Satisfaction with the use of different technologies for insulin delivery and glucose monitoring among adults with long-standing type 1 diabetes and problematic hypoglycaemia: 2-year follow-up in the HypoCOMPaSS Randomised Clinical Trial

Running Title

Satisfaction in the HypoCOMPaSS trial

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Abstract **(250 words)**

Background

In the HypoCOMPaSS trial, adults with long-standing type 1 diabetes and problematic hypoglycaemia were randomised to compare insulin pump (CSII) vs multiple daily injections (MDI) and real-time continuous glucose monitoring (RT-CGM) vs conventional self-monitoring (SMBG). Our aim was to investigate participants' satisfaction with these technologies at 6-month RCT endpoint and at 2-year follow-up.

Methods

Participants completed the Insulin Treatment Satisfaction Questionnaire (ITSQ) subscales 'device delivery' and 'hypoglycaemia control'; and Glucose Monitoring Experience Questionnaire (GME-Q), assessing 'convenience', 'effectiveness', 'intrusiveness' and 'total satisfaction'. We assessed change over time and between group differences by insulin and monitoring modalities.

Results

Participants (N=96) were: 64% women, aged 49±12 years, diabetes duration 29±12 years. At 6 months, participants reported improvements compared to baseline (all $p<0.001$) in satisfaction with insulin 'delivery device' ($r=0.39$) and 'hypoglycaemia control' ($r=0.52$), and trends towards significance in perceived 'effectiveness' ($r=0.42$) and 'intrusiveness' ($r=0.27$) of monitoring device (but not 'convenience', $p=0.139$). All improvements were sustained at 2 years. At 6 months, the only difference between arms was that greater satisfaction with insulin 'delivery device' was reported in the CSII group compared to MDI ($p<0.001$, $r=0.40$). No between-group differences were observed at 2 years.

Conclusions

Overall, significant improvements in participant satisfaction with diabetes technologies were observed over the 6-month RCT, in all domains except 'convenience', maintained at 2 years. While HypoCOMPaSS demonstrated non-inferiority of SMBG versus CGM, and MDI versus CSII in terms of biomedical outcomes, detailed assessments confirm participants satisfaction with delivery device was greater in those allocated to CSII than MDI.

Introduction

Despite advances in diabetes care, problematic hypoglycaemia continues to impose a major burden on people with type 1 diabetes and remains one of its most feared complications.[1] Previously, the HypoCOMPaSS randomised controlled trial (RCT) demonstrated that it is possible to improve awareness of hypoglycaemic symptoms and prevent recurrent severe hypoglycaemia in a high-risk population of adults with long-standing type 1 diabetes without relaxing HbA1c targets.[2] Furthermore, after the initial 6-month RCT, these benefits were sustained for a further eighteen months.[3] The HypoCOMPaSS RCT compared insulin pumps (CSII) with multiple daily injections (MDI) and adjuvant real-time continuous glucose monitoring (RT-CGM) with conventional self-monitoring of blood glucose (SMBG) for the first time in adults with type 1 diabetes who had demonstrable hypoglycaemia unawareness and/or a history of recurrent severe hypoglycaemia. Moreover, participants received equivalent education, clinical support and attention regardless of their trial allocation.[4] The observed improvements in hypoglycaemia awareness and severe hypoglycaemia rates were equivalent across insulin delivery and glucose monitoring modalities, highlighting the pivotal roles of insulin titration, brief psycho-educational training and intensive clinical support.[2]

We have reported previously that treatment satisfaction was improved in all trial arms (CSII vs. MDI; RT-CGM vs. SMBG) from baseline to 6-month RCT endpoint.[2] Furthermore, those randomised to CSII reported greater satisfaction at 6 months than those using MDI, while no difference was observed between those allocated to RT-CGM and SMBG.[2] Satisfaction was assessed using the Diabetes Treatment Satisfaction Questionnaire (DTSQ),[5] which is a brief, validated and widely used measure, designed to provide a 'total satisfaction' score incorporating all aspects of diabetes treatment "including insulin, tablets and/or diet". However, depending on the respondent's interpretation of 'treatment', their score may or may not reflect their satisfaction with glucose monitoring. Further, a brief 'all purpose' assessment, designed to be suitable for all types of diabetes treatment, may not fully capture satisfaction with insulin treatment, as it does not consider specific features of, and experiences with, insulin delivery devices. Various scales have been developed to overcome these potential limitations.[6, 7]

