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Title: Extent of satisfaction with tablets and food-timing in sulphonylurea-treated diabetes

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Abstract

This study measured patient views about following tablet-taking and food-timing recommendations in Type 2 diabetes. Two new questionnaires were validated. Outpatients with Type 2 diabetes treated with sulphonylurea agents (n=131) completed the seven-item Diabetes Tablet Treatment Questionnaire (DTTQ) and nine-item Diabetes Food Timing Questionnaire (DFTQ). Mean glycosylated haemoglobin (HbA1c) was 7.8% (sd 1.8%). At least 74% had optimal DTTQ item scores for tablet-taking as recommended, difficulty taking tablets, side effects, perceived hypoglycaemia and willingness to continue current tablets, but 71% scored sub-optimally regarding recent hyperglycaemia. Under half scored optimally on DFTQ items concerning eating at recommended times, difficulty with food-timing, denying oneself food and guilt about eating. Principal components and reliability analyses identified a two-item *tablet problem* scale within the DTTQ (alpha 0.72) and a seven-item *food-timing problem* scale in the DFTQ (alpha 0.77). Satisfaction and adherence were not closely related to glycaemic control. Only scores for *perceived hyperglycaemia* (r=0.38), *perceived hypoglycaemia* (r=-0.24) and satisfaction to *continue* current tablets (r=-0.20) correlated significantly with HbA1c. Clinicians found that the DTTQ helped to raise tablet-taking issues otherwise missed in consultations. Both questionnaires can be used to guide the need for focussed discussion, educational intervention and/or treatment change and to evaluate their impact.

Key words: Type 2 diabetes, oral medication, satisfaction, adherence, diet.

Introduction

Conventional long-acting sulphonylureas are taken initially as a single dose at breakfast-time to control blood glucose levels in Type 2 diabetes. Larger doses, if needed, are taken twice or even three times daily with meals[1]. Patients need to eat regular meals to avoid hypoglycaemia, but weight gain is common[1,2]. Simpler regimens with less rigid eating requirements are likely to be associated with greater treatment adherence[3]. Modern oral hypoglycaemic agents use two strategies to overcome problems of conventional sulphonylureas: a single daily dose of a long-acting agent, activated by ingested carbohydrate (glimepiride) or frequent daily dosing of a short-acting agent with meals, with the option of missing a dose if the meal is omitted (nateglinide, repaglinide). With either mode of action, irregular eating patterns are likely to be less problematic and weight gain less likely than with conventional sulphonylureas. The patient-completed Diabetes Tablet Treatment Questionnaire (DTTQ) was designed initially (by CB) to promote discussion of patient views and concerns about tablets in general practice diabetes consultations [4].

Research involving people with both Type 1 and Type 2 diabetes has shown that freedom to eat as they wish is often greatly impacted by diabetes and its treatment[7-10]. People taking tablets are advised which foods to eat[11,12], but recommendations about timing meals and snacks[11] may for some be an additional burden. The Diabetes Food Timing Questionnaire (DFTQ) aims to determine the extent of this burden.

Table 1

This study aimed firstly to determine the extent to which people with sulphonylurea-treated Type 2 diabetes acknowledged sub-optimal adherence to and satisfaction

with recalled tablet-taking and food-timing recommendations and secondly, to validate the DTTQ and DFTQ and provide scoring recommendations. This formed part of a larger study to determine the impact of using the DTTQ in consultations, to be reported elsewhere.

Materials and Methods

Materials

The Diabetes Tablet Treatment Questionnaire (DTTQ) has seven items (Table 1). The first asks patients to name each diabetes tablet prescribed, then recall dosage instructions and other recommendations. Items DTTQ2-7 require respondents to circle a number 0-6, indicating their level of agreement with a statement about their tablets. Items DTTQ2-4 were designed originally to help identify deficits that might be addressed by changing to glimepiride: reported *tablet-taking as recommended*, *difficulty* taking tablets as recommended and being bothered by *side effects.* Items DTTQ5-7, taken from the Diabetes Treatment Satisfaction Questionnaire (DTSQ)[5,6], ask about recent high and low blood glucose levels (*perceived hyper-* and *hypoglycaemia*) and satisfaction to *continue* the present form of treatment. In previous DTSQ validation, the *perceived hyper-* and *hypoglycaemia* items each loaded separately from the other six DTSQ items in factor analysis[5,6] and the *continue* item was the strongest contributor to the *total satisfaction* scale[7]. These three items are therefore not expected to form a scale in psychometric validation of the DTTQ. Response options for items DTTQ2-7 are displayed horizontally, with the optimal response always to the left. Glancing quickly down the page, the healthcare professional responsible for prescribing can easily notice any deviation from optimal responding and initiate relevant discussion.

