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The WISDOM self-management intervention: A cost-effectiveness analysis to support the transformation of type 2 diabetes care in England

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Abstract

Objectives: To assess the cost-effectiveness of the WISDOM self-management intervention for type 2 diabetes compared with care as usual.

Design: We performed a difference-in-differences analysis to estimate differences in risk factors for diabetes complications between people in the WISDOM group ($n = 25,276$) and a control group ($n = 15,272$) using GP records. A decision analytic model was then used to extrapolate differences in risk factors into costs and outcomes in the long term.

Setting: Participating GP practices in West Hampshire and Southampton, UK.

Participants: All people diagnosed with type 2 diabetes between January 1990 and March 2020 ($n = 40,548$).

Outcomes: Diabetes-related complications, quality-adjusted life years (QALYs) and costs to the English National Health Service at 5 years and lifetime.

Interventions: The WISDOM intervention included risk stratification, self-management education programme to professionals and people with type 2 diabetes, and monitoring of key treatment targets.

Results: WISDOM was associated with less atrial fibrillation [$p = 0.001$], albuminuria [$p = 0.002$] and blood pressure [$p = 0.098$]. Among all people in the intervention group, WISDOM led to 51 [95%CI: 25; 76] QALYs gained and saved £278,036 [95%CI: −631,900; 176,392] in the first 5 years after its implementation compared with care as usual. During those people' lifetime, WISDOM led to 253 [95%CI: 75; 404] QALYs gained and cost saving of £126,380 [95%CI: −1,466,008; 1,339,628]. The gains in QALYs were a result of reduced diabetes-related complications through improved management of the associated risk factors.

Conclusions: The WISDOM risk-stratification and education intervention for type 2 diabetes appear to be cost-effective compared to usual care by reducing diabetes complications.

1 | INTRODUCTION

Diabetes affects approximately 9% of the UK adult population and is associated with several complications that reduce people's quality of life and survival.[1] Diabetes care accounts for 10% of England's National Health Service (NHS) budget and is projected to increase two-fold in the next 25 years.[2] This poses a threat to the sustainability of the NHS given tight healthcare budgets. Over 90% of total diabetes costs are for the treatment of type 2 diabetes and 80% of the diabetes care costs are due to mostly preventable complications.[3]

Therefore, Clinical Commissioning Groups (CCGs) throughout England are developing and implementing new models of care that accommodate the transition from hospital-led care to patient-centred and community-based care for chronic conditions including diabetes.[4] CCGs were responsible for allocating £44 million from the Diabetes Transformation Fund between 2017 and 2019 to new models of diabetes care aiming to increase uptake of structured education and improve the achievement of key treatment targets issued by the National Institute for Health and Care Excellence (NICE).[5] However, little evidence exists about whether these expectations are being met.

The West Hampshire Improving Shared Diabetes Outcome Measures (WISDOM) project is a promising new model of diabetes care in England that has been funded by the Diabetes Transformation Fund and praised by NHS England for improving the three treatment targets (i.e., blood glucose control, blood pressure and cholesterol). WISDOM encouraged GP surgeries to focus on people with type 2 diabetes who were narrowly missing their treatment targets and were likely to benefit from small practice-level interventions to improve their diabetes care. Reviewing data regularly enabled the surgeries to understand their performance and this informed a wider change in culture.

The demonstration of cost-effectiveness of WISDOM would not just justify the investment from the Transformation Fund but it would also provide a solid evidence base for other areas in England to roll out a similar potentially cost-effective intervention. The aim of this study was to assess the cost-effectiveness of WISDOM by investigating its impact on diabetes complications, quality and length of life, and costs to the NHS compared with care as usual.

What's new?

- There is little evidence about the ongoing reorganisation of diabetes services in England.
- We analysed a large dataset of patient records using a combination of advanced quasi-experimental and economic modelling methods to estimate long-term treatment effects.
- The WISDOM type 2 diabetes risk stratification and healthcare professional education programme together with "refresher" participant education appears to be cost-effective by reducing diabetes complications compared with usual care.
- We provide economic evidence about NHS investment to transform diabetes care in South East England.
- Stakeholders involved in the process of transforming diabetes care in England should consider a rollout of this intervention across the country.

