

A randomised controlled trial in diabetes demonstrating the positive impact of a patient activation strategy on diabetes processes and HbA1c: The WICKED project.

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Abstract

Background:

Patient activation is a demonstration of people participating effectively in their own care as measurable in objective outcomes. Techniques of activating patients are various.

Aims:

We developed a structured information booklet to promote patient activation and report the 1 year outcomes of a randomised controlled trial assessing its impact on diabetes care processes and on glycaemic control.

Design and Setting:

It is an open label cluster randomised trial involving all people with diabetes aged more than 18 years within Wolverhampton Clinical Commissioning Group.

Methods:

All people with diabetes were cluster randomised into a group who were multiply mailed (MM) at 0, 3 and 6 months whilst a control group were mailed once at 3 months. Comparison of a Failed Process Score (FPS) between active and control groups was performed at the 0, 3 and 12 months and of HbA1c at baseline and 12 months.

Results and Conclusion:

FPS improved significantly with multiple mailing ($p=0.013$), with particular impact on those with poor baseline FPS (≥ 2) (achieved FPS ≤ 1 at 12 months 49.2% vs. 46.0%, $\chi^2=6.09$, $p<0.05$).

Overall HbA1c% across the year (adjusted) was significantly better with MM ($p=0.021$), with specific impact in those with a baseline HbA1c ≤ 7.5 (MM HbA1c% 6.7 ± 0.07 (mean \pm SEM) vs. 7.0 ± 0.09 ; mean difference (\pm SEM) 0.3 ± 0.1 , $F=11.1$, $p=0.009$).

The direct provision of structured information to the people with diabetes activates them to engage in their care delivery as reflected in care process and glycaemic control outcomes.

Introduction

Diabetes is a costly world-wide epidemic that requires further exploration of the concepts of patient engagement, enablement and empowerment and partnership working to activate people to self-care (1), and thus contribute to the amelioration of the many personal and societal aspects of the diseases' burden (2, 3). Patient activation is a broad behavioural concept (4), and its intent is to encourage people with long term conditions such as diabetes to acquire the knowledge, skills and confidence to participate actively but also effectively in their own disease management as measurable in defined outcomes. A number of user focused non pharmacological interventions have demonstrated an effect on diabetes specific surrogate markers (5) and there is evidence that increased patient activation is associated with better behaviours and outcomes (6). As such, it perhaps should be considered as an outcome of diabetes care provision in its own right (7).

One traditional mechanism is to promote knowledge acquisition through structured education programs but they are costly, with uncertain outcomes and they have very poor uptake in the United Kingdom (8, 9). Another technique is the provision of structured and easy to understand information directly to users in an attempt to instigate action through self-directed reflective learning (10) which more recently has been encapsulated in the "Information prescription" initiative (11). It is not our intention in this paper to suggest one mechanism is better than the other, nor have we compared these 2 methodologies and both aspire to modify behaviour. Our focus is on the use of information.

In our local model of diabetes care, WICKED (Wolverhampton Interface Care, Knowledge Empowered Diabetes) , we have determined that it should be user centric, that patient activation is a service objective, that patients have a right to their own specific information, that patients should have the opportunity to use that information to improve their care and to liaise in equal and informed partnership with those providers of care by establishing their agreed care plans in a recognised processes of care planning (12). We also understand, as will any larger scale provider, that in our local health economy of around 265,000 people, with more than

17,000 people with known diabetes and a high incidence rate of new diabetes, we must deliver any mechanism systematically and equitably, without exclusion or exception, and cheaply so as not to embarrass resource requirements, and effectively so that it must be evidenced to be of benefit. Yet there is no known trial to evaluate the impact of provision of individualised diabetes specific information to people with diabetes, agnostic of their attitudes, aptitudes or degree of engagement with the health service, on any measure of patient engagement.

Having published preliminary outcomes (13) we are now presenting the end study full year findings of this large RCT to determine the impact of the universal provision of diabetes specific information on patient activation as measured by the rate of completion of key care processes in diabetes and, in addition, on the key diabetes surrogate marker of glycaemic control, the HbA1c.

Methods

As previously described (13), a systematically designed, structured and individualised report containing their core key diabetes related information, which was the intervention called “My Diabetes, My Information, My Plan” (available at www.wdconline.org.uk, attached as appendix 1), was mail delivered across our entire health economy to people with diabetes divided into 2 groups according to a cluster randomisation protocol (13).