The Diabetes Food Timing Questionnaire (DFTQ) has a similar layout to the DTTQ. Item DFTQ1 comprises questions about recalled meal and snack-timing recommendations. Eight further items with 0-6 response options (DFTQ2-9) address adherence to those recommendations and a range of possible difficulties with the food-timing regimen (Table 1). Again, the optimal response is always to the left of the page.

Methods

Wolverhampton District and East Birmingham Local Research Ethics Committees gave approval. In two hospital diabetes clinics, all patients treated with a conventional sulphonylurea (not combined with another oral agent or insulin) and due to attend a routine monitoring consultation were eligible. Each received a mailed invitation two weeks before their appointment. A research nurse/assistant obtained written consent at the clinic and administered questionnaires. Before seeing the clinician, patients provided demographic details, diabetes duration and current medication. After the consultation, they completed the DFTQ. The 71 patients recruited during Phase 1 (over one year) completed the DTTQ after the consultation (33 in centre 1 and 38 in centre 2). After Phase 1, the clinicians were trained to interpret and discuss DTTQ responses. During the following year (Phase 2), 60 patients (30 in each centre) completed the DTTQ before the consultation and discussed responses with their clinician.

Each patient provided a blood sample for central laboratory assessment of HbA1c, hereafter termed ‘central HbA1c’ (high performance liquid chromatography with non-porous cation exchange column; test range 0-15; reference range 4.2-6.4, providing Diabetes Care and Complications Trial-aligned results[13,14]). A clinician (one of two

in centre 1; one of five in centre 2) performed routine clinical checks and recorded date of birth, blood pressure, weight, height, measure of glycaemic control used for decision-making, current diabetes medication and dose. At the close of the study, five clinicians were interviewed about using the DTTQ.

Analysis

Extent of self-reported adherence and satisfaction

SPSS provided distributions of questionnaire responses. Wilcoxon Matched Pairs tests compared responses to similarly-worded questions about tablet-taking on the one hand and food-timing on the other.

Data checks

Before each principal components analysis to determine questionnaire structure, a data check (raw-score/z-score regression of loadings) was conducted to determine whether it was possible to combine data from patients in the four subgroups (two phases in each of two centres). First, a principal components analysis (PCA) with forced single factor solution was performed on raw questionnaire item scores. Then, within each of the four patient subgroups, normalised z-scores were computed for each item. After recombining the four subgroups, a PCA (forced single-factor solution) was conducted on the z-scores. Factor loadings from the z-scores were regressed against those from the raw-scores. A regression coefficient close to 1, with a constant close to zero, indicated that the four subgroups could be combined for validation analyses[15].

Validation of DTTQ and DFTQ

Structure and internal consistency reliability

To determine structure, principal components analysis (PCA) was conducted first on the DTTQ and DFTQ items together and then on the items from each questionnaire separately. PCA, sometimes called 'factor analysis', shows which scores are interrelated. In questionnaire validation, it shows which items 'hang together' in a potential scale or subscale. Varimax rotation seeks distinct components (factors) with minimal correlations between them. Loadings >0.4 are acceptable, provided one item does not load >0.4 on more than one component (double or multiple loading). In that case, items may be removed and replaced systematically until a clearer structure is found and each suggested scale has satisfactory 'internal consistency reliability'. Cronbach's coefficient alpha, based upon inter-correlation between items, determines internal consistency reliability. A scale alpha (α) >0.7 is acceptable for most group comparison purposes[16]. Using these statistical procedures, scales were identified and scale scores computed.

