

# Nudging people with Type 2 diabetes towards better self-management through personalized risk communication: A pilot randomized controlled trial in primary care

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## Summary

**Objectives:** To assess the feasibility in routine primary care consultation and investigate the effect on risk recall and self-management of a new type of risk communication intervention based on behavioural economics (“nudge-based”) for people with Type 2 diabetes mellitus (T2DM).

**Methods:** Forty adults with poorly controlled T2DM (HbA1c > 7.5%) were randomized to receive a personalized, nudge-based risk communication intervention (n = 20) or standard care (n = 20). Risk recall and self-management were evaluated at baseline and 12 weeks after the intervention.

**Results:** Both in terms of feasibility and acceptability, this new risk communication intervention was very satisfactory. Study retention rate after 12 weeks was very high (90%) and participants were highly satisfied with the intervention (4.4 out of 5 on the COMRADE scale). Although not powered to identify significant between-group effects, the intervention significantly improved risk recall after 12 weeks and intentions to make lifestyle changes (dietary behaviour) compared to standard care.

**Conclusions:** This pilot study provides the first evidence of the feasibility of implementing in primary care a nudge-based risk communication intervention for people with T2DM. Based on the promising results observed, an adequately powered trial to determine the effectiveness of the intervention on long-term self-management is judged feasible. As a result of this feasibility study, some minor adaptations to the intervention and study methods that would help to facilitate a definitive trial are also reported.

## KEYWORDS

behavioural economics, pilot randomized trial, primary care, risk communication, self-management, Type 2 diabetes

## 1 | BACKGROUND AND OBJECTIVES

Good self-management behaviour has become the cornerstone of Type 2 diabetes mellitus (T2DM) management. Interventions that aim to improve self-management have been associated with improved biometric measures and, as a result, clinical outcomes.<sup>1</sup> However, despite this consensus, the most effective method to trigger sustainable adherence to self-management in T2DM populations is still unclear.

The field of behavioural economics, which is concerned with understanding and influencing how people make decisions, offers a promising way to improve behavioural interventions. Behavioural economics integrates insights from economics, psychology and behavioural science to identify systematic *biases* (or *irrationalities*) in people's decision-making processes. Targeting these biases to develop more effective interventions has been of increasing interest, especially in the health domain.<sup>2</sup> Known as *nudges*, these interventions have shown promising results in helping people change their behaviour, including people with T2DM.<sup>3</sup>

In recent years, several systematic biases underlying health behaviour have been documented. For example, people tend to discount delayed rewards, such as avoiding cancer or heart disease, relative to more immediate, smaller rewards, such as having a cigarette or an extra dessert now ("present biasedness"). Because diabetes management is centred on people's daily behaviour, many of these biases also apply to T2DM populations<sup>4,5</sup> and can be used to inform new interventions. So far, health nudges have mostly relied on mitigating present biasedness by means of incentives or rewards. In particular, the use of monetary-based rewards has been effective in encouraging weight loss,<sup>6</sup> enhancing exercise<sup>7</sup> or improving medication adherence.<sup>8</sup>

In the risk communication field, however, targeting decision-making biases to enhance the impact of interventions is not common practice. Although substantial work has been done to test the impact of *framing effects* (the tendency that people have to draw different conclusions from the same risk information, depending on whether it is expressed in terms of gains or losses) on screening or precautionary behaviours,<sup>9</sup> most biases influencing health behaviour change have not yet been targeted. This is an issue since the effect of risk communication interventions could be enhanced with the use of adapted formats or metrics that specifically target such biases.<sup>10</sup> Existing risk communication interventions for people with T2DM have shown mixed results, with many participants barely understanding the explanations of health professionals about risks and having poor recall of risk information.<sup>11</sup> There is an urgent need to improve risk communication in this area, making people with T2DM prime candidates to receive an intervention informed by behavioural economics.

Based on these observations, we developed a risk communication intervention aiming to target 7 decision-making biases known to have an influence on the decision-making process of people with T2DM (see Section 2). The intervention aims to improve insight and

recall of diabetes-related risks and, in turn, nudge people with T2DM towards better self-management.

The objectives of this pilot study are to assess the feasibility of adopting this new intervention in primary care and investigate its effect on risk recall and self-management. The results of the pilot study aim to inform the development of an adequately powered randomized controlled trial (RCT).