The HypoCOMPaSS study offers a unique opportunity to provide a detailed assessment of satisfaction with insulin delivery and glucose monitoring devices in adults with type 1 diabetes and problematic hypoglycaemia. Thus, the aims of the current study were to use additional patient-reported outcome measures (PROMs) to examine specifically: a) satisfaction with insulin delivery modality and perceived glucose monitoring experience at the conclusion of the 6-month trial; b) whether satisfaction at 6 months differ by device allocation (CSII vs. MDI; RT-CGM vs. SMBG); c) these outcomes at 2-year follow-up overall, and by device allocation; d) these outcomes at 2-year follow-up using per protocol analysis for insulin delivery and glucose monitoring device use.

Methods

Study design

The HypoCOMPaSS study protocol and findings have been reported elsewhere.[2-4] In brief, HypoCOMPaSS was a multi-centre trial (including 5 UK tertiary referral diabetes centres), over a 6-month period, with a 2x2 factorial design. The overall aim was to investigate whether impaired awareness of hypoglycaemia could be improved, and recurrent severe hypoglycaemia prevented. Prior to randomisation, all participants attended a single, brief (1-2 hour) structured psycho-educational program ('My HypoCOMPaSS') focused on hypoglycaemia avoidance, delivered individually or in small groups of up to four participants.[2] Participants were then randomised to one of four groups comparing two insulin delivery modalities (CSII vs. MDI) in combination with two glucose monitoring modalities (RT-CGM vs. SMBG). All participants received equivalent intensive clinical support, including 4-weekly follow-up visits, throughout the RCT.

All participants were given an insulin pump that could receive and display CGM data (Paradigm Veo; Medtronic) as well as receive data transmitted from their SMBG meter at the time of each 'finger prick' blood glucose check. All were taught how to use the on-board bolus calculator. Only those randomised to CSII used the insulin pump for insulin aspart administration, while those allocated to MDI only used the bolus calculator and, if allocated to RT-CGM, the CGM feature. Those allocated to CSII were given a single additional session restricted to technical aspects of pump management. Those allocated to MDI administered insulin aspart and glargine using 3ml cartridges 100 Units/mL in pre-

filled pens (Flexpen® and Solostar® respectively). All participants were given a Contour link® meter (Bayer Healthcare) and required to undertake daily 4-point and weekly 8-point self-monitored capillary glucose profiles. In addition, those allocated to RT-CGM were provided with sensors for uninterrupted use of the CE-marked REAL-time monitor (Medtronic) and given a single additional session restricted to technical aspects of RT-CGM. At the conclusion of the 6-month RCT, participants had the option of switching their insulin delivery modality. Access to RT-CGM sensors continued beyond the RCT for those randomised to the RT-CGM.

Ethical approval was obtained from a central Research Ethics Committee and the Medicines and Healthcare products Regulatory Agency, with independently-chaired Trial Steering Committee and Data Monitoring and Ethics Committee oversight. Informed consent was obtained from all participants. For the purposes of secondary data analyses, ethics approval was subsequently granted by Deakin University Human Research Ethics Committee (2016-011).

