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Estimating the minimally important difference (MID) of the Diabetes Health Profile-18 (DHP-18) for Type 1 and Type 2 Diabetes Mellitus

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Running title: Estimating the minimally important difference of the DHP-18

Summary:

Aims: The DHP-18 is a widely used measure of health related quality of life in diabetes mellitus but it is unclear what constitutes a meaningful change in score on each domain. The aim of this study was to establish estimates for the minimally important difference (MID) for each of the domains.

Methods: The MID for each domain was estimated using both anchor and distribution based approaches which were applied to data from both the United Kingdom and France. A range of anchors were tested.

Results: A global health change anchor was found to be more acceptable for Type 1 diabetes than for Type 2. MID estimates varied by domain, by estimation approach used, and by diabetes type. For Type 1 diabetes the Psychological Distress domain estimates ranged from 2.86 to 11.05, Barriers to Activity domain from 2.87 to 11.32 and Disinhibited Eating domain from 1.03 to 11.53. For Type 2 diabetes the Psychological Distress estimates ranged from 0.94 to 9.71; Barriers to Activity from 1.66 to 9.88 and Disinhibited Eating from 0.90 to 11.64.

Conclusions: This is the first attempt to derive estimates for the MID of an English language measure of health related quality of life in diabetes. For Type 1 diabetes we recommend using the mean MID value using both approaches. For Type 2 we recommend applying more weight to the distribution based estimations. The MID values identified in this study will help clinicians and researchers using the DHP-18 to identify clinically meaningful change in patient reported outcomes.

Key words: Minimally Important Difference, DHP-18, Diabetes Mellitus

Introduction:

Despite the plethora of diabetes-specific patient reported outcome measures (PROM) which have been developed to assess the various constructs associated with the impact of living with diabetes and its treatment on quality of life, well-being, health status and treatment satisfaction, there remains a lack in understanding as to what a PROM score represents and what is a meaningful change in score.

In addition to being valid (measure what is intended) and responsive (able to detect small but, important change in outcome) a PROM must also provide a score which is interpretable to enable important effects of treatment or intervention to be determined which are not only statistically significant, but are also of clinical relevance. However, when establishing what is a clinically meaningful PROM score, we must first understand what is a meaningful significant change in individual patient scores and what changes in score correspond to being trivial, small, moderate and large [1].

Although no one approach to interpreting PROM scores is perfect, the use of multiple approaches such as anchor- and distribution based methods is more likely to enhance our understanding of the scores of a particular instrument.

In this paper we report on our findings using both anchor and distribution-based approaches to determine the minimally important difference (MID) of the Diabetes Health Profile (DHP-18) which is a multidimensional diabetes-specific quality of life (QoL) measure developed for use with people with Type 1 and Type 2 diabetes [2].

Methods:

Measures and anchors used

DHP-18:

Developed from the longer DHP-1 [3] the DHP-18 [2] consists of 18 items assessing QoL in diabetes across three domains: Psychological Distress (PD; 6 items), Barriers to Activity (BA; 7 items) and Disinhibited Eating (DE; 5 items). The domains are based on a conceptual framework which focuses on the emotional and behavioural impact of living with diabetes. The raw scores for each domain are rescaled to a metric score between 0 and 100 which can also be converted into a norm score (with a mean of 50 and an SD of 10). This enables an assessment of a score in relation to a reference group, sample or population. The DHP-18 has demonstrated high levels of reliability, validity and patient acceptability. It has been used in multinational clinical trials, quality of life outcome research as well as population surveys and clinical practice and has been completed by more than 6000 people with Type 1 and Type 2 Diabetes. The DHP-18 is also the diabetes-specific outcome measure selected for the UK Department of Health Patient Reported Outcome Measures (PROMs) Pilot for Long Term Conditions in Primary Care. It has also been adapted for use in 26 different languages and can be completed using a range of media including face to face and telephone interviews, using paper/pencil, online, and also electronic form.

Global health change item:

A global health change item is used as an external anchor to identify respondents who have experienced a small but important change. This item assesses whether health has improved or worsened on a 5 point Likert scale (much better (5), somewhat better (4), stayed the same (3), somewhat worse (2) or much worse (1)) and has previously been used as an external anchor to calculate MID estimations [4].

