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RESEARCH ARTICLE

Educational and Psychological Aspects

Assessing thoughts, feelings and behaviours related to hypoglycaemia: Psychometric evaluation of the Hypoglycaemia Cues Questionnaire (HypoC-Q)

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Abstract

Aims: To describe the design and examine the psychometric properties of the Hypoglycaemia Cues Questionnaire (HypoC-Q) for assessing thoughts, feelings, and behaviours related to hypoglycaemia among adults with type 1 diabetes (T1D).

Methods: The HypoC-Q was designed iteratively, informed by exploratory interviews with 17 adults with T1D with impaired awareness of hypoglycaemia and/or recurrent severe hypoglycaemia, and consultation with diabetologists. Psychometric analyses were completed on baseline data from the Hypo-METRICS study. Data from adults with T1D, reporting at least one hypoglycaemic event, were eligible if they had completed the baseline HypoC-Q. Completion rates, latent structure, internal consistency, construct and known-groups validity were examined.

Results: In Hypo-METRICS, 154 participants (62% females; mean ± SD age 44 ± 15 years; T1D duration: 23 ± 16 years) were eligible. All completed all 40 HypoC-Q items, demonstrating its acceptability. Exploratory factor analysis identified four scales with satisfactory internal consistency ($\alpha = 0.69–0.81$): 1) low concern (7 items), 2) burnout (6 items), 3) missing cues (5 items), and 4) delaying treatment (9 items); plus eight items, treated separately. Construct validity was supported by significant moderate correlations between 'burnout' and fear of hypoglycaemia and diabetes distress, and between 'missing' and 'delay' with impaired awareness of hypoglycaemia; all three distinguished between those with

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intact and impaired awareness (known-groups validity); but not by history of severe hypoglycaemia.

Conclusions: The HypoC-Q is an acceptable, valid, and reliable measure of thoughts, feelings, and behaviours related to hypoglycaemia among adults with T1D. It is available for informing and assessing the effect of interventions to reduce hypoglycaemia exposure and impact.

KEYWORDS

behaviours, cognitions, diabetes, hypoglycaemia, impaired awareness, PREM

1 | INTRODUCTION

Hypoglycaemia is a frequent and burdensome complication of insulin treatment among people with type 1 diabetes (T1D). Hypoglycaemia can induce a range of symptoms, including hunger, sweating, and confusion, which may alert the individual to act to prevent or manage hypoglycaemia[1]; but may also occur without (perception of) such symptoms, referred to as impaired awareness of hypoglycaemia (IAH). IAH increases the risk of hypoglycaemia considerably, in particular severe episodes (requiring the assistance of another person for recovery), which can be dangerous, leading to seizures, coma, and, rarely, death.[2] Despite technological advances in glycaemic management, many people with T1D continue to experience problematic hypoglycaemia (such as severe hypoglycaemia, episodes while asleep, frequent self-treated episodes, IAH, or fear of hypoglycaemia).[3–5]

An individual's thoughts and feelings about hypoglycaemia and hyperglycaemia can influence their exposure to hypoglycaemia.[6,7] For example, in their efforts to reduce their risk of long-term complications, some people are more motivated to accept hypoglycaemia than hyperglycaemia, showing low levels of concern about hypoglycaemia.[8,9] For others, preventing hypoglycaemia is preferred at the expense of more hyperglycaemia.[9] Neuro-imaging research shows differences in brain activation among people with IAH compared to those with intact awareness, which may influence their perceptions of the importance and urgency with which they respond to hypoglycaemia and other treatment recommendations by their health professionals.[10,11]

Exploring an individual's thoughts and feelings about hypoglycaemia enables appreciation of the complex biopsychosocial processes involved in reducing exposure to, improving awareness of, and minimising negative personal impact from, hypoglycaemia. The Attitudes to Awareness of Hypoglycaemia (A2A) questionnaire was developed to assess beliefs about hypoglycaemia among adults with T1D with IAH who experience recurrent severe hypoglycaemia.[6,8,12] This instrument has enabled important insights into barriers to optimising hypoglycaemia management.[6,7,10,12] It is sensitive to differences between groups, including among those using continuous glucose monitoring (CGM).[9] However, while the A2A captures thoughts and beliefs about hypoglycaemia, it does not capture associated feelings or behaviours. So, additional person-reported experience measures (PREMs) are needed to enable these aspects to be understood in research and clinical practice. Such a PREM may be able to further our understanding of how to improve hypoglycaemia prevention and management. The aim of the current study was to examine the acceptability and psychometric properties of the Hypoglycaemia Cues Questionnaire (HypoC-Q).