Construct validity

To test construct validity, questionnaire scores are examined against hypotheses that make sense, given the construct that the score intends to measure. To determine construct validity of the DTTQ and DFTQ, scale and item scores were correlated against central HbA1c (Spearman's rank correlation). It was hypothesised that those with higher HbA1c would report more *perceived hyperglycaemia* (item DTTQ5) and would be less satisfied to *continue* current treatment (item DTTQ7). Those with lower HbA1c would report more *perceived hypoglycaemia* (item DTTQ6).

Clinician views

Interview transcripts were content analysed to identify recurring themes.

Results

Table 2

Patient characteristics

Of 227 patients contacted, 131 were recruited (57.7%). Recruitment rate was similar in Phase 1, 71/121 (58.7%) and Phase 2, 60/106 (56.6%). Reasons for non-participation included non-English speaking patient, non-attendance, clinic cancellation, and GP changed prescription since previous clinic attendance. Self-reports and clinician reports revealed that participants were mostly older people, about twice as many men as women. On average, the sample had somewhat elevated blood pressure and was rather overweight (details in Table 2). All but eight were prescribed gliclazide and 36 reported a medication change within the last year.

Extent of self reported adherence and satisfaction

Table 3

All DTTQ and DFTQ items had distributions skewed towards more favourable responding. This was more pronounced for the DTTQ (Table 3), on which the majority had the optimal item score for *tablet-taking as recommended* (77.1%), *difficulty* (86.3%), *side effects* (87.8%), *perceived hypoglycaemia* (74.0%) and *continue* (74.0%). However, only 29.0% scored optimally on *perceived hyperglycaemia*. Thus, 71% reported at least some high blood glucose levels. Conversely, DFTQ items were often rated sub-optimally. The proportion scoring optimally on *food-timing as recommended* was 35.1%, *difficulty* (45.0%), *felt had to eat* (59.5%), *felt shouldn't eat* (57.3%), *denied self food* (only 19.8%) and felt *guilty about eating* (40.5%). Nonetheless, 74.0% were not *bothered* that they *had to eat* at certain times and 71.0% were very satisfied to *continue* their present way of eating.

Every patient indicated some dissatisfaction (sub-optimal score) on one or more DFTQ item. Comparing similarly-worded items from the two measures, patients had significantly more favourable (higher) scores for *tablet-taking as recommended* (DTTQ2 median 6 (ranging 0-6)) than for *food-timing as recommended* (DFTQ2 median 5 (ranging 0-6); n=124, Wilcoxon *Z*=-5.32; p<0.001). They reported significantly less *tablet-taking difficulty* (lower score) (DTTQ3 median 0 (0-6)) than *food-timing difficulty* (DFTQ3 median 1 (0-6); n=126; Wilcoxon *Z*=-4.80; p<0.001). However, satisfaction to continue their present treatment (*tablet continue* DTTQ7 median 6 (ranging 0-6)) did not differ from satisfaction to continue their present way of eating (*present eating continue* DFTQ9 median 6 (ranging 0-6); n=127; Wilcoxon *Z*=-0.13; p=0.90). Both significant differences survived Bonferroni correction for three analyses (p=0.02 accepted).

Validation of DTTQ and DFTQ

Structure and internal consistency reliability

Prior to each of the following analyses, except where otherwise stated, the data check (raw-score/z-score regression of loadings) found a negligible constant (≤0.04) and a high regression coefficient (R^2≥=0.97) confirming that the four subgroups could be combined for subsequent analysis.

An initial PCA, including all fourteen Likert-scale items from both measures together, found five components with Eigenvalues >1. Three components comprised only DTTQ items and two included only DFTQ items. There was no overlap, indicating that each measure should be analysed separately.