## 2 | METHODS

Study design, methods and results are reported in accordance with the CONSORT statement for pilot and feasibility trials.<sup>12</sup>

### 2.1 | Recruitment

Forty adults with poorly controlled T2DM (HbA1c > 7.5% measured at least once over the past year) between 30 and 75 years of age were recruited from a single-site surgery practice in Oxford, UK. Subjects were excluded if (i) they were non-English speakers; (ii) unable to give informed consent; or (iii) diagnosed with T2DM for less than a year. We followed Hertzog,<sup>13</sup> who found sample sizes between 20 and 40 sufficient for pilot and feasibility studies. The study was approved by the competent UK NHS research ethics committee (ref. 17/NW/0267), and each participant gave written consent.

### 2.2 | Design

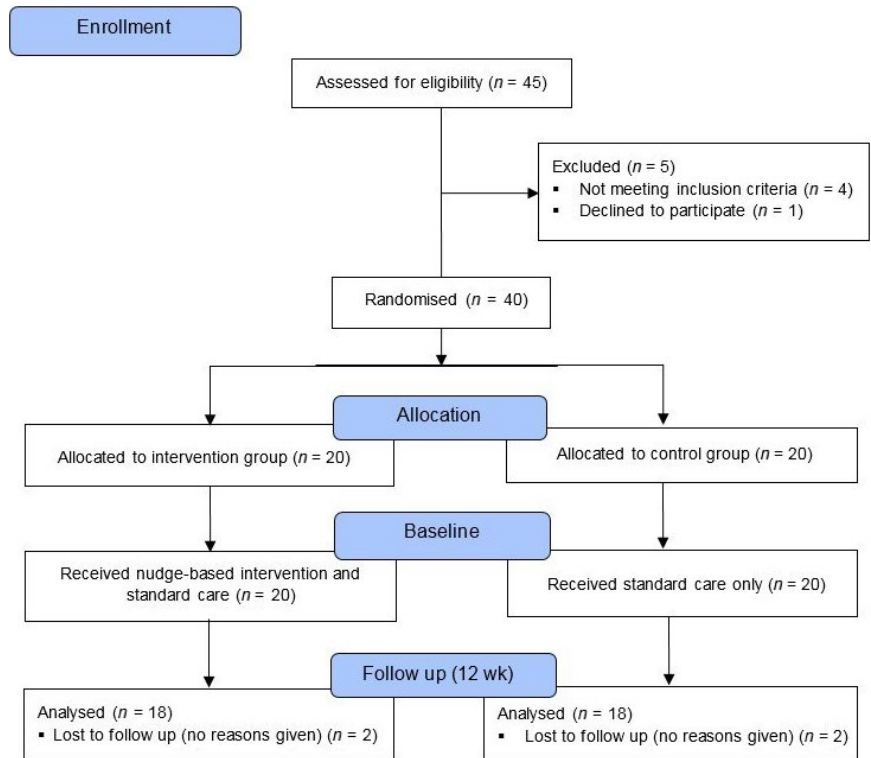
#### 2.2.1 | Randomization

Participants were randomly assigned to either the intervention group, receiving the nudge-based risk communication intervention in addition to the standard care provided in routine primary care consultation, or to the control group, receiving standard care only (see Figure 1).

In order to balance the 2 groups in terms of sex and age, we used a stratified randomization method so that each group had the same number of males and females aged above and below 57 years old. This age threshold was chosen in accordance with the distribution of age at diagnosis of diabetes.<sup>14</sup> Group allocation sequence was determined using a computerized generated random number table. Given the nature of the study, participants were blinded to group assignment, but the research team was not.

