arm were more likely to make an autonomous decision using PANDAs when the intervention and control groups were compared allowing for both age and gender. This is consistent with the findings of other studies. [29 30]

These findings of an improvement in decision quality when a decision aid is used in clinical consultations in other conditions and contexts are also supported by a large number of other studies. [23 31]

Decisional Outcomes

The glycaemic control improved in both groups six months after the intervention although no significant difference in glycaemic control was observed between the two groups. Some GPs in the study expressed concern at the start of the trial that glycaemic control could deteriorate in some patients in the intervention group as a result of them choosing not to start insulin. Further study is necessary to confirm this as this study did not have sufficient power to detect the difference in glycaemic control.

Treatment decisions made using a decision aid should, of course, be ones that are both informed and value-based, and the PANDAs intervention was focussed on the process of decision making rather than the outcomes of those decisions. It is therefore important to note

that PANDAs was not designed to persuade people to start treatment with insulin but to help them make an informed treatment decision which was consistent with their values and wishes.

Indeed, there was reduced decisional conflict within the intervention group compared to the control and the decisions which were made were far more likely to be autonomous in nature rather than passive. Participants in the intervention group were also significantly more likely to persist with their chosen option at 6 months. This supports the hypothesis that people who use a decision aid such as PANDAs are more likely to make an informed and value-based decision and are therefore more likely to persist with their treatment choice. Concordance with agreed treatment is, in turn, more likely to lead to better health outcomes and quality of life.

No significant difference was observed on the regret scale scores and although people in the intervention group were over three times more likely to change from undecided to decided [ie come to a treatment decision after their consultation] in the control group, this difference was not statistically significant.

Finally, no significant difference was observed in the preferred choices [ie the treatment decision they came to] of the two groups although a higher proportion of people in the intervention group did choose to initiate insulin. However it is important to note that the use of a decision aid is not intended to produce a particular outcome but to support the patient making a treatment choice based on their knowledge and values. These findings are also consistent with current understanding of the anticipated decisional outcomes when a decision aid such as PANDAs is used in clinical consultations to make treatment choices. [31]

Impact on Clinical Practice

The results of the PANDAs trial demonstrate that the use of the decision aid in usual general practice by both practice nurses and GPs, provided the patient has the opportunity to complete their individualised decision aid prior to their consultation, does not require significant additional consultation time**.** Given the potential benefits of improved adherence to treatment choices and an improved therapeutic relationship between clinicians and their patients, this is likely to make the use of the decision aid acceptable to all parties in general practice, although, its use may require some initial 'investment' in consultation time. In particular, both clinician and patient satisfaction with their consultations, as well as the healthcare provided and received, are both likely to be increased. A further potential advantage is that the decision aid could be used by other clinical members of the primary care team (eg healthcare assistants) potentially increasing the consultation time available to doctors and nurses for other patients. However, the efficient use of the decision aid in consultations may in part be attributed to the familiarity of the clinicians with the decision aid as a result of the brief training clinicians received at entry to the trial. In addition, this may also be due to the process by which the decision aid was developed with the active involvement of both clinicians and people with diabetes to ensure that it was as 'user friendly' as possible. This involvement of users in the development of the decision aid and a process evaluation of its use in the consultation by both parties has been described elsewhere.[32]

Health service utilisation

The PANDAs trial was a pragmatic one reflecting the reality of primary care diabetes clinics which are mainly run by practice nurses. The mean number of consultations with the nurses,

for example, was greater than the mean number of consultations with the GPs and within the intervention group patients were more likely to use the PANDAs decision aid with the practice nurse than the GP. At baseline the distribution of the mean number of diabetes related general practice visits was different in the intervention and control groups with the practice nurses providing more clinical care to people with diabetes in the former reflecting different patterns of care in the different practices.

Patient decision aids

The PANDAs decision aid is one of the few decision aids which focus on decision making in chronic diseases, which take place over several consultations. According to the latest Cochrane Decision Aid Inventory, 10 decision aids have been developed for diabetes.[31] Four decision aids focus on insulin treatment, of which two are for children, one for adults deciding on premixed insulin and one for insulin initiation in T2DM (PANDAs decision aid). However, unlike PANDAs, none have been developed for making treatment decisions about glycaemic control.

Although decision aids have positive effects on many aspects of the decision making process, there remains a large gap in the literature on how decision aids fare "in the real world". O'Cathain and Thomas (2004) conducted a pragmatic trial of decision aid in a maternity ward and found that health professional were not making use of the available decision aids, although they reported that they approved of them. The reasons for not using them included 'disagreement' with the available decision aids, lack of resources, perceived patients' reluctance to participate and unwillingness to change their "routine care".[33] O'Donnell, Cranney et al, classified the barriers to the use of decision aids in the clinical situation under three categories – the nature of the decision aid itself, the attitudes of patients and healthcare

professionals and organisational barriers such as institutional culture and commitment, time constraint and costing. [34]

A number of authors have proposed various strategies to facilitate such use of decision aids in different clinical settings.[35] The effectiveness of these proposed strategies has not yet been formally evaluated. The PANDAs trial however found the decision aid to be highly acceptable to both clinicians and people with diabetes in NHS general practice – a detailed process evaluation of its use can be found elsewhere. This report identifies some of the key challenges to its widespread implementation in NHS general practice.

However, most studies of decision aids have not shown an increase in the level of satisfaction with the decision making process or the decision itself. This may be another example of the 'ceiling effect' whereby the satisfaction with the service or consultation was already high before the intervention. It has also been observed that people tend to report satisfaction after they have made the decisions because they tend to "rationalise" and adapt quickly to uncertain events.[36] Moreover, the effect of decision aids on quality of life and health outcomes indicators which are commonly used in health technology assessments, have yet to be proved. More plausible intermediate outcomes, such as concordance with treatment and health service utilisation, could be used as alternative indicators to evaluate the use of decision aids.

General practice is a unique healthcare setting where multidisciplinary teams provide holistic, comprehensive and continuity of care to people in the community. Practitioners usually have an established relationship with their patient and an appreciation of their medical and psychosocial background as well as their associated multi-morbid conditions. This puts them

in a very good position to advise patients on their treatment options. The use of decision aids to facilitate treatment choices in general practice fits well with the adoption of a Care Planning model for long-term conditions. This model of care, developed by the Diabetes UK Year of Care Programme and recently adopted as a professional standard by the RCGP, is a good way of ensuring that patients with diabetes are both fully informed and fully involved in decisions about their care by supporting their "empowerment" and facilitating the "activation" of people with long-term conditions. [37 38]

Implications for research and clinical practice

For the use of patient decision aids, such as PANDAs, in routine clinical practice to become the accepted norm, the new GP clinical commissioning groups will need to be aware of the benefits of the use of such aids to ensure that decision aids become a professional standard in, for example, newly commissioned pathways for a long-term condition such as diabetes. Investment will also be necessary for the development and the continuing evaluation of decision aid use, as well as for the training of all members of the multidisciplinary team in the importance and in the practical use of decision aids in primary care. Both the patient's experience and patient/clinician satisfaction with the care received and provided is likely to be much improved if this professional standard is adopted by commissioning groups.

Conclusions

The use of the PANDAs decision aid by health care professionals in usual NHS clinical practice with T2DM patients who are making treatment choices in general practice improves decision quality by reducing decisional conflict, improving knowledge and promoting realistic expectations but has no demonstrable effect on glycaemic control.

Patient autonomy however is strengthened by the use of the decision aid and longer term clinical outcomes are likely to be improved. A larger trial of the PANDAs decision aid will

be necessary to determine if biomedical parameters are improved when the decision aid is used in normal NHS practice.

Strengths and limitations of this study

The study failed to achieve its planned sample size as a result of recruitment difficulties. The reasons for this were the increase in availability of new oral and injectable glucose lowering drugs (e.g. GLP1 agonosts, exenatide) which were not available at the start of the project, significant staff changes in 2008/9 and the reluctance of practices to participate in the study because of a potential H1N1 flu pandemic in summer 2009. As a result each practice was only able to identify 3-5 eligible patients for inclusion in the trial. It proved impossible to secure a funded time-extension to the study and as a result recruitment ceased at 175 participants. This meant that the study was underpowered to detect a difference of 0.5% in HbA1c between the two groups. The original recruitment period was 12 months but because of the problems surrounding recruitment outlined above, recruitment was extended to 20 months. There was also some evidence of inadvertent recruitment bias with 95 participants allocated to the intervention group and 80 to the control group. This is an important and well recognised consequence of a cluster RCT design and is probably the result of the PANDAs practices being more likely to recruit participants to the trial. There were some differences in baseline characteristics between the intervention and the control and these were included in an analysis which explored how the estimates of the treatment effect changed when baseline differences were controlled for.

Contributorship statement:

Substantial contribution to conception and design, acquisition of data or analysis and interpretation of data:

NM, CJN, MCJ, BC, AB, IB

Drafting the article or revising it critically for important intellectual content:

NM, CJN, MCJ

Final approval of the version to be published:

NM, CJN, MCJ, BC, AB, IB

NM is the guarantor.

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All authors have completed the Unified Competing Interest form at www.icmje.org./coi_disclosure.pdf and declare that (1) NM, CJN, MC, BC, IB, AB have support from the University of Sheffield for the submitted work; (2) NM, CJN, MC, BC, IB, AB have no relationships with any companies that night have an interest in the submitted work in the previous 3 years; (3) their spouses, partners or children have no financial relationships that may be relevant to the submitted work; and (4) NM, CJN, MC, BC, IB, AB have no none-financial interests that may be relevant to the submitted work.

