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## Is it possible to predict improved diabetes outcomes following Diabetes Self-Management Education: a mixed methods longitudinal design

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3 **Is it possible to predict improved diabetes outcomes following Diabetes Self-Management**  
4 **Education: a mixed methods longitudinal design**  
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**ABSTRACT**

**Objective:** To predict the diabetes related outcomes of people undertaking a type 2 Diabetes Self-Management Education (DSME) programme from their baseline data.

**Design:** A mixed methods longitudinal experimental study. Six practice nurses and two clinical academics undertook blind assessments of all baseline and process data to predict clinical, behavioural and psychological outcomes at 6-months post-DSME programme

**Setting:** Primary Care

**Participants:** Thirty one people with type 2 diabetes who had not previously undertaken Diabetes Self-management Education (DSME).

**Intervention:** All participants undertook the Diabetes Manual 1:1 self-directed learning 12-week DSME programme supported by practice nurses trained as Diabetes Manual facilitators.

**Outcome Variables:** HbA1c, Diabetes Knowledge, Physical Activity, Waist Circumference, Self-efficacy, Diabetes Distress, Anxiety, Depression, Demographics, Change Talk and Treatment Satisfaction. These variables were chosen because they are known to influence self-management behaviour or to have been influenced by a DSME programme in empirical evidence.

**Results:** Baseline and 6-month follow up data were available for 27 participants of which 13 (48%) were male, 22 (82%) White British, mean age 59 yrs and mean duration of type 2 diabetes 9.1 years. Significant reductions were found in HbA1c  $t(26)=2.35$ ,  $p=.03$ , and diabetes distress  $t(26)=2.30$ ,  $p=.03$ , and a significant increase in knowledge  $t(26)=-2.06$ ,  $p=.05$  between baseline and 6-months. No significant changes were found in waist circumference, physical activity, anxiety, depression or self-efficacy. Accuracy of predictions varied little between clinical academics and Practice Nurses but greatly between outcome (0% to 100%). The median and mode accuracy of predicted outcome was 66.67%. Accuracy of prediction for the key outcome of HbA1c was 44.44%. Diabetes distress had the highest prediction accuracy (81.48%).

**Conclusions:** Clinicians are unreliable in identifying individuals likely to achieve improvement in outcomes from DSME, despite extensive clinical data. DSME should be promoted to all patients with diabetes according to guidelines.

**Strengths and limitations of the study**

- Thirteen diabetes related clinical, behavioural and psychological outcomes were assessed for each participant
- Data from quantitative and qualitative sources were used
- Participants were new to diabetes self-management education
- Selection bias regarding psychological outcomes was possible
- In clinical practice, nurses have access to non-verbal clues and patient history in making assessments

## INTRODUCTION

Diabetes Self-Management Education (DSME) is advocated for people with diabetes by major diabetes organisations across the developed world<sup>1-4</sup>. Outcomes of DSME trials have been equivocal with most programmes demonstrating some effect on a range of outcomes including glycaemic control<sup>5,6</sup>, smoking cessation and illness beliefs<sup>7</sup>, diabetes distress and self-efficacy<sup>8</sup> and quality of life<sup>6</sup>. However, not all have demonstrated effects on the outcome of greatest clinical importance, namely glycaemic control<sup>7-9</sup>. This has contributed to variability in healthcare professionals' views of DSME, and the extent to which DSME is commissioned and delivered in health economies<sup>2</sup>. NICE guidance advocates DSME for all people with diabetes<sup>10-12</sup>, with education being a considered a key priority in the management of Type 2 diabetes:

“Offer structured education to every person and/or their carer at and around the time of diagnosis, with annual reinforcement and review. Inform people and their carers that structured education is an integral part of diabetes care.”<sup>12 p6</sup>.

However, in 2012-13, in England only 6.0% of all people with type 2 diabetes, and 16.7% of those newly diagnosed, had been offered a DSME programme<sup>13</sup>. Uptake of DSME was even lower; only 1.6% of all people with type 2 diabetes, and 3.6% of the newly diagnosed, were recorded as attending DSME<sup>13</sup>. In addition to ambivalence towards DSME, some healthcare professionals (HCPs) have explained low referral rates to DSME by arguing that they can anticipate who will benefit from such programmes and will only refer those for whom advantages are perceived<sup>8,14</sup>. For example, HCPs have described reasons for low referrals based on their perceptions of patients' ability to understand the content and awareness of the need for education and self-management<sup>14</sup>. To address HCP ambivalence to refer patients to DSME, in England provision of DSME (Structured Education) became a Quality and Outcomes Framework<sup>15</sup> item (pay for performance) in 2013 with the aim that more people will be referred. Nonetheless, referral does not guarantee uptake and attendance, and primary care professionals continue to have an important role in communicating the importance of DSME in improving a range of patient outcomes and encouraging attendance. The opportunity remains for HCPs to decide who to encourage based on their perceptions of likely patient benefit. Our objective was to assess the reliability of the argument offered by HCPs that they know who to offer DSME to. This paper presents findings from a broader study whose aims were to assess the feasibility of an enhanced Diabetes Manual programme. The research question addressed in this paper is: *Is possible to predict the diabetes related outcomes of people undertaking a type 2 Diabetes Self-Management Education (DSME) programme from their baseline and process data set?*

## METHOD

### Design

A mixed-method longitudinal experimental research design was employed between 2010-12. Patients completed data collection when they consented to participate in the Diabetes Manual programme at the study baseline and at six months follow-up. Minimal important difference, i.e. the smallest difference in outcome for a patient that is perceived to be meaningful<sup>16</sup>, was used to measure change in outcomes for each individual. Ethical approval for the study was given by Coventry and Warwickshire Research Ethics Committee. This paper presents a person-centred analysis<sup>17</sup>. The detailed longitudinal dataset enabled the construction of individual narratives examining how baseline variables are linked to specific outcomes<sup>18</sup>.

### The DSME Intervention

The Diabetes Manual is an evidence based 1:1 DSME programme for type 2 diabetes largely self-directed with support from Practice Nurses who have been trained as Diabetes Manual Facilitators (DMF) to elicit behavioural changes and to provide psychological support. The Diabetes Manual consists of a workbook, relaxation audio components and a minimum of three face-to-face or telephone DMF contacts as preferred by the participant. The Diabetes Manual is designed to take three months to complete, involving approximately an hour a day for participants. Examples of how this hour may be spent includes reading the Diabetes Manual, taking physical activity, reading food labels, cooking a healthy meal, blood glucose monitoring or listening to the relaxation audio programme. The Diabetes Manual is evidence based<sup>8,19-20</sup> and available for commissioning in the NHS or direct purchase by people with Type 2 diabetes<sup>21</sup>.

### Participants

Six Practice Nurses employed at general practices were recruited through the Primary Care Research Network and opportunistic sampling and two nurses were recruited from a hospital diabetes clinic. All were trained to become DMFs. The nurses each were asked to recruit up to 10 patients with type 2 diabetes, the ability to read English, HbA1c >7.4% (57.4 mmol/mol), and who had not attended diabetes self-management education. Our sample size was based on the aims of the broader study in which we aimed to recruit 50 participants to give 80% confidence for assessing changes in diabetes management self-efficacy. After two months 2 DMFs withdrew due to time pressures without recruiting patients. The remaining six DMFs consented 31 patients, 4 of whom subsequently withdrew.

## Procedures

Following completion of the training, DMFs arranged an appointment with participants to obtain informed consent, introduce them to the Diabetes Manual programme and collect baseline clinical assessments. The DMFs also gave the participants psychological outcome questionnaires and an accelerometer with instructions for use, which were collected from the participant 7 days later by the researcher. Within two months of recruiting their first patient, the DMFs were observed in two or three consultations by a trained facilitator for Quality Assurance (QA) purposes as per NICE guidance<sup>11</sup>. A total of 17 QA consultations took place and were recorded. After their QA consultation, each patient took part in a brief interview with a researcher about their experiences in the consultation. Follow-up data collection took place six months post-baseline. Participants attended an appointment with their DMF where clinical measurements were taken. The psychological measures and accelerometer were sent to patients a week before their follow-up appointment. These measures were completed prior to their appointment. Finally, all participants took part in a follow-up interview to discuss their experiences of the DM programme, and any areas where the DSME had impacted on their diabetes management.

## Outcome assessment framework

We collected a range of clinical, psychological, behavioural and process outcome data along with demographic data. Each variable is described, and inclusion justified, in table 1. Variables were included in the framework if they were i) known to influence self-management behaviour (e.g. ethnicity<sup>22</sup>; depression<sup>23</sup>) or ii) known to have been influenced by a DSME programme in empirical evidence (e.g. HbA1c<sup>5,6</sup>; diabetes distress<sup>8,24</sup>). Data were collected at baseline and 6-month follow-up. Process indicator data, such as any patient change talk or value verbalised about the DSME, was collected during the QA process. Baseline measures and process indicators formed the dataset used to ask the question, "based on this patient's data do I think that engaging with DSME will result in any changes in HbA1c, waist circumference, exercise levels, anxiety, depression, and distress in 6-months' time for this patient?" With each patient and each outcome, the DMFs made a prediction through recording one of three expectations 1) the outcome would improve by a minimally important difference<sup>16</sup>, 2) the outcome would deteriorate or 3) there would be no change. Specifically for prediction purposes, data were presented in a table format alongside clinical guidelines relevant to each outcome. All data in the framework could be available to nurses during routine consultations if they chose to access the information.

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3 *Table 1 Variables within the predictive framework*  
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5 *Table 2: Example prediction framework data*  
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### 10 **Methods of predicting outcome**

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12 Two clinical academic research team members (JS a Nurse and FG a GP) developed and pilot tested  
13 the prediction method using the outcome assessment framework. They independently examined  
14 individual patient baseline and process data and made predications pertaining to 6-month follow up  
15 outcome. This iterative process was piloted with 7 patients and then applied with the study  
16 population. Following individual predictions, discussion took place to reach agreement. On a  
17 separate occasion, six DMFs used the framework to predict outcomes on each other's anonymized  
18 patient data (i.e. participants not known to them) in a recorded focus group. Patient data was  
19 randomly allocated to individual DMFs, ensuring that each DMF examined a unique subset of  
20 different patients, and that all patients' data was examined by 2 different DMFs. Initially the DMFs  
21 made individual predictions for their own subset of 9 patients, then collectively they discussed and  
22 made predictions for 14 patients. Therefore, each participant dataset was individually assessed by 2  
23 DMFs (different for each patient) to produce specific predictions and a brief outcome narrative (see  
24 Table 2 for example data and predictions). Once all predictions were completed the 6-month follow-  
25 up data were entered into the framework to enable analysis. The standard of assessment for  
26 determining a positive change in outcomes for each patient was the minimally important difference  
27 unique to each outcome (as listed in Table 1). During analysis, where no prediction was given for  
28 change or stability this was classed as 'no change' predicted. Where there were disagreements  
29 about the prediction, this was noted and the prediction made by the majority was used in analysis.  
30 Accuracy is described per patient (i.e. how many of the six outcome predictions per patient were  
31 accurate), and per outcome (i.e. what percentage of the 27 predictions made for each outcome  
32 were accurate).  
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### 50 **RESULTS**

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52 Quantitative data on clinical, psychological and behavioural outcomes was collected at baseline from  
53 30 patients and at 6-months from 27 patients. Of the latter, 13 (48%) were male, 22 (82%) were  
54 White British, ages ranged from 39 to 81 years (mean 59.2 years), and duration of type 2 diabetes  
55 was 3 months to 34 years (mean 9.1 years). See Table 3 for participant clinical and psychological  
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3 characteristics at baseline and follow-up. Among the whole group, there were significant reductions  
4 in HbA1c %  $t(26)=2.35, p=.03$ , and diabetes distress  $t(26)=2.30, p=.03$ , and a significant increase in  
5 knowledge  $t(26)=-2.06, p=.05$  between baseline and 6-months (see Table 3). No significant changes  
6 were found in waist circumference  $t(26)=-0.43, p=.67$ , physical activity  $t(26)=0.99, p=.33$ , anxiety  
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8  $t(26)=-1.39, p=.18$ , depression  $t(26)=-0.38, p=.71$ , or self-efficacy  $t(26)=-1.83, p=.08$ .  
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14 *Table 3: Clinical and psychological characteristics of participants*  
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### 19 **Researcher predictions (pilot)**

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21 The accuracy of the researcher predictions for change in the key clinical, behavioural and  
22 psychological outcomes for the seven pilot patients was examined. Accuracy of predictions ranged  
23 from no accurate outcome predictions to all six outcome predictions accurate. Accuracy of  
24 predictions per outcome varied from 42.86% to 71.43% (i.e. of the seven predictions made for each  
25 outcome [one for each patient], between three and five were accurate). Prediction agreement  
26 between the two researchers was 96%.  
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### 32 **DMF predictions**

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34 The accuracy of the DMF predictions for key clinical, behavioural and psychological outcomes for the  
35 whole data set was examined. Although there were disagreements in individual predictions, an  
36 overall reduction in HbA1c was predicted for all patients. Change was less widely predicted for other  
37 variables. Clinically important outcomes not captured by clinical, psychological and behavioural data  
38 but revealed during interview include dietary changes and reduction in alcohol intake (n=7),  
39 increased medication adherence (n=1) and smoking cessation (n=1).  
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### 45 **Accuracy per patient**

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47 Accuracy of the six outcome predictions per patient ranged from one to six, with the median and  
48 mode being four out of six predictions. There were between one and six prediction agreements per  
49 patient, with an average of 4.12 prediction agreements in outcomes per patient. Overall, prediction  
50 agreement for the DMFs was 68%.  
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## Accuracy per outcome

Accuracy for predictions by outcome varied from 44.44% for HbA1c to 81.48% for diabetes distress. The median and mode accuracy was 66.67%. Table 4 shows the nature of the change predicted for each outcome and the percentage of patients in which changes were predicted for each outcome, the nature of actual change observed, and the percentage of accurate predictions made. Many predictions were correct because no change was predicted and this was accurate. Examination of the focus group recording reveals that the DMFs made broad inferences from the available data. For example, inferences about participant 17's body size, eating habits and attitudes towards food were made based on his waist circumference. This participant was described as "slim" by the DMFs (he was one of 3 participants whose baseline waist circumference was under recommended clinical limits) and discussion took place about his probable eating habits without any available data regarding this.