The recording or measurement of 9 key diabetes process measures and their outcomes were analysed (HbA1c, systolic blood pressure, cholesterol or cholesterol / HDL cholesterol ratio, body mass index, recording of smoking status, retinal screening, urinary albumin creatinine ratio, serum creatinine, foot examination). For process outcomes, a reading within 15 months was taken as positive. The Failed Process Score (FPS) was zero if all measures were attained within 15 months and 9 meant all failed to be measured.

The positive 3 month impact of a single mailing versus no mailing on diabetes process measure outcomes, measured as the Failed Process FPS, which taken as a marker of patient activation, has already been published (13).

At the end of 3 months, all people in the control group were crossed over also to receive the information booklet for the first time and for once only (single mailed, SM). People in the active group received the booklet a second time at 3 months and then finally a third time at 6 months (multiply mailed, MM).

Both groups were followed up for 12 months from baseline. We continued to accrue data on a rolling monthly basis ensuring systematic quality in data capture as is our routine service practice (14) but it was not analysed until the end of 12 months period. Therefore, the final analysis is a comparison of multiple mailings (n=3) delivered at baseline, 3 and 6 months versus a single mailing undertaken at 3 months. Compared to the baseline population, at the end of 12 months, 866 people in total were lost to ascertainment (deceased=453, moved away=378 and not

traceable=35) leaving a final cohort of 13,956 people at the end of 12 months of the trial period.

A complete log of all failed deliveries returned back to the department and all enquiry phone calls received was kept but this was not subject to any form of analysis as it was less than 1% and unlikely to be of any meaningful significance.

Results are presented as the mean \pm the standard deviation (SD) unless otherwise stated.

All data were analysed on SPSS version 22 with the results of statistical tests taken as significant at $p < 0.05$. Comparison of means was by Student's t test or by the Man Whitney U tests for parametric and non-parametric data respectively, differences between proportions by the Chi square test and the analysis of the effects of confounding factors was by univariate or binary logistic regression analysis for ordinal or categorical data respectively.

The study was registered in the UK national research database (UK CRN ref: DRN 795, available at <http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=14324>) and US clinical trials database (Clinical Trials Registration: NCT02200965). Ethical permission was obtained from NHS Health Research Authority (NRES committee North East-York, REC Ref: 13/NE/0052) and further clarification was obtained from National Information Governance Board.

Results

Demographic and clinical data are presented in Table 1, noting the minor differences between groups for deprivation score, BMI, systolic blood pressure and CHD risk status.

The Failed Process Score

The mean baseline FPS was not significantly different between groups (Table 2) whilst mean FPS was significantly lower at 12 months in those multiply mailed ($p = 0.013$). For those with a baseline FPS ≤ 1 , neither the baseline FPS score nor the 12 months FPS score was different between groups and nor was there any significant difference in the proportion that deteriorated to FPS ≥ 2 (MM 28% vs. SM 28%, ns). However, for those with a baseline FPS ≥ 2 , the mean baseline FPS was similar, but, at 12 months, FPS was significantly better in those multiply mailed ($p=0.002$) and significantly more attained a good FPS category of ≤ 1 (MM 49% vs. SM 46%; $\chi^2 = 6.09$, $p = 0.014$). In those with baseline FPS ≥ 2 , in binary logistic regression ($\chi^2 = 370.9$, $p < 0.001$), significant factors for attaining 12 months FPS ≤ 1 were baseline FPS ($p < 0.001$), gender ($p=0.022$) and multiple mailing ($p=0.028$) such that the likelihood ratio of achieving the good attainment category of FPS ≤ 1 with multiple mailing was 1.15 (95% CI 1.02 – 1.29) compared to those mailed once.

HbA1c

We selected those who had both a baseline HbA1c measure and a repeat HbA1c at least 6 months after the initial mailing date ($n= 10015$, MM 5637, single SM 4378). Their baseline characteristics showed no significant difference for age, gender, ethnicity, type of diabetes, duration of diabetes, baseline FPS score or baseline % glycated HbA1c (MM 7.8 ± 1.64 vs. 7.8 ± 1.62) but small but significant differences were found for the index of deprivation (MM 34.7 ± 15.8 vs. 35.9 ± 16.5 , $p = 0.001$) and BMI (MM 30.8 ± 6.1 vs. SM 31.2 ± 6.2 kg/m², $p = 0.013$). In the whole cohort HbA1c improved over the year (baseline HbA1c% 7.8 ± 1.6 vs. final HbA1c 7.5 ± 1.6 , $p < 0.001$) (Fig 1, top panel). The crude end year HbA1c was not significantly