#### 2.2.2 | Intervention group

The intervention consisted of communicating the impact of being poorly controlled on 2 types of outcome: (i) absolute 10-year risk of experiencing a cardiovascular event, ie, heart attack or stroke (10-year CV risk); (ii) life expectancy. Personalized risk estimates and life expectancies were calculated based on the UKPDS outcomes model (version 2).<sup>15</sup>



**FIGURE 1** CONSORT flow chart of participants

The intervention differs from classical risk communication interventions in that it aims to target people's irrationalities to improve risk recall and motivate behaviour change. Specifically, it was designed to take into account 7 decision-making biases inherent in T2DM populations:

- In order to mitigate people's *optimistic bias* (i) (the tendency they have to underestimate their risks of developing health problems, compared with their peers),<sup>16</sup> all risks were communicated in comparison to those of a similar, well-controlled individual (ie, same age, sex and medical history, but with all risk factor levels in normal ranges).
- In an effort to increase the emotional impact and representativeness of the risk (ie, target people's *affect heuristic* (ii) and *representativeness heuristic* (iii), respectively),<sup>17</sup> the 10-year CV risk was also expressed through a new metric: the "effective heart age."<sup>18,19</sup> A subject's effective heart age was calculated as the chronological age of a similar, well-controlled individual with the same predicted risk score.<sup>19</sup>
- In order to take advantage of people's *loss aversion* (iv) ("the pain of losing a given outcome is psychologically more powerful than the pleasure of gaining the same outcome")<sup>20</sup> and mitigate their *present biasedness* (v),<sup>4</sup> the impact of being poorly controlled on life expectancy was communicated with an innovative metric: the "hours of lifetime lost per day," in comparison with a similar, well-controlled individual.<sup>21</sup>
- In order to increase people's *limited attention* (vi),<sup>17</sup> we made the intervention interactive by showing how better adherence to self-management could lower all these risks.

- Because people tend to be more risk averse in the gain domain (*sensitivity to framing effects*<sup>20</sup>) (vii), variations in personalized risks were expressed using a gain-framed message ("you would avoid losing X hours of lifetime per day if you manage to lower your HbA1c level to Y").<sup>22</sup>

Examples are provided in Appendix S1.

### 2.2.3 | Control group

Participants in the control group were given an estimate of their absolute 10-year CV risk based on the UKPDS outcomes model (version 2) but were not given information on life expectancy or access to the nudge-based risk communication intervention.

### 2.2.4 | Primary care setting

The intervention was developed to allow real-time, individualized risk communication in routine primary care consultation. Recent studies have shown that primary care is the key point of contact with the healthcare system for people with T2DM<sup>23</sup> and that general practitioners (GP) play a crucial role in the management of T2DM,<sup>24</sup> making such consultations a logical focus for promoting lifestyle change in this population.

All consultations were conducted by the same GP. In both groups, participants were also given personalized lifestyle advice. They were orally reminded of the importance of adhering to self-care behaviours in order to reduce their risks. Emphasis was placed, where appropriate, on increasing consumption of fruits

and vegetables, decreasing consumption of high-fat foods, increasing physical activity, maintaining adherence to medications and decreasing alcohol consumption and smoking, depending on each participant's familial or financial constraints. The GP also provided information about the causes and consequences of the risk. No reminders were provided to the participants during the 12 weeks that followed the intervention.

## 2.3 | Primary outcomes

Primary outcomes were selected to assess the feasibility of implementing the intervention in routine primary care consultation and to obtain patient outcome data (satisfaction, worry and anxiety) for the development of a larger RCT.

Study feasibility was assessed by examining consent rate, retention rate and rates of missing data. In addition, we measured participants' satisfaction with the intervention using adapted questions from the validated COMRADE scale.<sup>25</sup> Acceptability of the intervention was further assessed by measuring participants' worry and anxiety levels immediately after the intervention. Following Welschen et al,<sup>26</sup> we used questions adapted from Claassen et al<sup>27</sup> to assess how worried or anxious they were about their personalized risk information. General anxiety was assessed by the validated Short Form Spielberger State-Trait Anxiety Inventory (SF-STAI).<sup>28</sup>

## 2.4 | Secondary outcomes

Recall of personalized risk information was measured immediately and 12 weeks after the intervention (binary outcome: recalled or not recalled). Intentions to make lifestyle changes were measured immediately before and after the intervention using the validated Determinants of Lifestyle Behaviour Questionnaire (DLBQ).<sup>29</sup> Change in self-management behaviour from baseline to 12 weeks was measured using the validated Summary of Diabetes Self-Care Activities (SDSCA) questionnaire.<sup>30</sup> Finally, HbA1c levels (%) were measured before and 12 weeks after the intervention.

## 2.5 | Data analysis

### 2.5.1 | Demographics and baseline characteristics

Between-group baseline differences were tested using Student *t*-test (means) and Chi-square test (proportions). For each test, 2-tailed *P*-values were reported.