Table 4

When the data check was conducted for DTTQ items, the regression coefficient was rather low (n=6 items; R^2=0.93; df=4; constant=-0.08, F=50.2; p=0.002). Items DTTQ5 and 6 (*perceived hyper-* and *hypoglycaemia*) were removed, because they usually load separately in the DTSQ and are more informative if considered as separate items[5,6,16]. For the remaining four DTTQ items, the data check was satisfactory. Table 4 provides PCA loadings for these four items (PCAa), with Cronbach's alpha for suggested scales. There were two components with Eigenvalues >1. DTTQ component 1a suggested a scale with α=0.72, but alpha for component 2a was poor (α=0.22). Therefore, DTTQ4-7 should each be considered separately and the *tablet problem* scale is computed as the mean of DTTQ2 and DTTQ3, after reversal of DTTQ2:

$$\textit{tablet problem}\ \text{scale score} = \frac{(6 - \text{DTTQ2} + \text{DTTQ3})}{2}$$

The higher the *tablet problem* scale score (possible range 0-6), the more 'problematic' the tablet-taking regimen is perceived to be. Because the scale comprises only two items, both must be completed for the scale score to be computed. This was possible for all 131 patients, because everyone completed both DTTQ2 and 3 (Table 3).

Table 5

The DFTQ's eight Likert-scale items yielded two components with Eigenvalues >1 (PCAb, Table 5), but only DFTQ component 1a yielded a scale with alpha >0.7. DFTQ6 loaded >0.4 onto both components (double loading), so it was removed from analysis PCAc, which found two components. DFTQ2-5 and 9 formed a scale with α=0.74 (DFTQ component 1c) but DFTQ component 2c (DFTQ7 and 8) had a low

alpha (α=0.46). DFTQ6 was returned to the analysis and DFTQ7 removed. In PCAd, the seven remaining items all loaded >0.5 onto a single component (α=0.77). Finally, both items DFTQ6 and 7 were removed, leaving six items. PCAe yielded a single component with all loadings >0.5 (α=0.73) but this was poorer than for PCAd (α=0.77). The seven-item scale (PCAd) has the advantage of including more items, two with an emotional element *(*DFTQ6 and 8). Therefore, item DFTQ7 *(denied self food)* should be scored separately. After reversing DFTQ2 and DFTQ9 scores, DFTQ2-6, 8 and 9 may be used to compute a seven-item *food-timing problem* scale. The higher the score (possible range 0-6), the more 'problematic' the food-timing regimen is perceived to be:

$$\textit{food-timing problem}\ \text{scale score} = \frac{12 - \text{DFTQ2} - \text{DFTQ9} + \text{DFTQ3} + \text{DFTQ4} + \text{DFTQ5} + \text{DFTQ6} + \text{DFTQ8}}{7}$$

When considering how to deal with missing values, the worst possible scenario would be if someone missed the item contributing most to the scale (DFTQ3). With DFTQ3 removed, alpha fell to 0.71 (just acceptable). Removal of DFTQ6, (the item now contributing most to the scale) caused alpha to fall to 0.64 (unacceptably low). Therefore, the *food-timing problem* scale can be computed for anyone who misses up to one contributing item (125/131 patients in this sample).

Construct validity

Table 6

The two scale scores and remaining individual item scores were each correlated against central HbA1c. It was predicted that HbA1c would correlate with responses to items DTTQ5, 6 and 7. No correlation was strong (Table 6), but these three were significant ($p<0.05$). The correlation between HbA1c and DTTQ5 ($r=0.38$; $p<0.001$)

indicated that those with more frequent recent *perceived hyperglycaemia* had significantly higher HbA1c. The correlation with DTTQ6 (r=-0.24; p=0.006) indicated that those with more frequent recent *perceived hypoglycaemia* had significantly lower HbA1c. The correlation with DTTQ7 (r=-0.20; p=0.02) indicated that people with lower HbA1c were more satisfied to *continue* their current treatment. The correlations with *perceived hyperglycaemia* and *hypoglycaemia* survived a Bonferroni correction (seven analyses, p<0.007 accepted).

Table 7

Clinician views

Table 7 summarises clinician views about using the DTTQ in consultations.