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Title:

Clinical effectiveness of a patient decision aid to improve decision quality and glycaemic control in people with diabetes making treatment choices – a cluster randomised controlled trial (PANDAs) in General Practice.

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ARTICLE FOCUS:

- Does the use of the PANDAs decision aid in general practice improve decision quality and glycaemic control in people who are making treatment choices about their type 2 diabetes mellitus (T2DM) treatment, including whether or not to start insulin?

KEY MESSAGES:

- Patient decision aids provide evidence-based information about treatment options, help patients to clarify their values and guide them systematically to make an informed decision.
- The use of the PANDAs decision aid by doctors and nurses in usual NHS general practice with people who have T2DM and are making treatment choices reduces decision conflicts and improves knowledge, realistic expectations and patients' involvement in decision making.
- HbA1c levels were reduced in both groups at six months when compared to baseline (0.24% controls and 0.37% intervention) with a non-significant mean difference between the two groups of 0.351, p=0.117).

STRENGTHS AND LIMITATIONS

- This study was underpowered to detect a minimally, clinically important difference in glycaemic control between the two groups due to slow recruitment.
- There was no blinding in this study due to the nature of the intervention which may have influenced the outcome assessment.
- This was a pragmatic trial and there may have been variations in how the decision aid was used in different General Practices which may have diluted the effect of the study.

Abstract

Objective

To determine the effectiveness of a patient decision aid (PDA) to improve decision quality and glycaemic control in people with diabetes making treatment choices using a cluster RCT.

Design

A cluster randomised controlled trial.

Setting

49 general practices in UK randomised into intervention (n=25) and control (n=24).

Participants

General Practices: Inclusion criteria: > 4 medical partners; list size > 7000; and a diabetes register with > 1% of practice population. 191 Practices assessed for eligibility, 49 Practices randomised and completed the study.

Patients: People with T2DM taking at least two oral glucose-lowering drugs with maximum tolerated dose with an HbA1c greater than 7.4% (IFCC HbA1c >57mmol/mol) or advised in the preceeding six months to add or consider changing to insulin therapy. Exclusion criteria: currently using insulin therapy; difficulty reading or understanding English; difficulty in understanding the purpose of the study; visual or cognitive impairment or mentally ill. 182 assessed for eligibility, 175 randomised to 95 intervention and 80 controls, 167 completion and anlaysis.

Intervention

Brief training of clinicians and use of PDA with patients in single consultation.

Primary Outcomes

Decision quality (decisional conflict scores, knowledge, realistic expectations and autonomy) and glycaemic control (glycosolated haemoglobin, HbA1c).

Secondary Outcomes

Knowledge and realistic expectations of the risks and benefits of insulin therapy and diabetic complications.

Results

Intervention Group: lower total decisional conflict scores (17.4 v 25.2, p<0.001); better knowledge (51.6% v 28.8%, p<0.001); realistic expectations (risk of 'hypo', 'weight gain', 'complications'; 81.0% v 5.2%, 70.5% v 5.3%, 26.3% v 5.0% respectively, p<0.001); and were more autonomous in decision making (64.1% v 42.9%, p=0.012).

No significant difference in the glycaemic control between the two groups.

Conclusions

Use of the PANDAs decision aid reduces decisional conflict, improves knowledge, promotes realistic expectations and autonomy in people with diabetes making treatment choices in general practice.

ISRCTN Trials Register Number 14842077

Data sharing statement: There are no additional data available

Introduction

Diabetes mellitus is a growing health problem in England with a total of 2.4 million people (5.5% of population) living with the disease in 2011.[1] Diabetes currently accounts for 10% of all NHS expenditure.[2] However, overall diabetes control is less than satisfactory. In 2008/2009, 67% of people with T2DM achieved a glycosolated haemoglobin (HbA1c) of less than 7.5% (IFCC HbA1c 58 mmol/mol).[3]

The UK Prospective Diabetes Study (UKPDS) has established the importance of maintaining good blood glucose control in patients with T2DM. For every 1.0% increase in HbA1c, there is an increase, in risk, of 14% for myocardial infarction, 21% for diabetes-related deaths and 37% for micro-vascular complications.[4] In the same study, it was reported that only 25% were able to achieve good glycaemic control with monotherapy after 9 years of the trial. Most patients will require combination therapy, including insulin, 5-10 years after diagnosis.[5]

Currently, the NICE guidelines recommend a combination of metformin and insulin secretagogues in those who have inadequate blood glucose control with monotherapy. In those in whom dual therapy has been unsuccessful, either insulin or a thiozolidinedione should be added to optimise glycaemic control.[3] Frequently, this poses a clinical dilemma for both patients and healthcare providers; both parties need to agree which next treatment option to pursue and this includes whether or not to start insulin therapy. However, patients may be fearful of needles and the side effects of insulin (e.g. hypoglycaemia); they need to acquire new skills; change their daily routine and address the challenge of glucose monitoring.[6] Similarly, doctors may be hesitant to prescribe insulin due to their own lack of relevant skills, time pressures, and a fear of increasing the risk of side effects.[7 8] In this category of patients, the decision making process is a complex one. Studies have shown that patients usually make

decisions based on emotions such as trust, rather than on the information given by their healthcare providers.[9] For their part, doctors do not necessarily follow evidence-based guidelines[10] and it was in this context that the PANDAs decision aid was developed to facilitate shared decision making between clinicians and patients when making decisions about the treatment of their diabetes at this stage of their illness. The development of the PANDAs decision aid will be described elsewhere.

Patient decision aids are tools that provide evidence-based information about treatment options, help patients to clarify their values and guide them systematically to make an informed decision. Patient decision aids have been shown to improve knowledge, realistic expectations, value-decision concordance and patient involvement in decision making.[11]

The primary research question was “Does the use of the PANDAs decision aid improve decision quality in patients with T2DM who are making a decision whether or not to start insulin in general practice?”.

The study focussed on people with T2DM who had poor glycaemic control (HbA1c >7.4mmol/l or IFCC HbA1c >57 mmol/mol) and who, despite receiving optimal oral glucose lowering therapy, required "step-up" treatment. A cluster randomised controlled trial was carried out to evaluate the clinical effectiveness of the decision aid on decision quality and glycaemic control.

Methods

The setting for this study was general practices in Sheffield, Rotherham and Doncaster with recruitment being undertaken through the National Institute for Health Research Primary Care Research Network (PCRN) and the Cutler Group of South Yorkshire Research Practices. The recruitment of practices and patients began in 2008 and the data collection ended in 2011.

Practices were invited to take part by postal invitation following a publicity campaign using a modified viral marketing technique involving sequential non-specific PANDAs post cards ('PANDAs are coming') to 'pique' interest, followed by increasingly informative flyers (Figure 1). [12]

Figure 1

The inclusion criteria for general practices were: > 4 medical partners; list size > 7000; and a diabetes register with > 1% of practice population.The participating general practices were asked to screen their computerised diabetes register for eligible patients with T2DM (aged > 21 years). The inclusion criteria were: people with T2DM who were taking at least two oral glucose-lowering drugs with maximum tolerated dose and had a latest HbA1c greater than 7.4% (IFCC HbA1c >57mmol/mol) or had been advised in the preceeding six months to add or consider changing to insulin therapy. The exclusion criteria were: patients who were currently using insulin therapy; had difficulty reading or understanding English; had difficulty in understanding the purpose of the study; had visual or cognitive impairment and were mentally ill.

The patients were contacted by a letter from their general practitioners (GPs) and invited to participate in this study. If they agreed, they were sent details of the study (including the information sheet) and asked to attend an appointment at their regular practice where consent to the study was obtained by the researchers. Practices were incentivised to take part in the trial, receiving a nominal payment to cover legitimate expenses.

Randomisation and concealment:

This was a pragmatic trial and all eligible and willing practices were randomly allocated by computer to two groups: the intervention group used the PANDAs decision aid when making the specified treatment choices and the control group delivered usual care. We stratified the practices according to the Practice list size. Each practice was considered a cluster and all patients within the cluster received either the intervention or usual care. The practices were the units of randomisation, since it would have been difficult to allocate two patients in the same practice to different arms of the trial. Blinding of the intervention and assessment of the

process measures were not feasible in view of the nature of the intervention studied. A statistician generated the random allocation sequence while a secretary who was not involved in the research study assigned participants to either the intervention or control groups. A researcher and a research nurse enrolled the participants into the study.

Intervention and control groups

This was a complex intervention comprised three components: PDA; healthcare professional training workshop; and use of the PDA in a consultation. The development of the intervention was based on the UKMRC framework for the development and evaluation of complex interventions [13] and this will be reported in another study. The doctors and/or the nurses who were primarily involved in the diabetes care of the practice attended a short training session lasting between one to two hours on how to use the PANDAs decision aid. The training topics covered included the principles of shared decision making, the importance and clinical effectiveness of decision aids, the evidence for various treatment options for poorly controlled T2DM and essential skills in risk communication.[14]

The patient participants were given the PANDAs decision aid (Table 1) by the researcher to read and complete prior to the consultation in the waiting room. This was followed by the consultation with the GP or the practice nurse facilitated by the use of the PANDAs decision aid. In the control group, the GP and the practice nurse did not receive any training and the PANDAs decision aid was not used. The GPs or the nurses conducted a normal consultation with the patient.