different between groups (MM 7.5 ± 1.6 vs. SM 7.6 ± 1.6 , ns). However, adjusting for relevant factors (univariate regression analysis, $F=54.4$, $r^2 = 0.12$, $p<0.001$: age ($p<0.001$); duration of diabetes ($p<0.001$), BMI ($p<0.001$) but gender, ethnicity and type of diabetes all non-significant), then the MM group differed significantly from those singly mailed ($F = 5.32$, $p = 0.021$) with an adjusted mean (\pm SEM) difference of 0.2 ± 0.08 HbA1c%. Introducing baseline HbA1c% categories as ≤ 7.5 , 7.6-8.4 and ≥ 8.5 into the model ($F=99.9$, $r^2=0.40$, $p<0.001$: age, $p<0.001$; duration of diabetes, $p<0.001$; gender, ethnicity, IMD score, BMI and type of diabetes all not significant), showed the impact of being multiply mailed remained significant ($F = 3.97$, $p=0.046$) but with a strong effect according to baseline HbA1c category ($F=363.9$, $p<0.001$). The significant point difference lay amongst those in the baseline HbA1c category ≤ 7.5 (MM HbA1c% 6.7 ± 0.07 (mean \pm SEM) versus 7.0 ± 0.09 , mean difference (\pm SEM) of 0.3 ± 0.1 , $F=11.1$, $p=0.009$). Analysis of the change between final and initial HbA1c values by HbA1c category (Fig 1, bottom panel) showed this to be an improvement or at least avoidance of deterioration of HbA1c levels in those multi mailed in the HbA1c% category ≤ 7.5 , amongst whom the delta HbA1c% was 0.07 ± 0.07 vs. $+ 0.20 \pm 0.08$ (delta HbA1c 0.3 ± 0.1 , $F=7.05$, $p=0.008$).

Discussion

Summary:

The positive outcomes for the impact of a patient activation tool, “My Diabetes, My Information, My Plan”, on diabetes process attainment (FPS) and glycaemic control (HbA1c) are novel.

They should be considered in relationship to the potential to benefit as well as the balance of the likely impact of patient activation versus the magnitude of service inactivation.

For the Failed Process Score, in the overall cohort, the cyclical impact of the UK primary care QOF, in which maximal service effort is exerted to complete the key diabetes process measures in order to achieve end of year financial reimbursement, can easily be discerned. Both groups showed a significant improvement over the QOF time frame but with a significant better attainment in those multiply mailed, meaning that a discernable effect was demonstrated in the face of performance managed service activation. In the whole cohort, almost 60% were already in a high attainment position and thus could not be further benefitted. When considering those with poorer baseline attainment ($FPS \geq 2$), at the end of 12 months they were 15% relatively more likely to be in the higher attainment category ($FPS \geq 1$). Thus the impact of mailing singly (as initially published) and then multiply versus singly can be seen to have achieved its objective of having a significant impact over and above that of the current maximal driver of diabetes service activation, namely QOF, and to have separately benefited the intended target groups in lower attainment categories.

The impact on HbA1c can be similarly considered. Our a-priori expectation was that if any differential impact were to have occurred, it would have been in those with poorer baseline glycaemic control but, in hind sight, the opposite outturn is perhaps both predictable and understandable. As is well recognised, the focus of clinicians and services will be on poorly controlled patients (5, 15), service inertia and delay is a crucial reason for poor attainment in such patients (16, 17) and the propensity to improve is almost certainly dependent on service intervention through drug titration

and, in many patients, escalation to injectable therapies (18). A patient in this category is unlikely to have been able to influence their own outcome over and above the impact of service interventions. However, in the better baseline HbA1c attainment cohort (HbA1c \leq 7.5%), the service would have been less focused on them as they were already at or below the UK HbA1c attainment target (19), there would have been no perception that drug therapies required modification, and patients would have been more likely to have been able to significantly modify their own already good attainment perhaps by diet and life style interventions or by improved concordance. The multiply mailed group essentially maintained their HbA1c whilst the comparators deteriorated relatively by 0.3 HbA1c%. This seems small, but roughly equates half of the size of effect of the addition of a second or third line oral hypoglycaemic agent in Type 2 diabetes (20) but in this case, a benefit deliverable to thousands of patients. It is the same if not better magnitude of effect as seen in highly structured education programmes such as DESMOND or DAFNE(21, 22). It is regrettable that we are not able to comment on the potential impact of single mailing, or otherwise multiple mailing, compared to not being mailed at all, but a logical assumption is that multiple mailing would have achieved some degree of greater benefit if it had been compared to no mailing at all. We have already addressed the question as to where a single mailing has benefit (to FPS) and now show multiple mailing has added benefit over single mailing (to FPS and HbA1c).