Participants

Eligible participants were adults (aged 18-74 years) with type 1 diabetes and impaired awareness of hypoglycaemia and no prior experience with RT-CGM. As described in full elsewhere,[2, 4] 96 participants were randomised: 50 (52%) participants were randomised to MDI, with the remaining randomised to CSII (n=46, 48%). Half of the sample (n=48) were randomised to either SMBG or RT-CGM. At the conclusion of the 6-month RCT, participants had the option of switching their insulin delivery modality. At 2 years, 20 (21%) participants were lost to follow-up. Baseline characteristics were similar across those retained and lost.[2] Half of participants (n=41) had switched insulin delivery modality, with use of both MDI and CSII during the 2-year study.[3] Access to RT-CGM sensors continued beyond the RCT for those randomised to the RT-CGM, with 11 (30%) participants using RT-CGM throughout the 18-month follow-up period.

Measures

All outcome measures have been described in the study protocol,[4] and primary outcomes of the 6-month RCT and 2-year follow-up have been reported previously.[2, 3] The current study examines data

collected from the following patient-report outcome measures completed at baseline, 6 months (RCT endpoint), and 2 years (study endpoint).

Satisfaction with insulin delivery device was assessed with two subscales of the Insulin Treatment Satisfaction Questionnaire (ITSQ): 'hypoglycaemia control' (5 items) and 'device delivery' satisfaction (6 items).[7] Other subscales were excluded as they were deemed not relevant to the aims of the HypoCOMPaSS study. Participants respond to questions about their insulin treatment on a 7-point scale (1-7). Subscale scores are calculated by summing reversed item scores and standardizing as a score out of 100, where higher scores indicate greater satisfaction. The ITSQ was designed and validated for use across insulin administration types, including manual injections and insulin pump therapy.[7]

Satisfaction with glucose monitoring device was assessed using the 22-item Glucose Monitoring Experience Questionnaire (GME-Q).[6] Participants indicate their level of agreement (1='strongly disagree' to 5= 'strongly agree') with 22 statements about their current monitoring device. Monitoring experience is assessed across three domains: 'effectiveness' (9 items), 'intrusiveness (6 items)', 'convenience' (7 items). Within each domain, item scores are summed and divided by the number of items resulting in a composite score (range=1-5), with higher scores indicating greater experience of that domain. A GME-Q composite score ('total satisfaction') can also be calculated, where higher scores indicate more positive overall experience of (greater satisfaction with) their monitoring device. For the 'effectiveness' and 'convenience' domain scores, and the 'total satisfaction' score, negatively worded items are reversed before scoring. The GME-Q was designed to be applicable for both SMBG and CGM users.[6]

In addition, the following variables were analysed: RCT arm allocation (MDI vs CSII; SMBG vs RT-CGM); change in insulin device delivery and use of RT-CGM (<50 versus ≥50% of days in study) following the 6-month RCT; other demographic and clinical characteristics.

Statistical analysis

Statistical analysis was undertaken using SPSS Version 24 (Chicago, USA). Missing data were not imputed, and participants with missing ITSQ and GME-Q scores were excluded from analysis as relevant. Scale distributions were graphed and inspected to check for normality. All scales scores had non-normal distributions and, consequently, non-parametric tests were conducted. Descriptive statistics (median [interquartile range], or n, %) are reported for ITSQ and GME-Q domain scores across all time points (baseline to 2 years). Due to the incomplete data across all time points, and the subsequent pair-wise deletion in analysis, repeated measures Wilcoxon-signed-rank tests were conducted first to explore change in ITSQ and GME-Q subscales from baseline to 6 months, followed by repeated measures Freidman's analysis of variance (ANOVA) to compare change from baseline, to 6 months and 2 years. Mann-Whitney tests were conducted to assess between-group differences in ITSQ scores (MDI vs. CSII) and GME-Q scores (RT-CGM vs. SMBG) at 6 months and 2 years. As participants had the freedom to change their insulin delivery modality following the RCT, at 2 years, ITSQ descriptive statistics were examined comparing three scenarios: those who used MDI only throughout, those switched (with use of both MDI and CSII) during the 2 years, and CSII only throughout. Among participants with complete RT-CGM usage data at 2 years, GME-Q descriptive statistics were inspected for those who used RT-CGM for <50% vs. ≥50% of the time but statistical analysis was deemed inappropriate given the small samples included in per protocol groups. All statistical tests were two-sided and, given these are secondary analyses, differences were accepted as significant at a conservative $p<0.001$. Effect sizes are reported as r; interpretation coincides with that used for Pearson's correlation coefficient (r).