What's new?

- Despite technological advances in glycaemic management, many people with type 1 diabetes continue to experience problematic hypoglycaemia.
- Exploring an individual's thoughts and feelings about hypoglycaemia enables appreciation of the complex biopsychosocial processes involved in reducing exposure to, improving awareness of, and minimising negative personal impact from hypoglycaemia.
- The current study found the Hypoglycaemia Cues Questionnaire (HypoC-Q) to be an acceptable and psychometrically appropriate new measure to assess thoughts, feelings, and behaviours related to hypoglycaemia among adults with type 1 diabetes.
- The HypoC-Q is available for informing and assessing the effect of interventions to reduce hypoglycaemia exposure and impact.

2 | METHODS

2.1 | Design of the Hypoglycaemia Cues Questionnaire (HypoC-Q)

The HypoC-Q was developed for the HypoCOMPaSS study,[13] which was a 2×2 factorial randomised controlled trial that examined the impact of glycaemic technologies (pump vs. injections; CGM vs. finger-pricks) in a population with IAH. The study protocol, including ethics approval, has been reported elsewhere.[14] The questionnaire was designed through an iterative process, informed by literature, consultations with diabetologists, and exploratory and cognitive debriefing interviews with 17 adults with T1D, IAH, and severe hypoglycaemia.[9] HypoC-Q was developed concurrently with, and following the same process used to develop the Hypoglycaemia Awareness Questionnaire (HypoA-Q)[15] and the Glucose Monitoring Experiences Questionnaire (GME-Q).[16]

2.2 | Psychometric validation in the hypo-METRICS study

Hypo-METRICS was designed to explore the bio-psycho-social impact of self-treated hypoglycaemia on adults living with insulin-treated diabetes, and to develop an evidence-based threshold for defining hypoglycaemia by sensor technology. Details and findings of Hypo-METRICS have been published.[17–22] Participants wore a blinded CGM and used the purpose-built Hypo-METRICS smartphone app to record hypoglycaemia experiences for 70 days, completing several PREMS and person-reported outcome measures (PROMs) at baseline and study end. Hypo-METRICS recruited 602 adults with type 1 or type 2 diabetes ($n = 277$ with T1D) across 5 European countries. Only UK participants were invited to complete the HypoC-Q due to it being available only in English.

2.3 | Procedure

After eligibility screening and providing informed consent, baseline demographic and clinical data (see Table 1) were collected by research staff and recorded electronically for each participant. Participants were then directed to an online survey (Qualtrics ©2023, Provo, UT) and asked to complete a series of questionnaires, including HypoC-Q (see Section 2.4). Participants could skip any items on the questionnaire (i.e. forced responses were not used).

TABLE 1 Participants' demographic and clinical characteristics ($N = 154$).

Demographic characteristics	$N = 154$[a]
Gender: Female	96 (62%)
Age, years	44.3 ± 15.3
Ethnicity	
Asian	1 (0.6%)
Black	2 (1.3%)
White	149 (97%)
Other	2 (1.3%)
Employment	
Working/studying	115 (75%)
Not working/not studying	14 (9.1%)
Retired	25 (16%)
Education, highest level	
Secondary/High school	29 (19%)
Undergraduate degree	75 (49%)
Postgraduate degree	42 (27%)
Other	8 (5.2%)
Clinical characteristics	
Type 1 diabetes duration, years	22.8 ± 16.1
Impaired awareness (Gold score ≥4)	28 (18%)
Usual means of glucose monitoring	
Continuous glucose monitoring (including flash)	117 (75.9%)
Self-monitoring of blood glucose (finger prick)	37 (24%)
Usual mode of insulin delivery[c]	
Multiple daily injections	109 (72%)
Insulin pump	43 (28%)
Time in glucose ranges (across 70 day study period)[b]	
Percent time within 3.9–10 mmol/L	60.6 ± 15.6
Percent time above 10 mmol/L	33.9 ± 16.8
Percent time below 3.9 mmol/L	5.4 ± 4.6
HbA1c (mmol/mol)[c]	57.3 ± 9.6

[a]Mean ± SD; *n* (%).

[b]Data from the blinded continuous glucose monitor that all participants wore for the duration of the Hypo-METRICS study.

[c]Only data from 152 participants is available.