Table 1: Content of the PANDAs decision aid

The PANDAs Decision Aid contains the following information in line with the International Patient Decision Aid Standards criteria:

1. Information about the insulin and other treatment options
- Reasons for starting insulin
- The procedure of insulin injection
- Common concerns about insulin
- Treatment options: Make no change; lifestyle modification; insulin therapy

2. Present probablities of outcomes
- The advantages and disadvantages of each option were described in words, numbers and pictures ('smiley faces')

3. Patient value clarifications
- A list of patients' values about the advantages and disadvantages of insulin therapy

4. Structured guidance

Outcome measures and follow-up

Primary outcome measure:

The primary outcome measures were decisional conflict based on the Decisional Conflict Scale score,[15 16] (immediate) used as an indicator of decision quality and glycaemic control (glycosolated haemoglobin, HbA1c) at six months.

Secondary outcome measures:

Knowledge and realistic expectations of the risks and benefits were assessed by asking the patients to indicate their perceived chance of experiencing the side effects of insulin therapy and diabetic complications.

Operational definitions of the secondary outcome measures were agreed as (1) knowledge: about the treatment option that is most effective in reducing blood glucose level and diabetic complications; (2) realistic expectations: a self-reported chance of experience hypoglycaemia, gaining weight and developing complications; (3) preference option: preferred treatment options of initiate insulin, adhere more to diabetes advice more regularly or make no change;

(4) participation in decision making: using the Control Preference Scale scores and (5) regret: using the Regret Scale scores.

The secondary measures were other decision quality indicators (knowledge of treatment options, realistic expectation, preference option, proportion undecided, participation in decision making); duration of consultation; and outcome of decision making (regret and persistence with the chosen option). Persistence with the chosen option is a single self-reported item which the participant was asked what their treatment was six months after the intervention. They were considered to be persistent with their decision if there was no change in the treatment in the past six months.

The practice provided the baseline and six-month follow up data. Baseline data comprised: practice and clinician profile, patients' socio-demography, diabetes profile (duration, complication, prescription, glycaemic control), comorbidities (e.g. hypertension, coronary artery disease, dyslipidaemia, chronic kidney disease); and previous T2DM education. Immediate post-intervention data collected were: decision quality indicators and duration of consultation. Six-month data comprised: HbA1c, regret score and persistence with the decision.

Instruments:

Decisional conflict scale (DCS)

The DCS measures personal perceptions of (a) uncertainty in choosing options; (b) modifiable factors contributing to uncertainty such as feeling uninformed, unclear about personal values and unsupported in decision making; and (c) effective decision making such as feeling the choice is informed, value-based, likely to be implemented and expressing

satisfaction with the choice. It was derived from the decisional conflict construct.[17] The traditional 16-item DCS with five response categories was used in this study. There are five subscales: 'uncertainty subscale'; 'informed subscale'; 'values clarity subscale'; 'support subscale'; and 'effective decision subscale'.[15] The DCS has been shown to be reliable and is correlated with the constructs of knowledge, regret and discontinuance, and has the ability to discriminate between those who make and delay decisions. Scores lower than 25 are associated with implementing decisions while scores exceeding 37.5 are associated with decisional delay or feeling unsure about implementation.[16]

Control preference scale (CPS)

The CPS aims to measure the extent to which patients prefer or are involved in decision making during a clinical consultation. It measures the preferred or actual role in decision making by asking a single question which contains five items: two represents active or patient controlled role; one a shared or collaborative role; and two items represent a passive or practitioner controlled role.[18] It has proven validity and reliability in both general public and patients with medical conditions.[18 19] A recent study found a good inter-rater reliability and good agreement between self and researcher ratings on Control Preference Scale.[20]

Regret scale

This scale measures 'distress or remorse after a (health care) decision'. It is a five-item scale with five responses (1 strongly agree to 5 strongly disagree). Regret is measured at a point where the respondent can reflect on the effects of the decision that has been made. A score of 0 means no regret while a score of 100 means high regret. The regret scale correlates with satisfaction with the decision, decisional conflict and overall quality of life.[21]

Sample size and statistical analysis (HbA1c)

Assuming an intracluster correlation coefficient of 0.047 for HbA1c[22] and a cluster sample size of 5 patients per practice, with 80% power and 5% (two-sided) significance, 160 patients in each group are required to allow the detection of 0.5% (SD 1.5%) difference in HbA1c.[23] The total number of Practices required, therefore, was estimated to be 64. When using the total DCS score as the primary outcome measure and using a similar method to calculate sample size, the total number of participants needed was 86 and the total cluster size was estimated to be 17. We aimed for the larger sample size for the design of this study.

The outcome variables, were treated as continuous and we used multiple regressions with generalised estimating equations (GEE) and exchangeable correlation to allow for clustering. Multiple logistic regression with GEE was used for binary outcomes in the secondary analysis. If a patient in the intervention arm refused to use the decision aid, they were still included in the intervention group for analysis and were analysed according to the intention-to-treat principle.

Results

Study practices profile (Table 2)

Forty-nine general practices were recruited into the study. The practices in both arms of the study were well matched in terms of mean list size, mean diabetes list size, mean number of partners and practice nurses and mean Index of Multiple Deprivation Scores.

Table 2 Study practice profile (mean and range)

	Intervention	Control
Number of Practices	25	24
List Size	7,510 (3,129-20,900)	7,325 (1,974-13,500)
People with diabetes	350(96-912)	356 (143-634)
No of partners	5 (1-13)	5 (2-10)
No of practice nurses	3 (1-6)	3 (1-5)
IMD* score	30.35 (range 8.9 - 59.5)	30.20 (range 6.5 - 55)

*Index of Multiple Deprivation

Participants

182 patients were assessed for eligibility, of whom seven were excluded for not meeting the inclusion criteria (n=5), or declined to participate (n=2). 175 patients were randomised, of whom 95 were allocated to the intervention group and 80 to the control group. Six participants in the intervention group were lost to follow-up (3 died, 1 moved away and 2 withdrew their consent), and 2 participants in the control group were also lost to follow-up (1 died and 1 moved away). The results from 167 participants were analysed (89 interventions and 78 controls) (Figure 2). [24]

Figure 2

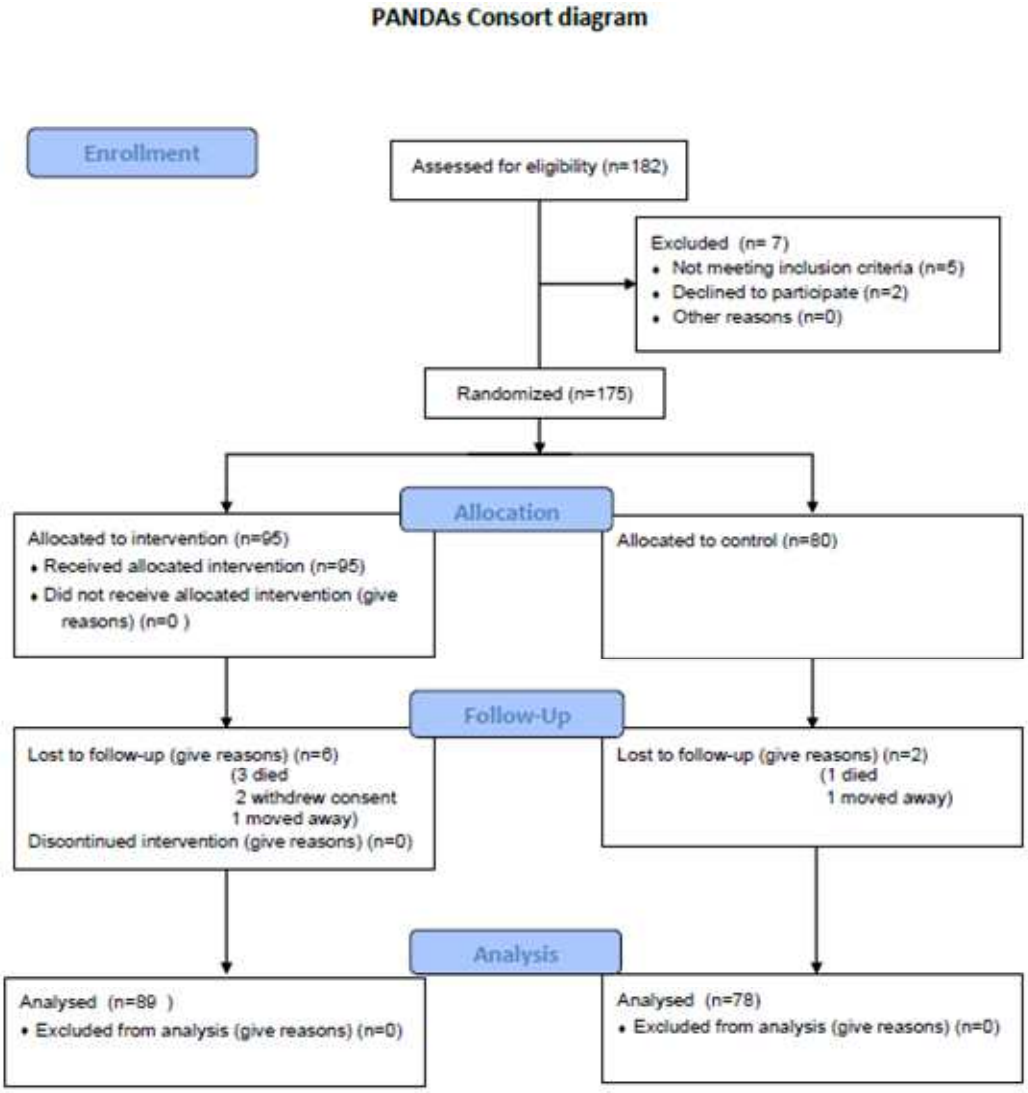

Table 3 compares the socio-demographic and clinical profiles of patients between intervention and control groups. The mean age of the patients was 64.6 years (range 39 – 87). The patients in the intervention group and control group were broadly similar except that the patients in the intervention group were older and more likely to have coronary heart disease. In both groups the patients were more likely to consult nurses for diabetes related conditions than a doctor (mean number of consultations with nurses and GPs were 2.03 and 1.15 respectively). The mean length of the initial consultation for patients, when entering the

study, in the intervention and control groups was 15.31 and 16.95 minutes respectively (mean difference 1.67min, 95% CI 0.93 to 4.27 mins).