2 | MATERIALS AND METHODS

2.1 | Setting and intervention

The West Hampshire CCG received poor rating in the 2016/17 CCG Improvement and Assessment Framework (replaced by the NHS Oversight Framework in 2019) for diabetes care based on data from the National Diabetes Audit.[6] As a response, it used resources from the Diabetes Transformation Fund to commission the WISDOM project in order to achieve the three NICE diabetes treatment targets in primary care and improve attendance in structured education.[6] WISDOM was first implemented in December 2017 and recruited 94% of GPs in West Hampshire within a year. Facing similar difficulties in reaching the NICE Diabetes targets, the Southampton City CCG started commissioning the WISDOM project in September 2018, with an uptake by GPs of about 54% by the end of this year. Diabetes care services in the two CCG areas are different in size, range from long-established specialist-led community-based care in West Hampshire to traditional hospital-led care in Southampton City, and cover a variety of population in terms of socioeconomic deprivation and residence and urban/rural area.[7] However, the prevalence of type 2 diabetes and the achieved NICE diabetes targets are very similar between the two CCG areas.[8] Detailed information about WISDOM and a graphical illustration is provided in Appendix 1.

2.2 | Data

Participant-level data from electronic patient records routinely collected at GP practices were used consisting of 40,548 people from January 1990 to March

2020 (4,743,413 total observations) recorded as having a diagnosis of type 2 diabetes in West Hampshire and Southampton City. Data included patient characteristics including age, sex, ethnicity and multiple deprivation index (IMD)[9] based on postcode of residence, test results on risk factors of diabetes-related complications including HbA1c, HDL and LDL cholesterol, systolic blood pressure, heart rate, haemoglobin, eGFR, white cell blood count, smoking status, atrial fibrillation, pulmonary vascular disease, number of GP attendances and albuminuria. Data also included information on co-morbidities and disease events including duration of diabetes, years since myocardial infarction, ischemic heart disease, amputation, stroke, ulcers, mental health diagnosis. Lastly, we also included data on family history of disease events and prescriptions. People younger than 15 years old were excluded as WISDOM was an intervention for adults living with Type 2 diabetes and those who were younger than 15 may have been incorrectly included and may have had Type 1 diabetes. We also excluded people who did not have at least one observation before and one observation after WISDOM started.

There were three dates when the intervention was rolled out across GP practices, December 2017, June 2018 and September 2018. As all people in our sample (n = 40,548) received WISDOM eventually, we included people in the intervention group as people who received WISDOM starting in December 2017 (n = 25,276) and people in the control group as people who received WISDOM in September 2018 (n = 15,272). This is akin to a stepwedge study design where there was continuous recruitment of the intervention.[10,11] The data was transformed to a pseudo-panel using participant's identifier as the panel variable and observation number as the time variable. The observation number at the latest observation before the intervention was $t = -1$ and the first observation after the intervention was $t = 0$.

2.3 | Statistical analysis

We performed two-sample t tests and a χ^2 tests to determine significant differences between the intervention and control group at baseline (i.e., last observation per individual before WISDOM implementation) including participant characteristics, diabetes risk factors, comorbidities and diabetes prescriptions. We estimated a fixed effects difference-in-differences (DID) model using panel ordinary least squares regressions (OLS) for each of the 13 outcome variables (i.e., risk factors) as the main analysis.

As our data was a pseudo-panel, we also controlled for the number of months between the observation number and the first date when the participant was exposed to the intervention. Specifications further include a participant level fixed-effect to control for differences in risk factors across people and time-fixed effects, which controls for differences in risk factors across the time unit of the pseudo-panel.

The main assumption in DID analysis is that in absence of the intervention, the intervention and control group follow the same trend in the outcome variables (i.e., parallel trends assumption). To test this assumption, we performed a lead variable analysis by estimating additional specifications introducing leads of one, two and three observation points before each individual was exposed to the intervention. If the coefficients on the lead variables were close to zero and insignificant, the parallel trends assumption was considered to be met. Where the parallel trends assumption was not met, we added differential time trends to account for differences across GP practices over time (see Appendix 2).

Moreover, we conducted a sensitivity analysis where people receiving WISDOM in June 2018 were added to the control group (i.e., together with those receiving WISDOM in September 2018) to investigate whether the treatment effect was different if we included those participants who had received the treatment the longest (i.e., from December 2017 to June 2018). We judged a difference to be significant if $p < 0.05$. Details about the modelling approaches are provided in Appendix 2.

All statistical analyses were performed in STATA MP 15.