EQ-5D:

The EQ-5D [5,6] is a widely used generic preference based measure of health status across 5 dimensions (mobility, self-care, daily activities, pain/discomfort, and anxiety/depression) providing a single figure utility score (anchored on a scale of one for full health and zero for dead) for use in cost utility analysis to generate Quality Adjusted Life Years (QALYs). In this study the EQ-5D was tested for use as an anchor.

SF-6D:

The SF-6D is a generic preference based measure developed by Brazier et al. [7, 8]. The classification system assesses health status across 6 dimensions (physical functioning, role limitations, social functioning, pain, mental health and vitality). A selection of the possible 18,000 health states have been valued to produce a single figure utility score anchored at one for full health and zero for dead, and with a range from 0.296 to 1. The SF-6D was tested for use as an anchor in this study.

Sample data

For the anchor based analysis a longitudinal dataset of a community-based postal survey of 1802 participants, aged ≥18 years of age, with positive diagnosis of Type II diabetes and on diabetes patient registers in primary care was used to estimate values for the MID, and the characteristics of this sample are displayed in Table 1 [9]. For the distribution based method a cross sectional dataset of 3476 participants who had received insulin or treatment for hypoglycaemia during the past 3 months in France was also used [10]. Respondents completed a postal questionnaire investigating a range of factors relating to diabetes including lifestyle, medical and clinical status and HRQL. Respondents in this study completed the DHP-1 but only theDHP-18 items were included in this study.

Analysis:

To determine the MID for the DHP-18, both anchor based and distribution based approaches were used as recommended by Revicki et al. [11]. The anchor based approach assesses change on the target measure in comparison to some external indicator of health or clinical change which can be a subjective

measure of change in global health status, a clinical indicator, or change in another instrument with established MID values. Distribution based approaches were used to estimate the MID based on the distribution of responses within the sample. Estimating MID values using both distribution based and anchor based methods allows for a more precise estimate of the true MID to be calculated. So that values were available for all patient groups where the DHP-18 is used, MID estimations were derived separately for Type 1 and Type 2 diabetes.

Anchor based approach:

Three anchors were tested for use in this study, an external indicator of health change, the EQ-5D and SF-6D which both have established MID values. Small but important change on the global health item was defined by a score of 2 or 4 on the 5 point Likert scale. Patients scoring 3 were defined as reporting no change in health status. The MID for the EQ-5D has been tested in a range of settings and is estimated as a utility score change of 0.074, with a range of 0.011 to 0.140 [12]. In this study a change in utility between baseline and follow up within this range was defined as a small but important change, with change between +/- 0 and 0.011 indicating no difference in health status across the study period. The MID for the SF-6D from a range of patient groups has been estimated at 0.041 with a range of 0.011 to 0.097 [12]. A difference between baseline and follow up within this range was defined as a small but important change, with the score range of /-0 to 0.011 indicating no change.

Initially both the metric and norm scores for the three DHP-18 domains were calculated. To test the validity of the three anchors, each was correlated with the three DHP-18 metric and norm domain scores at baseline and follow up. To conduct a MID analysis, a minimum correlation of 0.3 is recommended [11], and the correlation at follow up should be greater than the correlation at baseline. To ensure a range of estimations, values for the MID were produced using two methods:

Method 1: The MID value was produced by calculating the mean change in each of the three DHP-18 domains scores for patients reporting a small change in health status. Direction of the change was reversed (multiplied by minus 1) for those reporting a small negative change in HRQL [4].

Method 2: The MID was calculated by subtracting the mean change on the DHP domains for patients reporting no change on the anchors from those who report minimal but important change. As with method 1 the direction of the change was reversed for those reporting a small negative change in health status [13].

Distribution based approach:

Three commonly used distribution based methods were employed in this study. These were the 0.2 and 0.5 Standard Deviation (SD) and Standard Error of Measurement (SEM) estimations [14, 15]. For the 0.2 and 0.5 SD approach the MID was calculated by multiplying the standard deviation of the three metric dimension scores at baseline by 0.2 or 0.5 which corresponds to testing using an effect size of 0.2 and 0.5 respectively. For the SEM approach the following equation was used.

The test-retest statistic and the internal consistency statistic (Cronbach's Alpha) were used for the longitudinal and cross-sectional study data respectively. The effect size statistic, which measures responsiveness by dividing the change between two points by the standard deviation at time point one, was also calculated. Effect sizes between 0.2 and 0.5 are small, 0.5 to 0.8 are considered moderate, and above 0.8 large [16].