Results

Participant characteristics

As reported elsewhere,[2] the RCT participants were 96 adults with long-standing type 1 diabetes (diabetes duration: 29±12 years), aged 49±12 years. Sixty-one (64%) were women. Ninety-three (97%) were using MDI and three (3%) CSII prior to randomisation. Demographic characteristics of the 76 (79%) participants retained at 2-year study follow-up were comparable with the RCT sample, and retention was consistent across study arms (between 77% and 81%).[3]

6-month RCT

Table 1 displays median [lower, upper inter quartile] ITSQ and GME-Q scores for the whole sample across all time-points. Comparing baseline to the 6-month endpoint of the RCT (using pair-wise deletion), participants reported significant improvements in their satisfaction with insulin 'delivery device' (median diff=8.3[0,27.8], T=2452, p<.001, *r*=0.39) and 'hypoglycaemia control' (median diff=23.3[5.0,40.0], T=2793,p<.001, *r*=0.52). Similarly, participants reported significant improvements in their 'total satisfaction' with their monitoring device (median diff=0.22[0.0,0.5], T=2550, p<.001, *r*=0.40). Specifically, participants' reports of the perceived 'effectiveness' of their monitoring device increased (median diff=0.3[0.0,0.9], T=2333, p<.001, *r*=0.42), while 'intrusiveness' reduced (median diff=-0.2 [-0.5,0.2], T=595, p<.001, *r*=0.27). There was no change in perceived 'convenience' (median diff=0.14[-0.3,0.4], T=1518.5, p=0.105).

Table 2 displays median [lower, upper inter quartile] ITSQ and GME-Q scores by study allocation at 6-month RCT endpoint and 2-year study endpoint (ITT). At the 6-month RCT endpoint, participants randomised to CSII reported greater satisfaction with their insulin 'device delivery' (U=1250, z=3.6, p<.001, *r*=0.40) than those allocated to MDI, and there was a trend towards greater satisfaction with 'hypoglycaemic control' (U=1049, z=2.0, p=.043, *r*=0.22). GME-Q 'total satisfaction' and domain scores were similar at 6 months between those allocated to RT-CGM and those allocated to SMBG alone. Those randomised to RT-CGM perceived a trend toward greater 'effectiveness' of their monitoring device than those allocated to SMBG (U=1090, z=2.10, p=0.036, *r*=0.23).

2-year study

For the whole sample, comparing baseline, 6-month RCT endpoint and 2-year study endpoint, significant improvements were observed in satisfaction with insulin 'delivery device' ($\chi^2(2)=26.0$, p<.001) and 'hypoglycaemic control' ($\chi^2(2)=36.4$, p<.001). A trend towards significant improvements was observed for perceived 'effectiveness' ($\chi^2(2)=13.4$, p=.001) and 'intrusiveness' of ($\chi^2(2)=6.9$, p=.032), and 'total satisfaction' ($\chi^2(2)=12.0$, p=.002) with, their glucose monitoring device. There was no significant change in perceived 'convenience' of glucose monitoring device across time points for the whole sample ($\chi^2(2)=5.3$, p=0.071).

Post-hoc comparisons revealed no significant change from RCT endpoint to 2-year study endpoint in any of the ITSQ or GME-Q scores, suggesting that satisfaction stabilised post 6 months. However, there was a non-significant trend towards increased satisfaction with insulin 'delivery device' following conclusion of the RCT (Table 1).