### 2.5.2 | Recall of personalized risk information

Between-group differences were assessed using Chi-square test. In the intervention group, differences in recall of the different types of personalized risk information were also tested using Chi-square test, taking 10-year CV risk score as the reference category. Within-group differences in risk recall after 12 weeks were tested using McNemar's test.

### 2.5.3 | Behavioural outcomes

Within-group pre-post-intervention differences for intentions to make lifestyle changes and self-management behaviour (SDSCA scores and HbA1c levels) were tested using paired *t*-test. Between-group differences were investigated using regression analysis to model secondary outcomes as a function of intervention status while adjusting for potential confounders (age, sex, ethnicity, education, duration of diabetes) and the corresponding baseline measure. General linear models were used for continuous outcome variables (all self-care behaviours except medication adherence) and a logistic model was used for the only dichotomous outcome variable (medication adherence).

Intention-to-treat (ITT) analyses were conducted, both with complete cases only (excluding participants with missing follow-up data) and with all cases (including participants with missing follow-up data). In the analysis including all cases (see Appendix S2), missing data for follow-up measures were replaced by baseline data.<sup>31</sup>

## 3 | RESULTS

### 3.1 | Demographics and baseline characteristics

Forty individuals with poorly controlled T2DM were randomized to the intervention (*n* = 20) or control group (*n* = 20). Statistical tests showed no between-group differences in terms of age, ethnicity, employment status, education level, duration of diabetes, smoking status and baseline HbA1c level, indicating an effective randomization process (see Table 1).

### 3.2 | Primary outcomes

Only 1 eligible individual did not give consent to be enrolled in the study. Of 40 participants, 4 individuals did not attend the follow-up visit (without giving any reason). Therefore, the study retention rate was 90%. Missing data were confined to the dropouts, and to participants who could not recall their risk information and so were logically not able to indicate how anxious or worried they felt about it.

Table 2 summarizes the results for the outcomes used to evaluate the acceptability of the intervention. There was no between-group difference regarding satisfaction with the intervention (*P* = .79) and ease of understanding of the information (*P* = .49). In the intervention group, communicating heart age was associated with higher levels of anxiety and worry than 10-year CV risk (*P* = .01 and *P* = .02, respectively).

### 3.3 | Secondary outcomes

#### 3.3.1 | Recall of personalized risk information

A summary of the results for risk recall is provided in Table 3 (ITT analysis with complete cases only). No between-group

**TABLE 1** Demographics and baseline characteristics

	Intervention group (n = 20)	Control group (n = 20)	P-value
Age (years), mean (SD)	57.4 (12.5)	61.1 (11.2)	.32
<b>Sex, n (%)</b>			
Male	12 (60)	12 (60)	1.00
Female	8 (40)	8 (40)	
<b>Ethnicity, n (%)</b>			
White British	16 (80)	16 (80)	1.00
Asian British	4 (20)	4 (20)	
<b>Education, n (%)</b>			
High school or no degree	11 (55)	8 (40)	.35
Bachelor or Graduate degree	9 (45)	12 (60)	
<b>Employment, n (%)</b>			
Employed	10 (50)	11 (55)	.75
Unemployed or retired	10 (50)	9 (45)	
Duration of T2DM (years), mean (SD)	9.7 (7.1)	12.1 (9.8)	.38
<b>Smoking status, n (%)</b>			
Smoker	2 (10)	2 (10)	1.00
Non-smoker	18 (90)	18 (90)	
HbA1c (%), mean (SD)	8.6 (1.6)	8.4 (1.3)	.73

difference was found regarding recall of 10-year CV risk score. In the intervention group, recall for effective heart age was significantly better than recall for any of the other formats both immediately and 12 weeks after the intervention. Effective heart age was also the only format that was satisfactorily recalled after 12 weeks (no within-group difference between baseline and follow-up).

### 3.3.2 | Behavioural outcomes

A summary of the results for intentions to make lifestyle changes and self-management behaviour (SDSCA scores and HbA1c levels) is provided in Table 4 (ITT analysis with complete cases only). In addition, results of the regression analyses are presented in Table 5 (complete cases only). Controlling for potential confounders and the corresponding baseline measures, the intervention had significant, positive effects on participants' intentions to change their diet ( $P = .07$ ) and self-monitoring of blood glucose ( $P = .07$ ). Moreover, although between-group differences were not significant, all other behavioural outcomes except foot checks were improved in the intervention group after 12 weeks.