*Table 4: DMF predictions as to the impact of the DSME on clinical outcomes, and the accuracy of these predictions*

## DISCUSSION

### Summary of main findings

Findings from this study identified that accuracy for predicting change in HbA1c by the nurses was low with their accuracy for reductions in diabetes distress higher. We found that the majority of accurate predictions related to an anticipation of no change (i.e. the nurses thought the patients 6 month outcomes would not change) in relation to waist circumference, physical activity levels, anxiety and depression. Overall, there was greater accuracy in predictions about lack of change, than in identifying individuals who would achieve improvement in outcome. Predictions for change were made most frequently for measures that showed the greatest room for change (i.e. those outcomes in those patients with high baseline scores). The Diabetes Manual DSME programme has continued to demonstrate improvements in glycaemic control and diabetes distress in this new population<sup>8</sup>. High HbA1C was an inclusion criterion for participation in the study and there was consistency in the prediction that the DSME intervention would reduce this, suggesting that health professionals can find it difficult to predict in what ways people will benefit from DSME. Health professionals appear to believe that their patients will change (optimistic bias) where scope for change is evident, and

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3 where they believe in the efficacy of their treatment endeavours. Prediction agreement within the  
4 group of nurses was much lower than for the researchers. This could indicate the lack of experience  
5 in undertaking this exercise in contrast to the researchers who had developed the process (so were  
6 more practised in applying it). It was notable that, where available, the qualitative data was heavily  
7 drawn on by the nurses to inform predictions. Qualitative evidence was used to provide insight into  
8 underlying motivations for behaviour change and attitudes towards the intervention, consistent with  
9 the narrative development process for narratives exploring how baseline variables are linked to  
10 specific outcomes<sup>18</sup>.

### 17 **Strengths and limitations of the study**

19 The research intervention used a tried and tested DSME programme which enabled the DMFs to  
20 focus on the research questions presented and not on DSME programme evaluation. The nurses  
21 were aware of the earlier RCT findings which may have influenced their decision making. This  
22 research benefits from the assessment of a wide range of clinical and psychological measures, so  
23 that the anticipated impact of DSME on a variety of outcomes could be assessed. However, it is  
24 limited by the lack of a measure of eating habits. This is a key behavioural change targeted by the  
25 DSME, and which has the potential to significantly improve HbA1c<sup>25</sup>. The baseline characteristics  
26 show that our participants' anxiety and depression levels were low so few changes were expected.  
27 This may indicate a participant selection bias, as people with depression could have been less likely  
28 to consent, or be offered the opportunity, to participate in the study. The DMFs were all  
29 experienced at working with people with Type 2 Diabetes, and so were able to draw on their clinical  
30 experience of this patient group when making predictions. The process and outcome narratives  
31 were, however, produced in a fairly artificial setting. In consultations, health professionals often  
32 have prior knowledge of their patients and draw on non-verbal data to make their assessments.  
33 Despite this, the health professionals did articulate why they would expect particular outcomes,  
34 making explicit the clinical evaluation process. In relation to study eligibility criteria, the DMFs  
35 struggled to firstly identify, and then recruit, patients who had not previously attended locally-  
36 offered diabetes self-management education and who could read English. This could indicate that  
37 patients in the settings served by these nurses had already been extensively offered diabetes  
38 education in contrast to the national average of 6.0%<sup>13</sup>.

### 52 **Comparison with wider literature**

54 Nurses tend to draw heavily on their experience when interpreting the different sources of  
55 information available during routine consultations experience<sup>26,27</sup>. In this study, the DMFs used  
56 their experience to make inferences from the available data. Such inferences demonstrate how  
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3 previous clinical experiences inform (or even bias) current evaluations<sup>28,29</sup>. Physicians' clinical  
4 experience and knowledge have long been viewed as the "quintessential skills" that they have to  
5 offer<sup>30 p 657</sup>. Used alone, however, professional opinion has been described as the "least reliable and  
6 valid form of evidence" on which to base clinical decisions<sup>29 p 232</sup>, below hierarchies of research  
7 evidence. One systematic review found that physicians with more experiential knowledge were less  
8 likely to adhere to appropriate standards of care, a finding which they describe as inconsistent with  
9 the notion that experience enhances knowledge and skills, leading to better patient care<sup>31</sup>. Other  
10 authors have claimed that experienced clinicians form hypotheses and diagnostic plans more  
11 quickly and to a higher standard than inexperienced clinicians<sup>32</sup>. The benefit of clinical experience in  
12 making evaluations and decisions, is somewhat contested then. In this study, where nurses had to  
13 make clinical judgements without physically seeing a patient, they had few other resources to draw  
14 on other than their experience with similar patients.

### 22 23 **Conclusions**

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25 Our research indicates that while clinicians draw on their extensive clinical experience in assessing  
26 the benefit of DSME it is not possible for them to reliably and accurately determine outcomes,  
27 despite a volume of data on which to make these assessments. Our result indicate that all people  
28 with diabetes should continue to be offered DSME programmes according to national<sup>2,10,11</sup> and  
29 international guidelines<sup>1,3,4</sup>. Furthermore, research should explore the clinical decision making  
30 process, to make explicit the process through which clinicians make judgements on the potential  
31 benefit (or not) of self-management education for different patients. Further exploration of this  
32 topic could highlight how clinical experience is used to interpret data within current situations, and  
33 the outcome this has for the patient in their access to care.

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### Author Contributions

JS developed the Diabetes Manual DSME programme. JS, JD, FG, IC, RW and JO'H designed and managed the study and interpreted the findings. RW & IC carried out the DMF training. CH carried out the data collection and outcome analysis. JS, FG & CH designed the predictions framework, undertook predictions and CH analysed the data. All authors contributed to the development of the manuscript.

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Table 1: Variables within the predictive framework

| Framework data and, for outcomes only, minimal important difference (MID) | Measure, cut offs as appropriate and completion mechanisms   | Justification for inclusion   |
|---|--|---|
| Demographic data  | <p>Index of Multiple Deprivation: Participant's home postcode was used to identify IMD ward. Deprived areas are those ranked lower than 6562 (the 20% most deprived wards in the UK) <sup>35</sup>.</p> <p>Ethnicity: Self-report</p> <p>Gender, age, time since diagnosis and occupation are not known to be related to DSME effects so were not included in the framework.</p> | <p>Deprivation is linked to less successful management of type 2 diabetes <sup>33</sup>.</p> <p>Ethnicity is linked to type 2 diabetes prevalence <sup>22</sup> and poorer self-management/diabetes outcomes <sup>34</sup>.</p> |
| Knowledge of diabetes   | <p>Revised Diabetes Knowledge Scale (RDKS) <sup>36</sup> is a 19-item multiple choice scale assessing diabetes-related knowledge. Correct responses are coded as '1' and incorrect responses are coded as '0', and these are summed to give a possible score between 0 and 23.</p>   | <p>Knowledge is modifiable by intervention and people with low knowledge at baseline might expect to increase their knowledge, and subsequently improve their behavioural outcomes, following DSME <sup>37</sup>.</p>           |
| Self-efficacy   | <p>Diabetes Management Self-Efficacy Scale (DMSES) tool is a 15-item scale that has been validated with UK populations <sup>36,38</sup>. Items are scored on a 0-10 Likert-type scale to indicate how confident they are at the task described. Responses are summed, giving possible self-efficacy scores between 0 (no self-efficacy) and 150 (very high self-efficacy).</p>   | <p>Self-efficacy is modifiable by DSME <sup>8</sup>.</p> <p>People with low self-efficacy might be expected to raise this following DSME.</p>   |



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|---|--|--|
| <p>Diabetes distress</p> <p>The MID= half a standard deviation (SD)<sup>39</sup>. The SD was 20.84, therefore the MID = 10 scale points</p> | <p>Problem Areas In Diabetes Scale (PAID)<sup>40</sup> is a 20-item scale measuring emotional functioning relating to diabetes, with each item scored on a 5-point Likert-type scale (0-4). Responses are summed and multiplied by 1.25 to give an overall score between 0 and 100. In order to categorise baseline levels of distress, PAID scores were categorised as either high distress (over 40 scale points), medium distress (20-40), or no distress (under 20).</p> | <p>Diabetes-distress is modifiable by DSME<sup>8</sup>.<sup>24</sup>. People with high distress might be expected to have lower diabetes distress following DSME.</p>                                    |
| <p>Depression</p> <p>MID=1.5 scale points<sup>41</sup>.</p> <p>Anxiety</p> <p>MID=1.5 scale points<sup>41</sup>.</p>                        | <p>Hospital Anxiety and Depression Scale (HADS)<sup>42</sup> is a 4-point Likert-type scale to indicate the extent of 14 anxious and depressive feelings over the past week. Responses are coded from 0 to 3 and the total is computed for each subscale (giving total scores between 0 and 21). Scores over 8 indicate clinical levels of anxiety/depression<sup>43</sup>. The HADS has been used and validated with diabetic populations<sup>44</sup>.</p>                 | <p>Depression is known to compromise self-management efforts<sup>23</sup> and so it is likely that no changes in depression or key self-management outcomes will be seen in someone with depression.</p> |
| <p>HbA1c</p> <p>MID= 0.5%<sup>39</sup>.</p>   | <p>The clinical cut off for uncontrolled diabetes, and for participation in the study, is 7.4% or 57 mmol/mol<sup>45</sup>.</p>  | <p>DSME has been shown to have an effect on HbA1c, and this is a key clinical marker of disease control<sup>6,7</sup>.</p>   |
| <p>Waist circumference</p> <p>MID = 5%<sup>46</sup>.</p>  | <p>For white and black men waist measurement should be below 94cm, for Asian men it should be below 90cm, and for all women it should be below 80cm<sup>47</sup>.</p>  | <p>Waist circumference is a better predictor of health, and particularly type 2 diabetes, than is overall weight or BMI<sup>48,49</sup>.</p>   |
| <p>Physical activity</p> <p>MID = an increase of 2500</p>   | <p>Yamax Powerwalker accelerometer was used for 3 days (including one weekday and one weekend day) to record a) the number of steps b) the</p>   | <p>DSME focus on physical activity was high so the potential for 2500 step increase was</p>  |

|                                  |   |   |
|----------------------------------|---|---|
| steps per day <sup>50</sup> .    | number of kilometres walked and c) number of calories burned. Data from the accelerometer was averaged for the three days. The recommended average steps per day is 10,000 <sup>50</sup> .  | change easy to observe.   |
| Change talk: changes made        | Process measure identified during Quality Assurance audio-recordings and mid-point interviews for 17/27 participants. A brief description of changes already made since starting the DSME was included. For example, patient 1 said: <i>"I go to the gym three times a week now [...] which I haven't done for about 20 years."</i>   | Patient-led change talk indicates readiness to initiate/sustain behaviour changes <sup>51</sup> . |
| Change talk: changes planned     | Process measure identified during Quality Assurance audio-recordings and mid-point interviews for 17/27 participants. A brief description of changes planned during the QA consultation was included. For example, patient 24 said that she planned to increase her exercise so that she made herself out of breath: <i>"Just when I do walk to step it up, yes to make sure to stop walking on the flat and taking it nice and easy, just to pick a few hills and go for it [laughs]. [...] just make myself out of breath [for] more than five or ten minutes."</i> | Patient-led change talk indicates readiness to initiate/sustain behaviour changes <sup>51</sup> . |
| Treatment satisfaction with DSME | Process measure identified during Quality Assurance audio-recordings and mid-point interviews for 17/27 participants. A brief description of comments made about the DSME was included. For example, patient 4 was very positive about the DSME: <i>"I'm feeling actually much better and after going through my manual I felt it was quite informative..... I enjoyed reading it."</i>   | Assessment of treatment satisfaction of an indicator of usefulness to participant.                |