2.4 | Economic modelling

The United Kingdom Prospective Diabetes Study UKPDS Outcome Model version 2 (UKPDS-OM2)[12] was used to translate significant differences in risk factors for diabetic complications between the WISDOM and control group to diabetes complications, participant life-years, quality-adjusted life years (QALYs). The UKPDS-OM2 is a individual-level simulation model that uses baseline characteristics and risk factor profiles of people with type 2 diabetes to predict the occurrence of diabetes-related complications, that is, myocardial infarction, stroke, other ischaemic heart diseases, heart failure, blindness, amputation, ulcer and renal failure and to predict years of life, quality-adjusted life years (QALYs) and the cost of complications over a participant's lifetime.[1,2] Estimates of the costs (i.e., GP costs, other primary care costs and inpatient care costs) and quality of life associated with each complication in the model were derived from UKPDS at 5 years and over life-time (70 years) taking the NHS perspective. We simulated 5 years to provide budgetary insights and over life-time to comply

with NICE guidelines. We simulated two populations, one where all statistically significant treatment effects from the DID analyses were applied for the intervention group and one where there were no treatment effects for the control group, therefore comparing a population that received the WISDOM intervention to one that did not. The estimated differences in risk factors were held constant over a period of 5 years and were assumed to be 0 after that period. We applied a discount rate of 3.5% following NICE guidance. We estimated results over 5 years and lifetime in order to capture both shorter and longer-term impacts of WISDOM on people' health outcomes. Incremental cost-effectiveness ratios (ICERs) were estimated to express cost-effectiveness in terms of cost per QALY gained.

Intervention costs (i.e., costs to develop and implement WISDOM) were calculated from the annual budget from December 2017 to June 2018 as £6.56 per enrolled participant (i.e., £302,253/46,099). Intervention costs also included the GPs' remuneration medication costs of £5.92 per participant per year as there were signs that WISDOM led to the prescription of more expensive medicines such as Dapagliflozin. Intervention costs included as one-off costs in the UKPDS-OMS2 model. All costs were reported in 2020 UK Sterling values.

2.5 | Imputation of missing data

In order to have a complete dataset for the diabetes risk factors to use in the UKPDS model, we performed multiple imputation with chained equations and predictive mean matching and created 100 complete datasets in line with standard practice.[13] Table 1 includes information on missing variables. Values were imputed at the last observation before each participant was exposed to the intervention i.e., at $t = -1$. Patient characteristics, co-morbidities and prescriptions were used as predictors in imputing values. For continuous variables, values were pooled as averages per participant across the imputed datasets using Rubin's rules whereas for categorical variables, such as smoking status, we took the mode of each variable across the datasets per participant.

2.6 | Uncertainty and sensitivity analysis

We performed 1000 bootstraps with replacement to address parameter uncertainty in the risk equations used in the UKPDS-OM2 model and 100 loops per participant in each bootstrap to address stochastic uncertainty (i.e., random variability in outcomes between identical participants).[14] Uncertainty around the ICERs was illustrated by plotting 1000 pairs of bootstrapped incremental costs and incremental QALYs on cost-effectiveness planes. The probability of WISDOM to be cost-effective at different cost-effectiveness thresholds for a QALY was graphically presented in cost-effectiveness acceptability curves. We also performed sensitivity analysis by running the UKPDS model including treatment effects only on risk factors that the DID estimator (i.e., WISDOM effect) was weakly statistically significant (i.e., p-value<0.10).

3 | RESULTS

3.1 | Descriptive statistics

As Table 1 shows, the intervention group included slightly (by 2.6 years) older people as well as more men, people of white ethnicity and those with affluent socio-economic backgrounds. Although the duration of diabetes was slightly lower in the intervention group, differences in risk factors did not show a clear pattern favouring either group. However, people in the intervention group consumed proportionally less medication. Additional descriptive statistics are in Appendix 3.

3.2 | Intervention effect on risk factors for diabetes complications

Table 2 shows results for risk factors controlling for patient characteristics, co-morbidities, prescriptions and fixed effects. Appendix 4 includes results for the parallel trends assumption. When parallel trends were not met, we present specifications with differential trends in order to net out any differential impacts across GP practices over time (proxied by IMD) over time in Table 2. The main explanatory variable of interest is the difference-in-differences estimator representing the treatment effect of WISDOM (Table 2). WISDOM led to a statistically significant decrease in an AF event of 0.4% [$p = 0.001$] and in Albuminuria of 2% [$p = 0.002$]. WISDOM also led to a decrease in blood pressure of 0.270 mmHg [$p = 0.098$]. Results also show a statistically significant but small increase in HbA1c of 0.064% [$p = 0.008$] (DCCT unit, or 0.5 mmol/mol), 0.075 g/dl increase in haemoglobin [$p = 0.043$], and an increase in smoking of 0.9% [$p = 0.01$]. Appendix 5 shows the results of the sensitivity analysis where people receiving WISDOM in June 2018 are added to the control group. WISDOM led to a statistically significant decrease in an AF event of 0.5% [$p = 0.000$], decrease in Albuminuria of 0.6% [$p = 0.027$], and a decrease in blood pressure of 0.282 mmHg [$p = 0.034$] (Table A4). We find similar statistically significant and small increases in HbA1c of 0.073% [$p = 0.001$] (DCCT unit, or 0.6 mmol/