Results:

Anchor based approach:

Suitability for MID analysis (Type 1 Diabetes):

The correlations to assess whether the global health item, EQ-5D and SF-6D were suitable external anchors to assess a MID in the Type 1 Diabetes population are displayed in Table 2. For the global health change anchor, the overall correlation with the PD and BA domains was above the minimum 0.3 level but not with the DE domain. For the EQ-5D, only the BA domain was above the minimum 0.3 level. The correlation with the follow up score was greater than the baseline correlation for both the global health anchor and the EQ-5D. The SF-6D correlations were not significant and below the minimum 0.3 level. Therefore, the SF-6D was excluded as an anchor at this stage as was the EQ-5D as only one of the correlations was above the minimum required level. As the majority of the correlations between the global health anchor and the DHP-18 domains were above the minimum required value, the MID was estimated using this external indicator.

Suitability for MID analysis (Type 2 Diabetes):

The correlations to assess whether the three anchors were suitable to establish the MID in a Type 2 Diabetes population are displayed in Table 2. The correlations between the global health change anchor and the domain scores at follow up were significant but did not reach the minimum 0.3 level. Neither the EQ-5D or the SF-6D displayed correlations with the follow up DHP domain scores above 0.1, and therefore were not used as a basis for the calculation of MID values in the Type 2 population. To assess and compare the values achieved using the anchor based method for both Type 1 and Type 2 Diabetes, the global health change anchor was also used to estimate the MID for the Type 2 sample.

Estimation of MID values for Type 1 and Type 2 Diabetes:

The anchor based MID estimations for the Type 1 sample and the estimations for Type 2 diabetes are displayed in Tables 3 & 4 respectively. The MID values estimated for Type 1 diabetes were higher than for Type 2, with variance in the values across the DHP-18 domains.

Distribution based approach

The MID estimations for the distribution based approach are displayed in Table 5. For the PD domain, MID estimates (when both datasets are combined) range from 4.37 to 11.05 for Type 1 diabetes and 3.88 to 8.64 for Type 2 Diabetes. The 0.5 SD and 1SEM estimations are of a similar magnitude. This pattern is continued for both the BA (Type 1 range = 4.15 to 11.32; Type 2 range = 3.68 to 9.98) and DE (Type 1 range = 4.62 to 11.54; Type 2 range = 4.72 to 11.64) domains. Overall the effect sizes were found to be within the range regarded as small or lower (Table 6).

Overall range of MID estimations

Combining both approaches, the range of MID values reported for the PD domain are 2.86 to 11.05 (Type 1) and 0.94 to 9.71 (Type 2). The ranges for the BA domain are 2.87 to 11.32 (Type 1) and 1.66 to 9.98 (Type 2), and for the DE domain are 1.03 to 11.55 (Type 1) and 0.90 to 11.64 (Type 2). The MID values for each estimation method are displayed in Figures 1 and 2.Table 7 reports the proportion displaying small but important change for each of the MID estimations, and also for the mean MID value. The magnitude of the sensitivity of the MID values generated varies depending on the estimation approach used due to the distribution based MID estimations being uniformly larger than the anchor estimations.

Discussion

In this study we have estimated minimally important difference (MID) values for each of the three DHP-18 domains using both anchor and distribution based methods. For Type 1 Diabetes we recommend examining the full range of MID values for all 3 dimensions, and the mean MID value for each domain may be useful in determining those who display clinically meaningful change in HRQL. This is because the anchor used correlates acceptably with the domain scores, and the proportion of patients demonstrating minimally important change is similar across the domains. For Type 2 Diabetes the anchor and domain correlations are lower, and therefore for the PD and BA domains we recommend considering the full range of MID values, but applying more weight to the distribution based approach values, particularly as the sample size is large. The proportion of the sample changing by the mean MID on the PD and BA domains is of a similar magnitude. For the DE domain we recommend focusing on the distribution based MID values, as the low anchor based values impacts on the overall mean value, and therefore the proportion of the sample who display minimum important change according to this value is significantly higher. Following these recommendations will help clinicians and researchers using the DHP-18 to identify clinically meaningful change in patient reported outcomes.

This is the first attempt to calculate MID values for the DHP instrument, and also the first study to report MID values for an English language measure of HRQL for both Type 1 and Type 2 Diabetes mellitus. MID values have previously been estimated for a diabetes specific HRQL instrument (DQOL) but, in a Taiwanese population [17]. The method of combining anchor and distribution based approaches has previously been used in a range of studies estimating the MID for measures of HRQL [18, 19, 20]. The global health change anchor used in this study was used to derive the MID for the SF-6D [4]. Other similar global health change anchors have been used for a range of instruments [13].