Table 2: Example prediction framework data

| Patient   | Guidelines   | Patient 3 Data          | Patient 3 Predictions   | Patient 24 Data         | Patient 24 Predictions  |
|-----------|--|-------------------------|---|-------------------------|---|
| IMD       | <i>Deprived areas &lt;6437.6</i>                                 | 13349                   |   | 18942                   |   |
| Ethnicity |  | Indian                  |   | White British           |   |
| HbA1c     | <i>&lt;7.4% or 57.4 mmol/mol</i>                                 | 11.10%<br>97.8 mmol/mol | Reduced<br>(Baseline measurement is high so there is scope for change.) | 12.1%<br>108.7 mmol/mol | Reduced<br>(Had baseline been a bit lower no change would have been predicted because current dietary changes are not substantial and she is already doing enough exercise) |
| Waist     | <i>94cm white/ black men; &lt;90cm Asian men; &lt;80cm women</i> | 96.52 cm                | None  | 114                     | Reduced   |
| Exercise  | <i>&gt;10,000 steps per day</i>                                  | 4872                    | Increase<br>(He talks about increasing his exercise.)                   | 10700.67                | None<br>(Already exercising enough.)  |
| Anxiety   | <i>Clinical limit &gt;8</i>                                      | 3                       | None  | 6                       | None  |

| <b>Depression</b>                   | <i>Clinical limit &gt;8</i>  | 3   | None  | 0   | None |
|-------------------------------------|--|---|---|---|------|
| <b>Diabetes Distress</b>            | <i>&gt;40 high distress; 20-40 moderate distress; &lt;20 no distressed</i> | 53.75   | Reduced<br>(Baseline measurement is high so there is scope for change.) | 10  | None |
| <b>Self-efficacy</b>                | <i>&gt;101 High; 51-100 moderate; &lt;50 low</i>                           | 120   |   | 96  |      |
| <b>Knowledge</b>                    |  | 13  |   | 14  |      |
| <b>Change talk: changes made</b>    |  | Eats a healthy diet (mainly vegetarian, no alcohol, healthy food). Eats smaller portions. Has started walking more. |   | Cut down on butter and fat in diet. Has started walking more. |      |
| <b>Change talk: changes planned</b> |  | To increase exercise (walking, cycling, swimming), and find time for it.  |   | To increase her exercise- walk enough to get out of breath    |      |
| <b>Treatment satisfaction</b>       |  | Very positive about DSME.   |   | DSME is a bit repetitive at times                             |      |

Table 3: Clinical and psychological characteristics of participants

|                          | Baseline          |                   | 6 month Follow-up |                   | Difference between<br>baseline & follow-up<br>* = sig |
|--------------------------|-------------------|-------------------|-------------------|-------------------|---|
|                          | Range             | Mean (SD)         | Range             | Mean (SD)         | t   |
| <b>HbA1c (%)</b>         | 7.10 - 13.60      | 9.20 (1.92)       | 5.60 - 13.30      | 8.40 (1.90)       | 2.35 (p = 0.03)*                                      |
| <b>HbA1c (mmol/mol)</b>  | 46.00 - 125.00    | 76.19 (21.90)     | 38.00 - 122.00    | 68.96 (20.90)     | 1.79 (p = 0.09)                                       |
| <b>Waist</b>             | 77.00 - 148.00    | 109.72 (15.12)    | 88.40 - 160.00    | 110.60 (16.34)    | -0.43 (p = 0.67)                                      |
| <b>Steps</b>             | 106.00 - 17223.67 | 5985.77 (3971.09) | 12.67 - 16593.00  | 5469.88 (3923.11) | 0.99 (p = 0.33)                                       |
| <b>Diabetes Distress</b> | 0.00 - 83.75      | 22.82 (21.35)     | 0.00 - 70.00      | 16.71 (17.39)     | 2.30 (p = 0.03)*                                      |
| <b>Anxiety</b>           | 0.00 - 15.00      | 5.26 (4.37)       | 0.00 - 13.00      | 4.37 (3.61)       | 1.39 (p = 0.18)                                       |
| <b>Depression</b>        | 0.00 - 9.00       | 3.07 (2.43)       | 0.00 - 13.00      | 3.26 (2.98)       | -0.38 (p = 0.71)                                      |
| <b>Knowledge</b>         | 7.00 - 20.00      | 14.37 (2.92)      | 9.00 - 22.00      | 15.67 (3.20)      | -2.06 (p = 0.05)*                                     |
| <b>Self-Efficacy</b>     | 62.00 - 146.54    | 104.66 (22.66)    | 75.00 - 157.00    | 113.00 (19.84)    | -1.83 (p = 0.08)                                      |

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Table 4: DMF predictions as to the impact of the DSME on clinical outcomes, and the accuracy of these predictions

|  | HbAc1                          | Waist                         | Exercise                        | Distress                      | Anxiety                       | Depression                    |
|--|--------------------------------|-------------------------------|---------------------------------|-------------------------------|-------------------------------|-------------------------------|
| <b>Direction of predicted change</b><br>(n = number of patients for which this change was predicted) | Reduced = 27<br>No change = 0  | Reduced = 6<br>No change = 21 | Increased = 9<br>No change = 18 | Reduced = 6<br>No change = 21 | Reduced = 4<br>No change = 23 | Reduced = 1<br>No change = 26 |
| <b>% Patients for which change was predicted</b>   | 100.00                         | 22.22                         | 33.33                           | 22.22                         | 14.81                         | 3.70                          |
| <b>Total number of agreements in predictions</b>   | 12/? 27                        | 19                            | 13                              | 17                            | 23                            | 26                            |
| <b>Direction of actual change</b><br>(n = number of patients for which this change was observed)     | Reduced = 12<br>No change = 15 | Reduced = 4<br>No change = 23 | Increased = 2<br>No change = 25 | Reduced = 7<br>No change = 20 | Reduced = 8<br>No change = 19 | Reduced = 8<br>No change = 19 |
| <b>% Accuracy of predictions</b>   | 44.44                          | 70.37                         | 62.96                           | 81.48                         | 62.96                         | 74.07                         |

# BMJ Open

## Is it possible to predict improved diabetes outcomes following Diabetes Self-Management Education: a mixed methods longitudinal design

|                                 |   |
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|                                 |   |

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3 **Is it possible to predict improved diabetes outcomes following Diabetes Self-Management**  
4 **Education: a mixed methods longitudinal design**  
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**ABSTRACT**

**Objective:** To predict the diabetes related outcomes of people undertaking a type 2 Diabetes Self-Management Education (DSME) programme from their baseline data.

**Design:** A mixed methods longitudinal experimental study. Six practice nurses and two clinical academics undertook blind assessments of all baseline and process data to predict clinical, behavioural and psychological outcomes at 6-months post-DSME programme

**Setting:** Primary Care

**Participants:** Thirty one people with type 2 diabetes who had not previously undertaken Diabetes Self-management Education (DSME).

**Intervention:** All participants undertook the Diabetes Manual 1:1 self-directed learning 12-week DSME programme supported by practice nurses trained as Diabetes Manual facilitators.

**Outcome Variables:** HbA1c, Diabetes Knowledge, Physical Activity, Waist Circumference, Self-efficacy, Diabetes Distress, Anxiety, Depression, Demographics, Change Talk and Treatment Satisfaction. These variables were chosen because they are known to influence self-management behaviour or to have been influenced by a DSME programme in empirical evidence.

**Results:** Baseline and 6-month follow up data were available for 27 participants of which 13 (48%) were male, 22 (82%) White British, mean age 59 yrs and mean duration of type 2 diabetes 9.1 years. Significant reductions were found in HbA1c  $t(26)=2.35$ ,  $p=.03$ , and diabetes distress  $t(26)=2.30$ ,  $p=.03$ , and a significant increase in knowledge  $t(26)=-2.06$ ,  $p=.05$  between baseline and 6-months. No significant changes were found in waist circumference, physical activity, anxiety, depression or self-efficacy. Accuracy of predictions varied little between clinical academics and practice Nurses but greatly between outcome (0% to 100%). The median and mode accuracy of predicted outcome was 66.67%. Accuracy of prediction for the key outcome of HbA1c was 44.44%. Diabetes distress had the highest prediction accuracy (81.48%).

**Conclusions:** Clinicians in this small study were unable to identify individuals likely to achieve improvement in outcomes from DSME. DSME should be promoted to all patients with diabetes according to guidelines.

**Strengths and limitations of the study**

- Thirteen diabetes related clinical, behavioural and psychological outcomes were assessed for each participant
- Data from quantitative and qualitative sources were used
- Participants were new to diabetes self-management education
- Selection bias regarding psychological outcomes was possible
- In clinical practice, nurses have access to non-verbal clues and patient history in making assessments

## INTRODUCTION

Diabetes Self-Management Education (DSME) is advocated for people with diabetes by major diabetes organisations across the developed world<sup>1-4</sup>. Outcomes of DSME trials have been equivocal with most programmes demonstrating some effect on a range of outcomes including glycaemic control<sup>5,6</sup>, smoking cessation and illness beliefs<sup>7</sup>, diabetes distress and self-efficacy<sup>8</sup> and quality of life<sup>6</sup>. However, not all have demonstrated effects on the outcome of greatest clinical importance, namely glycaemic control<sup>7-9</sup>. This has contributed to variability in healthcare professionals' (HCP) views of DSME, and the extent to which DSME is commissioned and delivered in health economies<sup>2</sup>. UK NICE guidance advocates DSME (which in the UK is generally referred to as Diabetes Structured Patient Education) for all people with diabetes<sup>10-12</sup>, with education being considered a key priority in the management of type 2 diabetes:

“Offer structured education to every person and/or their carer at and around the time of diagnosis, with annual reinforcement and review. Inform people and their carers that structured education is an integral part of diabetes care.”<sup>12 p6</sup>.

However, in 2012-13, in England only 6.0% of all people with type 2 diabetes, and 16.7% of those newly diagnosed, had been offered a DSME programme<sup>13</sup>. Uptake of DSME was even lower; only 1.6% of all people with type 2 diabetes, and 3.6% of the newly diagnosed, were recorded as attending DSME<sup>13</sup>. In addition to ambivalence towards DSME, some HCPs have explained low referral rates to DSME by arguing that they can anticipate who will benefit from such programmes and will only refer those for whom advantages are perceived<sup>8,14</sup>. For example, HCPs have described reasons for low referrals based on their perceptions of patients' ability to understand the content and awareness of the need for DSME<sup>14</sup>. To address HCP ambivalence to refer patients to DSME, in England provision of DSME (Structured Education) became a Quality and Outcomes Framework<sup>15</sup> item (pay for performance) in 2013 with the aim that more people will be referred. Nonetheless, referral does not guarantee uptake and attendance, and primary care professionals continue to have an important role in communicating the importance of DSME in improving a range of patient outcomes and encouraging attendance. The opportunity remains for HCPs to decide who to encourage based on their perceptions of likely patient benefit. Our objective was to assess the reliability of the argument offered by HCPs that they know whom to offer DSME. This paper presents findings from a broader study whose aims were to assess the feasibility of an enhanced Diabetes Manual programme. The research question addressed in this paper is: *Is it possible to predict the*

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3 *diabetes related outcomes of people undertaking a type 2 Diabetes Self-Management Education*  
4 *(DSME) programme from their baseline and process data set?*  
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## 7 **METHOD**

### 8 **Design**

9  
10 A mixed-method longitudinal experimental research design was employed between 2010-12.  
11 Patients completed data collection when they consented to participate in the Diabetes Manual  
12 programme at the study baseline and at six months follow-up. Minimal important difference, i.e. the  
13 smallest difference in outcome for a patient that is perceived to be meaningful <sup>16</sup>, was used to  
14 measure change in outcomes for each individual. Ethical approval for the study was given by  
15 Coventry and Warwickshire Research Ethics Committee. This paper presents a person-centred  
16 analysis <sup>17</sup>. The detailed longitudinal dataset enabled the construction of individual narratives  
17 examining how baseline variables are linked to specific outcomes <sup>18</sup>.  
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### 25 **The DSME Intervention**