TABLE 1 Descriptive statistics by intervention group at the last observation before WISDOM implementation

	Intervention ($n = 25,276$)	Control ($n = 15,272$)	Difference in means [95% CI] or Chi^2 p-value	Intervention % missing	Control % missing
Patient characteristics					
Age (years)	68 ± 14	65 ± 15	3 [2, 3]		
Women (%)	43%	45%	Chi^2 p-value: 0.002		
Ethnicity			Chi^2 p-value: < 0.001		
White	97%	89%			
Afro-Caribbean	1%	3%			
Asian-Indian	2%	8%			
Index of multiple deprivation			Chi^2 p-value: < 0.001		
1–2	2%	31%			
3–4	9%	33%			
5–6	20%	18%			
7–8	28%	13%			
9–10	40%	5%			
Duration of diabetes (years)	9.2 ± 8.1	9.4 ± 7.9	−0.2 [−0.3, −0.01]		
Outcome variables (risk factors)					
HbA1c (% HA [mmol/mol])	7.4 (57) ± 1.4	7.5 (58) ± 1.6	−0.1 [−0.1, −0.07]	29%	26%
Months before intervention	12 ± 12	11 ± 9	1 [0.9, 1.4]		
HDL cholesterol (mmol/l)	1.27 ± 0.4	1.26 ± 0.4	0.01 [−0.06, 0.09]	69%	99%
Months before intervention	20 ± 18	31 ± 27	−11 [−15, −8]		
LDL cholesterol (mmol/l)	2.35 ± 0.9	2.30 ± 0.9	0.04 [−0.01, 0.09]	89%	79%
Months before intervention	19 ± 14	20 ± 13	−0.3 [−1.0, 0.3]		
Systolic blood pressure (mmHg)	133 ± 15	131 ± 15	2 [1.7, 2.4]	17%	27%
Months before intervention	11 ± 10	11 ± 9	0.5 [0.3, 0.8]		
Heartrate (bpm)	77 ± 13	77 ± 14	−0 [−0.9, 0.3]	65%	82%
Months before intervention	21 ± 19	23 ± 22	−2 [−3, −1]		
Haemoglobin (g/dl)	13.8 ± 1.7	13.5 ± 1.8	0.3 [0.3, 0.4]	36%	42%
Months before intervention	17 ± 17	14 ± 14	3 [2, 4]		
eGFR (ml/min/1.73m^2)	74 ± 24	59 ± 29	15 [11, 18]	89%	98%
Months before intervention	15 ± 14	29 ± 22	−14 [−16, −12]		
White cell blood count (x10^9/l)	7.8 ± 2.6	8.1 ± 2.8	−0.4 [−0.4, −0.3]	35%	42%
Months before intervention	17 ± 17	14 ± 16	3 [2, 4]		
Currently Smokers	11%	16%	Chi^2 p-value <0.001	7%	10%
Months before intervention	4 ± 20	5 ± 23	−0.9 [−1.4, −0.5]		
Percentage with an atrial fibrillation event	7%	5%	Chi^2 p-value <0.001	0%	0%
Months before intervention	10 ± 35	13 ± 40	−3.4 [−4.1, −2.6]		
Percentage with a peripheral vascular disease event	4%	5%	Chi^2 p-value <0.001	0%	0%
Months before intervention	10 ± 35	13.4 ± 40.3	−3.4 [−4.1, −2.6]		
Percentage with micro- or macro-albuminuria	21%	32%	Chi^2 p-value <0.001	0%	0%
Months before intervention	10 ± 35	13.4 ± 40.3	−3 [−4, −2]		
GP attendances per month	0.8 ± 0.9	0.7 ± 0.9	0.2 [0.1, 0.2]		
Months before intervention[a]	1 ± 0	1 ± 0	0		

(Continues)

TABLE 1 (Continued)