Table 3. Baseline patient socio-demographic and clinical information of the intervention and control groups (mean and range unless otherwise stated)

	Intervention	Control
Socio-demographic profile		
Number	95	80
Demography		
Age (years)	66 (39 – 82)	62 (42 – 87)
Male (%)	50 (52%)	46 (57%)
Duration of education (years) (SD)	12.22 (4.83) (8 – 45*)	11.49 (2.74) (2 – 22)
Ethnicity white (%)	85 (89.5%)	71 (88.8%)
Clinical profile		
Duration of diabetes (years) (SD)	8.4(4.1)(1 – 25)	7.07(3.83) (1 – 16)
HbA1c (IFCC HbA1c mmol/mol) in past 12 months (%) (SD)	8.6 {70}(1.9) (7.4 – 13.1){57-120}	8.8 {73}(0.98) (7.5 – 11.5){58-102}
Number with diabetic complications (%)		
Coronary Heart Disease	29/93 (31.1)	13/80 (16.2)
Peripheral vascular disease	3/93 (3.22)	3/80 (3.75)
Stroke	8/93 (8.6)	5/80 (6.25)
Retinopathy	20/93 (21.5)	10/80 (12.5)
Nephropathy	5/93 (5.37)	10/80 (12.5)
Neuropathy	5/93 (5.37)	3/80 (3.75)
Number with co-morbidities (%)		
Hypertension	58/93 (62.3)	43/80 (53.75)
Dyslipidaemia	52/93 (55.9)	38/80 (47.5)
Health Service Utilisation		
Number of diabetes-related visits to the general practice in the past 6 months (SD)		
General Practitioners	0.92 (1.13) (0-5)	1.41 (1.68) (0–11)
Nurse	2.15 (1.84)	1.89 (1.36)
Number of diabetes-related visits to the hospital in the past six months (SD)	0.51 (0.87)	0.45 (0.67)
Length of consultation (min)	15.31 (2 – 39)	16.95 (5 – 45)

** Self-report (this figure includes self taught continuing education outwith a formal educational programme).

Decisional Conflict

The mean difference between the intervention and the control groups on the total score for decisional conflict was -7.72 (95% CI -12.5 to -2.97). The distribution of decisional conflict sub-scores are shown in Table 4**.** The total and subscores for every decisional conflict domain, apart from the support sub-score, were significantly lower in the intervention group. The difference in uncertainty, informed, value clarity and effective decision subscores between the intervention and control groups remained statistically significant after adjusting for differences in age, education and gender.

Table 4: Comparison of decisional conflict scores between the intervention and control groups (0=no decisional conflict, 100=maximum decisional conflict).

Subscore	Intervention	Control	Mean difference unadjusted	Mean difference adjusted*	95% CI p value
Uncertainty	20.1 (16.6)	29.4 (20.8)	-9.29	-8.72	-14.9 to -2.53 p=0.006
Informed	18.1 (13.3)	26.0 (16.6)	-7.65	-8.69	-13.3 to -4.10 p<0.001
Values Clarity	16.7 (13.9)	26.7 (18.2)	-9.74	-9.84	-14.8 to -4.84 p<0.001
Support	17.4 (13.1)	20.8 (15.3)	-3.41	-3.66	-8.58 to 1.25 p=0.144
Effective Decision	16.1 (14.4)	23.3 (15.2)	-9.70	-9.80	-16.8 to 2.75 p=0.006
Total Score	17.4 (12.6)	25.2 (14.9)	-7.67	-7.72	-12.5 to –2.97 p<0.001

* adjusted for clustering, insulin initiation, age, gender and education level

Glycosolated Haemoglobin (HbA1c)

Table 5 shows the HbA1c levels for both the intervention and the control groups at six months. HbA1c levels reduced in both groups at six months compared to baseline (0.24% in the control group and 0.37% in the intervention group). The mean difference in the HbA1c level at 6 months between the two groups was 0.351 (95%CI -0.088 to 0.789, p=0.117) after adjusting for age, education, gender, baseline HbA1c, insulin status and clustering.

Table 5: The effect of the PANDAs decision aid on HbA1c at 6 months

Intervention	Control	Mean	Mean	95% CI

		difference in HbA1c unadjusted	difference in HbA1c adjusted*	
8.64 (SD 1.37)	8.40 (SD 1.31)	0.244	0.351	-0.088 to 0.789

* adjusted for age, education, gender, baseline HbA1c, insulin status and clustering. P=0.117

Secondary outcomes:

Knowledge

A comparison of the proportions of patients who answered the 'knowledge' questions correctly between the intervention and the control groups showed there were more patients in the intervention group who answered the questions correctly compared to those who received 'usual care'. (Table 6)

Table 6: Secondary outcomes: Knowledge and realistic expectations (Questions answered correctly)

	Intervention Decision Aid	Control Usual Care	Unadjusted Odds Ratio	Adjusted[+] Odds Ratio (95% CI)	ICC	p value
Knowledge						
Number	95	80				
Which choice has the greatest chance of lowering your blood sugar?	49 (51.6%)	23 (28.8%)	2.63	1.31 (1.14 to 1.50)	0.071	<0.001
Which choice has the greatest chance of lowering your complications?	29 (30.5%)	23 (28.8%)	1.09	1.20 (0.07 to 19.05)	0.202	0.90
Realistic expectations						
If you take insulin, about how many times might you experience 'hypos' in a year?	77/95 (81.0%)	4/75 (5.2%)	75.9	^	-	<0.001[*]
If you take insulin, about how much more weight might you gain in a year?	67/95 (70.5%)	4/75 (5.3%)	42.5	^	-	<0.001[*]
Out of 100 people like you who take insulin, how many may get complications in five years?	25/95 (26.3%)	4/80 (5%)	6.8	^	-	<0.001[*]

[+] adjusted for clustering, insulin initiation, age, gender and education level

[^] Numbers answering correctly in the control group were too few to control for clustering.

[*] Chi-squared p value

Realistic expectations

Patients who used the decision aid had significantly more realistic expectations about the side effects of insulin therapy compared to those who did not (Table 6). Almost all patients in the intervention group, compared to those of the control group, knew correctly their risk of hypoglycaemia (81.0% vs 5.2%, p<0.001) and weight gain (70.5% vs 5.3%, p<0.0010). More people knew their risk of complications in the intervention group if they were to take insulin, although most still got it wrong (26.3% vs 5.0%, p<0.001).

Preferred option

Table 7 shows that the preferred choices of patients in the intervention and control groups were similar after consultation.

Table 7: Preferred choices of patients in intervention and control groups post-consultation

	Make No Change	Follow the diabetes advice more regularly	Start insulin	I am not sure	Total
Control	33 (42.3.8%)	29 (37.1%)	9 (11.5%)	7 (9%)	78
Intervention	32 (34.7%)	38 (41.3 %)	17 (18.4%)	5 (5.4%)	92
Total	65	67	26	12	170

(X^2_3=2.88, p =0.410)

Proportion undecided

Table 8 shows that patients in the intervention group were over 3 times more likely to change from undecided to decided than in the control group, although, this was not statistically significant (P=0.15).

Table 8: Comparison of the proportion of patients who remained undecided between the intervention and control group immediately after intervention

	Intervention	Control	OR	95%CI
Undecided (pre-consultation)	23	14		
Undecided (post-consultation)	8*	9*		
Odds in favour of changing: undecided (pre) to decided (post)/ decided (pre) to undecided (post)	18/3**	11/6**	3.27	0.69 to 16.3 (p=0.15)

* This figure of 8 patients includes 5 who remained 'undecided' post consultation and includes 3 patients who moved from 'decided' pre consultation to 'undecided' post consultation. Similarly for the 9 'undecided' post consultation patients in the control group, 3 remained 'undecided' and 6 had moved from 'decided' to 'undecided'.

**This ratio means that a total of 18 patients changed from 'undecided' to 'decided' in the intervention group and that 3 moved in the opposite direction (ie a net total of 15 patients [18 – 3] had 'decided' post consultation). In the control group the corresponding numbers were 11 and 6 (ie a net total of 5 patients [11 – 6] had 'decided' post-consultation).

Participation in decision making

There were significant differences in patients' decision making role between the intervention and control groups (p=0.012 Chi square) (Table 9). It may be seen that a smaller proportion of patients in the intervention group described their decision about their diabetes treatment as "passive" or "collaborative".

Table 9: Decision making roles of patients in the intervention and control groups, post consultation with their doctor/nurse

	How did you make your decision about your diabetes treatment? (n = 169)			
	Passive	Collaborative	Autonomous	Total
Control	16 (21%)	28 (36%)	33 (43%)	77 (100%)
Intervention	8 (9%)	25 (27%)	59 (64%)	92 (100%)

(X^2=8.9, df=2, p=0.012)

However, patients in the intervention arm were more likely to demonstrate autonomy in their decision making about their treatment compared to the control group (64% compared to 43%). Further analysis showed that an individual patient was 1.23 (95% CI 1.05 to 1.44, p=0.008) times more likely to make an 'autonomous' decision using the PANDAs decision aid when the intervention and control groups are compared, allowing for age and gender.