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27 The Diabetes Manual is an evidence based 1:1 DSME programme for type 2 diabetes largely self-  
28 directed with support from practice nurses who have been trained as Diabetes Manual Facilitators  
29 (DMF) to elicit behavioural changes and to provide psychological support. The Diabetes Manual  
30 consists of a workbook, relaxation audio components and a minimum of three face-to-face or  
31 telephone DMF contacts as preferred by the participant. The Diabetes Manual is designed to take  
32 three months to complete, involving approximately an hour a day for participants. Examples of how  
33 this hour may be spent includes reading the Diabetes Manual, taking physical activity, reading food  
34 labels, cooking a healthy meal, blood glucose monitoring or listening to the relaxation audio  
35 programme. The Diabetes Manual is evidence based <sup>8,19-20</sup> and available for commissioning in the  
36 NHS or direct purchase by people with type 2 diabetes<sup>21</sup>.  
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### 45 **Participants**

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47 Six practice nurses employed at general practices were recruited through the Primary Care Research  
48 Network and opportunistic sampling and two nurses were recruited from a hospital diabetes clinic.  
49 All were trained to become DMFs. The nurses each were asked to recruit up to 10 patients with type  
50 2 diabetes, the ability to read English, HbA1c >7.4% (57.4 mmol/mol), and who had not attended  
51 diabetes self-management education. Our sample size was based on the aims of the broader study  
52 in which we aimed to recruit 50 participants to give 80% confidence for assessing changes in  
53 diabetes management self-efficacy. After two months 2 DMFs withdrew due to time pressures  
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3 without recruiting patients. The remaining six DMFs consented 31 patients, 4 of whom subsequently  
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5 withdrew.  
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### 8 **Procedures**

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10 Following completion of the training, DMFs arranged an appointment with participants to obtain  
11 informed consent, introduce them to the Diabetes Manual programme and collect baseline clinical  
12 assessments. The DMFs also gave the participants psychological outcome questionnaires and an  
13 accelerometer with instructions for use, which were collected from the participant seven days later  
14 by the researcher. Within two months of recruiting their first patient, the DMFs were observed in  
15 two or three consultations by a trained facilitator for Quality Assurance (QA) purposes as per NICE  
16 guidance <sup>11</sup>. A total of 17 QA consultations took place and were recorded. After their QA  
17 consultation, each patient took part in a brief interview with a researcher about their experiences in  
18 the consultation. Follow-up data collection took place six months post-baseline. Participants  
19 attended an appointment with their DMF where clinical measurements were taken. The  
20 psychological measures and accelerometer were sent to patients a week before their follow-up  
21 appointment. These measures were completed prior to their appointment. Finally, all participants  
22 took part in a follow-up interview to discuss their experiences of the DM programme, and any areas  
23 where the DSME had impacted on their diabetes management. The clinical, psychological,  
24 behavioural, process and demographic data known to impact upon, or be impacted by DSME, and  
25 collected for the main study, represents the dataset used to develop the outcome assessment  
26 framework.  
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### 39 **Outcome assessment framework**

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41 Our earlier Diabetes Manual RCT<sup>8</sup> had found improvements in Diabetes Distress and Self-efficacy.  
42 Subsequent meta-analyses <sup>22</sup> had identified reduction in HbA1c with psychological intervention. We  
43 hypothesised therefore that with the addition of psychological care components to the Diabetes  
44 Manual, we would find clinically and statistically significant reductions in HbA1c. We further  
45 hypothesised that the more sub-optimal the outcome in each patient, the greater the improvement  
46 would be although we did not develop hypotheses regarding DMF's outcome prediction accuracy.  
47 We did not involve participants in making self-assessments regarding their anticipated outcomes of  
48 participating in the study. Each variable used in the outcome assessment framework is described,  
49 and inclusion justified, in table 1. Variables were included in the framework if they were i) known to  
50 influence self-management behaviour (e.g. ethnicity <sup>23</sup>; depression <sup>24</sup>) or ii) known to have been  
51 influenced by a DSME programme in empirical evidence (e.g. HbA1c <sup>5,6</sup>; diabetes distress <sup>8,25</sup>). Data  
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3 were collected at baseline and 6-month follow-up. Process indicator data, such as any patient  
4 change talk or value verbalised about the DSME, was collected during the QA process. Baseline  
5 measures and process indicators formed the dataset used to ask the question, "based on this  
6 patient's data do I think that engaging with DSME will result in any changes in HbA1c, waist  
7 circumference, exercise levels, anxiety, depression, and distress in 6-months' time for this patient?"  
8  
9 With each patient and each outcome, the DMFs made a prediction through recording one of three  
10 expectations 1) the outcome would improve by a minimally important difference<sup>16</sup>, 2) the outcome  
11 would deteriorate or 3) there would be no change. Specifically for prediction purposes, data were  
12 presented in a table format alongside clinical guidelines relevant to each outcome. All data in the  
13 framework could be available to nurses during routine consultations if they chose to access the  
14 information.  
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24 ***Table 1 Variables within the predictive framework***

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26 ***Table 2: Example prediction framework data***  
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31 **Methods of predicting outcome**  
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34 Two clinical academic research team members (JS a Nurse and FG a GP) developed and pilot tested  
35 the prediction method using the outcome assessment framework. They independently examined  
36 individual patient baseline and process data and made predications pertaining to 6-month follow up  
37 outcome. This iterative process was piloted with 7 patients and then applied with the study  
38 population. Following individual predictions, discussion took place to reach agreement. On a  
39 separate occasion, six DMFs used the framework to predict outcomes on each other's anonymized  
40 patient data (i.e. participants not known to them) in a recorded focus group. Patient data was  
41 randomly allocated to individual DMFs, ensuring that each DMF examined a unique subset of  
42 different patients, and that all patients' data was examined by two different DMFs. Initially the DMFs  
43 made individual predictions for their own subset of nine patients, then collectively they discussed  
44 and made predictions for 14 patients. Therefore, each participant dataset was individually assessed  
45 by two DMFs (different for each patient) to produce specific predictions and a brief outcome  
46 narrative (see Table 2 for example data and predictions). Once all predictions were completed the 6-  
47 month follow-up data were entered into the framework to enable analysis. The standard of  
48 assessment for determining a positive change in outcomes for each patient was the minimally  
49 important difference unique to each outcome (as listed in Table 1). During analysis, where no  
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3 prediction was given for change or stability this was classed as 'no change' predicted. Where there  
4 were disagreements about the prediction, this was noted and the prediction made by the majority  
5 was used in analysis. Accuracy is described per patient (i.e. how many of the six outcome predictions  
6 per patient were accurate), and per outcome (i.e. what percentage of the 27 predictions made for  
7 each outcome were accurate).  
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## 11 12 13 14 **RESULTS**

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16 Quantitative data on clinical, psychological and behavioural outcomes was collected at baseline from  
17 30 patients and at 6-months from 27 patients. Of the latter, 13 (48%) were male, 22 (82%) were  
18 White British, ages ranged from 39 to 81 years (mean 59.2 years), and duration of type 2 diabetes  
19 was 3 months to 34 years (mean 9.1 years). See Table 3 for participant clinical and psychological  
20 characteristics at baseline and follow-up. Among the whole group, there were significant reductions  
21 in HbA1c %  $t(26)=2.35, p=.03$ , and diabetes distress  $t(26)=2.30, p=.03$ , and a significant increase in  
22 knowledge  $t(26)=-2.06, p=.05$  between baseline and 6-months (see Table 3). No significant changes  
23 were found in waist circumference  $t(26)=-0.43, p=.67$ , physical activity  $t(26)=0.99, p=.33$ , anxiety  
24  $t(26)=-1.39, p=.18$ , depression  $t(26)=-0.38, p=.71$ , or self-efficacy  $t(26)=-1.83, p=.08$ .  
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35 **Table 3: Clinical and psychological characteristics of participants**

### 36 37 38 39 **Researcher predictions (pilot)**

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41 The accuracy of the researcher predictions for change in the key clinical, behavioural and  
42 psychological outcomes for the seven pilot patients was examined. Accuracy of predictions ranged  
43 from no accurate outcome predictions to all six outcome predictions accurate. Accuracy of  
44 predictions per outcome varied from 42.86% to 71.43% (i.e. of the seven predictions made for each  
45 outcome [one for each patient], between three and five were accurate). Prediction agreement  
46 between the two researchers was 96%.  
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### 52 53 **DMF predictions**

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55 The accuracy of the DMF predictions for key clinical, behavioural and psychological outcomes for the  
56 whole data set was examined. Although there were disagreements in individual predictions, an  
57 overall reduction in HbA1c was predicted for all patients. Change was less widely predicted for other  
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3 variables. Clinically important outcomes not captured by clinical, psychological and behavioural data  
4 but revealed during interview include dietary changes and reduction in alcohol intake (n=7),  
5 increased medication adherence (n=1) and smoking cessation (n=1).  
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#### 8 Accuracy per patient

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10 Accuracy of the six outcome predictions per patient ranged from one to six, with the median and  
11 mode being four out of six predictions. There were between one and six prediction agreements per  
12 patient, with an average of 4.12 prediction agreements in outcomes per patient. Overall, prediction  
13 agreement for the DMFs was 68%.  
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#### 17 Accuracy per outcome

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19 Accuracy for predictions by outcome varied from 44.44% for HbA1c to 81.48% for diabetes distress.  
20 The median and mode accuracy was 66.67%. Table 4 shows the nature of the change predicted for  
21 each outcome and the percentage of patients in which changes were predicted for each outcome,  
22 the nature of actual change observed, and the percentage of accurate predictions made. Many  
23 predictions were correct because no change was predicted and this was accurate.  
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30 ***Table 4: DMF predictions as to the impact of the DSME on clinical outcomes, and the accuracy of***  
31 ***these predictions***  
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## 36 DISCUSSION

### 37 Summary of main findings

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39 Findings from this study identified that accuracy for predicting change in HbA1c by the nurses was  
40 low with their accuracy for reductions in diabetes distress higher. We found that the majority of  
41 accurate predictions related to an anticipation of no change (i.e. the nurses thought the patients 6  
42 month outcomes would not change) in relation to waist circumference, physical activity levels,  
43 anxiety and depression. Overall, there was greater accuracy in predictions about lack of change, than  
44 in identifying individuals who would achieve improvement in outcome. Predictions for change were  
45 made most frequently for measures that showed the greatest room for change (i.e. those outcomes  
46 in those patients with high baseline scores). The Diabetes Manual DSME programme has continued  
47 to demonstrate improvements in glycaemic control and diabetes distress in this new population <sup>8</sup>.  
48 High HbA1C was an inclusion criterion for participation in the study and there was consistency in the  
49 prediction that the DSME intervention would reduce this, suggesting that health professionals can  
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3 find it difficult to predict in what ways people will benefit from DSME. Health professionals appear  
4 to believe that their patients will change (optimistic bias) where scope for change is evident, and  
5 where they believe in the efficacy of their treatment endeavors. Prediction agreement within the  
6 group of nurses was much lower than for the researchers. This could indicate the lack of experience  
7 in undertaking this exercise in contrast to the researchers who had developed the process (so were  
8 more practiced in applying it). It was notable that, where available, the qualitative data was heavily  
9 drawn on by the nurses to inform predictions. Qualitative evidence was used to provide insight into  
10 underlying motivations for behaviour change and attitudes towards the intervention, consistent with  
11 the narrative development process for narratives exploring how baseline variables are linked to  
12 specific outcomes<sup>18</sup>.

### 19 20 **Strengths and limitations of the study**

21  
22 The research intervention used a tried and tested DSME programme which enabled the DMFs to  
23 focus on the research questions presented and not on DSME programme evaluation. The nurses  
24 were aware of the earlier RCT findings which may have influenced their decision making. This  
25 research benefits from the assessment of a wide range of clinical and psychological measures, so  
26 that the anticipated impact of DSME on a variety of outcomes could be assessed. However, it is  
27 limited by the lack of a measure of eating habits. This is a key behavioural change targeted by the  
28 DSME, and which has the potential to significantly improve HbA1c<sup>26</sup>. The baseline characteristics  
29 show that our participants' anxiety and depression levels were low so few changes were expected.  
30 This may indicate a participant selection bias, as people with depression could have been less likely  
31 to consent, or be offered the opportunity, to participate in the study. Several outcomes in our  
32 framework were self-report and completing these could have been interventional in themselves by  
33 causing the participant to reflect on their mood, coping, confidence or knowledge. The DMFs were  
34 all experienced at working with people with type 2 diabetes, and so were able to draw on their  
35 clinical experience of this patient group when making predictions. The process and outcome  
36 narratives were, however, produced in a fairly artificial setting. In consultations, health professionals  
37 often have prior knowledge of their patients and draw on non-verbal data to make their  
38 assessments. Despite this, the health professionals did articulate why they would expect particular  
39 outcomes, making explicit the clinical evaluation process. In relation to study eligibility criteria, the  
40 DMFs struggled to firstly identify, and then recruit, patients who had not previously attended locally-  
41 offered DSME and who could read English. This could indicate that patients in the settings served by  
42 these nurses had already been extensively offered DSME in contrast to the national average of 6.0%  
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### Comparison with wider literature

Nurses tend to draw heavily on their experience when interpreting the different sources of information available during routine consultations experience<sup>27,28</sup>. In this study, the DMFs used their experience to make inferences from the available data. Such inferences demonstrate how previous clinical experiences inform (or even bias) current evaluations<sup>29,30</sup>. Physicians' clinical experience and knowledge have long been viewed as the "quintessential skills" that they have to offer<sup>31 p 657</sup>. Used alone, however, professional opinion has been described as the "least reliable and valid form of evidence" on which to base clinical decisions<sup>30 p 232</sup>, below hierarchies of research evidence. One systematic review found that physicians with more experiential knowledge were less likely to adhere to appropriate standards of care, a finding which they describe as inconsistent with the notion that experience enhances knowledge and skills, leading to better patient care<sup>32</sup>. Other authors have claimed that experienced clinicians form hypotheses and diagnostic plans more quickly and to a higher standard than inexperienced clinicians<sup>33</sup>. The benefit of clinical experience in making evaluations and decisions, is somewhat contested then. In this study, where nurses had to make clinical judgements without physically seeing a patient, they had few other resources to draw on other than their experience with similar patients. This wider literature and the findings of this study have implications for the training of clinicians who refer people to DSME. If this study were repeated with GPs the findings may have been different.