	Intervention ($n = 25,276$)	Control ($n = 15,272$)	Difference in means [95% CI] or Chi^2 p-value	Intervention % missing	Control % missing
Diabetes complications					
Ischaemic heart disease	15%	16%	Chi^2 p-value = 0.071		
Heart failure	6%	7%	Chi^2 p-value <0.001		
Amputation	1%	2%	Chi^2 p-value <0.001		
Stroke	6%	7%	Chi^2 p-value = 0.008		
Myocardial infarction	8%	10%	Chi^2 p-value <0.001		
Left foot ulcer	13%	22%	Chi^2 p-value <0.001		
Right foot ulcer	13%	22%	Chi^2 p-value <0.001		
Mental health diagnosis	21%	26%	Chi^2 p-value <0.001		
Family history of diabetes	18%	23%	Chi^2 p-value <0.001		
Family history of myocardial infarction	8%	6%	Chi^2 p-value <0.001		
Family history of cardiovascular disease	6%	5%	Chi^2 p-value = 0.371		
Prescriptions[b]					
Diabetic diagnostic and monitoring agents	35%	40%	Chi^2 p-value <0.001		
Drugs used in diabetes	16%	22%	Chi^2 p-value <0.001		
Hypodermic equipment	31%	37%	Chi^2 p-value <0.001		
Insulins	16%	22%	Chi^2 p-value <0.001		
Short-acting insulins	23%	27%	Chi^2 p-value <0.001		
Intermediate and long-acting insulins	27%	34%	Chi^2 p-value <0.001		
Oral hypoglycaemic drugs	23%	26%	Chi^2 p-value <0.001		
Other anti-diabetic drugs	28%	34%	Chi^2 p-value <0.001		
Sulfonylureas	33%	39%	Chi^2 p-value <0.001		
Treatment of hypoglycaemia	17%	23%	Chi^2 p-value <0.001		

Notes: Data are presented as mean ± *SD* or %. Difference in means are conducted via t-tests for continuous variables and Chi^2 for categorical variables. The history of diabetes complication goes back in time to as early as 1990. Months before intervention was included in the DID analyses.

[a]GP attendances are provided on a monthly basis.

[b]Categories of prescriptions are presented as recorded in the GP patient records.

mol) and 0.086 g/dl increase in haemoglobin [$p = 0.021$] (Table A4). The results from the sensitivity analysis were similar except that the increase in smoking ceased to be statistically significant (see Appendix 5).

3.3 | Impact of the intervention on diabetes complications

Figure 1 shows the impact of WISDOM on diabetes complications over 5 years and life-time. Providing WISDOM to a population of 25,276 people (i.e., the size of our intervention group), there would be 25 (95%CI: 11–34) fewer heart failure diagnoses, 13 (95%CI: 1–28) fewer strokes, 16 (95%CI: 4–34) fewer renal failure diagnoses, and 22 (95%CI: 0–29) fewer deaths, of which 16 would be (95%CI: 0–29) cardiovascular deaths, over 5 years than if WISDOM was not provided to the same population. The avoided heart failure diagnoses were increased to 49 (95%CI: 2–92) and the renal failure diagnoses to 34 (95%CI: 2–78) in the same population's life-time.

3.4 | Results of cost-effectiveness analysis

Findings of the main cost-effectiveness analysis can be found in Table 3. The 5 year analysis showed that WISDOM led to increased life expectancy in the intervention group by 0.002 years [95% CI: 0.001, 0.004], increased

TABLE 2 Difference-in-differences estimation results on diabetes risk factors, main analysis

	WISDOM Difference-in-differences estimator	Cluster-adjusted standard error	p-value	Differential Trends	Observations
HbA1c (DCCT unit [mmol/mol])	0.064 (0.5)	0.008	0.019	Yes	362,261
HDL (mmol/mol)	−0.015	0.750	0.047	Yes	66,104
LDL[a] (mmol/mol)	0.021	0.227	0.016	No	29,481
BP (mmHg)	−0.270	0.098	0.146	Yes	567,612
Heart rate[a] (bpm)	0.344	0.247	0.278	No	65,038
Haemoglobin (g/dl)	0.075	0.043	0.032	Yes	301,170
eGFR (ml/min/1.73m^2)	−2.250	0.106	2.029	Yes	48,036
White Cell Blood Count C[a] (x10^9/l)	−0.047	0.255	0.038	No	339,738
Smoking[a] (%)	0.009	0.010	0.003	No	4,220,488
Atrial Fibrillation[a] (%)	−0.004	0.001	0.001	No	4,681,384
Peripheral vascular disease (%)	−0.0002	0.739	0.001	Yes	4,681,384
GP monthly attendances	0.015	0.297	0.014	Yes	4,274,469
Albuminuria[a] (%)	−0.020	0.002	0.002	No	4,681,384

Notes: All specifications include controls for patient characteristics, co-morbidities, prescriptions, patient fixed-effects, observation number fixed-effects, delta and differential trends unless otherwise noted; Differential trends were used in the difference-in-differences analysis based on the lead variables analysis as presented in the Appendix 4. If any of the lead variables were significant, then we used differential trends in order to net out any differential trends across GP practices over time; The number of observations refers to the number in the sample where individuals can have multiple observations since our data is a pseudo-panel.

[a]Specifications for LDL, heart rate, white cell blood count, smoking, atrial fibrillation and albuminuria do not include differential trends.