Regret and persistence with decision

Table 10 shows that there was no difference at 6 months in the regret scale, but that patients in the intervention group were rather more likely to persist with their chosen option.

Table 10: Comparison of the decision Regret Score and persistence with chosen option between the intervention and usual care groups after six months

	Intervention	Control	Mean difference unadjusted	Mean difference adjusted*	p value
Regret Score	44.63	44.57	0.06	0.22 (-2.48 to 2.93)	0.872
Persistence with chosen option	68.1%	56.3%	1.65†	1.17^ (1.00 to 1.36)	0.041

* adjusted for age, education, gender, baseline HbA1c, insulin status and clustering
†Crude odds ratio
^Adjusted odds ratio

Acceptability

Most of the PDA users found the PDA useful. When asked about their opinion of the PDA, 83.2% (n=88), 86.3% (n=89), 86.3% (n=89) and 88.4%(n=90) thought that the PDA had helped them: to recognize that a decision needs to be made; know that the decision depends on what matters most to them; think about how involved they wanted to be in the decision; and prepare to talk to the nurse or doctor about what mattered most to them', respectively.

Discussion

The PANDAs decision aid was designed to facilitate decision making between clinicians and their patients with T2DM who were taking at least two oral glucose-lowering drugs at maximum tolerated dose, had a high HbA1c level and were considering future treatment options including the introduction of insulin. Its evaluation was based on the IPDAS recommendations [25] and the use of the ODSF Framework.[26] The PANDAs trial provides good evidence not only for the clinical effectiveness of decision aids in usual NHS general practice but also for the utility and feasibility of use by both nurses and doctors. In addition, the PANDAs decision aid itself and its use were both effective and acceptable to people with diabetes making treatment choices during clinical consultations.

Decision quality

The findings from the PANDAs trial support the results of other studies which have evaluated the clinical effectiveness of decision aids[11 15] in demonstrating an improvement in decision quality when a decision aid is used in clinical consultations.

Decisional conflict scores, for example, when adjusted for age, education and gender were significantly lower in the intervention group post consultation when compared to the controls, apart from the support sub-score. It is interesting to note that the support sub-score in the intervention group was not significantly lower than the control group - this may be the result of a 'ceiling effect' since patients in both the intervention and control groups may already have been receiving very good diabetes care from their general practices.

Other indicators of decision quality used in the study also demonstrated an improvement when PANDAs was used in consultations – there was, for example, a highly significant

difference in the knowledge of people which particular treatment choice had the greatest chance of lowering blood sugar in those who used the decision aid - although this was not the case when the chance of insulin in lowering complications was considered - here no difference in knowledge was observed. Some patients believe that insulin itself causes complications as a result of misperception [27 28] and this may explain why knowledge did not improve in the intervention group. However, highly significant differences were observed between the intervention and control groups in all the three domains of realistic expectations ['hypos', weight gain and complications] supporting the notion that the PANDAs decision aid ensured that people were fully informed about the potential risks of each option when making their treatment choices.

As far as autonomy was concerned, patients in the intervention arm were more likely to make an autonomous decision using PANDAs when the intervention and control groups were compared allowing for both age and gender. This is consistent with the findings of other studies. [29 30]

These findings of an improvement in decision quality when a decision aid is used in clinical consultations in other conditions and contexts are also supported by a large number of other studies. [23 31]

Decisional Outcomes

The glycaemic control improved in both groups six months after the intervention although no significant difference in glycaemic control was observed between the two groups. Some GPs in the study expressed concern at the start of the trial that glycaemic control could deteriorate in some patients in the intervention group as a result of them choosing not to start insulin.

Further study is necessary to confirm this as this study did not have sufficient power to detect the difference in glycaemic control.

Treatment decisions made using a decision aid should, of course, be ones that are both informed and value-based, and the PANDAs intervention was focussed on the process of decision making rather than the outcomes of those decisions. It is therefore important to note that PANDAs was not designed to persuade people to start treatment with insulin but to help them make an informed treatment decision which was consistent with their values and wishes.

Indeed, there was reduced decisional conflict within the intervention group compared to the control and the decisions which were made were far more likely to be autonomous in nature rather than passive. Participants in the intervention group were also significantly more likely to persist with their chosen option at 6 months. This supports the hypothesis that people who use a decision aid such as PANDAs are more likely to make an informed and value-based decision and are therefore more likely to persist with their treatment choice. Concordance with agreed treatment is, in turn, more likely to lead to better health outcomes and quality of life.

No significant difference was observed on the regret scale scores and although people in the intervention group were over three times more likely to change from undecided to decided [ie come to a treatment decision after their consultation] in the control group, this difference was not statistically significant.

Finally, no significant difference was observed in the preferred choices [ie the treatment decision they came to] of the two groups although a higher proportion of people in the intervention group did choose to initiate insulin. However it is important to note that the use of a decision aid is not intended to produce a particular outcome but to support the patient making a treatment choice based on their knowledge and values. These findings are also consistent with current understanding of the anticipated decisional outcomes when a decision aid such as PANDAs is used in clinical consultations to make treatment choices. [31]

Impact on Clinical Practice

The results of the PANDAs trial demonstrate that the use of the decision aid in usual general practice by both practice nurses and GPs, provided the patient has the opportunity to complete their individualised decision aid prior to their consultation, does not require significant additional consultation time**.** Given the potential benefits of improved adherence to treatment choices and an improved therapeutic relationship between clinicians and their patients, this is likely to make the use of the decision aid acceptable to all parties in general practice, although, its use may require some initial 'investment' in consultation time. In particular, both clinician and patient satisfaction with their consultations, as well as the healthcare provided and received, are both likely to be increased. A further potential advantage is that the decision aid could be used by other clinical members of the primary care team (eg healthcare assistants) potentially increasing the consultation time available to doctors and nurses for other patients. However, the efficient use of the decision aid in consultations may in part be attributed to the familiarity of the clinicians with the decision aid as a result of the brief training clinicians received at entry to the trial. In addition, this may also be due to the process by which the decision aid was developed with the active involvement of both clinicians and people with diabetes to ensure that it was as 'user

friendly' as possible. This involvement of users in the development of the decision aid and a process evaluation of its use in the consultation by both parties has been described elsewhere.[32]

Health service utilisation

The PANDAs trial was a pragmatic one reflecting the reality of primary care diabetes clinics which are mainly run by practice nurses. The mean number of consultations with the nurses, for example, was greater than the mean number of consultations with the GPs and within the intervention group patients were more likely to use the PANDAs decision aid with the practice nurse than the GP. At baseline the distribution of the mean number of diabetes related general practice visits was different in the intervention and control groups with the practice nurses providing more clinical care to people with diabetes in the former reflecting different patterns of care in the different practices.

Patient decision aids

The PANDAs decision aid is one of the few decision aids which focus on decision making in chronic diseases, which take place over several consultations. According to the latest Cochrane Decision Aid Inventory, 10 decision aids have been developed for diabetes.[31] Four decision aids focus on insulin treatment, of which two are for children, one for adults deciding on premixed insulin and one for insulin initiation in T2DM (PANDAs decision aid). However, unlike PANDAs, none have been developed for making treatment decisions about glycaemic control.

Although decision aids have positive effects on many aspects of the decision making process, there remains a large gap in the literature on how decision aids fare "in the real world".

O'Cathain and Thomas (2004) conducted a pragmatic trial of decision aid in a maternity ward and found that health professional were not making use of the available decision aids, although they reported that they approved of them. The reasons for not using them included 'disagreement' with the available decision aids, lack of resources, perceived patients' reluctance to participate and unwillingness to change their "routine care".[33] O'Donnell, Cranney et al, classified the barriers to the use of decision aids in the clinical situation under three categories – the nature of the decision aid itself, the attitudes of patients and healthcare professionals and organisational barriers such as institutional culture and commitment, time constraint and costing. [34]

A number of authors have proposed various strategies to facilitate such use of decision aids in different clinical settings.[35] The effectiveness of these proposed strategies has not yet been formally evaluated. The PANDAs trial however found the decision aid to be highly acceptable to both clinicians and people with diabetes in NHS general practice – a detailed process evaluation of its use can be found elsewhere. This report identifies some of the key challenges to its widespread implementation in NHS general practice.

However, most studies of decision aids have not shown an increase in the level of satisfaction with the decision making process or the decision itself. This may be another example of the 'ceiling effect' whereby the satisfaction with the service or consultation was already high before the intervention. It has also been observed that people tend to report satisfaction after they have made the decisions because they tend to "rationalise" and adapt quickly to uncertain events.[36] Moreover, the effect of decision aids on quality of life and health outcomes indicators which are commonly used in health technology assessments, have yet to be proved. More plausible intermediate outcomes, such as concordance with treatment and

health service utilisation, could be used as alternative indicators to evaluate the use of decision aids.