In this study, the MID values generated by the anchor and distribution based approaches vary for each domain, with the anchor method consistently producing MID values of a smaller magnitude than the

distribution method. This demonstrates that when attempting to develop an accurate measure of the MID it is essential to use a range of methods to develop the estimations that will guide the assessment of clinically meaningful change within a group of patients. The distribution based approach may be particularly valid in this study as values have been estimated on two data sources.

Although low correlations identified between the global health anchor and a number of the DHP domains across both Type 1 and Type 2 Diabetes, the correlations were larger at the follow up time point than at baseline which is expected when estimating the MID [11]. For the Type 1 Diabetes sample, the anchor reached the minimum correlation for the PD and BA domains but not for the DE domain. The finding of a low correlation between the global health indicator and the DE domain can be possibly explained by the fact that disinhibited eating behaviour is unlikely to impact on perceived general health change. This would indicate that when estimating the true MID value for DE domain, more weight should be applied to the distribution based estimations. However, further research is required using a more sensitive indicator of change which is more closely related to the disinhibited concept.

For the Type 2 Diabetes group, none of the correlations reached the minimum level, suggesting more weight should be given to the distribution based estimations. The EQ-5D and SF-6D were not used as anchors as the correlations with the DHP-18 dimensions were consistently below the recommended level. This may be because the generic measures are measuring health status rather than diabetes-specific behavioural and psychological elements that are measured by the DHP-18. This highlights the need for further work to investigate the relationship between health status measures such as the EQ-5D and condition specific instruments such as the DHP-18 in more detail and which would help to inform decisions around which measures to use in diabetes research and clinical practice.

The MID estimations also varied between the Type 1 and Type 2 Diabetes populations. However the size of the samples for each diabetes type differed substantially, and future work should estimate MID values

on a larger Type 1 Diabetes group as well as validate the estimations derived here as part of studies where the DHP-18 is used alongside potential anchors.

In conclusion, we have estimated values for the MID of the DHP-18 using different samples and both anchor and distribution based approaches. Using the MID values developed in this study will assist both researchers and clinician who are using the DHP-18 instrument as part of their assessment of both Type 1 and Type 2 patients with diabetes mellitus.

Declaration of competing interests:

Nothing to declare

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Table 1: Participant characteristics

	Longitudinal	Cross sectional
Overall n	1802	3476
Age (m, sd)	65.60 (11.89)	63.20 (12.42)
Age (range)		
18-45	106 (5.9)	300 (8.6)
46-60	459 (25.7)	1044 (30.0)
61-70	567 (31.7)	1131 (32.5)
71-80	480 (26.8)	836 (24.1)
81+	177 (9.9)	165 (4.7)
Gender		
Male	1056 (58.8)	1900 (54.7)
Female	739 (41.2)	1576 (45.3)
Type		
Type I	143 (97.9)	231 (6.8)
Type 2	1613 (89.5)	3156 (93.2)
DHP-18 scores (baseline)		
PD	19.76 (21.50)	20.53 (19.34)
BA	23.32 (19.86)	23.99 (18.38)
DE	36.03 (23.03)	33.46 (23.81)
DHP-18 scores (follow up)		
PD	18.82 (21.35)	-
BA	23.37 (20.41)	-
DE	35.80 (22.62)	-
EQ-5D score (baseline)	0.644 (0.32)	-
EQ-5D score (follow up)	0.639 (0.33)	-
SF-6D score (baseline)	0.687 (0.16)	-
SF-6D score (follow up)	0.682 (0.16)	-

Table 2: Correlations between the anchors and the baseline/follow up domain scores for Type 1 and Type 2 Diabetes (longitudinal data only, anchors used in bold)