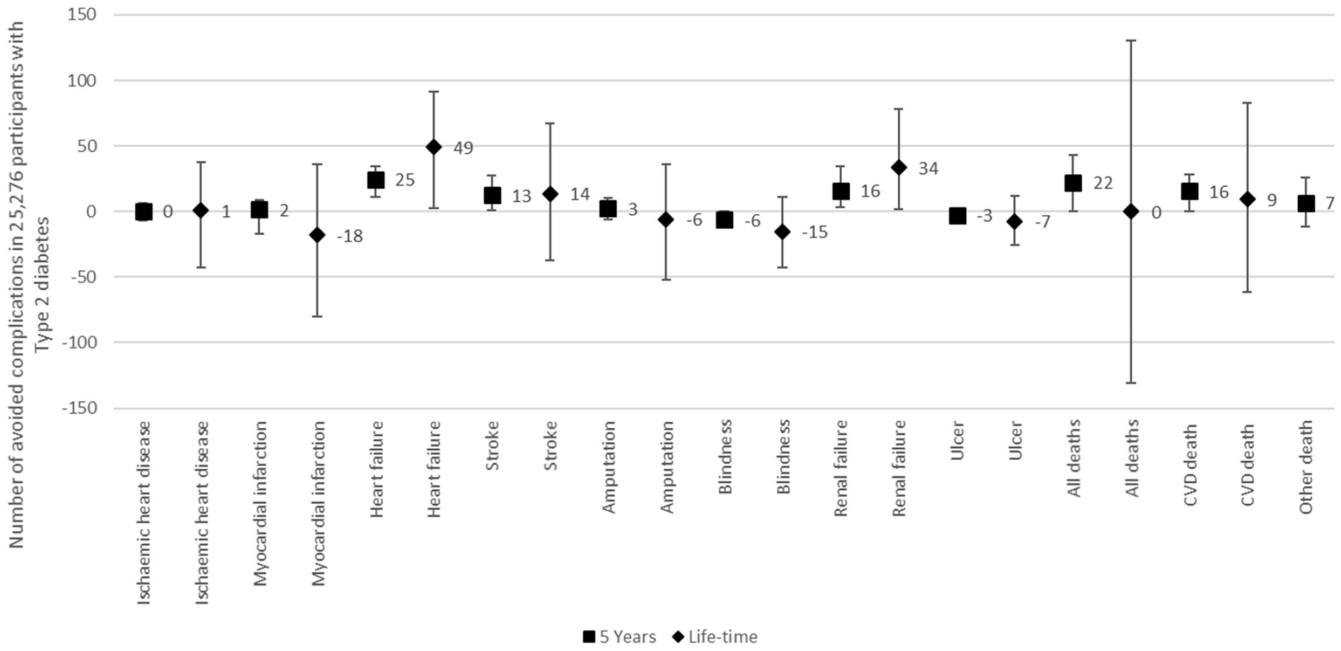

FIGURE 1 Impact of WISDOM on diabetes complications

total QALY of 0.002 [95% CI: 0.001, 0.003] and reduced costs by £11 [95% CI: −£25, £7]. The life-time analysis also showed that WISDOM led to an increased life expectancy in the intervention group by 0.011 years [95% CI: 0.003, −0.02], increased total QALY of 0.010 [95% CI: 0.003, 0.016] and reduced costs by £5 [95% CI: −£58, £53]. Therefore, WISDOM was the dominant strategy (i.e., more effective and less expensive) in both 5 years and life-time analyses.

Appendix 6 presents the results of the sensitivity analyses. The addition of the impact of WISDOM on

TABLE 3 Results of cost-effectiveness analysis

	Life expectancy Mean [95% CI]	Total QALY Mean [95% CI]	Total cost Mean [95% CI]
5 years			
WISDOM	4.105 [4.07, 4.14]	3.227 [3.19, 3.25]	12,098 [11,805, 12,521]
Control	4.103 [4.07, 4.13]	3.225 [3.19, 3.25]	12,109 [11,804, 12,541]
Difference	0.002 [0.001, 0.004]	0.002 [0.001, 0.003]	−11 [−25, 7]
Life time			
WISDOM	10.976 [10.78, 11.30]	8.535 [8.37, 8.79]	32,903 [31,583, 34,808]
Control	10.964 [10.77, 11.29]	8.526 [8.36, 8.78]	32,908 [31,569, 34,841]
Difference	0.011 [0.003, 0.02]	0.010 [0.003, 0.016]	−5 [−58, 53]

Notes: Life expectancy is measured in years; QALYs are quality-adjusted life years; cost is expressed in GBP.