Discussion

Patients prescribed conventional sulphonylureas were more likely to acknowledge sub-optimal adherence to and sub-optimal satisfaction with food-timing recommendations than with tablet-taking recommendations. This was supported by a significant difference between similarly-worded items from the two questionnaires. Nonetheless, in order to avoid hypoglycaemia, patients treated with conventional sulphonylureas need to follow a regimen in which food-timing is linked to medication-taking[1]. Despite some dissatisfaction with both tablet-taking and food-timing, study participants were mostly satisfied to *continue* with both aspects of their self-care regimen, perhaps because there was little awareness of alternatives. DTTQ items concerning *perceived hyper-* and *hypoglycaemia* and satisfaction to *continue* current treatment correlated as expected with HbA1c, but no correlation was strong. Clinicians found that the DTTQ helped patients to prepare for the consultation, facilitated non-judgmental discussion of tablet-taking and drew attention to patient

issues often missed in busy clinics, including patient perceptions of blood glucose levels.

Strengths and limitations of the study

This study has provided two questionnaires with similar formats that can be used separately or together as consultation tools, outcome measures or audit instruments. The Diabetes Tablet Treatment Questionnaire provides clinicians with detailed information about each patient's understanding of their tablet-taking regimen and views on the regimen the patient believes they should be following. It complements the DTSQ[6], which is already widely-used to gather patient views about a range of treatments (insulin, tablets and diet alone). There was previously no existing measure that captured patient perceptions of food-timing restrictions.

The study shows the feasibility of administering these questionnaires in a busy waiting room. Participants were selected because they were prescribed conventional sulphonylureas alone. The fact that so few were recruited over two years in two hospital clinics indicates either that this tablet regimen is less common than previously, or that sulphonylurea-treated patients are usually managed in primary care. By restricting the sample, views about conventional sulphonylureas could be ascertained, unconfounded by other diabetes medications. The restricted sample did, however, limit the validation part of the study. Research with people taking other classes of oral hypoglycaemic agent or combinations of agents is now justified. Although the questionnaires were designed originally for identifying people who might benefit by changing to glimepiride, they are likely to be equally useful for discussing other medication changes and this will need to be evaluated.

Implications

Correlations between HbA1c and the DTTQ items concerning *perceived hyper-* and *hypoglycaemia* provide evidence of construct validity. The fact that the correlations with *perceived hyper- and hypoglycaemia* were rather weak indicates that blood glucose awareness may not be very accurate so responses need to be discussed alongside recent HbA1c and home monitoring results. The correlation between HbA1c and satisfaction to *continue* current tablet treatment was only -0.20, indicating that glycaemic control is not the only determining factor. Only those three items correlated significantly with HbA1c, meaning that there were people with both high and low HbA1c who had sub-optimal adherence and satisfaction scores on other questionnaire items. Correlation between HbA1c and the *tablet problem* scale was negligible, and this scale provides an indication of adherence. Therefore, if clinicians adjust prescriptions on the basis of HbA1c alone, this will not address non-adherence and dissatisfaction issues. For example, someone with poor glycaemic control may be having difficulty remembering their tablets, but the clinician may try to improve glycaemic control by prescribing more tablets per day ~ even more to remember (or forget). Clinicians could consider a wider range of options, perhaps prescribing tablets with fewer doses and/or more acceptable lifestyle demands.

Every patient indicated some dissatisfaction with food-timing. Some problems, such as denying oneself food, may stem from dietary advice for diabetes in general rather than advice specific to sulphonylurea use. Whilst it is usually clinicians who prescribe medication, nurses and dieticians are often required to provide education and counselling to patients experiencing difficulty making the associated lifestyle

changes. Clinicians need to consider the widespread dissatisfaction with eating restrictions when prescribing. Medication decisions and dietary advice need to go hand in hand in the effort to fit treatments to individual patients, rather than trying to mould patients to their existing treatment. The DFTQ may facilitate discussion of non-adherence as well as emotional problems related to efforts to be adherent. If less inconvenient and difficult treatments were prescribed, professionals would not need to convince patients to make so many sacrifices, and non-adherence would be less of an issue.

The financial cost of asking patients to complete these measures in the waiting room would be small ~ just two photocopies per patient. Brief introduction by a receptionist or nurse would become unnecessary as the questionnaires became part of clinic routine. Weighed against this are several predicted benefits: clinicians indicated that consultations are more efficient, with discussions moving to important issues more rapidly; clinicians are likely to experience greater job satisfaction because they are no longer frustrated by patients who will not 'do as they are told'; patients are likely to feel more understood as they are treated as part of a problem-solving partnership, not recalcitrant children, repeatedly chastised for lifestyle transgressions.