Comparison with existing literature:

The small size of any magnitude of effect can be further considered in the light of know evidence. In a recent metanalysis, non - pharmacological interventions were extensively reviewed (5) and they can be categorised into 3 categories of quality improvement strategies targeting health systems, healthcare providers and people with diabetes. It was concluded in this review that health system wide interventions and patient focused strategies are more likely to influence outcomes in low to intermediate risk groups, while the high risk group gets most benefit from strategies focusing on interventions by healthcare professionals; pointing to the possible beneficial impact and increasing need for service activation in this high risk group (16, 17). In this context, all such non – pharmacological interventions have only shown modest improvements in hard; albeit surrogate, outcomes such as HbA1C of

the average magnitude of 0.37 %, precisely in line with the magnitude of benefit that we currently demonstrate.

Strengths and Limitations:

The strength of the study is its large size, no selection bias and a cluster randomised design that made it possible to evidence this intervention in a highly complex care delivery structure of the NHS.

The limitations of the study are acknowledged to be the relatively small magnitude of change observed, the relatively short time frame to first assessment of the multiply mailed vs. the single mailed group and the inability to assess hard longer term clinical outcomes within that time frame. It is possible that the reported observed benefit at 3 months (13) could have been by chance or random finding but persistence of improvement at the end of 12 months has confirmed the benefits of intervention. A significant disadvantage of the study is that there is not a control group that received no intervention of any sort, but we were obligated to fit in the with local NHS service cycles and to accept a perception of lack of equity in having a control group with no intervention at a time when we had already demonstrated a variety of benefits of the proposed intervention (13,14, 23, 24, 25). We were not aware of the language and literacy status of our studied population and the booklet was not translated into multiple other languages but considering that Wolverhampton is an urban area ranked 21st for deprivation in England (26) , with a 30% ethnic minority build, is ranked 16th in the UK for poor attainment of qualifications (27); although the data were tested for the impact of deprivation score which did not have an impact on our findings, and probably adds to the strength of our findings. The strength of the study also includes its minimal loss to follow up and cluster randomisation methodology used to provide robust evidence in this evidence deficient arena of diabetes care.

In summary, in a large randomised controlled trial, we have demonstrated that the provision of structured diabetes-specific clinical information, through a specifically designed booklet, led to significant improvements in diabetes process outcomes. We also show impact on the long term measure of glucose control. We are not aware of any previously published randomised control trial in diabetes of a whole health economy intervention that is evidence to lead to patient activation.

Implications for Research and Practice:

We conclude that people with diabetes are manifestly able to understand their most important diabetes related information when it is presented to them in a simple but structured format and that this promotes their activation in discernible and measurable outcomes. The booklet is easy to generate, and is seemingly low tech, with the proviso that the enabling background complexities of data integration and quality assurance are at a very high and well governed standard. Thus it should be easily reproducible in other health economies. It can be disseminated independently of health care professionals, and so is not reliant on service activation, nor dogged by service inertia, and it can be systematically distributed across a whole population.

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How it Fits:

1. Completion of structured diabetes care processes can be influenced by patient focused interventions.
2. Provision of patient specific written information can drive care and improve access to health care and diabetes specific surrogate marker such as HbA1C.
3. Improved engagement and better access can be taken as indirect measures of patient activation which in itself should be an outcome in diabetes care.

Table 1

The demographics and clinical parameters of those receiving multiple mailings of a structured information booklet (MM, 0, 3 and 6 months) compared to those mailed singly (SM, 3 months). Results are the means \pm SD or otherwise percentages.