### Conclusions

Our research indicates that while clinicians draw on their extensive clinical experience in assessing the benefit of DSME, in our relatively modest group of six practice nurses and outcome data on 27 people with diabetes, it was not possible for them to reliably and accurately determine outcomes utilising ten to twelve pieces of data per person on which to make these assessments. Our result indicate that all people with diabetes should continue to be offered DSME programmes according to national<sup>2,10,11</sup> and international guidelines<sup>1,3,4</sup>. Furthermore, research should explore the clinical decision making process, to make explicit the process through which clinicians make judgements on the potential benefit (or not) of DSME for different patients. Further exploration of this topic could highlight how clinical experience is used to interpret data within current situations, and the outcome this has for the patient in their access to care.

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### 11 **Author Contributions**

12  
13  
14 JS developed the Diabetes Manual DSME programme. JS, JD, FG, IC, RW and JO'H designed and  
15 managed the study and interpreted the findings. RW & IC carried out the DMF training. CH carried  
16 out the data collection and outcome analysis. JS, FG & CH designed the predictions framework,  
17 undertook predictions and CH analysed the data. All authors contributed to the development of the  
18 manuscript.  
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### 22 **Competing interests**

23  
24 Jackie Sturt and Rosie Walker have license to distribute the Diabetes Manual programme within the  
25 NHS for profit. Walker runs a small business to which this licence has been offered by University of  
26 Warwick. Sturt has IP rights associated with her development of the Diabetes Manual and has a  
27 royalty sharing agreement with University of Warwick.  
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34 necessarily those of the NHS, the NIHR, or the Department of Health.  
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### 37 **Data sharing statement**

38 Unpublished data relating to quality assurance of the Diabetes Manual delivery is available to  
39 anyone commissioning, or considering commissioning or using, the Diabetes Manual programme by  
40 contacting the corresponding author.  
41

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Table 1: Variables within the predictive framework

| Framework data and, for outcomes only, minimal important difference (MID) | Measure, cut offs as appropriate and completion mechanisms   | Justification for inclusion   |
|---|--|---|
| Demographic data  | <p>Index of Multiple Deprivation: Participant's home postcode was used to identify IMD ward. Deprived areas are those ranked lower than 6562 (the 20% most deprived wards in the UK) <sup>36</sup>.</p> <p>Ethnicity: Self-report</p> <p>Gender, age, time since diagnosis and occupation are not known to be related to DSME effects so were not included in the framework.</p> | <p>Deprivation is linked to less successful management of type 2 diabetes <sup>34</sup>.</p> <p>Ethnicity is linked to type 2 diabetes prevalence <sup>22</sup> and poorer self-management/diabetes outcomes <sup>35</sup>.</p> |
| Knowledge of diabetes   | <p>Revised Diabetes Knowledge Scale (RDKS) <sup>37</sup> is a 19-item multiple choice scale assessing diabetes-related knowledge. Correct responses are coded as '1' and incorrect responses are coded as '0', and these are summed to give a possible score between 0 and 19.</p>   | <p>Knowledge is modifiable by intervention and people with low knowledge at baseline might expect to increase their knowledge, and subsequently improve their behavioural outcomes, following DSME <sup>38</sup>.</p>           |
| Self-efficacy   | <p>Diabetes Management Self-Efficacy Scale (DMSES) tool is a 15-item scale that has been validated with UK populations <sup>37,39</sup>. Items are scored on a 0-10 Likert-type scale to indicate how confident they are at the task described. Responses are summed, giving possible self-efficacy scores between 0 (no self-efficacy) and 150 (very high self-efficacy).</p>   | <p>Self-efficacy is modifiable by DSME <sup>8</sup>.</p> <p>People with low self-efficacy might be expected to raise this following DSME.</p>   |

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|---|--|--|
| <p>Diabetes distress</p> <p>The MID= half a standard deviation (SD)<sup>40</sup>. The SD was 20.84, therefore the MID = 10 scale points</p> | <p>Problem Areas In Diabetes Scale (PAID)<sup>41</sup> is a 20-item scale measuring emotional functioning relating to diabetes, with each item scored on a 5-point Likert-type scale (0-4). Responses are summed and multiplied by 1.25 to give an overall score between 0 and 100. In order to categorise baseline levels of distress, PAID scores were categorised as either high distress (over 40 scale points), medium distress (20-40), or no distress (under 20).</p> | <p>Diabetes-distress is modifiable by DSME<sup>8, 25</sup>. People with high distress might be expected to have lower diabetes distress following DSME.</p>  |
| <p>Depression</p> <p>MID=1.5 scale points<sup>42</sup>.</p> <p>Anxiety</p> <p>MID=1.5 scale points<sup>42</sup>.</p>                        | <p>Hospital Anxiety and Depression Scale (HADS)<sup>43</sup> is a 4-point Likert-type scale to indicate the extent of 14 anxious and depressive feelings over the past week. Responses are coded from 0 to 3 and the total is computed for each subscale (giving total scores between 0 and 21). Scores over 8 indicate clinical levels of anxiety/depression<sup>44</sup>. The HADS has been used and validated with diabetic populations<sup>45</sup>.</p>                 | <p>Depression is known to compromise self-management efforts<sup>24</sup> and so it is likely that no changes in depression or key self-management outcomes will be seen in someone with depression.</p> |
| <p>HbA1c</p> <p>MID= 0.5%<sup>40</sup>.</p>   | <p>The clinical cut off for uncontrolled diabetes, and for participation in the study, is 7.4% or 57 mmol/mol<sup>46</sup>.</p>  | <p>DSME has been shown to have an effect on HbA1c, and this is a key clinical marker of disease control<sup>6,7</sup>.</p>   |
| <p>Waist circumference</p> <p>MID = 5%<sup>47</sup></p>   | <p>For white and black men waist measurement should be below 94cm, for Asian men it should be below 90cm, and for all women it should be below 80cm<sup>48</sup>.</p>  | <p>Waist circumference is a better predictor of health, and particularly type 2 diabetes, than is overall weight or BMI<sup>49,50</sup>.</p>   |
| <p>Physical activity</p> <p>MID = an increase of 2500</p>   | <p>Yamax Powerwalker accelerometer was used for 3 days (including one weekday and one weekend day) to record a) the number of steps b) the</p>   | <p>DSME focus on physical activity was high so the potential for 2500 step increase was</p>  |



|                                  |   |   |
|----------------------------------|---|---|
| steps per day <sup>51</sup> .    | number of kilometres walked and c) number of calories burned. Data from the accelerometer was averaged for the three days. The recommended average steps per day is 10,000 <sup>51</sup> .  | change easy to observe.   |
| Change talk: changes made        | Process measure identified during Quality Assurance audio-recordings and mid-point interviews for 17/27 participants. A brief description of changes already made since starting the DSME was included. For example, patient 1 said: <i>"I go to the gym three times a week now [...] which I haven't done for about 20 years."</i>   | Patient-led change talk indicates readiness to initiate/sustain behaviour changes <sup>52</sup> . |
| Change talk: changes planned     | Process measure identified during Quality Assurance audio-recordings and mid-point interviews for 17/27 participants. A brief description of changes planned during the QA consultation was included. For example, patient 24 said that she planned to increase her exercise so that she made herself out of breath: <i>"Just when I do walk to step it up, yes to make sure to stop walking on the flat and taking it nice and easy, just to pick a few hills and go for it [laughs]. [...] just make myself out of breath [for] more than five or ten minutes."</i> | Patient-led change talk indicates readiness to initiate/sustain behaviour changes <sup>52</sup> . |
| Treatment satisfaction with DSME | Process measure identified during Quality Assurance audio-recordings and mid-point interviews for 17/27 participants. A brief description of comments made about the DSME was included. For example, patient 4 was very positive about the DSME: <i>"I'm feeling actually much better and after going through my manual I felt it was quite informative..... I enjoyed reading it."</i>   | Assessment of treatment satisfaction of an indicator of usefulness to participant.                |

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Table 2: Example prediction framework data

| Patient   | Guidelines  | Patient 3 Data          | Patient 3 Predictions   | Patient 24 Data         | Patient 24 Predictions  |
|-----------|---|-------------------------|---|-------------------------|---|
| IMD       | Deprived areas <6437.6                              | 13349                   |   | 18942                   |   |
| Ethnicity |   | Indian                  |   | White British           |   |
| HbA1c     | <7.4% or 57.4 mmol/mol                              | 11.10%<br>97.8 mmol/mol | Reduced<br>(Baseline measurement is high so there is scope for change.) | 12.1%<br>108.7 mmol/mol | Reduced<br>(Had baseline been a bit lower no change would have been predicted because current dietary changes are not substantial and she is already doing enough exercise) |
| Waist     | 94cm white/ black men; <90cm Asian men; <80cm women | 96.52 cm                | None  | 114                     | Reduced   |
| Exercise  | >10,000 steps per day                               | 4872                    | Increase<br>(He talks about increasing his exercise.)                   | 10700.67                | None<br>(Already exercising enough.)  |
| Anxiety   | Clinical limit >8                                   | 3                       | None  | 6                       | None  |

|                                     |  |  |   |   |      |
|-------------------------------------|--|--|---|---|------|
| <b>Depression</b>                   | <i>Clinical limit &gt;8</i>  | 3  | None  | 0   | None |
| <b>Diabetes Distress</b>            | <i>&gt;40 high distress; 20-40 moderate distress; &lt;20 no distressed</i> | 53.75  | Reduced<br>(Baseline measurement is high so there is scope for change.) | 10  | None |
| <b>Self-efficacy</b>                | <i>&gt;101 High; 51-100 moderate; &lt;50 low</i>                           | 120  |   | 96  |      |
| <b>Knowledge</b>                    |  | 13   |   | 14  |      |
| <b>Change talk: changes made</b>    |  | Eats a healthy diet (mainly vegetarian, no alcohol, healthy food).<br>Eats smaller portions. Has started walking more. |   | Cut down on butter and fat in diet. Has started walking more. |      |
| <b>Change talk: changes planned</b> |  | To increase exercise (walking, cycling, swimming), and find time for it.   |   | To increase her exercise- walk enough to get out of breath    |      |
| <b>Treatment satisfaction</b>       |  | Very positive about DSME.  |   | DSME is a bit repetitive at times                             |      |

Table 3: Clinical and psychological characteristics of participants

|                          | Baseline (N=30)   |                   | 6 month Follow-up (N=27) |                   | Difference between baseline & follow-up<br>* = sig |
|--------------------------|-------------------|-------------------|--------------------------|-------------------|--|
|                          | Range             | Mean (SD)         | Range                    | Mean (SD)         | t  |
| <b>HbA1c (%)</b>         | 7.10 - 13.60      | 9.20 (1.92)       | 5.60 - 13.30             | 8.40 (1.90)       | 2.35 (p = 0.03)*                                   |
| <b>HbA1c (mmol/mol)</b>  | 46.00 - 125.00    | 76.19 (21.90)     | 38.00 - 122.00           | 68.96 (20.90)     | 1.79 (p = 0.09)                                    |
| <b>Waist</b>             | 77.00 - 148.00    | 109.72 (15.12)    | 88.40 - 160.00           | 110.60 (16.34)    | -0.43 (p = 0.67)                                   |
| <b>Steps</b>             | 106.00 - 17223.67 | 5985.77 (3971.09) | 12.67 - 16593.00         | 5469.88 (3923.11) | 0.99 (p = 0.33)                                    |
| <b>Diabetes Distress</b> | 0.00 - 83.75      | 22.82 (21.35)     | 0.00 - 70.00             | 16.71 (17.39)     | 2.30 (p = 0.03)*                                   |
| <b>Anxiety</b>           | 0.00 - 15.00      | 5.26 (4.37)       | 0.00 - 13.00             | 4.37 (3.61)       | 1.39 (p = 0.18)                                    |
| <b>Depression</b>        | 0.00 - 9.00       | 3.07 (2.43)       | 0.00 - 13.00             | 3.26 (2.98)       | -0.38 (p = 0.71)                                   |
| <b>Knowledge</b>         | 7.00 - 20.00      | 14.37 (2.92)      | 9.00 - 22.00             | 15.67 (3.20)      | -2.06 (p = 0.05)*                                  |
| <b>Self-Efficacy</b>     | 62.00 - 146.54    | 104.66 (22.66)    | 75.00 - 157.00           | 113.00 (19.84)    | -1.83 (p = 0.08)                                   |