General practice is a unique healthcare setting where multidisciplinary teams provide holistic, comprehensive and continuity of care to people in the community. Practitioners usually have an established relationship with their patient and an appreciation of their medical and psychosocial background as well as their associated multi-morbid conditions. This puts them in a very good position to advise patients on their treatment options. The use of decision aids to facilitate treatment choices in general practice fits well with the adoption of a Care Planning model for long-term conditions. This model of care, developed by the Diabetes UK Year of Care Programme and recently adopted as a professional standard by the RCGP, is a good way of ensuring that patients with diabetes are both fully informed and fully involved in decisions about their care by supporting their "empowerment" and facilitating the "activation" of people with long-term conditions.[37 38]

Implications for research and clinical practice

For the use of patient decision aids, such as PANDAs, in routine clinical practice to become the accepted norm, the new GP clinical commissioning groups will need to be aware of the benefits of the use of such aids to ensure that decision aids become a professional standard in, for example, newly commissioned pathways for a long-term condition such as diabetes. Investment will also be necessary for the development and the continuing evaluation of decision aid use, as well as for the training of all members of the multidisciplinary team in the importance and in the practical use of decision aids in primary care. Both the patient's experience and patient/clinician satisfaction with the care received and provided is likely to be much improved if this professional standard is adopted by commissioning groups.

Conclusions

The use of the PANDAs decision aid by health care professionals in usual NHS clinical practice with T2DM patients who are making treatment choices in general practice improves decision quality by reducing decisional conflict, improving knowledge and promoting realistic expectations but has no demonstrable effect on glycaemic control.

Patient autonomy however is strengthened by the use of the decision aid and longer term clinical outcomes are likely to be improved. A larger trial of the PANDAs decision aid will be necessary to determine if biomedical parameters are improved when the decision aid is used in normal NHS practice.

Strengths and limitations of this study

The study failed to achieve its planned sample size as a result of recruitment difficulties. The reasons for this were the increase in availability of new oral and injectable glucose lowering drugs (e.g. GLP1 agonosts, exenatide) which were not available at the start of the project, significant staff changes in 2008/9 and the reluctance of practices to participate in the study because of a potential H1N1 flu pandemic in summer 2009. As a result each practice was only able to identify 3-5 eligible patients for inclusion in the trial. It proved impossible to secure a funded time-extension to the study and as a result recruitment ceased at 175 participants. This meant that the study was underpowered to detect a difference of 0.5% in HbA1c between the two groups. The original recruitment period was 12 months but because of the problems surrounding recruitment outlined above, recruitment was extended to 20 months. There was also some evidence of inadvertent recruitment bias with 95 participants allocated to the intervention group and 80 to the control group. This is an important and well recognised consequence of a cluster RCT design and is probably the result of the PANDAs practices being more likely to recruit participants to the trial. There were some differences in

baseline characteristics between the intervention and the control and these were included in an analysis which explored how the estimates of the treatment effect changed when baseline differences were controlled for.

Contributorship statement:

Substantial contribution to conception and design, acquisition of data or analysis and interpretation of data:

NM, CJN, MCJ, BC, AB, IB

Drafting the article or revising it critically for important intellectual content:

NM, CJN, MCJ

Final approval of the version to be published:

NM, CJN, MCJ, BC, AB, IB

NM is the guarantor.

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All authors have completed the Unified Competing Interest form at www.icmje.org./coi_disclosure.pdf and declare that (1) NM, CJN, MC, BC, IB, AB have support from the University of Sheffield for the submitted work; (2) NM, CJN, MC, BC, IB, AB have no relationships with any companies that night have an interest in the submitted work in the previous 3 years; (3) their spouses, partners or children have no financial

relationships that may be relevant to the submitted work; and (4) NM, CJN, MC, BC, IB, AB have no none-financial interests that may be relevant to the submitted work.

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Members of the Sheffield Diabetes UK Group

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The University Of Sheffield.

School Of Medicine & Biomedical Sciences.

Practice Information Sheet

Study Title: ***'PANDAs':*** **Patient Decision Aids for Type 2 Diabetes**
Protocol Ref: **ZH25**
Version: **V6-06-08-2009**

Part 1 tells you the purpose of this study and how your practice will be involved if you take part.

Part 2 gives you more detailed information about the conduct of the study.

Part 1

We would like to invite your practice to take part in a research study. This study will find out whether a patient decision booklet is useful for people with type 2 diabetes who need to make decisions about their diabetes treatment.

Before you decide whether your practice should participate, you need to understand why the research is being done and what it would involve. Please take time to read the following information carefully; talk to others about the study if you wish.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

---

1. What is the purpose of the study?

It is sometimes difficult for patients with Type 2 diabetes to make decisions about the treatment of their illness, especially when it involves taking additional medications or changing to another medication. Informed decision-making not only requires them to know the risks and benefits of the treatment, it also depends on how they feel and think about the treatment. Sometimes, they may not have had opportunity to discuss this information in detail with their doctor or nurse.

A Patient Decision Aid is a simple booklet which contains useful information on diabetes and its treatment. It also explores what patients feel and think about these treatments. It has been used widely to help people to make decisions about their specific illnesses, for example the menopause or a prostate problem.

So the purpose of this study is to find out whether using a patient decision aid before the GP's/Nurse's consultation will improve the quality of patients' decision-making and, eventually, their blood sugar control.

2. Why have I been invited?

Your practice is thought to have at least 1% of its practice population on a practice diabetes register.

3. Do I have to take part?

The participation of your practice is entirely voluntary and it is up to you to decide. We will describe the study and go through this information sheet with you when we visit your surgery if you invite us to do so. We will then ask you to sign a consent form to show you have agreed to take part.

4. What type of study is this?

This is a "Cluster Randomised Trial" in which practices which have consented to participate will be randomly allocated for their participating patients to be given the Patient Decision Aid or to the control group of practices in which normal diabetic practice will be followed.

5. What will happen to my practice if I take part?

If you agree to take part in this study, all GPs and one or two nurses in your practice will be given a *PANDAs* Training Package and the nurses will receive a brief training session at your practice, based on the package. If your practice has been randomised to the Patient Decision Aid, the package will be distributed immediately and this training will take place straightaway. Otherwise the package and training will be offered to your practice at the end of the study, if you wish to opt for this.

However the researchers will, before randomisation, have assisted the practice manager and nurses in how to identify eligible patients based on the following inclusion and exclusion criteria:

Inclusion criteria:
Patients with type 2 DM aged ≥ 21who
- are taking the maximally tolerated doseof oral glucose-lowering drugs at AND have a latest HbA1c ≥ 7.5% throughout the last six months
OR
- have been advised to add or change to insulin therapy but declined previously AND have a latest HbA1c ≥ 7.5%.

Exclusion criteria:
Patients who:
- have a latest HbA1c ≥ 11% unless they have previously declined insulin
- are currently using insulin therapy
- have chronic debilitating illness (including mental illness, visual or cognitive impairment)
- have difficulty understanding English or are unable to read or are without essential reading glasses at the time of consent

Your eligible patients will need to attend your normal clinic twice within six months for the purposes of the study.

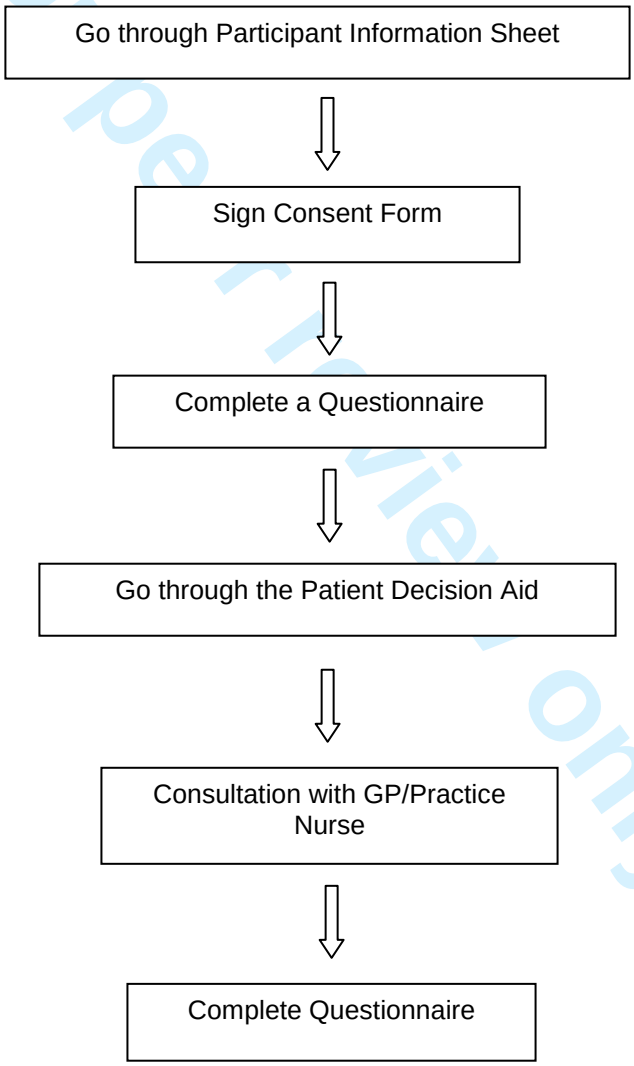
A total of 446 people with type 2 diabetes will be invited to participate in the study and up to 15 would be recruited from your practice until May 2009.

During the first visit, the researcher will go through the Participant Information Sheet with patients. If they agree to participate, the researcher will ask them to sign a consent form, and then to answer a questionnaire (10 minutes).