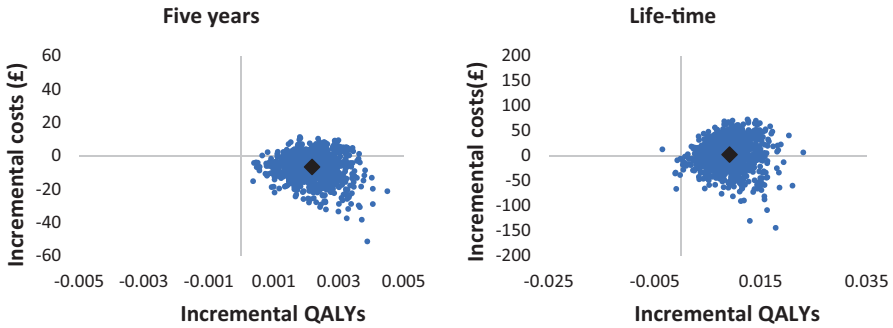

FIGURE 2 Cost-effectiveness planes

blood pressure led to a doubling of the incremental QALYs from 0.002 to 0.004 in the 5-year time horizon, while the cost savings were close to zero. Similarly, the incremental QALYs over participant's lifetime were doubled to 0.026 but the incremental costs were positive resulting in an ICER of £1952 per QALY over the life-time. Adding people who received WISDOM in June 2018 into control group led to similar incremental QALYs to the main analysis but the costs were higher in the WISDOM group resulting in an ICER of £431 per QALY over 5 years and £250 per QALY over the life-time.

Figures 2 shows the cost-effectiveness plane for 5-year and life-time estimates. The black dot in the middle is the point estimate of the ICER and the blue dots are the 1000 bootstrapped ICERs that display the uncertainty around the point estimate. As this figure shows, there high certainty in the estimated QALY gains but there is uncertainty in the estimated cost savings, especially in the life-time results. The cost-effectiveness acceptability curves (Appendix 7) show that WISDOM was 100% likely to be cost-effective at £5000 threshold over 5 years and at £10,000 threshold over the life-time.

4 | DISCUSSION

Our findings show that the WISDOM type 2 diabetes risk stratification and primary care healthcare professional education programme together with "refresher" participant education is cost-effective as it reduced diabetes complications through better management of the associated risk factors. Notably, we find significant impacts of WISDOM on reducing atrial fibrillation and albuminuria and weakly significant impacts on reducing blood pressure. It should be noted that WISDOM targeted eventually people stratified into amber risk of diabetes complications, which may be another reason for the small magnitude of the estimated treatment effect on risks for diabetes complication. Similar to other educational interventions for self-management of type 2 diabetes,[15] the impact of WISDOM on health and costs at individual level appeared to be marginal but when aggregating them to population level, the magnitude of the impact is more apparent. For example the DESMOND trial in the UK, which had 3 years follow-up, concluded that the incremental lifetime QALYs and costs of people with type 2 diabetes that received a group educational self-management intervention were 0.0392

(95%CI: −0.0813 to 0.1786) and £209 (95%CI: −704 to 1137), respectively, and concluded that the intervention was very likely to be cost-effective.[16] Among 25,276 people with type 2 diabetes (our intervention group), WISDOM led to a gain of 51 QALYs and saved £278,036 in the first 5 years after its implementation. During those people' lifetime, WISDOM led to 278 QALYs gained and cost saving of £126,380. Moreover, WISDOM led to lower cost-savings in participant's lifetime compared with the 5-year time horizon as people who lived longer due to the intervention accrued more NHS costs. In addition, we estimate that the implementation of WISDOM has prevented 25 heart failure diagnoses, 13 strokes, 16 renal failure diagnoses and 22 deaths.

Furthermore, our analysis may have underestimated the cost-effectiveness of WISDOM due to a short post-period where we only had a control group for the 8 months after WISDOM implementation (i.e., December 2017–September 2018) and the impact of the WISDOM intervention may take longer to be observed on risk factors for diabetes complications due the diabetes being a chronic long-term illness.[17] This is supported by the results of the sensitivity analysis where the June 2018 cohort was added to the control group and we no longer found cost savings. However, we have kept the relatively small WISDOM effects on the risk factors constant for 5 years as studies of self-management and educational intervention have shown effects lasting longer than 3 years.[18]

Furthermore, we speculate that the increase in HbA1c in the intervention group occurred as a result of increased measurement of HbA1c particularly in people who have not had this tested for some time. Although we utilize difference-in-differences and inverse probability weighting to reduce confounding, there may still be residual confounding due to the recruitment of people. The programme encouraged primary care practices to search their databases for eligible people (i.e., people with amber risk for diabetes complications). We surmise that in doing so, GP practices searched for the most recent HbA1c result available and on discovering that this may have been some years ago arranged for the individual to have a repeat test. The lack of monitoring may suggest a lack of engagement with health care services and diabetes self-care and therefore, the HbA1c value in such individuals is likely to have increased.