Demographic data	MM N = 8045	SM N = 5911	P value
Age (years)	63.9 \pm 14.5	63.4 \pm 14.4	NS
Sex (male)	54%	55%	NS
Ethnicity (White)	69%	70%	NS
Deprivation Score	35.2 \pm 15.7	35.9 \pm 16.6	P < 0.05
Type 2 Diabetes	94%	94%	NS
Duration of Diabetes	10.4 \pm 8.4	10.5 \pm 8.7	NS
Smoking (never smoked)	60%	60%	NS
Clinical Parameters			
BMI (kg/m ²)	30.9 \pm 6.3	31.1 \pm 6.3	P <0.05
BP (mm Hg)	135 \pm 16	132 \pm 16	P <0.001
HbA1C DCCT (% glycated)	7.8 \pm 1.7	7.8 \pm 1.7	NS
HbA1c IFC (mmol/mol)	61.5 \pm 18.1	61.6 \pm 18.3	NS
Urine ACR (mg/mmol)	8.7 \pm 34.6	8.9 \pm 43.9	NS
Creatinine (μ mol/l)	88.3 \pm 43.2	89.1 \pm 46.4	NS
Chol /HDL Chol Ratio	3.8 \pm 1.4	3.8 \pm 1.4	NS
Cardiovascular status (primary risk)	71%	69%	P <0.01
10 year Framingham CHD risk (%)	18.0 \pm 7.5	17.8 \pm 7.4	NS
Any Retinopathy	58%	57%	NS
Any Foot Risk (intermediate or high)	57%	57%	NS

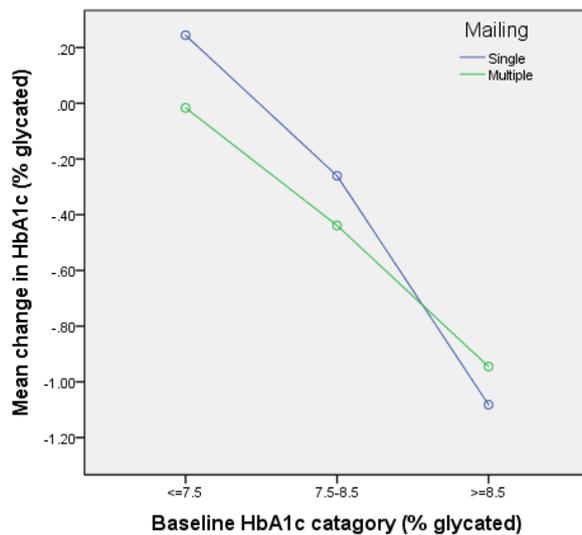
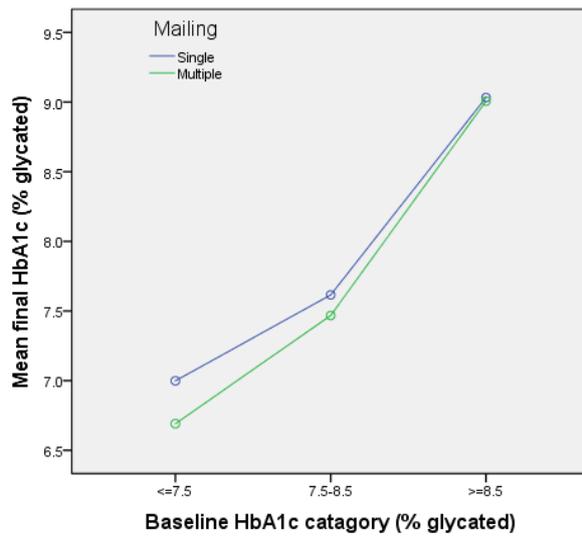
Table 2

A comparison of the Failed Process Score (FPS) between those multiply mailed (MM, 3 mailings) versus those singly mailed (SM) in the whole cohort or those with a baseline FPS ≤ 1 or ≥ 2 . Results are the means \pm SD and are analysed by the Mann Whitney U test.

	MM	SM	P value
FPS Whole cohort	N = 8045	N= 5911	
Baseline	1.70 \pm 1.78	1.71 \pm 1.81	NS
12 Months	1.65 \pm 1.92	1.72 \pm 1.95	P = 0.013
FPS ≤ 1	N = 4665	N = 3412	
	0.50 \pm 0.50	0.40 \pm .50	NS
	1.23 \pm 1.47	1.24 \pm 1.50	NS
FPS ≥ 2	N = 3380	N = 2499	
Baseline	3.35 \pm 1.58	3.38 \pm 1.61	NS
12 Months	2.25 \pm 2.30	2.38 \pm 2.28	P = 0.002

Legend Figure

The mean (top panel) and delta (bottom panel) HbA1c outcomes at the end of 12 months categorised by baseline HbA1c status in those receiving multiple versus single mailings.



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