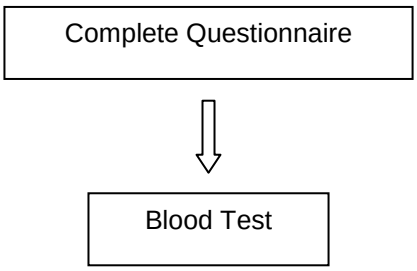
Depending on which treatment group your practice is put into, they will either receive the Patient Decision Aid followed by a consultation with their GP/Practice Nurse or just the consultation without the Patient Decision Aid. Going through the Patient Decision Aid will take 15 minutes. After the consultation, all patients will be asked to fill in another questionnaire (10 minutes).

During the second visit six months later, patients will be asked to answer a questionnaire and a blood sample will be taken to assess their blood sugar level (5 minutes).

Visit 1



Visit 2



6. Expenses and payment

The practice will receive £1,700 for set-up costs, including recruitment of the first consenting patient and then £50 per consenting patient thereafter, to compensate for costs of the time of all practice staff involved (practice manager, GPs, nurses and clerical officers)

At the end of the second visit, your patients will be given a £15 shopping voucher to compensate for the time they have taken to participate in this research.

7. What will the practice have to do?

A one-hour training session will be held at your practice for nurses (and GPs if they wish) on how to use the Patient Decision Aid. For practices in the intervention group this will be given immediately after the practice consents. For practices in the Control group this training will be available on request at the end of the trial.

Each practice will identify 15 eligible participants from the diabetes register and invite them to participate by telephone or mail.

Patients will attend a normal scheduled appointment at a diabetes clinic or a specially allocated appointment if the practice is willing. This appointment will, for practices in the intervention group, be after the proposed date for practice training and no later than 30 June 2009, the proposed closing date for recruitment of patients.

In the intervention group, the participants will use the Patient Decision Aid with the Nurse's assistance.

A questionnaire will be completed for each patient, but the researchers will administer that at your practice.

The GP or Nurse will then counsel the participants as in usual practice.

There will be a follow-up visit at 6-months to check the participants' HbA1c.

Your patients will be required to attend your clinic twice in six months during the study.

During their first visit, they will have to read the Patient Decision Aid, and answer a questionnaire before and after their routine consultation with the Doctor/Nurse. During the second visit, they will have to answer a questionnaire and a blood sample will be taken.

8. What is the procedure that is being tested?

We are testing the use of the Patient Decision Aid, which is a booklet containing evidence-based information about diabetes and its treatment options. It also contains questions which explore their ideas, concerns and values regarding the treatment. So far, more than 500 Patient Decision Aids have been developed in the world for various medical conditions to help patients with their decision-making. It is used to supplement GP- or nurse-led consultations .

9. What are the possible disadvantages and risks of taking part?

The Patient Decision Aid contains information about the possible side effects of different treatment options. Some people may feel anxious after reading this information. However, practice staff and/or the researchers will be able to answer any queries or concerns patients may have during and after the study.

10. What are the possible benefits of taking part?

Previous research on other medical conditions has shown that the use of Patient Decision Aids has helped people to make better-informed decisions about their treatments.

11. What happens when the research study stops?

The practice will continue to provide usual medical care.

12. What if there is a problem?

Any complaint about the way patients have been dealt with during the study or any possible harm they might suffer will be investigated. The detailed information on this is given in Part 2.

13. Will participation of patients in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about patients will be handled in confidence. The details are included in Part 2.

14. Is the purpose of this study educational?

Yes. Part of the data from this research will be used for a PhD study.

This completes Part 1.
If the information in Part 1 has interested your practice and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2

15. What if relevant new information becomes available?

Sometimes we get new information about the intervention being studied. If this happens, the researcher will tell the practice and then the study patients and discuss with them whether they should continue in the study. If patients decide not to carry on, they will be told that their care will be continued by your practice. If they decide to continue in the study, the researcher may ask them to sign an updated consent form.

If the study is stopped for any other reason, we will tell the practice and study patients. The practice will then continue the care of the study patients. The researchers will also keep practices and study patients informed of any new alternative treatment available for their diabetes care.

16. What will happen if patients don't want to carry on with the study?

Patients can withdraw from the study without giving a reason and without it affecting their care. The practice and its patients are also welcome to keep in contact with us to let us know of progress. Information already collected may still be used. Any stored blood samples that can still be identified as yours will be destroyed if you wish.

17. What if there is a problem?

If patients have a concern about any aspect of this study, they should ask to speak to the researchers who will do their best to answer their questions (Contact Brigitte Colwell/Rachel Dwyer at: 0114 271 5824/0114 226 9773 OR Professor Nigel Mathers at: 0114 271 5922). If they remain unhappy and wish to complain formally, they can do this through the NHS Complaints Procedure. Details can be obtained from the GP or the local Primary Care Trust.

In the event that something does go wrong and patients are harmed during the research and this is due to someone's negligence, then patients may have grounds for a legal action for compensation against the NHS but may have to pay their legal costs. The normal National Health Service complaints mechanisms will still be available to study patients.

18. Will patients' participation in this study be kept confidential?

Only the GP/Practice Nurse will have access to patients' medical records. All information collected will be coded and anonymised. The information we have collected as paper copies will be stored under lock and key, while the electronic data can only be accessed with a secure password. Only the researchers, sponsors, regulatory authorities and Research & Development auditors will have access to the identifiable data.

The data we collect will be used only for the purpose of this research; if data were to be used for future studies, further Research Ethics Committee approval will be sought. The data will be kept for 20 years according to the Medical Research Council guidelines.

All information which is collected about patients during the course of the research will be kept strictly confidential, and any information about patients which leaves the surgery will have their name, telephone and address removed so that they cannot be recognised.

19. Involvement of the practice

Patients will be told that the practice has been informed about their participation in this study.

20. What will happen to any samples patients give?

The blood sample patients give will be used to check their HbA1c as part of their routine care.

The blood sample will be collected and sent to a standard laboratory through the surgery. Only the researchers, GPs/Practice Nurse and the laboratory staff will have access to the blood results. An appointment will be arranged by the practice to provide feedback regarding patients' blood results.

21. What will happen to the results of the research study?

The results of this study will be published in medical journals. A summary of the results will be sent to the practice and to study patients by post and you and they will be invited to attend a public seminar.

Patients will not be identified in any report, publications or presentation without seeking their full consent.

22. Who is organising and funding the research?

Sheffield Health and Social Research Consortium is the sponsor of this study and the Department of Health will be funding it. Patients will be told that the practice will be compensated for its costs of including them in this study.

23. Who has reviewed the study?

This study has been reviewed and given favourable opinion by North Sheffield NHS Research Ethics Committee and scientifically reviewed by Sheffield Health and Social Research Consortium as well as the Research for Patient Benefit funding stream of the National Institute for Health Research. Research governance approval on behalf of Sheffield Primary Care Trust has been given by Sheffield Health and Social Research Consortium.

24. Further information and contact details.

General Information about research

Patients and the practice can visit the following web site to obtain more general information about research:

INVOLVE – Promotes public involvement in the NHS: http://www.invo.org.uk

National Electronic Library for Health:

http://www.library.nhs.uk/trials

Specific information about this research project

Ms Brigitte Colwell
Academic Unit of Primary Medical Care
University of Sheffield
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Sheffield
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Tel: 0114 2715824
Fax: 0114 2422136
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Advice to your patients as to whether they should participate

Rachel Dwyer
Academic Unit of Primary Medical Care
University of Sheffield
Sam Fox House
Northern General Hospital
Herries Road
Sheffield
S5 7AU

Tel: 0114 2269773
Fax: 0114 2422136
Email: rachel.dwyer@sheffield.ac.uk

Who should patients approach if unhappy with the study

The Chief Investigator:

Professor Nigel Mathers
Academic Unit of Primary Medical Care
University of Sheffield
Sam Fox House
Northern General Hospital
Herries Road
Sheffield
S5 7AU

Tel: 0114 2715922
Fax: 0114 2422136
Email: n.mathers@sheffield.ac.uk

OR

Using the NHS Complaint Procedures, which you can obtain from the surgery or your local NHS Primary Care Trust. You can visit the following web site for more details: http://www.nhs.uk/England/AboutTheNhs/ComplainCompliment.cmsx

The University Of Sheffield.

School Of Medicine & Biomedical Sciences.

Participant Information Sheet

Study Title: **Patient Decision Aid for Type 2 Diabetes**
Protocol Ref: **ZH25**
Version: **V3-22/04/07**

> **Part 1** tells you the purpose of this study and what will happen to you if you take part.
>
> **Part 2** gives you more detailed information about the conduct of the study.

Part 1

We would like to invite you to take part in a research study. This study will find out whether a patient decision booklet is useful for people with type 2 diabetes who need to make decisions about their diabetes treatment.

Before you decide whether to participate, you need to understand why the research is being done and what it would involve. Please take time to read the following information carefully; talk to others about the study if you wish.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

---

1. What is the purpose of the study?

It is sometimes difficult to make decisions about the treatment of your illness, especially when it involves taking additional medications or changing to another medication. Informed decision-making not only requires you to know the risks and benefits of the treatment, it also depends on how you feel and think about the treatment. Sometimes, you may not have had opportunity to discuss this information in detail with your doctor or nurse.

A Patient Decision Aid is a simple booklet which contains useful information on diabetes and its treatment. It also explores what you feel and think about these treatments. It has been used widely to help people to make decisions about their specific illnesses, for example menopause or prostate problem.

Therefore, the purpose of this study is to find out whether using a patient decision aid before the GP's/Nurse's consultation will improve the quality of your decision-making and, eventually, your blood sugar control.