Our study indicates that WISDOM is value for money and thus rolling it out as part of the diabetes care transformation to other areas in England could achieve greater health benefits and NHS cost savings. WISDOM may be an appealing investment, especially to commissioners in England who have to justify investments in new services with a return on investment in the short term. However, WISDOM is a complex intervention and we have evaluated as it was implemented in two large Clinical Commissioning Groups in the South of England. Therefore, its' cost-effectiveness depends on several factors that have to be considered when adopting this intervention elsewhere such as organisational structures, resource availability and the local context that WISDOM would be implemented.[19,20] It should however be noted that WISDOM appears to have been similarly successful in West Hampshire with a population of predominantly white Caucasian people with little social deprivation and Southampton City a far more diverse population both in terms of ethnicity and deprivation, indicating that it may be applicable to areas with diverse populations with type 2 diabetes.

The translation of achieving NICE treatment targets in type 2 diabetes in QALY gains and cost savings is in line with a previous study in the UK.[21] Moreover, our findings add to the increasing evidence that supports that type 2 diabetes risk stratification and healthcare professional education programme together with "refresher" participant education is cost-effective, if not cost saving.[18] Such interventions are integral components of new models of diabetes care in the UK that are expected to increase efficiency and improve population health.[22] This expectation is in line with the evidence from the pioneer disease management programmes for diabetes in Europe a decade ago.[23]

The methods used in this study are in line with state-of-the-art guidance in performing the evaluation of complex health interventions.[24,25] The combination of DID analysis with IPW has allowed us to adjust for unobserved and observed confounding between the intervention and control group, while the adoption of a pseudo-panel has accounted for the unbalanced measurements of risk factors between participants. Furthermore, the methods allow for not only causal inference on the impact of a non-randomised intervention but also the extrapolation of intermediate outcomes (i.e., risk factors) to long-term impact on quality-adjusted life expectancy and costs. Such a combined approach may be used in future studies as NHS manager, commissioners and clinicians have an increasing need for robust evidence.

The strengths of the study include the large and rich data spanning a long time period from 1990 to 2020 allowing us to account for a long time period of pre-trends in our outcome variables, the adoption of a quasi-experimental design to show causal impacts, and the use of a validated and widely used economic model to extrapolate results in the long-term into showing impacts on costs. The major limitation of the study is that we only had a control group for the 8 months after WISDOM implementation due to the observational nature of the study. Another limitation is that the UKPDS model is based on associations between the risk factors and outcomes, rather than causal impacts.

However, a recent validation study of the model provides us with confidence about its predictive accuracy.[26] Moreover, it is unknown how WISDOM would impact the measurement of risk factors (i.e., prompt GPs to measure risks in people with outdated measurements) in other settings, if it were to be rolled out. Another limitation is the substantial proportion of missing observations for some risk factors, which may have challenged the successful implementation of multiple imputation. The assumption that the WISDOM effects on risk factors would last 5 years is another limitation of the study. This assumption together with the small effects found in our study on risk factors could be subject of a prospective evaluation in the future.

We believe that this is the first cost-effectiveness analysis of an NHS England-funded diabetes transformation project in England. While the evaluation of complex interventions is challenging, we encourage future studies to further demonstrate the cost-effectiveness of publically-funded interventions that seek wider spread adoption in publicly-funded health care systems.

5 | CONCLUSION

The WISDOM type 2 diabetes risk stratification and healthcare professional education programme together with "refresher" participant education appears to be cost-effective in reducing diabetes complications. Stakeholders involved in the process of transforming diabetes care in England should consider a rollout of this intervention across the country keeping in mind, however, that it delivers small benefits at individual patient level.

AUTHOR CONTRIBUTIONS

Concept and design: HP, JL, PL, AT; Acquisition of data: AT, HP; Analysis and interpretation of data: SS, JL, AT; Drafting of the manuscript: HV, MV, SH, MR; Critical revision of the paper for important intellectual content: SS HP KF JL VD JH PL POH, AT; Statistical analysis: SS, AT; Obtaining funding: HP, JL, PL, AT; Administrative, technical or logistic support: VD; All authors read and approved the final version.

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CONFLICT OF INTEREST

None declared.

DATA AVAILABILITY STATEMENT

The data was obtained under a Data Sharing Agreement with the NHS South, Central and West Commissioning Support Unit that prohibits using or sharing the data beyond this study.

ETHICS STATEMENT

We used routinely collected de-identified data that was obtained by the NHS South, Central and West Commissioning Support Unit using all appropriate Data Sharing Agreement and Information Governance Policies. No ethical approval was required.

DISCLAIMER

The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health and Social Care.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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