Table 4: DMF predictions as to the impact of the DSME on clinical outcomes, and the accuracy of these predictions

|  | HbAc1                          | Waist                         | Exercise                        | Distress                      | Anxiety                       | Depression                    |
|--|--------------------------------|-------------------------------|---------------------------------|-------------------------------|-------------------------------|-------------------------------|
| <b>Direction of predicted change</b><br>(n = number of patients for which this change was predicted) | Reduced = 27<br>No change = 0  | Reduced = 6<br>No change = 21 | Increased = 9<br>No change = 18 | Reduced = 6<br>No change = 21 | Reduced = 4<br>No change = 23 | Reduced = 1<br>No change = 26 |
| <b>% Patients for which change was predicted</b>   | 100.00                         | 22.22                         | 33.33                           | 22.22                         | 14.81                         | 3.70                          |
| <b>Total number of agreements in predictions*</b>  | 12                             | 19                            | 13                              | 17                            | 23                            | 26                            |
| <b>Direction of actual change</b><br>(n = number of patients for which this change was observed)     | Reduced = 12<br>No change = 15 | Reduced = 4<br>No change = 23 | Increased = 2<br>No change = 25 | Reduced = 7<br>No change = 20 | Reduced = 8<br>No change = 19 | Reduced = 8<br>No change = 19 |
| <b>% Accuracy of predictions</b>   | 44.44                          | 70.37                         | 62.96                           | 81.48                         | 62.96                         | 74.07                         |

\*Disagreements were counted when one person or more disagreed with the majority prediction for the patient

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3 **Is it possible to predict improved diabetes outcomes following Diabetes Self-Management**  
4 **Education: a mixed methods longitudinal design**  
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**ABSTRACT**

**Objective:** To predict the diabetes related outcomes of people undertaking a type 2 Diabetes Self-Management Education (DSME) programme from their baseline data.

**Design:** A mixed methods longitudinal experimental study. Six practice nurses and two clinical academics undertook blind assessments of all baseline and process data to predict clinical, behavioural and psychological outcomes at 6-months post-DSME programme

**Setting:** Primary Care

**Participants:** Thirty one people with type 2 diabetes who had not previously undertaken Diabetes Self-management Education (DSME).

**Intervention:** All participants undertook the Diabetes Manual 1:1 self-directed learning 12-week DSME programme supported by practice nurses trained as Diabetes Manual facilitators.

**Outcome Variables:** HbA1c, Diabetes Knowledge, Physical Activity, Waist Circumference, Self-efficacy, Diabetes Distress, Anxiety, Depression, Demographics, Change Talk and Treatment Satisfaction. These variables were chosen because they are known to influence self-management behaviour or to have been influenced by a DSME programme in empirical evidence.

**Results:** Baseline and 6-month follow up data were available for 27 participants of which 13 (48%) were male, 22 (82%) White British, mean age 59 yrs and mean duration of type 2 diabetes 9.1 years. Significant reductions were found in HbA1c  $t(26)=2.35$ ,  $p=.03$ , and diabetes distress  $t(26)=2.30$ ,  $p=.03$ , and a significant increase in knowledge  $t(26)=-2.06$ ,  $p=.05$  between baseline and 6-months. No significant changes were found in waist circumference, physical activity, anxiety, depression or self-efficacy. Accuracy of predictions varied little between clinical academics and practice Nurses but greatly between outcome (0% to 100%). The median and mode accuracy of predicted outcome was 66.67%. Accuracy of prediction for the key outcome of HbA1c was 44.44%. Diabetes distress had the highest prediction accuracy (81.48%).

**Conclusions:** Clinicians in this small study were ~~are unable reliable in to~~ identifying individuals likely to achieve improvement in outcomes from DSME, ~~despite extensive clinical data~~. DSME should be promoted to all patients with diabetes according to guidelines.

**Strengths and limitations of the study**

- Thirteen diabetes related clinical, behavioural and psychological outcomes were assessed for each participant
- Data from quantitative and qualitative sources were used
- Participants were new to diabetes self-management education
- Selection bias regarding psychological outcomes was possible
- In clinical practice, nurses have access to non-verbal clues and patient history in making assessments



## INTRODUCTION

Diabetes Self-Management Education (DSME) is advocated for people with diabetes by major diabetes organisations across the developed world<sup>1-4</sup>. Outcomes of DSME trials have been equivocal with most programmes demonstrating some effect on a range of outcomes including glycaemic control<sup>5,6</sup>, smoking cessation and illness beliefs<sup>7</sup>, diabetes distress and self-efficacy<sup>8</sup> and quality of life<sup>6</sup>. However, not all have demonstrated effects on the outcome of greatest clinical importance, namely glycaemic control<sup>7-9</sup>. This has contributed to variability in healthcare professionals' (HCP) views of DSME, and the extent to which DSME is commissioned and delivered in health economies<sup>2</sup>. UK NICE guidance advocates DSME (which in the UK is generally referred to as Diabetes Structured Patient Education) for all people with diabetes<sup>10-12</sup>, with education being considered a key priority in the management of type 2 diabetes:

“Offer structured education to every person and/or their carer at and around the time of diagnosis, with annual reinforcement and review. Inform people and their carers that structured education is an integral part of diabetes care.”<sup>12 p6</sup>.

However, in 2012-13, in England only 6.0% of all people with type 2 diabetes, and 16.7% of those newly diagnosed, had been offered a DSME programme<sup>13</sup>. Uptake of DSME was even lower; only 1.6% of all people with type 2 diabetes, and 3.6% of the newly diagnosed, were recorded as attending DSME<sup>13</sup>. In addition to ambivalence towards DSME, some HCPs have explained low referral rates to DSME by arguing that they can anticipate who will benefit from such programmes and will only refer those for whom advantages are perceived<sup>8,14</sup>. For example, HCPs have described reasons for low referrals based on their perceptions of patients' ability to understand the content and awareness of the need for education and self-management DSME<sup>14</sup>. To address HCP ambivalence to refer patients to DSME, in England provision of DSME (Structured Education) became a Quality and Outcomes Framework<sup>15</sup> item (pay for performance) in 2013 with the aim that more people will be referred. Nonetheless, referral does not guarantee uptake and attendance, and primary care professionals continue to have an important role in communicating the importance of DSME in improving a range of patient outcomes and encouraging attendance. The opportunity remains for HCPs to decide who to encourage based on their perceptions of likely patient benefit. Our objective was to assess the reliability of the argument offered by HCPs that they know whom to offer DSME. This paper presents findings from a broader study whose aims were to assess the feasibility of an enhanced Diabetes Manual programme. The research question addressed in this

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3 paper is: *Is it possible to predict the diabetes related outcomes of people undertaking a type 2*  
4 *Diabetes Self-Management Education (DSME) programme from their baseline and process data set?*  
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6

## 7 **METHOD**

### 8 **Design**

9  
10 A mixed-method longitudinal experimental research design was employed between 2010-12.  
11 Patients completed data collection when they consented to participate in the Diabetes Manual  
12 programme at the study baseline and at six months follow-up. Minimal important difference, i.e. the  
13 smallest difference in outcome for a patient that is perceived to be meaningful<sup>16</sup>, was used to  
14 measure change in outcomes for each individual. Ethical approval for the study was given by  
15 Coventry and Warwickshire Research Ethics Committee. This paper presents a person-centred  
16 analysis<sup>17</sup>. The detailed longitudinal dataset enabled the construction of individual narratives  
17 examining how baseline variables are linked to specific outcomes<sup>18</sup>.  
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### 25 **The DSME Intervention**

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27 The Diabetes Manual is an evidence based 1:1 DSME programme for type 2 diabetes largely self-  
28 directed with support from practice nurses who have been trained as Diabetes Manual Facilitators  
29 (DMF) to elicit behavioural changes and to provide psychological support. The Diabetes Manual  
30 consists of a workbook, relaxation audio components and a minimum of three face-to-face or  
31 telephone DMF contacts as preferred by the participant. The Diabetes Manual is designed to take  
32 three months to complete, involving approximately an hour a day for participants. Examples of how  
33 this hour may be spent includes reading the Diabetes Manual, taking physical activity, reading food  
34 labels, cooking a healthy meal, blood glucose monitoring or listening to the relaxation audio  
35 programme. The Diabetes Manual is evidence based<sup>8,19-20</sup> and available for commissioning in the  
36 NHS or direct purchase by people with type 2 diabetes<sup>21</sup>.  
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### 45 **Participants**

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47 Six practice nurses employed at general practices were recruited through the Primary Care Research  
48 Network and opportunistic sampling and two nurses were recruited from a hospital diabetes clinic.  
49 All were trained to become DMFs. The nurses each were asked to recruit up to 10 patients with type  
50 2 diabetes, the ability to read English, HbA1c >7.4% (57.4 mmol/mol), and who had not attended  
51 diabetes self-management education. Our sample size was based on the aims of the broader study  
52 in which we aimed to recruit 50 participants to give 80% confidence for assessing changes in  
53 diabetes management self-efficacy. After two months 2 DMFs withdrew due to time pressures  
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3 without recruiting patients. The remaining six DMFs consented 31 patients, 4 of whom subsequently  
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5 withdrew.  
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## 8 9 **Procedures**

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11 Following completion of the training, DMFs arranged an appointment with participants to obtain  
12 informed consent, introduce them to the Diabetes Manual programme and collect baseline clinical  
13 assessments. The DMFs also gave the participants psychological outcome questionnaires and an  
14 accelerometer with instructions for use, which were collected from the participant [seven](#) 7 days  
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16 later by the researcher. Within two months of recruiting their first patient, the DMFs were observed  
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18 in two or three consultations by a trained facilitator for Quality Assurance (QA) purposes as per NICE  
19 guidance <sup>11</sup>. A total of 17 QA consultations took place and were recorded. After their QA  
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21 consultation, each patient took part in a brief interview with a researcher about their experiences in  
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23 the consultation. Follow-up data collection took place six months post-baseline. Participants  
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25 attended an appointment with their DMF where clinical measurements were taken. The  
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27 psychological measures and accelerometer were sent to patients a week before their follow-up  
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29 appointment. These measures were completed prior to their appointment. Finally, all participants  
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31 took part in a follow-up interview to discuss their experiences of the DM programme, and any areas  
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33 where the DSME had impacted on their diabetes management. [The clinical, psychological,  
34 behavioural, process and demographic data known to impact upon, or be impacted by DSME, and  
35 collected for the main study, represents the dataset used to develop the outcome assessment  
36 framework.](#)  
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## 39 **Outcome assessment framework**

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41 ~~We collected a range of clinical, psychological, behavioural and process outcome data along with~~  
42 ~~demographic data.~~ ~~Our earlier Diabetes Manual RCT<sup>8</sup> had found improvements in Diabetes Distress~~  
43 ~~and Self-efficacy. Subsequent meta-analyses<sup>22</sup> had identified reduction in HbA1c with psychological~~  
44 ~~intervention. We hypothesised therefore that with the addition of psychological care components to~~  
45 ~~the Diabetes Manual, we would find clinically and statistically significant reductions in HbA1c. We~~  
46 ~~further hypothesised that the more sub-optimal the outcome in each patient, the greater the~~  
47 ~~improvement would be although we did not develop hypotheses regarding DMF's outcome~~  
48 ~~prediction accuracy. We did not involve participants in making self-assessments regarding their~~  
49 ~~anticipated outcomes of participating in the study.~~ Each variable [used in the oOutcome aAssessment](#)  
50 [fFramework](#) is described, and inclusion justified, in table 1. Variables were included in the  
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52 framework if they were i) known to influence self-management behaviour (e.g. ethnicity <sup>23</sup>;  
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3 depression<sup>24</sup>) or ii) known to have been influenced by a DSME programme in empirical evidence  
4 (e.g. HbA1c<sup>5,6</sup>; diabetes distress<sup>8,25</sup>). Data were collected at baseline and 6-month follow-up.  
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6 Process indicator data, such as any patient change talk or value verbalised about the DSME, was  
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8 collected during the QA process. Baseline measures and process indicators formed the dataset used  
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10 to ask the question, "based on this patient's data do I think that engaging with DSME will result in  
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12 any changes in HbA1c, waist circumference, exercise levels, anxiety, depression, and distress in 6-  
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14 months' time for this patient?" With each patient and each outcome, the DMFs made a prediction  
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16 through recording one of three expectations 1) the outcome would improve by a minimally  
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18 important difference<sup>16</sup>, 2) the outcome would deteriorate or 3) there would be no change.  
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20 Specifically for prediction purposes, data were presented in a table format alongside clinical  
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22 guidelines relevant to each outcome. All data in the framework could be available to nurses during  
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24 routine consultations if they chose to access the information.  
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26 *Table 1 Variables within the predictive framework*