2. Why have I been invited?

Your GP/Practice Nurse has read through your medical notes and they found that your blood sugar is not well controlled. You might need a change in your treatment and this will involve you making a decision what you want to do to improve your blood sugar control.

A total of 446 people with type 2 diabetes will be invited to participate in the study.

3. Do I have to take part?

Your participation is entirely voluntary and it is up to you to decide. We will describe the study and go through this information sheet with you when you attend the clinic. We will then ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason. This would not affect your treatment or the standard of care you receive.

4. What type of study is this?

This is a "Randomised Trial". Sometimes we don't know which way of treating patients is best. To find out, we need to complete different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same to start with, patients from each practice are put into a group by chance.

5. What will happen to me if I take part?

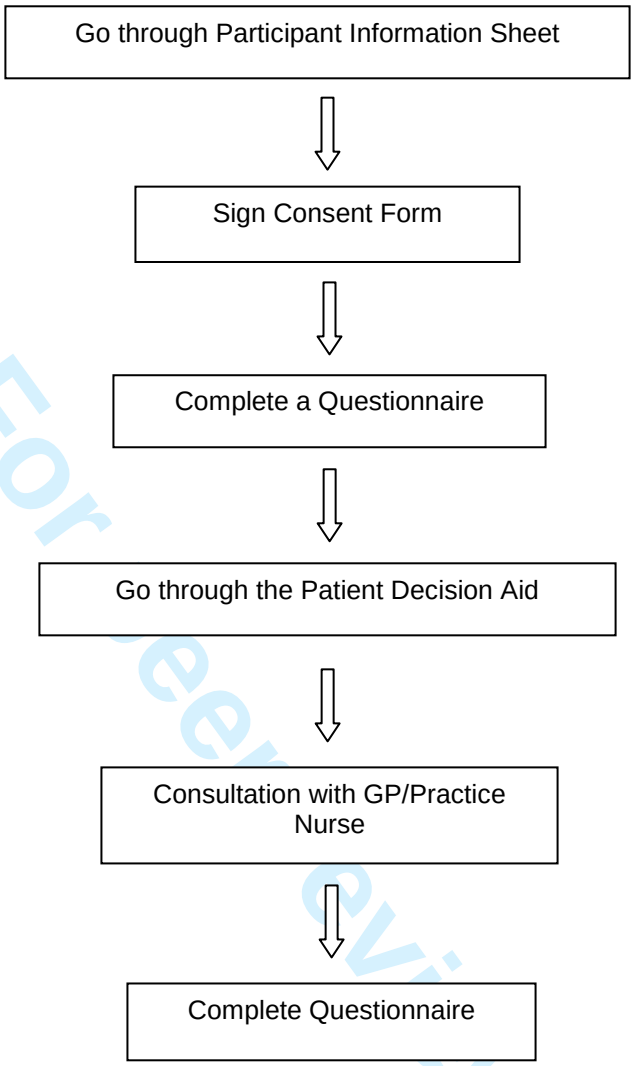
If you agree to take part in this study, you will attend your normal clinic twice within six months. These visits, as far as possible, will coincide with your routine follow-up.

During the first visit, the researcher will go through the Participant Information Sheet with you. If you agree to participate, the researcher will ask you to sign a consent form, followed by answering a questionnaire (10 minutes).

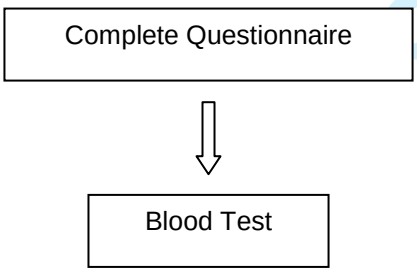
Depending on which treatment group you are put into, you will either receive the Patient Decision Aid followed by a consultation with your GP/Practice Nurse or just the consultation without the Patient Decision Aid. Going through the Patient Decision Aid will take 15 minutes. After the consultation, you will be asked to fill in another questionnaire (10 minutes).

Six months later you will be contacted by a member of the PANDAs research team, prior to being sent a postal questionnaire for you to complete and return to us. We will also need a recent blood sugar level reading, which might mean that you will need to visit your practice to have this done.

Visit 1



Visit 2



6. Expenses and payment

When we have received your completed questionnaire, you will be sent a £15 shopping voucher to compensate for the time you have taken to participate in this research.

7. What will I have to do?

You are required to attend your clinic twice in six months during the study.

During the first visit, you will have to read the Patient Decision Aid, and answer a questionnaire before and after your routine consultation with the Doctor/Nurse. During the second visit, you will have to answer a questionnaire and a blood sample will be taken.

You should not participate in this research if you are currently involved in other drug studies, or have been in the past one-year.

8. What is the procedure that is being tested?

We are testing the use of the Patient Decision Aid, which is a booklet containing evidence-based information about diabetes and its treatment options. It also contains questions which explore your ideas, concerns and values regarding the treatment. So far, more than 500 Patient Decision Aids have been developed in the world for various medical conditions to help patients with their decision-making. It is used to supplement consultations with the doctors and nurses.

9. What are the possible disadvantages and risks of taking part?

The Patient Decision Aid contains information about the possible side effects of different treatment options. Some people may feel anxious after reading this information. However, your GP or nurse as well as the researchers will be able to answer any queries or concerns you may have during and after the study.

10. What are the possible benefits of taking part?

Previous research on other medical conditions has shown that the use of Patient Decision Aids has helped people to make better-informed decisions about their treatments.

11. What happens when the research study stops?

Your GP/Practice Nurse will continue to provide medical care for you.

12. What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be looked into. The detailed information on this is given in Part 2.

13. Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

14. Is the purpose of this study educational?

Yes. Part of the data from this research will be used for a PhD study.

This completes Part 1.
If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2

15. What if relevant new information becomes available?

Sometimes we get new information about the intervention being studied. If this happens, the researcher will tell you and discuss whether you should continue in the study. If you decide not to carry on, your care will be continued by your GP. If you decide to continue in the study, the researcher may ask you to sign an updated consent form.

If the study is stopped for any other reason, we will tell you and your GP will continue your care. We will also keep you informed of any new alternative treatment available for your diabetes care.

16. What will happen if I don't want to carry on with the study?

You can withdraw from the study without giving a reason and without affecting your care. You are also welcome to keep in contact with us to let us know your progress. Information already collected may still be used. Any stored blood samples that can still be identified as yours will be destroyed if you wish.

17. What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (Contact Ms Brigitte Colwell at: 0114 2715824 OR Professor Nigel Mathers at: 0114 2715922). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the GP or the local Primary Care Trust.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence, then you may have grounds for a legal action for compensation against the NHS but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

18. Will my taking part in this study be kept confidential?

Only your GP/Practice Nurse will have access to your medical records. All information will be coded and anonymised. The information we have collected as paper copies will be stored under lock and key, while the electronic data can only be accessed with a secure password. Only the researchers, sponsors, regulatory authorities and Research & Development auditors will have access to the identifiable data.

The data we collect will be used only for the purpose of this research; if data were to be used for future studies, further Research Ethics Committee approval will be sought. The data will be kept for 20 years according to the Medical Research Council guidelines.

All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you which leaves the surgery will have your name, telephone and address removed so that you cannot be recognised.

19. Involvement of the General Practitioner/Family doctor (GP)

Your GP has been informed about your participation in this study.

20. What will happen to any samples I give?

The blood sample you give will be used to check for your sugar control (HbA1c). This is part of your normal routine care.

The blood sample will be collected and sent to a standard laboratory through the surgery. Only the researchers, GPs/Practice Nurse and the laboratory staff will have access to the blood results. An appointment will be arranged by the practice to provide feedback regarding your blood results.

21. What will happen to the results of the research study?

The results of this study will be published in medical journals. A summary of the results will be sent to you by post and you will be invited to attend a public seminar.

You will not be identified in any report, publications or presentation without seeking your full consent.

22. Who is organising and funding the research?

The Sheffield Health and Social Research Consortium is the sponsor of this study and the Department of Health will be funding the research. Your healthcare providers will be paid for including you in this study.

23. Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, well-being and dignity. This study has been reviewed and given favourable opinion by North Sheffield Local Research Ethics Committee.

24. Further information and contact details.

General Information about research

You can visit the following web site to obtain more general information about research:

INVOLVE – Promotes public involvement in the NHS: http://www.invo.org.uk

National Electronic Library for Health:
http://www.library.nhs.uk/trials

Specific information about this research project

Ms Brigitte Colwell
Academic Unit of Primary Medical Care
University of Sheffield
Sam Fox House
Northern General Hospital
Herries Road Sheffield
S5 7AU

Tel: 0114 2715824
Fax: 0114 2715915
Email: b.colwell@sheffield.ac.uk

Advice as to whether you should participate

Ms Brigitte Colwell
Academic Unit of Primary Medical Care
University of Sheffield
Sam Fox House
Northern General Hospital
Herries Road Sheffield
S5 7AU

Tel: 0114 2715824
Fax: 0114 2715915
Email: b.colwell@sheffield.ac.uk

Who you should approach if unhappy with the study

Professor Nigel Mathers
Academic Unit of Primary Medical Care
University of Sheffield
Sam Fox House
Northern General Hospital
Herries Road Sheffield
S5 7AU

Tel: 0114 2715922
Fax: 0114 2715915
Email: n.mathers@sheffield.ac.uk

OR

Using the NHS Complaint Procedures, which you can obtain from the surgery or your local NHS Primary Care Trust. You can visit the following web site for more details: http://www.nhs.uk/England/AboutTheNhs/ComplainCompliment.cmsx