At the 2-year study endpoint, no significant between-group differences were observed in ITSQ subscale scores by insulin delivery group, or in GME-Q scores by glucose monitoring group (ITT) (Table 2). Following the RCT endpoint, descriptive statistics suggest that those who continued to use CSII, and those who switched their insulin delivery modality, reported greater satisfaction with their insulin 'device delivery' at 2 years compared to those who remained on MDI, while satisfaction with 'hypoglycaemia control' did not vary by insulin modality. Although numbers were low, participants with greater use of RT-CGM (≥50% vs <50%) perceived their monitoring method to be more convenient and effective, and less intrusiveness at 2 years (Table 3).

Discussion

Previous reports from the HypoCOMPaSS study described non-inferiority (of MDI versus CSII and SMBG versus RT-CGM) in terms of biomedical outcomes in adults with longstanding type 1 diabetes and problematic hypoglycaemia, and significantly improved satisfaction overall, but particularly for those allocated to CSII.[2, 3] The current study's more detailed assessments of participants' experiences with these diabetes technologies (using the ITSQ and GME-Q) confirms significant improvement over 6 months in several aspects of satisfaction for both insulin delivery and glucose monitoring devices. It confirms that participants were more satisfied with CSII than MDI, aspreviously shown with DTSQ,[2, 3] and that these improvements were maintained at 2 years. In addition, while data are limited, the 2-year per protocol analysis suggests that, when given their preference of insulin delivery and glucose monitoring device at the end of the 6-month RCT, there were no significant differences in ITSQ scores for those remaining on MDI or CSII or switching, i.e. everyone was equally satisfied with their choice. Finally, those who used RT-CGM more than half of the time throughout follow-up had the greatest satisfaction levels.

Systematic reviews and meta-analyses show there have been few RCTs that have examined satisfaction with advanced diabetes technologies compared with conventional modalities, with mixed findings for CSII compared with MDI, with no difference shown for RT-CGM compared with SMBG.[8, 9] However, prior to HypoCOMPaSS, none of the RCTs had been conducted in a high-risk group of adults with long-standing type 1 diabetes and problematic hypoglycaemia; indeed, it has usually been the case that those with impaired awareness and/or history of severe hypoglycaemia have been excluded from such studies. Further, HypoCOMPaSS is one of the few studies to compare such technologies while ensuring equal attention to education, clinical support and attention – the notable exception being the REPOSE trial, which compared MDI and CSII after structured type 1 diabetes education.[10] Similarly, REPOSE found biomedical non-inferiority of MDI compared with CSII and that treatment satisfaction was greater among those allocated to CSII.

Valid and reliable measurement of the experience of the person with diabetes is fundamental to improving the quality of diabetes care. While biomedical outcomes can tell us whether interventions are working, we will only know if they are working well enough, and likely to produce sustainable outcomes, if we ask the people who need to use them in their everyday lives. This study expanded upon our previous HypoCOMPaSS findings by examining responses to two detailed measures of diabetes treatment satisfaction, one focused on issues related specifically to insulin delivery (ITSQ) and one on glucose monitoring (GME-Q). Many previous trials of insulin delivery and glucose monitoring technologies have incorporated only brief and broad measures of diabetes treatment satisfaction.[11, 12] Brief measures offer a significant advantage in terms of low respondent burden but can be limited by not enabling the respondent to fully consider various specific aspects of their experience, and consequently, both respondent and researcher interpretation may be questionable. For example, the DTSQ instructions and questions do not readily highlight that glucose monitoring is part of the diabetes treatment experience. The current findings highlight that those allocated to CSII were more satisfied with their insulin delivery device than those allocated to MDI, with no significant differences in satisfaction with hypoglycaemic control, or in terms of other aspects of satisfaction

between those allocated to SMBG and RT-CGM. The DTSQ has shown differences between diabetes technologies in other randomised studies.[11, 13] Our discrepant finding may be explained by the fact that the design of HypoCOMPaSS ensured that all participants (regardless of treatment allocation) received equal education, clinical support and attention with particular focus on optimising the utility and potential benefits of MDI and SMBG, through direct linking of data to a bolus wizard and targeted testing including nocturnally to identify times of risk and inform proactive steps towards prevention and minimisation of significant hypoglycaemia. Regardless, it is clear that measures beyond DTSQ should be considered in future studies of advanced glucose monitoring technologies for valid assessment of the user's experience.