	Psychological distress		Barriers to activity		Disinhibited eating	
	Baseline (n)	Follow up (n)	Baseline (n)	Follow up (n)	Baseline (n)	Follow up (n)
Type 1 Diabetes (Metric/Norm score)						
Global health change anchor						
	0.183 (99)	**0.348* (98)**	**0.232** (99)**	**0.369* (99)**	**0.052 (99)**	**0.079 (98)**
EQ-5D						
	0.045 (95)	0.223** (94)	0.179 (95)	0.308* (94)	0.122 (95)	0.088 (94)
SF-6D						
	-0.124 (100)	0.081 (99)	0.042 (100)	0.172 (99)	-0.139 (100)	-0.011 (99)
Type 2 Diabetes (Metric/Norm score)						
Global health change anchor						
	0.146* (1158)	**0.185* (1130)**	**0.127* (1155)**	**0.202* (1129)**	**0.026 (1156)**	**0.111* (1130)**
EQ-5D						
	-0.084* (1100)	0.035 (1079)	-0.078* (1095)	0.017 (1076)	0.092 (1096)	0.033 (1080)
SF-6D						
	-0.071 (75)	0.026 (75)	-0.050 (75)	0.045 (75)	-0.142 (75)	-0.024 (75)

* significant at 0.01 level; ** significant at 0.05 level

Table 3: MID values for anchor based methods (Type 1 sample)

Anchor	n	Psychological distress		Barriers to activity		Disinhibited eating	
Method 1		M, SD	95% CI	M, SD	95% CI	M, SD	95% CI
Metric score							
Global health	33	-5.72 (18.08)	-11.89 to 0.45	-6.06 (18.91)	-12.51 to 0.39	-2.22 (15.24)	-7.42 to 2.98
Norm score							
Global health	33	-2.86 (8.58)	-5.79 to 0.09	-2.87 (9.31)	-5.98 to 0.38	-1.03 (6.71)	-3.32 to 1.26
Method 2							
Metric score							
Global health	88	7.67 (17.45)	4.02 to 11.32	6.61 (15.70)	3.33 to 9.89	6.46 (14.42)	3.45 to 9.47
Norm score							
Global health	88	4.25 (8.23)	2.53 to 5.97	3.00 (7.75)	1.38 to 4.62	3.00 (6.36)	1.67 to 4.33

Table 4: MID values for anchor based methods (Type 2 sample)

Anchor	Psychological distress		Barriers to activity		Disinhibited eating	
Method 1	M, SD	95% CI	M, SD	95% CI	M, SD	95% CI
n	336		336		337	
Metric score						
Global health	-1.73 (15.73)	-3.41 to -0.05	-3.48 (15.21)	-5.11 to -1.85	-1.95 (17.39)	-3.81 to -0.09
Norm score						
Global health	-0.94 (7.34)	-1.72 to -0.16	-1.66 (7.55)	-2.48 to -0.85	-0.90 (7.61)	-1.71 to -0.09
Method 2						
n	1032		1029		1033	
Metric score						
Global health	1.37 (14.67)	0.47 to 2.27	3.94 (13.90)	3.09 to 4.79	1.85 (16.36)	0.85 to 2.85
Norm score						
Global health	1.20 (6.85)	0.78 to 1.65	1.92 (6.91)	1.50 to 2.34	0.95 (7.16)	0.51 to 1.39

Nb. Effect size calculated as Change between baseline and follow up / SD at baseline

Table 5: MID values for Type 1 and 2 diabetes (distribution based method)

Level	Psychological distress	Barriers to activity	Disinhibited eating
Type 1 Diabetes			
UK data			
n	*143*	*142*	*142*
0.2 SD	4.78	4.02	4.49
0.5 SD	11.95	10.1	11.22
1 SEM	12.19	10.69	10.14
French data			
n	*230*	*222*	*222*
0.2 SD	4.11	4.23	4.69
0.5 SD	10.28	10.57	11.73
1 SEM	9.35	11.72	11.24
Overall MID (both datasets)			
n	*373*	*364*	*364*
0.2 SD	4.37	4.15	4.62
0.5 SD	10.92	10.39	11.53
1 SEM	11.05	11.32	10.81
Type 2 Diabetes			
UK data			
n	*1604*	*1603*	*1604*
0.2 SD	4.14	3.84	4.62
0.5 SD	10.35	9.60	11.54
1 SEM	10.55	9.79	11.54
French data			
n	*3075*	*2958*	*2953*
0.2 SD	3.75	3.59	4.77
0.5 SD	9.38	8.98	11.92
1 SEM	7.64	10.08	11.69
Overall MID (both datasets)			
n	*4679*	*4561*	*4557*
0.2 SD	3.88	3.68	4.72
0.5 SD	9.71	9.20	5.8
1 SEM	8.64	9.98	11.64

Table 6: Effect size statistics

	Psychological distress	Barriers to activity	Disinhibited eating
Type I			
Method 1	0.23	0.30	0.10
Method 2	0.32	0.33	0.29
Type 2			
Method 1	0.08	0.18	0.08
Method 2	0.07	0.21	0.08

