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BMJ Open Diabetes Research & Care

Six months of hybrid closed-loop therapy improves diabetes-specific positive well-being, and reduces diabetes distress and fear of hypoglycemia: secondary analysis of a randomized controlled trial

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ABSTRACT

Introduction This analysis aimed to investigate diabetes-specific psychological outcomes among adults with type 1 diabetes (T1D) using hybrid closed-loop (HCL) versus standard therapy.

Research design and methods In this multicenter, open-label, randomized, controlled, parallel-group clinical trial, adults with T1D were allocated to 26 weeks of HCL (MiniMed™ 670G) or standard therapy (insulin pump or multiple daily injections without real-time continuous glucose monitoring). Psychological outcomes (awareness and fear of hypoglycemia; and diabetes-specific positive well-being, diabetes distress, diabetes treatment satisfaction, and diabetes-specific quality of life (QoL)) were measured at enrollment, mid-trial and end-trial. Linear mixed models were conducted, using restricted maximum likelihood estimation, unadjusted and adjusted (for covariates: age, sex, diabetes duration, glycated hemoglobin, recent severe hypoglycemia, pre-trial insulin delivery modality, enrollment and mid-study scores).

Results 120 participants (mean age 44±12 years) were randomized to intervention (n=61) or standard therapy (n=59). At 13 weeks, the HCL group had better diabetes-specific positive well-being than the standard therapy group (unadjusted: Δ=1.0, p=0.025; adjusted: Δ=1.1, p=0.01), which was maintained at 26 weeks (unadjusted: Δ=0.9, p=0.042; adjusted: Δ=1.0, p=0.023). At 26 weeks, the HCL group also had less diabetes distress (adjusted: Δ=−6.4, p=0.039), fear of hypoglycemia ("maintain high": adjusted: Δ=−0.8, p=0.034; and "worry": adjusted: Δ=−1.8, p=0.048), and perceived "unacceptably high glucose levels" (unadjusted: Δ=−1.1, p<0.001; adjusted: Δ=−1.1, p<0.001). HCL did not improve diabetes treatment satisfaction, diabetes-specific QoL, hypoglycemia awareness, or perceived frequency of unacceptably low glucose levels.

Conclusions These findings imply that HCL offers important psychological benefits. In particular, improvement in diabetes-specific positive well-being was observed 13 weeks

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Hybrid closed-loop (HCL) automated insulin delivery improves glycemic outcomes compared with standard therapy in people with type 1 diabetes (T1D), however, few studies have investigated its effect on psychological outcomes.

WHAT THIS STUDY ADDS

⇒ The findings support that HCL can offer important psychological benefits over standard therapy to adults with T1D. Specifically, HCL led to higher diabetes-specific positive well-being, and lower diabetes distress, fear of hypoglycemia, and perceived frequency of unacceptably high glucose levels.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The study findings give insight into the lived experiences of adults with T1D using first-generation HCL to manage their diabetes, and factors that might impact uptake or continued use of HCL. We encourage similar comprehensive evaluations of psychological outcomes in future studies of diabetes technologies, to help ensure that psychological and biomedical benefits are achieved in parallel.

after HCL initiation and maintained at 26 weeks. Reduction in the perceived frequency of hyperglycemia was also apparent by 26 weeks. Adjusted analyses showed significant reductions in diabetes distress and fear of hypoglycemia at 26 weeks, suggesting these benefits were apparent for people with particular characteristics.

Trial registration number Australian New Zealand Clinical Trials Registry: ACTRN12617000520336.

INTRODUCTION

Glucose monitoring and administering insulin are core self-care behaviors for adults with type 1 diabetes (T1D).[1] Diabetes self-care can be burdensome;[2] it is challenging to achieve and maintain glucose levels in the recommended range to prevent or delay diabetes-related complications.[2] Advances in diabetes technologies aim to improve glycemic outcomes and the self-management experience. Among these advances are hybrid closed-loop (HCL), which combines an insulin pump (continuous subcutaneous insulin infusion; CSII), a real-time continuous glucose monitor (CGM), and a feedback-controlled algorithm. HCL partially automates insulin delivery requiring some human input, such as "announcing" meals and physical activity, and equipment changes (eg, CGM sensors and insulin reservoirs and delivery lines). Trials of commercial HCL focus primarily on safety, feasibility and biomedical outcomes,[3 4] and show improvements in glucose-related metrics.[5 6] The impact of HCL on psychological outcomes has received less attention.[3 4]