## 4 | DISCUSSION

### 4.1 | Feasibility and acceptability of the intervention

This study showed a very good acceptability of the intervention. Study retention after 12 weeks of follow-up was very high (90%), especially for a study population involving poorly controlled individuals with T2DM. Previous studies have reported that no-show rates to scheduled medical appointments in diabetic populations range from 4% to 40%.<sup>32</sup> Importantly, higher no-show rates are associated with poorer glycaemic control and suboptimal diabetes self-management.<sup>33</sup> Comparable studies testing risk communication or lifestyle interventions for people with T2DM have reported study retention rates ranging from 77% to 88% after 12 weeks.<sup>26,34,35</sup> In light of these findings, the observed retention rates are promising when designing a future RCT.

The intervention was also received very positively by participants. In particular, the ease of understanding of the information received was rated equally high in both groups. These satisfactory results were obtained despite a rise in worry and anxiety levels, due to the communication of heart age, in the intervention group. This is in line with what has been reported in a previous study investigating the impact of heart age estimates on people at high risk of CVD.<sup>36</sup> As a result, this metric should be used with caution. In particular, we recommend using alternative formats such as icon arrays to communicate CV risks to people with anxiety disorders. However, it should also be noted that no between-group difference was found in terms of general anxiety after the consultation. Overall, our results showed that, both in terms of feasibility and acceptability, this new nudge-based risk communication intervention is very satisfactory.

### 4.2 | Effects on risk recall and behavioural outcomes

Although not powered to identify significant effects, this pilot study showed promising results on the impact of the intervention on risk recall and behavioural outcomes.

First, we found that one of the formats used in the intervention had a very significant effect on risk recall: a very high proportion of participants in the intervention group accurately remembered their effective heart age 12 weeks after the intervention. To date, the effects on recall of the most effective (non-repeated) risk communication interventions in T2DM populations have lasted between 2<sup>26</sup> and 6 weeks.<sup>37</sup> Our results confirmed those observed by Lopez-Gonzalez et al,<sup>19</sup> who showed that using an effective heart age increased recalled CVD risk in a general population, as compared to absolute risk score. However, no improvement could be attributed to the provision of comparative risk estimates or daily hours of lifetime lost. These results differ from those reported by Galesic and Retamero,<sup>38</sup> who found that the consequences of health-related behaviours were recalled better when expressed as changes in life expectancy rather than as changes in risk of diseases. The absence of effect in our study may be due to the use of a daily time frame to express the variations in life expectancy. Despite making the risk

	Intervention group (n = 20)	Control group (n = 20)	P-value
Satisfaction <sup>a</sup> , mean (SD)	4.4 (0.7)	4.6 (1.1)	.79
Ease of understanding <sup>b</sup> , mean (SD)	4.7 (0.7)	4.7 (0.5)	.49
Anxiety, mean (SD)			
General <sup>c</sup>	11.4 (3.8)	9.9 (4.8)	.29
10-year CV risk <sup>d</sup>	3.6 (2.5) (n = 14)	2.9 (2.1) (n = 17)	.34
Effective heart age <sup>d</sup>	4.2 (2.2)	-	-
Number of hours lost per day <sup>d</sup>	2.6 (1.6) (n = 16)	-	-
Worry, mean (SD)			
10-year CV risk <sup>d</sup>	3.8 (2.5) (n = 14)	2.8 (2.0) (n = 17)	.21
Effective heart age <sup>d</sup>	4.3 (2.2)	-	-
Number of hours lost per day <sup>d</sup>	2.7 (1.7) (n = 16)	-	-

Variations in sample size for anxiety and worry outcomes are explained by variations in recall of personalized risk information.

<sup>a</sup>Assessed by an adapted version of the COMRADE scale,<sup>25</sup> which consists of 10 questions on a 5-point scale ranging from "strongly disagree" to "strongly agree," immediately after the intervention.

<sup>b</sup>Assessed by one of the COMRADE questions.