2.4 | Measures

The HypoC-Q is described in the Results. All PROMs and PREMs used in the Hypo-METRICS study are detailed elsewhere.[17] The following were selected to validate the HypoC-Q:

- Hypoglycaemia Fear Survey II (HFS-II)[23]: 33 items assessing behaviour and worries related to hypoglycaemia.

Total scores range 0–132. Higher scores indicate greater fear of hypoglycaemia.

- Problem Areas In Diabetes (PAID) scale[24]: 20 items assessing diabetes distress. Total scores range 0–100. Higher scores indicate greater diabetes distress. Scores ≥40 indicate severe diabetes distress
- Patient Health Questionnaire (PHQ) 9[25]: 9 items assess depressive symptoms. Total scores range 0–27. Higher scores indicate greater severity of depressive symptoms.
- General Anxiety Disorder (GAD) 7[26]: 7 items assess anxiety symptoms. Total scores range 0–21. Higher scores indicate greater severity of anxiety symptoms.
- Gold score[27]: a single item assessing hypoglycaemia awareness. Scores range 1–7. Higher scores indicate greater impairment of awareness. Scores ≥4 indicate IAH.
- Hypoglycaemia Awareness Questionnaire (HypoA-Q) Impaired Awareness (IA) 5-item subscale[15]: 5 items assess awareness of hypoglycaemia with statements about ability to detect symptoms, each rated on a 5-point scale. Total scores range 0–20. Higher scores indicate greater IAH. Scores ≥12 indicate IAH.[28]

2.5 | Statistical analysis

Statistical analyses were conducted using R (version 4.2.1) and Rstudio (version 2023.3.1.446).[29] *p*-values <0.05 were considered statistically significant. Descriptive statistics were used to examine participant characteristics and item completion rates and response patterns. Non-normality of item distributions, assessed by histogram distributions and Shapiro Wilk's test, suggested the need for non-parametric statistics. Item completion rates of ≥90% were considered indicative of acceptability. Item distributions were used to examine floor and ceiling effects, indicated by >20% of participants endorsing minimum or maximum responses.[30] Considering each part of the questionnaire separately, acceptable inter-item correlations were assessed using Bartletts' test of Sphericity (testing null hypothesis of no inter-item correlation) and the determinant (with values <0.0001 indicative of multicollinearity issues). Similarly, inter-item Spearman's rho (r_s) was calculated to assess high ($r_s > 0.7$) and low ($r_s < 0.3$) correlations suggesting item redundancy. Appropriateness of sample size was assessed using Kaiser-Meyer-Olkin (with >0.6 indicating appropriate size).[31]

Exploratory factor analyses were applied, using principal axis factoring and oblimin rotation, to assess the structural validity separately of parts B, C and D of the HypoC-Q. An iterative process—involving inspection of Eigenvalues ≥1, elbow-plots, variance explained, factor loadings, as well as internal consistency reliability (Cronbach's alpha)—guided decisions regarding the number of factors (scales) to retain and the number of items within each factor. Factor loadings of ≥0.3 and Cronbach's alpha of ≥0.7 (rounded to one decimal place) were deemed acceptable.[16] Acceptable levels of missing data were assessed iteratively by calculating and re-calculating Cronbach's alpha after removing the item with strongest correlation with the scale total, one at a time, until alpha was <0.7. For each scale identified, composite scores were calculated by summing all item scores and dividing by the number of items completed. Scale distributions were examined using boxplots.

Construct validity was assessed by correlating HypoC-Q scales with relevant questionnaires and clinical measures. Convergent validity was confirmed where correlations were expected to be and observed as moderate ($r_s > \pm 0.3$) or strong ($r_s > \pm 0.5$); while divergent validity was confirmed where low correlations ($r_s < \pm 0.3$) were expected and observed.[32] It was expected that:

- questionnaires assessing fear of hypoglycaemia (HFS-II), awareness of hypoglycaemia (Gold and HypoA-Q), and diabetes distress (PAID) would show at least moderate correlations with the scales of the HypoC-Q
- age, diabetes duration, HbA1c, and generic measures of well-being (GAD-7 and PHQ-9) would show low correlations with the HypoC-Q.

Known-groups validity was assessed using the Wilcoxon rank sum test (2 groups). It was expected that the HypoC-Q scale scores would differentiate:

- between those with intact and impaired awareness of hypoglycaemia (Gold score <4 or ≥4)
- between those with a history of severe hypoglycaemia and those without

In addition, the ability of the HypoC-Q to differentiate by usual monitoring (i.e. CGM versus finger-prick) and mode of insulin delivery (pump versus injections) was explored.