<u>The way forward</u>

Use of the two new measures with patients taking a range of different oral medications will allow confirmation of the scoring method. When evaluating interventions, the *tablet problem* scale may be used to detect improvements or differences between treatment groups in adherence-related issues. The *food-timing problem* scale may be useful to indicate a need to change to medication allowing

greater food-timing flexibility, then to measure the effects of this change. Individual items can provide more detailed insights into the impact of a treatment change or new approach to patient care. In consultations, item responses can guide the need for focussed discussion, educational intervention and/or treatment change.

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Table 1. DTTQ and DFTQ items

Item no.	Item name	Item wording	Response option to left of page (Optimal score [a])	Response option to right of page (indicating least satisfaction)
Diabetes Tablet Treatment Questionnaire (DTTQ) Item 1 comprised questions asking for description of and understanding of regimen				
DTTQ2	tablet-taking as recommended	How often have you taken your diabetes tablets exactly as recommended?	6 all of the time	0 none of the time
DTTQ3	tablet difficulty	How often do you find it inconvenient or difficult to take your tablets as recommended?	0 none of the time	6 all of the time
DTTQ4	tablet side effects	How much have you been bothered by any side effects of your tablets?	0 not at all	6 a great deal
DTTQ5	perceived hyper-glycaemia	How often have you felt that your blood sugars have been unacceptably high recently?	0 none of the time	6 all of the time
DTTQ6	perceived hypo-glycaemia	How often have you felt that your blood sugars have been unacceptably low recently?	0 none of the time	6 all of the time
DTTQ7	tablet continue	How satisfied would you be to continue with your present form of treatment?	6 very satisfied	0 very dissatisfied
Diabetes Food Timing Questionnaire (DFTQ) Item 1 comprised questions asking for description of and understanding of regimen				
DFTQ2	food-timing as recommended	How often have you eaten at times exactly as recommended?	6 all of the time	0 none of the time
DFTQ3	food- timing difficulty	How often did you find it inconvenient or difficult to time your meals and snacks as recommended?	0 none of the time	6 most of the time
DFTQ4	bothered had to eat	How much have you been bothered by having to eat at certain times?	0 not at all	6 a great deal
DFTQ5	felt had to eat	How often have you felt that you had to eat when you didn't want to?	0 none of the time	6 most of the time
DFTQ6	felt shouldn't eat	How often have you felt that you shouldn't eat when you wanted to?	0 none of the time	6 most of the time
DFTQ7	denied self food	How often have you denied yourself something that you wanted to eat?	0 none of the time	6 most of the time
DFTQ8	guilty about eating	How often have you felt guilty about eating something?	0 none of the time	6 most of the time
DFTQ9	present eating continue	How satisfied would you be to continue with your present way of eating?	6 very satisfied	0 not at all satisfied

[a] The optimal response was 0 for all items except DTTQ2, DTTQ7, DFTQ2 and DFTQ9, for which the optimal response was 6.

Table 2. Patient characteristics (n=131)