This study also has some limitations. It is not possible to conceal insulin delivery and glucose monitoring device allocations from study participants or clinicians when their features and capabilities are so different. While some biomedical outcomes are objective markers (e.g. HbA1c) and not subject to self-report bias, treatment satisfaction is necessarily a subjective, patient-reported outcome, and this could be considered problematic. Further, the concept of satisfaction can be criticised as being subject to factors such as 'gratitude bias' (i.e. participants feeling indebted for the opportunity to access the latest treatments), but it is also recognised that people want to provide valid responses reflecting the gap between their expectations and their experiences in order to improve healthcare.[14] Importantly, we used valid and reliable measures of satisfaction[6, 7] and have discussed these findings in relation to those of the DTSQ,[2, 3, 5] arguably the most widely-used brief measure of diabetes treatment satisfaction.

Another limitation is that uninterrupted RT-CGM was not achieved. Participants were trained in sensor insertion, calibration, and use of monitors (including trend analysis, individualizing alarm settings and low-glucose alerts) but did not use the low-glucose suspend feature. The fact that uninterrupted RT-CGM use was not realised may reflect the fact that the study used an early iteration of CGM technology, and problems with sensors, calibration etc are well-documented.[15] It may also reflect real-world use, whereby people with diabetes do not perceive the need for uninterrupted use in

order to experience benefits and/or that uninterrupted use represented an added burden to diabetes self-care.[16] It is also the case that HypoCOMPaSS took a very pro-active approach regarding SMBG, as evidenced by the equivalent satisfaction with this modality. Education was targeted to optimising the use of SMBG to increase awareness and understanding of times of risk for hypoglycaemia, increasing ability to detect, and confidence to respond safely and effectively, to glucose levels. Further, while a 95% reduction in severe hypoglycaemia rate was achieved over the 2-year study without activation of the low-glucose suspend feature, we acknowledge that greater satisfaction could have been achieved if the potential benefits of automated suspension of insulin delivery had been realised during HypoCOMPaSS.[3]

The HypoCOMPaSS study has several clinical and research implications, which have been reported previously.[2, 3] The use of more detailed assessments in the current study confirms that most aspects of satisfaction improved significantly at 6 months (overall, regardless of trial allocation) – including insulin 'delivery device' and 'hypoglycaemia control', and glucose monitoring 'total satisfaction', 'effectiveness' and 'intrusiveness' but not 'convenience' – and were maintained at 2 years, mirroring improvements in biomedical outcomes. This highlights the importance of ensuring equivalent education, clinical support and attention throughout the 6-month RCT and their continued benefits for maintaining biomedical outcomes and satisfaction at the 2-year study endpoint. These findings support current evidence-informed and cost-effective clinical practice recommendations,[17] in which insulin titration, structured education and intensive clinical support can be offered to all before introducing advanced diabetes technologies, in the anticipation that most will benefit in terms of both biomedical and psychological outcomes. The findings in relation to satisfaction with glucose monitoring highlight the limitations of the technology used in the HypoCOMPaSS trial as well as the burden of intensive monitoring. Given that technologies are advancing at a rapid pace, close attention needs to be paid to the users' experience (in clinical practice and research) using validated measures. When planning future diabetes technology trials, we suggest adoption of the approach used in the HypoCOMPaSS and REPOSE trials (i.e. ensuring equivalent education, clinical support and attention to all groups) and thus isolating the effect of the technology from any confounders.

In conclusion, the use of the ITSQ and GME-Q measures enabled detailed characterization of the experience of using insulin delivery and glucose monitoring devices. Significant improvements were observed over the 6-month RCT in satisfaction with insulin delivery and glucose monitoring technologies, in all domains except ‘convenience’, and these were maintained at 2 years. While HypoCOMPaSS demonstrated non-inferiority of SMBG versus CGM, and MDI versus CSII in terms of biomedical outcomes, detailed satisfaction assessments confirm participants were more satisfied with CSII than MDI in terms of insulin delivery device. Future trials of glucose monitoring devices would benefit from inclusion of monitoring-specific satisfaction measures in order to meaningfully determine participant experiences.