3 | RESULTS

3.1 | The HypoC-Q

Exploratory interviews showed that cognitive, behavioural, and psychological factors influence exposure to or prevention of severe hypoglycaemia.[9] Qualitative data informed the design of 40 items, forming the HypoC-Q, to enable adults with T1D to indicate:

- their experience of severe hypoglycaemia (part A; 1 item),
- their thoughts and feelings about hypoglycaemia (part B; 12 items),
- their attributions for the causes of their hypoglycaemic episodes (part C; 14 items), and
- their perceptions of their behaviours during the early stages of hypoglycaemia (part D; 13 items).

Part A has three response options (no previous severe hypoglycaemia, having severe hypoglycaemia because of not having warning symptoms or because of something else, with a free-text response option). Responses to the remaining items are rated on a 5-point Likert scale (Parts B and C: "Strongly disagree" to "Strongly agree"; Part D: "Never" to "Always").

3.2 | Hypo-METRICS sample characteristics

In total, 154 UK adults with T1D were invited to complete the HypoC-Q at baseline. Most (62%) were female; their mean ± SD age was 44 ± 15 years and T1D duration was 23 ± 16 years.

3.3 | Acceptability and response patterns

None of the participants skipped any items, supporting the acceptability of the HypoC-Q. They used the full range of response options with the exception of six questions (items: 18, 29, 32, 33, 36 and 39, see Table S1 and Figures S1–S3). Several items displayed floor effects (15 items) or ceiling effects (6 items).

3.4 | Inter-item correlation and scale structure

Low inter-item correlations (r_s <0.3) were observed for some items (for items 2, 8, 16, 17, 18, 19, 20, 33, 34 and 40), with only one high correlation (r_s >0.7) (between items 3 and 4). Barlett's Test of Sphericity was significant ($p < 0.001$) for all parts of the questionnaire, thereby rejecting the null hypothesis of no inter-item correlations. Four scales were identified (Table 2):

- For part B (items 2–15), the scree plot indicated a 2- or 3-factor solution. The 3-factor solution included three items that double-loaded (≥0.3) across two factors. Item 5 was the only item in the 2-factor solution that double-loaded. It focuses on anxieties related to weight management, to which >60% of respondents indicated 'strongly disagree' or 'disagree', suggesting low discriminant validity. Thus, item 5 was removed, and a 2-factor solution was retained, reflecting two meaningful scales, which were labelled "Low concern about hypoglycaemia" (items 2, 3, 4, 8, 9, 10 and 15) and "Hypoglycaemia burnout" (items 6, 7, 11, 12, 13 and 14). The two factors accounted for 18% and 15% of the variance, respectively.
- For part C (items 16–27), the scree plot indicated a single factor or 2-factor solution; the second factor explaining an additional 8% of variance. For both solutions, three items (item 16, 19, and 20) had low loadings (<0.3). Removing items 19 and 20 from the 2-factor solution resulted in all items loading >0.3. However, as the alpha on the second factor (5 items) was low (<0.5), a forced 1-factor solution (items 22, 23, 25, 26, and 27) was retained, explaining 45% of the variance, reflecting a meaningful scale, which was labelled "Missing cues to treat hypoglycaemia".
- For part D (items 28–40), the scree plot indicated a single factor or 2-factor solution; the second factor explaining an additional 6% of variance. Items loading on the second factor, or not loading >0.3 on any factors, were removed due to double-barrelled wording (item 28), conceptual overlap with other items (items 34 and 40), or minimal face validity (item 37). The 1-factor solution (items 29–33, 35, 36, 38, and 39) explained 35% of the variance, reflecting a meaningful scale which was labelled "Delaying treatment of hypoglycaemia".

For all four scales, Cronbach's alpha indicated strong internal consistency (alpha range 0.68–0.81; Table 2). The reliability of each scale could not be improved by deleting any items. The items not retained in the scales may be analysed separately if deemed relevant for future studies.