Variables	units/categories	frequency (%)		mean	(sd)	median	(min – max)
Demographic and diabetes characteristics (patient-reported)							
age	in years			63.2	(11.6)	64.4	(34.7-92.3)
gender	women	47	(35.9)				
	men	84	(64.1)				
marital status	single	14	(10.7)				
	married/with partner	83	(63.4)				
	separated/divorced	13	(9.6)				
	widowed	20	(15.3)				
employment status							
	employed	34	(26.0)				
	self-employed	8	(6.1)				
	unemployed	12	(9.2)				
	housewife	9	(6.9)				
	retired	68	(51.9)				
ethnicity	white	97	(74.0)				
	black	16	(12.2)				
	Asian	18	(13.7)				
left full-time education	up to age 16	111	(84.7)	15.7	4.1	15	(9-55)
	age17-55	18	(13.7)				
months with diabetes				66.8	61.2	48	(2-300)
months on current tablets				42.8	38.5	30	(2-192)
changes in medication	none	95	(72.5)				
in last year	diet to tablets	6	(4.6)				
	increase same tablets	17	(13.0)				
	change to different tablets	4	(3.1)				
	decrease number of tablets	5	(3.8)				
	other change	4	(3.1)				
Health characteristics (from clinician report)							
blood pressure	systolic			150.5	(22.9)	147	(106-230)
	diastolic			78.2	(12.0)	78	(47-110)
body mass index	(normal range is 18.5-25)			29.5	(4.9)	28.7	(20.4 - 47.8)
current tablet	gliclazide	123	(93.9)				
	glipizide	4	(3.1)				
	glibenclamide	3	(2.3)				
	tolbutamide	1	(0.8)				
HbA1c (analysed centrally)				7.8%	(1.8)	7.5%	(4.8-14.1)

Table 3. Frequency distribution for each DTTQ and DFTQ item

		Frequency for each response option (% of 131) **Optimal** response is shown in **bold** typeface : Response options were laid out on the questionnaire page with **optimal** response always to the left, as indicated in Table 1.							
Item no.	**Item name**	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**missed**
Diabetes Tablet Treatment Questionnaire (DTTQ)									
DTTQ2	tablet-taking as recommended	2 (1.5)	1 (0.8)	2 (1.5)	4 (3.1)	9 (6.9)	12 (9.2)	**101 (77.1)**	0 (0)
DTTQ3	tablet difficulty	**113 (86.3)**	4 (3.1)	3 (2.3)	1 (0.8)	2 (1.5)	3 (2.3)	5 (3.8)	0 (0)
DTTQ4	tablet side effects	**115 (87.8)**	3 (2.3)	3 (2.3)	2 (1.5)	0 (0)	5 (3.8)	3 (2.3)	0 (0)
DTTQ5	perceived hyper-glycaemia	**38 (29.0)**	24 (18.3)	20 (15.3)	11 (8.4)	11 (8.4)	16 (12.2)	7 (5.3)	4 (3.1)
DTTQ6	perceived hypo-glycaemia	**97 (74.0)**	15 (11.5)	7 (5.3)	5 (3.8)	3 (2.3)	1 (0.8)	0 (0)	3 (2.3)
DTTQ7	tablet continue	4 (3.1)	0 (0)	1 (0.8)	15 (11.5)	3 (2.3)	10 (7.6)	**97 (74.0)**	1 (0.8)
Diabetes Food Timing Questionnaire (DFTQ)									
DFTQ2	food-timing as recommended	2 (1.5)	3 (2.3)	4 (3.1)	11 (8.4)	25 (19.1)	34 (26.0)	**46 (35.1)**	6 (4.6)
DFTQ3	food- timing difficulty	**59 (45.0)**	17 (13)	15 (11.5)	19 (14.5)	8 (6.1)	6 (4.6)	2 (1.5)	5 (3.8)
DFTQ4	bothered had to eat	**97 (74.0)**	9 (6.9)	6 (4.6)	6 (4.6)	8 (6.1)	3 (2.3)	1 (0.8)	1 (0.8)
DFTQ5	felt had to eat	**78 (59.5)**	11 (8.4)	14 (10.7)	14 (10.7)	8 (6.1)	4 (3.1)	1 (0.8)	1 (0.8)
DFTQ6	felt shouldn't eat	**75 (57.3)**	10 (7.6)	14 (10.7)	10 (7.6)	11 (8.4)	7 (5.3)	4 (3.1)	0 (0)
DFTQ7	denied self food	**26 (19.8)**	11 (8.4)	10 (7.6)	20 (15.3)	25 (19.1)	22 (16.8)	16 (12.2)	1 (0.8)
DFTQ8	guilty about eating	**53 (40.5)**	10 (7.6)	23 (17.6)	16 (12.2)	10 (7.6)	8 (6.1)	9 (6.9)	2 (1.5)
DFTQ9	present eating continue	3 (2.3)	2 (1.5)	3 (2.3)	7 (5.3)	4 (3.1)	16 (12.2)	**93 (71.0)**	3 (2.3)