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Conflicts of interest

JS has participated in advisory boards for Medtronic, Roche Diabetes Care and Sanofi Diabetes; her research centre (ACBRD) has honoraria in respect of these activities, as well as: unrestricted educational grants from Abbott Diabetes Care, AstraZeneca and Sanofi Diabetes; in-kind support (products and consumables) for studies from Abbott Diabetes Care, Medtronic, Roche Diabetes Care and Sanofi Diabetes; speaker fees from Astra Zeneca, Medtronic, Novo Nordisk, Roche Diabetes Care and Sanofi Diabetes; sponsorship to attend educational meetings; and consultancy income from Roche Diabetes Care and Sanofi Diabetes. JS is a director of AHP Research Ltd, which owns the copyright of the GME-Q. EHT has participated in an advisory board for Astra Zeneca, has received unrestricted educational grants from Abbott Diabetes Care and Sanofi Diabetes, and speaker fees from Novo Nordisk; her research has received in-kind support (products and consumables) for studies from Abbott Diabetes Care and Roche Diabetes Care. MLE has received travel support from Medtronic, Roche and Novo Nordisk, speaker fees from Novo Nordisk, Eli Lilly, Astra Zeneca and Abbott Diabetes Care, has received research support from Boehringer Ingelheim, Novo Nordisk, MedImmune, Imcyse, NGM Pharma and Medtronic, and has sat on advisory boards for CellNovo, Medtronic, Abbott Diabetes Care, Dexcom and Roche. DF has received speaker's fees from Animas and Novo Nordisk. DK has received honoraria for participation in educational events and consultancy fees from Novo Nordisk, Sanofi and Ascensia. He is also medical advisor to Glooko and has received research support from Lilly. SRH has carried out consultancy work for device and insulin companies: Sanofi, Novo Nordisk, and Eli Lilly and Company, Boehringer Ingelheim, received research support from Medtronic, and speaker fees from Novo Nordisk, Eli Lilly and Company, and Astra Zeneca. JAMS has previously participated in advisory boards for Medtronic and received travel support for conference attendance from Novo Nordisk, and Sanofi. No other potential conflicts of interest relevant to this article were reported.

Author contributions

The HypoCOMPaSS Study was led by JAMS, MLE, DF, SRH, DK and JS. JS and JAMS determined the psychological measures to be included in the HypoCOMPaSS survey booklet, in liaison with the investigator team. JS, EHT and JAMS developed the plan for this study. EHT prepared the psychological dataset and conducted statistical analyses. JS and EHT prepared the first draft, with input from JAMS. All other authors reviewed the draft and provided critical input. All authors approve the final version.

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Table 1. ITSQ and GME-Q scores for the whole sample at all study time-points

	Baseline	**6 months (RCT endpoint)**	**2 years (Study endpoint)**
ITSQ			
Delivery Device	70.8 [53.5,83.3] (n=96)	83.3 [69.4,86.7] (n=82)	91.7 [83.3,97.2] (n=56)
Hypoglycaemic Control	43.3 [30.0,56.7] (n=94)	70.0 [59.2,84.2] (n=83)	70.0 [60.0,97.2] (n=55)
GME-Q			
Convenience	3.7 [3.3,4.1] (n=95)	4.0 [3.3,4.3] (n=82)	3.9 [3.4,4.3] (n=54)
Effectiveness	3.6 [3.0,3.9] (n=95)	3.9 [3.7,4.2] (n=83)	3.9 [3.5,4.1] (n=53)
Intrusiveness	2.5 [2.0,2.9] (n=94)	2.3 [2.0,2.8] (n=82)	2.2 [1.5,2.7] (n=54)
Total Satisfaction	3.6 [3.2,3.8] (n=94)	3.8 [3.4,4.1] (n=80)	3.9 [3.5,4.3] (n=53)

Data are median [lower, upper quartile]. Number of participants with available data is denoted by (n).
GME-Q = Glucose Monitoring Experience Questionnaire, ITSQ = Insulin Treatment Satisfaction Questionnaire.