3.5 | HypoC-Q scoring

Mean scale scores were calculated giving a score ranging 1 to 5, with higher scores indicating greater endorsement of the concept assessed. The 'reliability if an item is dropped' suggested that any missing data on the first two scales ('low concern' and 'burnout') could compromise their internal reliability. For the remaining two scales ('missing cues' and 'delaying treatment'), one missing datapoint was tolerated without compromising internal reliability. Median scale scores (including lower and upper interquartile range) are presented in Figure S4. While the first and third scale score distributions appear symmetrical, the second and fourth scale distributions appear negatively skewed, suggesting a potential floor effect.

TABLE 2 Structural validity and internal consistency reliability of the HypoC-Q.

Item no. and wording	Factor loadings[a]				
	Scale 1: Low concern	Scale 2: Hypo-glycaemia burnout	Scale 3: Missing cues	Scale 4: Delaying treatment	Single item[c]
Part A					
1. Sometimes people go "hypo" but still end up unable to treat it themselves or needing someone else's help. Does this ever happen to you?					X
Part B					
2. I prefer to keep my blood glucose levels low rather than high	0.37				
3. Having hypos doesn't concern me; it's just one of the things you have to put up with	0.86				
4. Hypos don't bother me much unless they're severe	0.84				
5. I prefer to have low blood glucose than to risk putting on weight because of snacking					Removed
6. Being hypo gives me a break from my diabetes		0.42			
7. Avoiding hypos is just too difficult		0.43			
8. If I keep my blood glucose low, I don't have to worry about long-term complications	0.34				
9. Hypos are inevitable if I'm to have good control of my diabetes	0.34				
10. I never feel panicky or worried about going hypo	0.42				
11. Sometimes letting the hypo take over is easier for me than coping with it		0.55			
12. When I have a hypo, I just don't want to have to deal with it		0.64			
13. The other stresses of life sometimes make dealing with hypos too hard		0.70			
14. There are some advantages in letting my blood glucose levels go low		0.42			
15. Long-term complications (e.g. blindness, kidney failure, amputation) worry me more than hypos	0.47				
Part C: If I go hypo, it's because...					
16. ... I've been exercising or doing a lot physically					X
17. ... I've not eaten or drunk enough					X

TABLE 2 (Continued)

Item no. and wording	Factor loadings[a]				
	Scale 1: Low concern	Scale 2: Hypo-glycaemia burnout	Scale 3: Missing cues	Scale 4: Delaying treatment	Single item[c]
18. … my insulin doses are not quite right					X
19. … my blood glucose is unpredictable					X
20. … I've been drinking alcohol earlier					X
21. … I've over-estimated the amount of carbs I've eaten					X
22. … I just haven't reacted to the warning signs			0.80		
23. … I've missed 'that moment' to treat it early			0.67		
24. … I've taken extra insulin due to high glucose levels					X
25. … I miss subtle symptoms until it's too late			0.78		
26. … I've not checked my blood glucose even though I've had some warning signs			0.62		
27. … I haven't checked my blood glucose at a time when hypos are more likely (e.g. after exercise, alcohol or at night)			0.44		
Part D: When I first start to go hypo …					
28. … I am able to think clearly and act quickly					Removed
29. … I treat it straight away[b]				−0.62	
30. … I find it difficult to recognise the signs				0.40	
31. … my symptoms are so mild that I feel I can delay treating it				0.57	
32. … I wait a while before treating it				0.64	
33. … I find it difficult to get to my glucose/food				0.33	
34. … I am relaxed about it, knowing there is time to treat it					Removed
35. … I am caught up in doing something else				0.68	
36. … I ignore the warning signs, thinking I can treat it 'in a minute'				0.77	
37. … it's impossible to stop it becoming severe					Removed
38. … I am distracted by other things				0.72	
39. … I miss the warning signs because I'm relaxing				0.40	
40. … carbohydrates or glucose are within reach					Removed

(Continues)

TABLE 2 (Continued)

Item no. and wording	Factor loadings[a]				
	Scale 1: Low concern	Scale 2: Hypo-glycaemia burnout	Scale 3: Missing cues	Scale 4: Delaying treatment	Single item[c]
No. of items per scale	7	6	5	9	N/A
Total variance explained	18%	15%	45%	35%	N/A
Internal consistency reliability: Cronbach's alpha	0.71	0.69	0.79	0.81	N/A

[a]Factor loadings <0.3 are suppressed.

[b]Item score must be reversed when including in scale score.

[c]Single item scores can be analysed separately but should not be included in scale score calculations. Items 5, 28, 34, 37 and 40 were removed (see details in text).