<sup>c</sup>Measured by the SF-STAI, a 6-item questionnaire to assess people's emotional state on a 4-point scale.<sup>28</sup> Participants had to evaluate how "calm," "tense," "upset," "relaxed," "content" and "worried" they felt on a 4-point Likert scale. Higher scores indicate a higher level of anxiety.

<sup>d</sup>Measured by a 7-point Likert scale, ranging from "not anxious/worried at all" to "very worried/anxious."<sup>27</sup>

**TABLE 2** Summary of results (primary outcomes and between-group comparisons)

**TABLE 3** Summary of results (risk recall, complete cases only)

	Intervention group (n = 18)			Control group (n = 18)				
	After intervention		12-week follow-up			After intervention		12-week follow-up
	Score	P-value	Score	P-value	P-value (within)	Score	Score	P-value (within)
Recall of personalized risk information, n (%) <sup>a</sup>								
10-year CV risk	14 (78)	-	6 (33)	-	.01***	16 (89)	2 (11)	<.01***
10-year CV risk (well-controlled)	14 (78)	1.00	2 (11)	.11	<.01***	-	-	-
Effective heart age	18 (100)	.04**	16 (89)	<.01***	.48	-	-	-
Number of hours lost per day	16 (89)	.37	4 (22)	.46	<.01***	-	-	-

<sup>a</sup>Number of individuals who accurately recalled their personalized risk information.

\*\*P < .05; \*\*\*P < .01.

more proximal, this may also have softened the magnitude of the risk as compared to a monthly or yearly period (as used in Galesic and Retamero's study).

Second, the intervention had a significant effect on participants' intentions to improve dietary behaviour. In terms of risk-reducing behaviours, risk perception is a reliable predictor of behavioural intentions. It is likely that the impact of the intervention on perceived risk also translated into a higher motivation to engage in risk-reducing behaviour. Although evidence is still scarce, previous studies using organ age estimates to motivate behaviour change have reported promising results, both in terms of intentions to make lifestyle changes<sup>36</sup> and behavioural outcomes.<sup>19,39</sup> Communication of changes in life expectancy, despite

improving risk recall,<sup>38</sup> has to our knowledge not yet been tested on risk-reducing behaviour. This is an issue since concepts such as "ageing faster or slower" or "gaining/losing daily hours of lifetime" have potential to improve people's understanding of the consequences of their risky behaviours.<sup>21</sup>

### 4.3 | Limitations

This study was conducted at a single-site surgery practice in Oxford, which limits the degree to which the findings can be generalized to the whole T2DM population. However, the local population in this area of Oxford is diverse, both socially and ethnically, and this was reflected in our sample. Although the intervention

**TABLE 4** Summary of results (intentions and self-management behaviour, complete cases only)

	Intervention group (n = 18)		Control group (n = 18)		P-value	12-week follow-up	12-week follow-up	P-value
	Baseline	After intervention	Baseline	After intervention				
Intentions <sup>a</sup> , mean (SD)								
Diet	3.1 (1.6)	4.3 (1.1)	4.5 (0.8)	4.5 (0.8)	<.01***	-	-	.80
Exercise	3.7 (1.5)	4.3 (1.0)	3.9 (1.3)	4.3 (1.0)	.05*	-	-	.07*
Self-management score <sup>b</sup>								
Diet (fruits and vegetables), mean (SD)	4.2 (1.8)	-	5.2 (1.8)	-	.48	4.7 (2.2)	4.6 (2.2)	.02**
Diet (high-fat foods), mean (SD)	2.8 (2.2)	-	4.2 (2.3)	-	.75	2.9 (1.6)	3.6 (2.4)	.19
Exercise <sup>c</sup> , mean (SD)	6.3 (3.9)	-	5.7 (3.5)	-	.16	5.2 (4.1)	5.5 (3.8)	.86
Blood glucose testing, mean (SD)	3.5 (3.3)	-	3.4 (3.1)	-	.27	4.2 (3.1)	3.2 (2.8)	.35
Foot checks, mean (SD)	1.9 (2.5)	-	3.1 (2.9)	-	.71	2.3 (2.7)	4.1 (2.7)	.14
Medication adherence								
No missed dose, n (%)	15 (83%)	-	16 (89%)	-	-	14 (70%)	17 (94%)	-
Missed dose, n (%)	3 (17%)	-	2 (11%)	-	-	4 (30%)	1 (6%)	-
HbA1c, mean (SD)	8.8 (1.6)	-	8.5 (1.3)	-	.37	8.5 (1.9)	8.4 (1.7)	.65

Given the small proportion of smokers in the sample, we did not model smoking status as an outcome variable.