Table 2. ITSQ and GME-Q scores by study arm allocation at 6-month RCT endpoint and 2-year study endpoint (ITT)

ITSQ	**Endpoint**	**MDI**	**CSII**	**P-value**
Delivery Device	RCT: 6 months	75.0 [61.1,94.4] (n=45)	94.4 [83.3,100] (n=38)	<.001
	Study: 2 years	87.5 [87.5,94.4] (n=28)	94.4 [84.0,99.4] (n=28)	0.203
Hypoglycaemic Control	RCT: 6 months	63.3 [63.3,80.0] (n=45)	76.7[63.3,88.3] (n=37)	0.043
	Study: 2 years	70.0 [53.3,80.0] (n=28)	70.0[63.3,83.3] (n=27)	0.691
GME-Q	**Endpoint**	**SMBG**	**RT-CGM**	
Convenience	RCT: 6 months	3.7 [3.3,4.2] (n=41)	3.7 [3.1,4.3] (n=41)	0.639
	Study: 2 years	4.0 [3.6,4.25] (n=28)	3.8 [3.4,4.3] (n=26)	0.549
Effectiveness	RCT: 6 months	3.8 [3.4,4.1] (n=41)	4.0 [3.7,4.4] (n=42)	0.036
	Study: 2 years	3.9 [3.3,4.0] (n=28)	4.0 [3.6,4.3] (n=25)	0.126
Intrusiveness	RCT: 6 months	2.3 [2.0,3.0] (n=40)	2.2 [1.8,1.7] (n=42)	0.396
	Study: 2 years	2.2 [1.7,2.5] (n=28)	2.3 [1.3,2.8] (n=26)	0.775
Total Satisfaction	RCT: 6 months	3.7 [3.3,4.0] (n=40)	3.7 [3.5,4.2] (n=40)	0.528
	Study: 2 years	3.8 [3.5,4.0] (n=28)	3.9 [3.4,4.4] (n=25)	0.649

Data are median [lower, upper quartiles]. Number of participants with available data denoted by (n).
P-values compare groups using independent-samples t-tests.
GME-Q = Glucose Monitoring Experience Questionnaire, ITSQ = Insulin Treatment Satisfaction Questionnaire.

Table 3. ITSQ and GME-Q scores at 2-year endpoint (per protocol): insulin delivery modality (MDI only vs. CSII only vs. switched) and RT-CGM use (<50% vs. ≥50% use)

ITSQ	**Insulin delivery modality throughout 2-year study**		
	MDI only	Switched (MDI & CSII)	CSII only
Delivery Device	80.6[72.2,86.1] (n=7)	93.1 [79.2,100] (n=28)	94.4 [86.1,97.2] (n=18)
Hypoglycaemic Control	70.0 [66.7,80.0] (n=7)	73.3 [55.0,82.5] (n=28)	71.7 [62.5,84.2] (n=18)
GME-Q	**RT-CGM use**		
	< 50%	≥50%	
Convenience	3.7[3.2,4.0] (n=5)	4.1 [2.9,4.8] (n=6)	
Effectiveness	3.7 [3.4,4.4] (n=5)	4.2 [3.6,4.5] (n=6)	
Intrusiveness	2.7 [1.9,2.9] (n=5)	1.5 [1.3,3.2] (n=6)	
Total Satisfaction	3.6 [3.3,4.2] (n=5)	4.3 [3.2,4.6] (n=6)	

Data are median [lower, upper quartile]. Number of participants with available data denoted by (n).
GME-Q = Glucose Monitoring Experience Questionnaire, ITSQ = Insulin Treatment Satisfaction Questionnaire.