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28 *Table 2: Example prediction framework data*  
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### 33 **Methods of predicting outcome**

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35 Two clinical academic research team members (JS a Nurse and FG a GP) developed and pilot tested  
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37 the prediction method using the outcome assessment framework. They independently examined  
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39 individual patient baseline and process data and made predications pertaining to 6-month follow up  
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41 outcome. This iterative process was piloted with 7 patients and then applied with the study  
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43 population. Following individual predictions, discussion took place to reach agreement. On a  
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45 separate occasion, six DMFs used the framework to predict outcomes on each other's anonymized  
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47 patient data (i.e. participants not known to them) in a recorded focus group. Patient data was  
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49 randomly allocated to individual DMFs, ensuring that each DMF examined a unique subset of  
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51 different patients, and that all patients' data was examined by two 2 different DMFs. Initially the  
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53 DMFs made individual predictions for their own subset of nine 9 patients, then collectively they  
54  
55 discussed and made predictions for 14 patients. Therefore, each participant dataset was individually  
56  
57 assessed by two 2 DMFs (different for each patient) to produce specific predictions and a brief  
58  
59 outcome narrative (see Table 2 for example data and predictions). Once all predictions were  
60  
61 completed the 6-month follow-up data were entered into the framework to enable analysis. The  
62  
63 standard of assessment for determining a positive change in outcomes for each patient was the

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3 minimally important difference unique to each outcome (as listed in Table 1). During analysis, where  
4 no prediction was given for change or stability this was classed as 'no change' predicted. Where  
5 there were disagreements about the prediction, this was noted and the prediction made by the  
6 majority was used in analysis. Accuracy is described per patient (i.e. how many of the six outcome  
7 predictions per patient were accurate), and per outcome (i.e. what percentage of the 27 predictions  
8 made for each outcome were accurate).  
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## 13 14 15 16 **RESULTS**

17  
18 Quantitative data on clinical, psychological and behavioural outcomes was collected at baseline from  
19 30 patients and at 6-months from 27 patients. Of the latter, 13 (48%) were male, 22 (82%) were  
20 White British, ages ranged from 39 to 81 years (mean 59.2 years), and duration of type 2 diabetes  
21 was 3 months to 34 years (mean 9.1 years). See Table 3 for participant clinical and psychological  
22 characteristics at baseline and follow-up. Among the whole group, there were significant reductions  
23 in HbA1c %  $t(26)=2.35, p=.03$ , and diabetes distress  $t(26)=2.30, p=.03$ , and a significant increase in  
24 knowledge  $t(26)=-2.06, p=.05$  between baseline and 6-months (see Table 3). No significant changes  
25 were found in waist circumference  $t(26)=-0.43, p=.67$ , physical activity  $t(26)=0.99, p=.33$ , anxiety  
26  $t(26)=-1.39, p=.18$ , depression  $t(26)=-0.38, p=.71$ , or self-efficacy  $t(26)=-1.83, p=.08$ .  
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36 *Table 3: Clinical and psychological characteristics of participants*  
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### 41 **Researcher predictions (pilot)**

42  
43 The accuracy of the researcher predictions for change in the key clinical, behavioural and  
44 psychological outcomes for the seven pilot patients was examined. Accuracy of predictions ranged  
45 from no accurate outcome predictions to all six outcome predictions accurate. Accuracy of  
46 predictions per outcome varied from 42.86% to 71.43% (i.e. of the seven predictions made for each  
47 outcome [one for each patient], between three and five were accurate). Prediction agreement  
48 between the two researchers was 96%.  
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### 53 **DMF predictions**

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55 The accuracy of the DMF predictions for key clinical, behavioural and psychological outcomes for the  
56 whole data set was examined. Although there were disagreements in individual predictions, an  
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3 overall reduction in HbA1c was predicted for all patients. Change was less widely predicted for other  
4 variables. Clinically important outcomes not captured by clinical, psychological and behavioural data  
5 but revealed during interview include dietary changes and reduction in alcohol intake (n=7),  
6 increased medication adherence (n=1) and smoking cessation (n=1).  
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8

#### 9 10 Accuracy per patient

11  
12 Accuracy of the six outcome predictions per patient ranged from one to six, with the median and  
13 mode being four out of six predictions. There were between one and six prediction agreements per  
14 patient, with an average of 4.12 prediction agreements in outcomes per patient. Overall, prediction  
15 agreement for the DMFs was 68%.  
16  
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#### 18 19 Accuracy per outcome

20  
21 Accuracy for predictions by outcome varied from 44.44% for HbA1c to 81.48% for diabetes distress.  
22 The median and mode accuracy was 66.67%. Table 4 shows the nature of the change predicted for  
23 each outcome and the percentage of patients in which changes were predicted for each outcome,  
24 the nature of actual change observed, and the percentage of accurate predictions made. Many  
25 predictions were correct because no change was predicted and this was accurate. Examination of  
26 the focus group recording reveals that the DMFs made broad inferences from the available data. For  
27 example, inferences about participant 17's body size, eating habits and attitudes towards food were  
28 made based on his waist circumference. This participant was described as "slim" by the DMFs (he  
29 was one of 3 participants whose baseline waist circumference was under recommended clinical  
30 limits) and discussion took place about his probable eating habits without any available data  
31 regarding this.  
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43 *Table 4: DMF predictions as to the impact of the DSME on clinical outcomes, and the accuracy of*  
44 *these predictions*  
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## 48 49 DISCUSSION

### 50 51 Summary of main findings

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53 Findings from this study identified that accuracy for predicting change in HbA1c by the nurses was  
54 low with their accuracy for reductions in diabetes distress higher. We found that the majority of  
55 accurate predictions related to an anticipation of no change (i.e. the nurses thought the patients  
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3 month outcomes would not change) in relation to waist circumference, physical activity levels,  
4 anxiety and depression. Overall, there was greater accuracy in predictions about lack of change, than  
5 in identifying individuals who would achieve improvement in outcome. Predictions for change were  
6 made most frequently for measures that showed the greatest room for change (i.e. those outcomes  
7 in those patients with high baseline scores). The Diabetes Manual DSME programme has continued  
8 to demonstrate improvements in glycaemic control and diabetes distress in this new population <sup>8</sup>.  
9 High HbA1C was an inclusion criterion for participation in the study and there was consistency in the  
10 prediction that the DSME intervention would reduce this, suggesting that health professionals can  
11 find it difficult to predict in what ways people will benefit from DSME. Health professionals appear  
12 to believe that their patients will change (optimistic bias) where scope for change is evident, and  
13 where they believe in the efficacy of their treatment [endeavoursendeavors](#). Prediction agreement  
14 within the group of nurses was much lower than for the researchers. This could indicate the lack of  
15 experience in undertaking this exercise in contrast to the researchers who had developed the  
16 process (so were more [practisedpracticed](#) in applying it). It was notable that, where available, the  
17 qualitative data was heavily drawn on by the nurses to inform predictions. Qualitative evidence was  
18 used to provide insight into underlying motivations for behaviour change and attitudes towards the  
19 intervention, consistent with the narrative development process for narratives exploring how  
20 baseline variables are linked to specific outcomes <sup>18</sup>.

### 21 22 23 24 25 26 27 28 29 30 31 32 33 **Strengths and limitations of the study**

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35 The research intervention used a tried and tested DSME programme which enabled the DMFs to  
36 focus on the research questions presented and not on DSME programme evaluation. The nurses  
37 were aware of the earlier RCT findings which may have influenced their decision making. This  
38 research benefits from the assessment of a wide range of clinical and psychological measures, so  
39 that the anticipated impact of DSME on a variety of outcomes could be assessed. However, it is  
40 limited by the lack of a measure of eating habits. This is a key behavioural change targeted by the  
41 DSME, and which has the potential to significantly improve HbA1c <sup>26</sup>. The baseline characteristics  
42 show that our participants' anxiety and depression levels were low so few changes were expected.  
43 This may indicate a participant selection bias, as people with depression could have been less likely  
44 to consent, or be offered the opportunity, to participate in the study. [Several outcomes in our  
45 framework were self-report and completing these could have been interventional in themselves by  
46 causing the participant to reflect on their mood, coping, confidence or knowledge.](#) The DMFs were  
47 all experienced at working with people with type 2 diabetes, and so were able to draw on their  
48 clinical experience of this patient group when making predictions. The process and outcome  
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3 narratives were, however, produced in a fairly artificial setting. In consultations, health professionals  
4 often have prior knowledge of their patients and draw on non-verbal data to make their  
5 assessments. Despite this, the health professionals did articulate why they would expect particular  
6 outcomes, making explicit the clinical evaluation process. In relation to study eligibility criteria, the  
7 DMFs struggled to firstly identify, and then recruit, patients who had not previously attended locally-  
8 offered [DSME diabetes self-management education](#) and who could read English. This could indicate  
9 that patients in the settings served by these nurses had already been extensively offered [DSME](#)  
10 [diabetes education](#) in contrast to the national average of 6.0%<sup>13</sup>.

### 17 **Comparison with wider literature**

19 Nurses tend to draw heavily on their experience when interpreting the different sources of  
20 information available during routine consultations experience<sup>27,28</sup>. In this study, the DMFs used  
21 their experience to make inferences from the available data. Such inferences demonstrate how  
22 previous clinical experiences inform (or even bias) current evaluations<sup>29,30</sup>. Physicians' clinical  
23 experience and knowledge have long been viewed as the "quintessential skills" that they have to  
24 offer<sup>31 p 657</sup>. Used alone, however, professional opinion has been described as the "least reliable and  
25 valid form of evidence" on which to base clinical decisions<sup>30 p 232</sup>, below hierarchies of research  
26 evidence. One systematic review found that physicians with more experiential knowledge were less  
27 likely to adhere to appropriate standards of care, a finding which they describe as inconsistent with  
28 the notion that experience enhances knowledge and skills, leading to better patient care<sup>32</sup>. Other  
29 authors have claimed that experienced clinicians form hypotheses and diagnostic plans more  
30 quickly and to a higher standard than inexperienced clinicians<sup>33</sup>. The benefit of clinical experience in  
31 making evaluations and decisions, is somewhat contested then. In this study, where nurses had to  
32 make clinical judgements without physically seeing a patient, they had few other resources to draw  
33 on other than their experience with similar patients. [This wider literature and the findings of this](#)  
34 [study have implications for the training of clinicians who refer people to DSME. If this study were](#)  
35 [repeated with GPs the findings may have been different.](#)

### 47 **Conclusions**

49 Our research indicates that while clinicians draw on their extensive clinical experience in assessing  
50 the benefit of DSME, [in our relatively modest group of six practice nurses and outcome data on 27](#)  
51 [people with diabetes, it was is-not possible for them to reliably and accurately determine outcomes](#)  
52 [utilising based upon, despite ten to twelve pieces a volume](#) of data [per person](#) on which to make  
53 these assessments. Our result indicate that all people with diabetes should continue to be offered  
54 DSME programmes according to national<sup>2,10,11</sup> and international guidelines<sup>1,3,4</sup>. Furthermore,  
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3 research should explore the clinical decision making process, to make explicit the process through  
4 which clinicians make judgements on the potential benefit (or not) of [self-management](#)  
5 [education](#) [DSME](#) for different patients. Further exploration of this topic could highlight how clinical  
6 experience is used to interpret data within current situations, and the outcome this has for the  
7 patient in their access to care.  
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### 26 **Author Contributions**

27  
28 JS developed the Diabetes Manual DSME programme. JS, JD, FG, IC, RW and JO'H designed and  
29 managed the study and interpreted the findings. RW & IC carried out the DMF training. CH carried  
30 out the data collection and outcome analysis. JS, FG & CH designed the predictions framework,  
31 undertook predictions and CH analysed the data. All authors contributed to the development of the  
32 manuscript.  
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### 38 **Competing interests**