3.6 | Construct and known-groups validity

Table 3 shows correlations between the four HypoC-Q scales and other validated PROM scores and clinical indicators. For scale 1 ('low concern'), convergent validity was not observed. For scales 2–4 ('burnout', 'missing' and 'delay') moderate correlations, partially supporting convergent validity hypotheses, were observed. Specifically, scale 2 ('burnout') was moderately associated with measures of fear of hypoglycaemia (HFS-II) and diabetes distress (PAID), while only small associations were observed with hypoglycaemia awareness (HypoA-Q IA subscale and Gold). Scales 3 ('missing') and 4 ('delay') were moderately associated with awareness of hypoglycaemia (Gold and/or HypoA-Q subscale), but not with fear of hypoglycaemia or diabetes distress. Divergent validity was confirmed for all scales.

In Table 4, known-group comparisons for each scale are presented. Statistically significant differences were observed by awareness status (Gold score) for scales 2, 3 and 4 (but not scale 1, 'low concern'): those with impaired awareness had higher median scale scores (indicating greater hypoglycaemia burnout, more missed cues to treat hypoglycaemia and greater delays in treating hypoglycaemia). HypoC-Q subscale scores did not differ by history of severe hypoglycaemia, usual means of glucose monitoring, nor mode of insulin delivery.

4 | DISCUSSION

The HypoC-Q provides a new measure for assessing thoughts, feelings and behaviours related to hypoglycaemia. High acceptability in combination with appropriate scale reliability and structural validity supports use of the HypoC-Q for identifying personal cues for problematic hypoglycaemia among adults with T1D. Psychometric analyses identified four scales (low concern about hypoglycaemia, hypoglycaemia burnout, missing opportunities to treat, and delaying treatment of hypoglycaemia). Additionally, eight items can be analysed separately for further investigation of hypoglycaemia cues such as physical activity, lack of food and carbohydrate intake, alcohol, insulin dosing, or just general unpredictability of blood glucose.

The HypoC-Q scale correlations with hypothesized similar constructs did not align with all hypotheses, suggesting more work may be needed in relation to construct validity. Scale 2 ('burnout') had highest correlations with measures of fear of hypoglycaemia and diabetes distress (HFS-II and PAID-20), while scales 3 and 4 ('missing' and 'delay') had higher correlations with measures of awareness of hypoglycaemia (HypoA-Q IA subscale and Gold). Future construct validity assessments could include measures such as the A2A questionnaire[6,12] and the Hyperglycaemia Avoidance Scale,[33] as these are more likely than those used here to be assessing similar underlying constructs to those captured by the HypoC-Q subscales. This is particularly pertinent to scale 1 ('low concern'), which we believe is capturing a central barrier to reducing problematic hypoglycaemia. It could be explored further in comparison to the A2A scale 'hypoglycaemia concerns minimised'. Known-groups validity was established for scales 2–4 ('burnout', 'missing' and 'delay'), which were able to discriminate significantly by awareness status. The lack of ability to discriminate on history of severe hypoglycaemia may be due to the relatively small group of people with a history of severe hypoglycaemic events.

Previous psychometric analysis of the A2A questionnaire revealed a three-factor solution with the following scales: 'asymptomatic hypoglycaemia normalised', 'hypoglycaemia concerns minimised' and 'hyperglycaemia avoidance prioritised'.[12] Similarly, the HypoC-Q scales addresses concepts regarding worry about high glucose (rather than low glucose) and also provides a more comprehensive understanding of why hypoglycaemia may be difficult to avoid. Examples include difficulties identifying early signs of hypoglycaemia, as well as perceptions about cause(s) and the person's behaviour when glucose levels are falling (including delayed treatment). These additional domains offered with the HypoC-Q allow for further insights, as well as opportunities

TABLE 3 Convergent and divergent validity of the HypoC-Q.

	1: Low concern	2: Hypo burnout	3: Missing cues	4: Delaying treatment
HypoC-Q scales				
1 Low concern about hypoglycaemia	—	—	—	—
2 Hypoglycaemia burnout	0.088	—	—	—
3 Missing cues to treat hypoglycaemia	−0.017	0.286***	—	—
4 Delays treatment of hypoglycaemia	0.154	0.430***	0.596***	—
Convergent validity				
Fear of hypoglycaemia: HFS-II	−0.171*	0.413***	0.146	0.225**
Awareness of hypoglycaemia: Hypo A-Q	0.033	0.231**	0.477***	0.481***
Awareness of Hypoglycaemia: Gold	0.019	0.180*	0.401***	0.445***
Diabetes distress: PAID	−0.147	0.413***	0.129	0.204*
Divergent validity				
Age, years	0.015	−0.174*	0.219**	0.054
T1D duration, years	0.148	−0.090	0.166*	0.076
HbA1c: mmol/mol	−0.136	0.035	−0.012	−0.042
Depressive symptoms: PHQ-9	0.014	0.199*	0.175*	0.116
Anxiety symptoms: GAD-7	0.027	0.217**	0.136	0.093