Table 7: MID summary table and the sample proportion reporting minimally important change

	Psychological distress		Barriers to activity		Disinhibited eating	
	MID	Proportion reporting change (%)	MID	Proportion reporting change (%)	MID	Proportion reporting change (%)
Type 1						
Anchor						
Method 1	2.86	57.4	2.87	59.0	1.03	77.0
Method 2	4.25	47.5	3.00	57.4	3.00	54.9
Distribution						
0.2 SD	4.37	47.5	4.15	57.4	4.62	45.9
0.5 SD	10.92	10.7	10.39	18.9	11.53	14.8
1 SEM	11.05	10.7	11.32	18.9	10.81	14.8
Mean MID	6.69	30.3	6.35	37.7	6.19	28.9
Type 2						
Anchor						
Method 1	0.94	66.8	1.66	75.2	0.90	79.4
Method 2	1.20	66.8	1.92	75.2	0.95	79.4
Distribution						
0.2 SD	3.88	40.5	3.68	46.6	4.72	45.8
0.5 SD	9.71	15.1	9.20	18.4	5.8	38.7
1 SEM	8.64	15.3	9.98	12.4	11.64	11.0
Mean MID	4.87	32.6	5.29	29.9	2.80	71.2

Figure 1: MID values for Type I diabetes

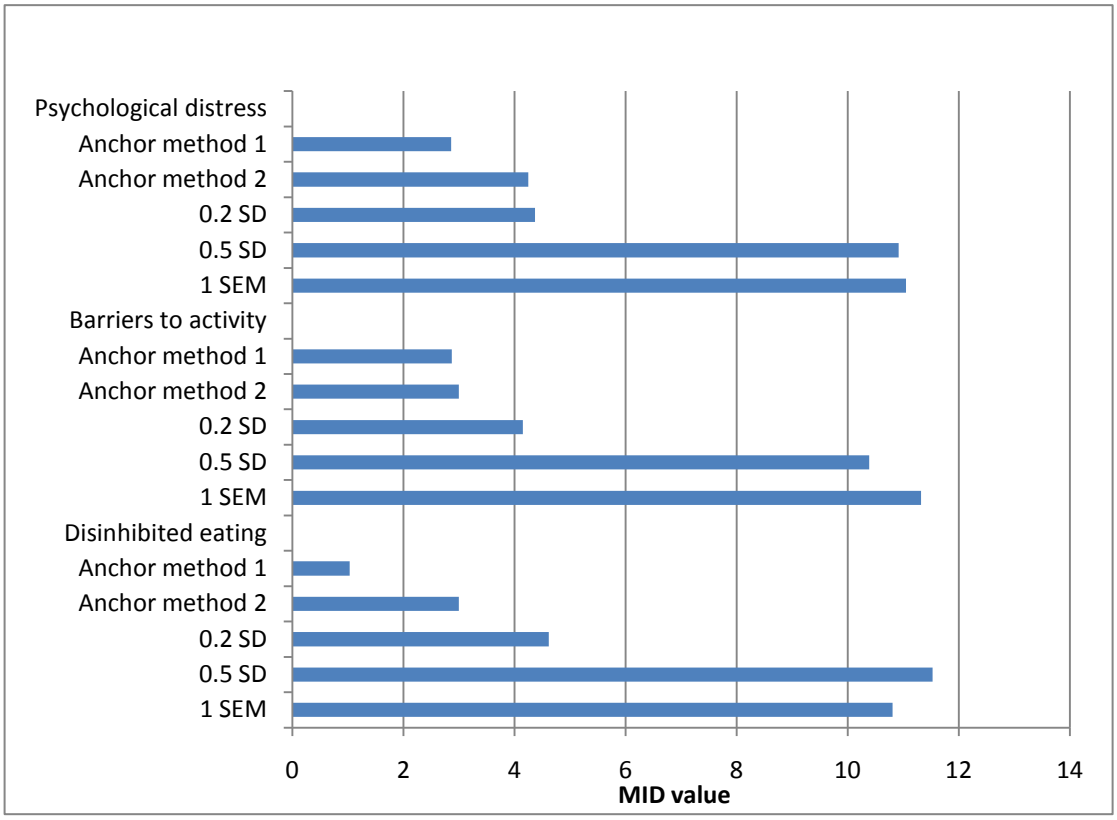

Figure 2: MID values for Type 2 Diabetes