39 [Jackie Sturt and Rosie Walker have license to distribute the Diabetes Manual programme within the](#)  
40 [NHS for profit. Walker runs a small business to which this licence has been offered by University of](#)  
41 [Warwick. Sturt has IP rights associated with her development of the Diabetes Manual and has a](#)  
42 [royalty sharing agreement with University of Warwick.](#)  
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48 [independent research funded by the NIHR. The views expressed are those of the author\(s\) and not](#)  
49 [necessarily those of the NHS, the NIHR, or the Department of Health.](#)  
50

### 51 **Data sharing statement**

52 [Unpublished data relating to quality assurance of the Diabetes Manual delivery is available to](#)  
53 [anyone commissioning, or considering commissioning or using, the Diabetes Manual programme by](#)  
54 [contacting the corresponding author.](#)  
55

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Table 1: Variables within the predictive framework

| Framework data and, for outcomes only, minimal important difference (MID) | Measure, cut offs as appropriate and completion mechanisms   | Justification for inclusion   |
|---|--|---|
| Demographic data  | <p>Index of Multiple Deprivation: Participant's home postcode was used to identify IMD ward. Deprived areas are those ranked lower than 6562 (the 20% most deprived wards in the UK) <sup>36</sup>.</p> <p>Ethnicity: Self-report</p> <p>Gender, age, time since diagnosis and occupation are not known to be related to DSME effects so were not included in the framework.</p> | <p>Deprivation is linked to less successful management of type 2 diabetes <sup>34</sup>.</p> <p>Ethnicity is linked to type 2 diabetes prevalence <sup>22</sup> and poorer self-management/diabetes outcomes <sup>35</sup>.</p> |
| Knowledge of diabetes   | <p>Revised Diabetes Knowledge Scale (RDKS) <sup>37</sup> is a 19-item multiple choice scale assessing diabetes-related knowledge. Correct responses are coded as '1' and incorrect responses are coded as '0', and these are summed to give a possible score between 0 and <a href="#">1923</a>.</p>   | <p>Knowledge is modifiable by intervention and people with low knowledge at baseline might expect to increase their knowledge, and subsequently improve their behavioural outcomes, following DSME <sup>38</sup>.</p>           |
| Self-efficacy   | <p>Diabetes Management Self-Efficacy Scale (DMSES) tool is a 15-item scale that has been validated with UK populations <sup>37,39</sup>. Items are scored on a 0-10 Likert-type scale to indicate how confident they are at the task described. Responses are summed, giving possible self-efficacy scores between 0 (no self-efficacy) and 150 (very high self-efficacy).</p>   | <p>Self-efficacy is modifiable by DSME <sup>8</sup>.</p> <p>People with low self-efficacy might be expected to raise this following DSME.</p>   |

|   |  |  |
|---|--|--|
| <p>Diabetes distress</p> <p>The MID= half a standard deviation (SD)<sup>40</sup>. The SD was 20.84, therefore the MID = 10 scale points</p> | <p>Problem Areas In Diabetes Scale (PAID)<sup>41</sup> is a 20-item scale measuring emotional functioning relating to diabetes, with each item scored on a 5-point Likert-type scale (0-4). Responses are summed and multiplied by 1.25 to give an overall score between 0 and 100. In order to categorise baseline levels of distress, PAID scores were categorised as either high distress (over 40 scale points), medium distress (20-40), or no distress (under 20).</p> | <p>Diabetes-distress is modifiable by DSME<sup>8, 25</sup>. People with high distress might be expected to have lower diabetes distress following DSME.</p>  |
| <p>Depression</p> <p>MID=1.5 scale points<sup>42</sup>.</p> <p>Anxiety</p> <p>MID=1.5 scale points<sup>42</sup>.</p>                        | <p>Hospital Anxiety and Depression Scale (HADS)<sup>43</sup> is a 4-point Likert-type scale to indicate the extent of 14 anxious and depressive feelings over the past week. Responses are coded from 0 to 3 and the total is computed for each subscale (giving total scores between 0 and 21). Scores over 8 indicate clinical levels of anxiety/depression<sup>44</sup>. The HADS has been used and validated with diabetic populations<sup>45</sup>.</p>                 | <p>Depression is known to compromise self-management efforts<sup>24</sup> and so it is likely that no changes in depression or key self-management outcomes will be seen in someone with depression.</p> |
| <p>HbA1c</p> <p>MID= 0.5%<sup>40</sup>.</p>   | <p>The clinical cut off for uncontrolled diabetes, and for participation in the study, is 7.4% or 57 mmol/mol<sup>46</sup>.</p>  | <p>DSME has been shown to have an effect on HbA1c, and this is a key clinical marker of disease control<sup>6,7</sup>.</p>   |
| <p>Waist circumference</p> <p>MID = 5%<sup>47</sup></p>   | <p>For white and black men waist measurement should be below 94cm, for Asian men it should be below 90cm, and for all women it should be below 80cm<sup>48</sup>.</p>  | <p>Waist circumference is a better predictor of health, and particularly type 2 diabetes, than is overall weight or BMI<sup>49,50</sup>.</p>   |
| <p>Physical activity</p> <p>MID = an increase of 2500</p>   | <p>Yamax Powerwalker accelerometer was used for 3 days (including one weekday and one weekend day) to record a) the number of steps b) the</p>   | <p>DSME focus on physical activity was high so the potential for 2500 step increase was</p>  |

|                                  |   |   |
|----------------------------------|---|---|
| steps per day <sup>51</sup> .    | number of kilometres walked and c) number of calories burned. Data from the accelerometer was averaged for the three days. The recommended average steps per day is 10,000 <sup>51</sup> .  | change easy to observe.   |
| Change talk: changes made        | Process measure identified during Quality Assurance audio-recordings and mid-point interviews for 17/27 participants. A brief description of changes already made since starting the DSME was included. For example, patient 1 said: <i>"I go to the gym three times a week now [...] which I haven't done for about 20 years."</i>   | Patient-led change talk indicates readiness to initiate/sustain behaviour changes <sup>52</sup> . |
| Change talk: changes planned     | Process measure identified during Quality Assurance audio-recordings and mid-point interviews for 17/27 participants. A brief description of changes planned during the QA consultation was included. For example, patient 24 said that she planned to increase her exercise so that she made herself out of breath: <i>"Just when I do walk to step it up, yes to make sure to stop walking on the flat and taking it nice and easy, just to pick a few hills and go for it [laughs]. [...] just make myself out of breath [for] more than five or ten minutes."</i> | Patient-led change talk indicates readiness to initiate/sustain behaviour changes <sup>52</sup> . |
| Treatment satisfaction with DSME | Process measure identified during Quality Assurance audio-recordings and mid-point interviews for 17/27 participants. A brief description of comments made about the DSME was included. For example, patient 4 was very positive about the DSME: <i>"I'm feeling actually much better and after going through my manual I felt it was quite informative..... I enjoyed reading it."</i>   | Assessment of treatment satisfaction of an indicator of usefulness to participant.                |

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Table 2: Example prediction framework data

| Patient   | Guidelines  | Patient 3 Data          | Patient 3 Predictions   | Patient 24 Data         | Patient 24 Predictions  |
|-----------|---|-------------------------|---|-------------------------|---|
| IMD       | Deprived areas <6437.6                              | 13349                   |   | 18942                   |   |
| Ethnicity |   | Indian                  |   | White British           |   |
| HbA1c     | <7.4% or 57.4 mmol/mol                              | 11.10%<br>97.8 mmol/mol | Reduced<br>(Baseline measurement is high so there is scope for change.) | 12.1%<br>108.7 mmol/mol | Reduced<br>(Had baseline been a bit lower no change would have been predicted because current dietary changes are not substantial and she is already doing enough exercise) |
| Waist     | 94cm white/ black men; <90cm Asian men; <80cm women | 96.52 cm                | None  | 114                     | Reduced   |
| Exercise  | >10,000 steps per day                               | 4872                    | Increase<br>(He talks about increasing his exercise.)                   | 10700.67                | None<br>(Already exercising enough.)  |
| Anxiety   | Clinical limit >8                                   | 3                       | None  | 6                       | None  |



| <b>Depression</b>                   | <i>Clinical limit &gt;8</i>  | 3   | None  | 0   | None |
|-------------------------------------|--|---|---|---|------|
| <b>Diabetes Distress</b>            | <i>&gt;40 high distress; 20-40 moderate distress; &lt;20 no distressed</i> | 53.75   | Reduced<br>(Baseline measurement is high so there is scope for change.) | 10  | None |
| <b>Self-efficacy</b>                | <i>&gt;101 High; 51-100 moderate; &lt;50 low</i>                           | 120   |   | 96  |      |
| <b>Knowledge</b>                    |  | 13  |   | 14  |      |
| <b>Change talk: changes made</b>    |  | Eats a healthy diet (mainly vegetarian, no alcohol, healthy food). Eats smaller portions. Has started walking more. |   | Cut down on butter and fat in diet. Has started walking more. |      |
| <b>Change talk: changes planned</b> |  | To increase exercise (walking, cycling, swimming), and find time for it.  |   | To increase her exercise- walk enough to get out of breath    |      |
| <b>Treatment satisfaction</b>       |  | Very positive about DSME.   |   | DSME is a bit repetitive at times                             |      |

Table 3: Clinical and psychological characteristics of participants

|                   | Baseline (N=30)   |                   | 6 month Follow-up (N=27) |                   | Difference between baseline & follow-up<br>* = sig |
|-------------------|-------------------|-------------------|--------------------------|-------------------|--|
|                   | Range             | Mean (SD)         | Range                    | Mean (SD)         | t  |
| HbA1c (%)         | 7.10 - 13.60      | 9.20 (1.92)       | 5.60 - 13.30             | 8.40 (1.90)       | 2.35 (p = 0.03)*                                   |
| HbA1c (mmol/mol)  | 46.00 - 125.00    | 76.19 (21.90)     | 38.00 - 122.00           | 68.96 (20.90)     | 1.79 (p = 0.09)                                    |
| Waist             | 77.00 - 148.00    | 109.72 (15.12)    | 88.40 - 160.00           | 110.60 (16.34)    | -0.43 (p = 0.67)                                   |
| Steps             | 106.00 - 17223.67 | 5985.77 (3971.09) | 12.67 - 16593.00         | 5469.88 (3923.11) | 0.99 (p = 0.33)                                    |
| Diabetes Distress | 0.00 - 83.75      | 22.82 (21.35)     | 0.00 - 70.00             | 16.71 (17.39)     | 2.30 (p = 0.03)*                                   |
| Anxiety           | 0.00 - 15.00      | 5.26 (4.37)       | 0.00 - 13.00             | 4.37 (3.61)       | 1.39 (p = 0.18)                                    |
| Depression        | 0.00 - 9.00       | 3.07 (2.43)       | 0.00 - 13.00             | 3.26 (2.98)       | -0.38 (p = 0.71)                                   |
| Knowledge         | 7.00 - 20.00      | 14.37 (2.92)      | 9.00 - 22.00             | 15.67 (3.20)      | -2.06 (p = 0.05)*                                  |
| Self-Efficacy     | 62.00 - 146.54    | 104.66 (22.66)    | 75.00 - 157.00           | 113.00 (19.84)    | -1.83 (p = 0.08)                                   |

Table 4: DMF predictions as to the impact of the DSME on clinical outcomes, and the accuracy of these predictions

|  | HbAc1                          | Waist                         | Exercise                        | Distress                      | Anxiety                       | Depression                    |
|--|--------------------------------|-------------------------------|---------------------------------|-------------------------------|-------------------------------|-------------------------------|
| <b>Direction of predicted change</b><br>(n = number of patients for which this change was predicted) | Reduced = 27<br>No change = 0  | Reduced = 6<br>No change = 21 | Increased = 9<br>No change = 18 | Reduced = 6<br>No change = 21 | Reduced = 4<br>No change = 23 | Reduced = 1<br>No change = 26 |
| <b>% Patients for which change was predicted</b>   | 100.00                         | 22.22                         | 33.33                           | 22.22                         | 14.81                         | 3.70                          |
| <b>Total number of agreements in predictions*</b>  | 12/ <del>2</del> 27            | 19                            | 13                              | 17                            | 23                            | 26                            |
| <b>Direction of actual change</b><br>(n = number of patients for which this change was observed)     | Reduced = 12<br>No change = 15 | Reduced = 4<br>No change = 23 | Increased = 2<br>No change = 25 | Reduced = 7<br>No change = 20 | Reduced = 8<br>No change = 19 | Reduced = 8<br>No change = 19 |
| <b>% Accuracy of predictions</b>   | 44.44                          | 70.37                         | 62.96                           | 81.48                         | 62.96                         | 74.07                         |

\*Disagreements were counted when one person or more disagreed with the majority prediction for the patient