Table 4. Principal Components Analysis (PCA) to determine structure of DTTQ, with internal consistency reliability of suggested scales (Cronbach's alpha)

Item no.	Item name	Loading on rotated components with Eigenvalues >1. All loadings > 0.4 are shown (Varimax rotation)	
		PCAa excluding items DTTQ5 and DTTQ6	
		DTTQ component 1a suggesting tablet problem scale	DTTQ component 2a
DTTQ2	tablet-talking as recommended	*- 0.88*	
DTTQ3	tablet difficulty	*0.89*	
DTTQ4	tablet side effects		0.75
DTTQ5	perceived hyperglycaemia	-	-
DTTQ6	perceived hypoglycaemia	-	-
DTTQ7	tablet continue		-0.74
	Cronbach's alpha	*0.72*	0.22

Table 5. Principal Components Analyses (PCA) to determine structure of DFTQ, with internal consistency reliability of suggested scales (Cronbach's alpha)

Item no.	Item name	**Loading on rotated components with Eigenvalues >1.** All loadings > 0.4 are shown (Varimax rotation) Lower loading shown with [square brackets] where two are >0.4 (double loading).					
		PCAb including all DFTQ items		PCAc excluding item DFTQ6		PCAd excluding item DFTQ7	PCAe excluding items DFTQ6&7
		DFTQ component 1b	DFTQ component 2b	DFTQ component 1c	DFTQ component 2c	*DFTQ component 1d suggesting food-timing problem scale*	DFTQ component 1e
DFTQ2	food-timing as recommended	-0.73		- 0.75		*-0.70*	- 0.74
DFTQ3	food-timing difficulty	0.75		0.77		*0.80*	0.82
DFTQ4	bothered has to eat	0.63		0.65		*0.68*	0.68
DFTQ5	felt had to eat	0.53		0.54		*0.55*	0.55
DFTQ6	felt shouldn't eat	[0.45]	0.54	-	-	*0.66*	-
DFTQ7	denied self food		0.81		0.87	-	-
DFTQ8	guilty about eating		0.71		0.67	*0.57*	0.53
DFTQ9	present eating continue	-0.74		- 0.73		*-0.62*	- 0.64
	Cronbach's alpha	0.74	0.54	0.74	0.46	*0.77*	0.73

Table 6. Correlation between HbA1c and the scales and individual items of the DTTQ and DFTQ

	Questionnaire score	n	Correlation with HbA1c (Spearman's coefficient r)	Probability [a] denotes significantly correlated after Bonferroni correction for 7 analyses, (p=0.007 accepted)
Diabetes Tablet Treatment Questionnaire				
tablet problem scale		131	-0.03	p =0.75
Item No:	Item name:			
DTTQ4	tablet side effects	131	-0.12	p = 0.18
DTTQ5	perceived hyperglycaemia	127	0.38	p < 0.001[a]
DTTQ6	perceived hypoglycaemia	128	-0.24	p = 0.006 [a]
DTTQ7	tablet continue	130	-0.20	p = 0.02
Diabetes Food Timing Questionnaire				
food-timing problem scale		125	0.13	p = 0.16
Item No:	Item name			
DFTQ7	denied self food	130	-0.09	p = 0.31

Table 7. Four categories of clinician views about using the DTTQ

No.	Category description	Examples
1	Encouraged clinician to make time to focus on patient views	*"It made me stop and discuss issues"*; "*It's a busy clinic - issues may not be picked up".*
2	Gave patients permission to talk about non-adherence issues	*"It takes away the judgmental aspect of any discussion about medication";* *"It's a real help in the consultation. It sets us off on a better footing to discuss compliance".*
3	Enabled clinicians to clarify whether glycaemic control was acceptable	*"It identified the issue of control - they think it's poor a lot of the time but I can reassure them it's OK".*
4	Encouraged patients to prepare for the consultation	*"It focuses their minds in the waiting room… If people come in with lists, they're usually heart-sink patients. Now, <u>others</u> bring questions";* *"I love patients to come prepared for the consultation".*