Note: Computed correlation using Spearman-method (Spearman's rho) with pairwise-deletion. Correlations consistent with hypothesised convergent and divergent validity of the HypoC-Q scales are shown underlined. Convergent validity was confirmed if moderate ($r_s > \pm 0.3$) or strong ($r_s > \pm 0.5$) correlations were observed where expected, while divergent validity was confirmed if low correlations ($r_s < \pm 0.3$) were observed where expected. Missing data was observed for HFS-II (1 missing), HbA1c (2 missing), and PHQ-9 (1 missing).

Abbreviations: GAD-7, 7-item Generalised Anxiety Disorder questionnaire; HFS-II, Hypoglycaemia Fear Survey II; HypoA-Q, Hypoglycaemia Awareness Questionnaire; PAID, Problem Areas In Diabetes; PHQ-9, Patient Health Questionnaire 9.

*$p < 0.05$. **$p < 0.01$. ***$p < 0.001$.

to target personal difficulties with avoiding hypoglycaemia. Despite technological advances, such as insulin pumps and glucose sensors, as well as development of structured educational programs, these interventions have been insufficient to avoid negative consequences from hypoglycaemia for all people with diabetes.[6,10] Therefore, the HypoC-Q may be useful in combination with other relevant clinical data (e.g. sensor data) to explore the extent of potentially problematic hypoglycaemia in clinical settings, guide conversations and structure treatment plans. It may also prove helpful in gathering evidence on how to optimise interventions designed to reduce hypoglycaemia exposure and impact.

The strong involvement of, and interviews with adults with T1D, in the design of the HypoC-Q are key strengths and support the face validity of the measure. The sample of participants interviewed during the development had experience of recurrent severe hypoglycaemia and IAH, thereby reflecting a highly relevant group of adults with T1D at risk of problematic and recurrent hypoglycaemia. Further work is needed to assess construct validity, in particular the first scale ('low concern'). That the questionnaire was completed by a largely predominantly white UK-based sample, educated to a high level (>75%) is a limitation and highlights the need for further assessments in culturally and linguistically diverse groups to understand whether acceptability, validity and reliability would be consistent (or different). The high completion rates observed may reflect high acceptability as reported

TABLE 4 Known-groups validity of the HypoC-Q.

HypoC-Q scale	Awareness status (Gold score)			Severe hypoglycaemia history[c]			Usual means of glucose monitoring[d]			Usual mode of insulin delivery[e]		
	Impaired ($n=28$)[a]	Intact ($n=126$)[a]	*p*-value[b]	No ($n=136$)[a]	Yes ($n=18$)[a]	*p*-value[b]	CGM ($n=117$)[a]	SMBG ($n=37$)[a]	*p*-value[b]	MDI ($n=109$)[a]	Pump ($n=43$)[a]	*p*-value[b]
1: Low concern about hypoglycaemia	2.86	3.07	0.4	3.00	3.36	>0.9	3.00	3.00	0.9	3.00	3.29	0.15
2: Hypoglycaemia burnout	2.17	2.00	**0.02**	2.00	2.17	0.5	2.00	1.83	0.06	2.00	2.17	0.2
3: Missing cues to treat hypoglycaemia	3.20	2.40	**<0.001**	2.60	2.60	0.6	2.60	2.60	>0.9	2.80	2.40	0.2
4: Delaying treatment of hypoglycaemia	2.39	1.89	**<0.001**	2.06	1.94	0.5	2.11	2.00	0.3	2.11	2.00	>0.9

Abbreviations: CGM, continuous glucose monitoring; MDI, multiple daily injections; Pump, insulin pump; SMBG, self-monitoring of blood glucose (finger prick).

Bold values are statistically significant (<0.05)

[a]Median scale score.

[b]Wilcoxon rank sum test.

[c]At least one severe hypoglycaemia episode experienced in the past year.

[d]CGM includes both CGM ($n=3$) and Flash Libre CGM ($n=113$).