<sup>a</sup>The DLBQ consists of 3 parts, investigating respectively dietary intake, physical activity and smoking habits. Intentions are assessed by a 5-point Likert scale ranging from "strongly agree" to "strongly disagree."<sup>29</sup>

<sup>b</sup>The SDSCA questionnaire explores 6 dimensions of self-management (healthy eating, physical activity, medication adherence, self-monitoring of blood glucose, foot checks and smoking behaviour) with 11 items, using the self-reported frequency of completing recommended activities during the past 7 days (SDSCA score ranging from 0 to 7 for each dimension).<sup>30</sup>

<sup>c</sup>Combination of 2 items: walk and specific exercise sessions.

\*P < .1; \*\*P < .05; \*\*\*P < .01.

**TABLE 5** Regression coefficients (intentions and self-management behaviour, complete cases only)

	Dependent outcome variable (n = 36)								
	Intentions <sup>a</sup> (Diet)	Intentions <sup>a</sup> (Exercise)	Diet 1 <sup>b</sup>	Diet 2 <sup>c</sup>	Exercise <sup>d</sup>	Blood glucose testing	Foot checks	Medication adherence <sup>e</sup>	HbA1c
Sex									
Male (reference)	-	-	-	-	-	-	-	-	-
Female	-0.09 (0.27)	-0.28 (0.24)	0.88 (0.75)	-0.21 (0.57)	-1.13 (1.17)	0.67 (0.55)	1.11 (0.73)	5.49 (6.40)	-0.14 (0.30)
Age	<0.01 (0.01)	<0.01 (0.01)	0.05** (0.02)	<0.01 (0.03)	0.07 (0.05)	<0.01 (0.03)	0.04 (0.03)	0.94 (0.06)	<0.01 (0.02)
Duration of diabetes	0.01 (0.01)	<0.01 (0.01)	-0.03 (0.05)	-0.02 (0.03)	-0.04 (0.07)	<0.01 (0.02)	0.11** (0.05)	0.99 (0.06)	0.01 (0.02)
Intervention status									
Control group (reference)	-	-	-	-	-	-	-	-	-
Intervention group	0.40* (0.22)	0.10 (0.23)	0.80 (0.69)	-0.07 (0.51)	-0.61 (1.07)	1.01* (0.55)	-0.86 (0.66)	3.92 (4.87)	-0.11 (0.38)
Education									
High school or no degree (reference)	-	-	-	-	-	-	-	-	-
Bachelor or graduate degree	-0.21 (0.27)	-0.58** (0.22)	1.00 (0.69)	0.33 (0.55)	-0.50 (1.12)	-1.26** (0.54)	-0.96 (0.63)	1.16 (1.44)	0.03 (0.42)
Baseline score	0.49*** (0.16)	0.47*** (0.14)	0.53*** (0.17)	0.48*** (0.10)	0.63*** (0.16)	0.75*** (0.10)	0.25* (0.14)	6.39 (8.57)	0.96*** (0.10)
Constant	2.87*** (0.93)	2.88*** (0.91)	-2.00 (1.58)	1.93 (1.84)	-0.85 (3.41)	1.19 (1.81)	-0.71 (2.02)	0.60 (2.00)	0.01 (1.43)

Sex categories (male = 0; female = 1); education categories (high school degree or no degree = 0; bachelor or graduate degree = 1). Given the small proportion of smokers in the sample, we did not model smoking status as an outcome variable.

<sup>a</sup>Measured immediately after the intervention.

<sup>b</sup>Consumption of fruits and vegetables.

<sup>c</sup>Consumption of high-fat foods.

<sup>d</sup>Combination of 2 items (walk and specific exercise sessions).

<sup>e</sup>Interpreted as a dichotomous variable (no missed dose = 0; missed dose = 1).

\* $P < .1$ ; \*\* $P < .05$ ; \*\*\* $P < .01$ .



could be beneficial to all patients with T2DM, the rationale behind the exclusion of people diagnosed with the condition for less than a year was to make sure that each participant was familiar with T2DM self-management.