[e]MDI includes 'Basal Plus' (basal insulin injection plus addition of one to three pre-meal short-acting insulin injections per day). Two participants were coded as 'Other' under mode of insulin delivery and were excluded from the current analysis.

earlier, but may also suggest that a highly motivated group of participants had been included. Future work includes exploring test–retest reliability as well as assessing the validity and reliability in other diabetes groups, including children, elderly, people with T2D and hybrid-closed loop users. Assessing the measure's ability to capture meaningful changes over time will be important additional work to understand its usefulness in evaluating interventional programs aiming at reducing hypoglycaemia impact. Furthermore, it would be highly relevant to explore whether the HypoC-Q may prove useful in identifying pre-disposing factors for developing impaired awareness of hypoglycaemia, such as hyperglycaemia aversion.[34]

The findings in the current study overall support the validity and reliability of the HypoC-Q and show promise as a highly acceptable tool for use in research to assess cues of potentially problematic hypoglycaemia experiences, perceptions and behaviours among adults with T1D.

AUTHOR CONTRIBUTIONS

JSp and JAMS conceived the idea for the HypoC-Q as part of the HypoCOMPaSS study, and JSp undertook the development with contributions from JAMS and other HypoCOMPaSS researchers. JSp proposed use of the HypoC-Q in the Hypo-METRICS study, led by PC and co-investigators, SAA, ME, BdG, SH, JKM, FP and JS. JSp, EH-T, and US conceived the psychometric analysis plan, and US developed it with contributions from JSp and EH-T. US undertook the data analysis and discussed presentation and interpretation of findings with JSp and EHT. US prepared the manuscript and all authors contributed suggestions to improve presentation and interpretation, and to finalise the manuscript. All authors approved the final version.

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CONFLICT OF INTEREST STATEMENT

US has previously been employed by Novo Nordisk A/S. SAA has served on advisory boards for Vertex Pharmaceuticals and Novo Nordisk and has spoken at educational events sponsored by Novo Nordisk and Sanofi. MLE has served on advisory boards and/or received lecture fees and/or research support from NovoNordisk, Eli Lilly, AstraZeneca, Medtronic, Dexcom, Ypsomed, Abbott Diabetes Care, Roche, NGM Pharma, Zucara, Pila Pharma and Sanofi. UPB has served on advisory boards for Novo Nordisk, Sanofi-Aventis, and Vertex and has received lecture fees from Novo Nordisk and Sanofi-Aventis. FP has received unrestricted funding for research from Novo Nordisk, Eli Lilly, and Sanofi. EHT has undertaken research funded by an unrestricted educational grant from Abbott Diabetes Care, AstraZeneca, and Sanofi, Australia; received speaker fees (to her research group) from Novo Nordisk and Roche; and has served on an advisory board for AstraZeneca. PC has received research support and personal fees from Novo Nordisk, Lilly, Sanofi, Medtronic, Abbott, Dexcom, Insulet, Vertex, and Glooko. JAMS has served on an Advisory Board for Mogrify. JKM is a member in the advisory boards of Abbott Diabetes Care, Becton-Dickinson/Embecta, Biomea Fusion, Eli Lilly, Medtronic, Novo Nordisk, Pharmasens, Roche Diabetes Care, Sanofi, and Viatris, received speaker honoraria from Abbott Diabetes Care, A. Menarini Diagnostics, Becton-Dickinson/Embecta, Dexcom, Eli Lilly, MedTrust, Novo Nordisk, Roche Diabetes Care, Sanofi, and Ypsomed, and is a shareholder of decide Clinical Software GmbH and elyte Diagnostics. JSp has served on advisory boards for Janssen, Medtronic, Omnipod, Roche Diabetes Care, and Sanofi Diabetes; received unrestricted educational grants and in-kind support from Abbott Diabetes Care, AstraZeneca, Medtronic, Roche Diabetes Care, and Sanofi Diabetes; received sponsorship to attend educational meetings from Medtronic, Roche Diabetes Care, and Sanofi Diabetes; and consultancy income or speaker fees from Abbott Diabetes Care, AstraZeneca, Insulet, Medtronic, Novo Nordisk, Roche Diabetes Care, Sanofi Diabetes, and Vertex. In all cases, JSp's research group (ACBRD) has been the beneficiary. JSp owns the copyright of the HypoC-Q. All other authors declare no conflicts of interest.

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SUPPORTING INFORMATION

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

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