On the one hand, the follow-up period (12 weeks), selected to allow comparisons with similar studies<sup>26,34,35</sup> and to detect changes in HbA1c levels, was short to evaluate lifestyle changes and improvements in health outcomes as a response to these changes. On the other, it could be argued that the motivating impact of the intervention may decrease after a few weeks, meaning that reinforcement activities may be necessary to maintain the initial impact and trigger a sustained effect.<sup>19</sup> So far, only repeated risk communication interventions have shown effects longer than 6 weeks.<sup>34</sup> The nudge-based intervention piloted in this study could be more effective as a long-term intervention (repeated use) in primary care, as the provision of updated risk scores at regular intervals may enhance its impact on behavioural outcomes. It would be interesting to assess if regularly receiving an improved heart age or a gain in life expectancy after the intervention would result in further reinforcement and motivation to adhere to self-management. Moreover, in order to maximize people's engagement and memorization, such repeated intervention could be supplemented with the provision, at each visit, of a written support (eg, one-page printout) summarizing the updated risk information. Finally, integrating the intervention into the clinic workflow may also help address clinical inertia ("the tendency to maintain current treatment strategies despite results demanding escalation") in the management of T2DM.<sup>40</sup>

In terms of outcome measurements, two limitations should be mentioned. First, individuals in the intervention group had more information content to remember than individuals in the control group (4 numbers vs 1 number, respectively). This could have biased the recall results ("memory bias"), leading to a lower recall rate in the intervention group. However, the absence of between-group difference in terms of recall of 10-year CV risk score, both immediately and 12 weeks after the intervention, suggests that this memory effect was negligible. Second, there is uncertainty concerning the best method to use to measure self-management. Quick, easy to use and efficient, the SDSCA questionnaire has gained the status of a gold standard. However, in practice, we observed that several participants found it difficult to quantify their daily intake of fruits and vegetables or high-fat food. Consequently, we suggest complementing the use of the SDSCA questionnaire, when possible, with more objective measures of behaviour. Such measures include, for example, plasma vitamin C as a robust measure of fruit and vegetable intake, or serum cotinine as a reliable indicator of the quantity of tobacco smoked.

## 5 | CONCLUSION

This pilot study provides the first evidence of the feasibility of implementing in primary care a nudge-based risk communication intervention for people with T2DM. Based on its promising results,

an adequately powered RCT to determine the effectiveness of the intervention on the behavioural outcomes of UK individuals with poorly controlled T2DM is judged feasible. Some minor adaptations to the intervention and study methods that would help to facilitate a definitive trial have been identified. We recommend the following adjustments:

- Modifying the inclusion criteria: excluding individuals diagnosed with anxiety disorders from the trial.
- Communicating variations in life expectancy associated with self-management in terms of months (over a period of 5 years, for example) rather than in terms of daily hours.
- Limiting the content of the intervention to the communication of effective heart age and loss of life expectancy (ie, removing the communication of absolute CV risk from the intervention).
- Complementing the self-reported measure of self-management with more objective measures of behaviour.
- Implementing a repeated intervention (with update of the risk scores at each visit) in place of a single intervention and increasing the follow-up period to maximize the chances of triggering a sustained effect on behavioural outcomes.
- Providing participants with a printout of their personalized risk information to facilitate memorization and promote their engagement in the behaviour change process.

It is worth highlighting that the intervention piloted in this study is simple, economical and not time consuming (between 5 and 10 minutes per patient). This makes it an ideal candidate to be used in routine primary care consultation with people with T2DM. The personalized risk information is easy and quick to calculate, and expressed in a way that makes it readily understandable by everyone. Its simplicity and ease of understanding also makes the approach a prime candidate to be adapted to other clinical areas.

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## CONFLICTS OF INTEREST

The authors state that no conflicts of interest exist.

## AUTHORS' CONTRIBUTION

TR, JL, RB and AG designed the study. CV and DS developed the risk communication tool. RB conducted the intervention and TR

collected the data. TR, JL and RB analysed and interpreted the data. TR wrote the manuscript. All authors revised and approved the final version of the manuscript.

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## SUPPORTING INFORMATION

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

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