Psychological outcomes include diabetes-specific quality of life (QoL), diabetes distress, well-being, fear of hypoglycemia, and treatment satisfaction. They enable understanding of lived experiences, including factors that may influence uptake and continued real-world use of HCL and other diabetes technologies.[3 7] Qualitative research provides valuable insights into HCL user experiences. For example, enhanced feelings of safety and fewer worries about glucose levels,[8 9] and frustration and inconvenience associated with technological problems and alarm intrusiveness.[8 9] To date, the largest quantitative study of psychological outcomes associated with HCL is a real-world cohort study of 1,435 people with T1D (95% aged≥18 years) who previously used CSII.[10] Over a 4-week period of HCL use, small statistically significant improvements were observed in device-related satisfaction and diabetes-related impact, countered by a small significant reduction in general emotional well-being. However, limitations include short follow-up, selection bias and lack of a control group, such that changes in psychological outcomes cannot necessarily be attributed to HCL.

A recent narrative review of studies examining diabetes technologies among adults with T1D identified only four randomized controlled trials (RCTs) (published since 2014) reporting psychological outcomes of HCL.[11] Three compared HCL with sensor-augmented pump (SAP) therapy and were limited by short timeframes (≤12 weeks) and small samples (N=15 to 63).[9 12 13] The only between-group difference at follow-up was a reduction in diabetes distress, favoring HCL.[11 12] To date, the largest and longest RCT examining psychological outcomes of HCL versus standard therapy (CSII or multiple daily insulin injections (MDI) without real-time CGM) among adults with T1D is our Australian 26-week RCT including 120 participants.[6 14] At 26 weeks, we found greater diabetes-specific positive well-being and diabetes-specific QoL favoring HCL, but no difference in diabetes treatment satisfaction or diabetes distress.[6] In summary, the psychological outcomes of HCL are not yet well understood; comprehensive examinations using RCT designs are vital.

This analysis builds on our initial report.[6] It is the first comprehensive examination of psychosocial outcomes in a 26-week RCT of HCL in adults with T1D, compared with standard therapy (CSII or (MDI) without real-time CGM). In this secondary analysis, we examine, for the first time, using both unadjusted and adjusted models which consider known covariates and mid-trial data, between-group differences: (1) at 13 and 26 weeks, in fear of hypoglycemia and hypoglycemia awareness; (2) at 13 weeks, in diabetes distress, diabetes-specific positive well-being, diabetes treatment satisfaction and diabetes-specific QoL.

MATERIALS AND METHODS

This was a preplanned psychological substudy of a 26-week open-label, randomized, controlled, parallel-group clinical trial comparing HCL and standard therapy. The methods are summarized below, with further details in the protocol[14] and primary report[6]. Governance was provided at each site, and trial oversight was provided by an independent Data Safety and Monitoring Board.

Adults with T1D were recruited through seven Australian tertiary, public hospitals (sites), and one associated private clinic (online supplemental file: Supplement 1) Eligible participants were age25–70 years, with T1D (≥12 months) managed with MDI or CSII, and glycated hemoglobin (HbA1c)≤91 mmol/mol (≤10.5%) (online supplemental file: Supplement 2). Participants were excluded if they had used real-time CGM in the past 3 months. Purposive sampling ensured that≥40% of participants used MDI or CSII. Data collection stopped once the intended sample size (N=120) was reached. The sample size calculation is reported elsewhere.[14]

Pre-randomization, all participants took part in a study "run-in" (five site visits over 5–9 weeks). The run-in incorporated data collection and 2–6 hours of individualized diabetes education with three additional 1-hour sessions offered if required (figure 1). Randomization was implemented by independent statisticians using central randomization software. A 1:1 ratio was implemented, with stratification for the proportion of time in the glucose range 3.9–10.0 mmol/L (70–180 mg/dL) pre-randomization (≤50% or >50%), insulin delivery modality at enrollment (MDI or CSII), and trial site.

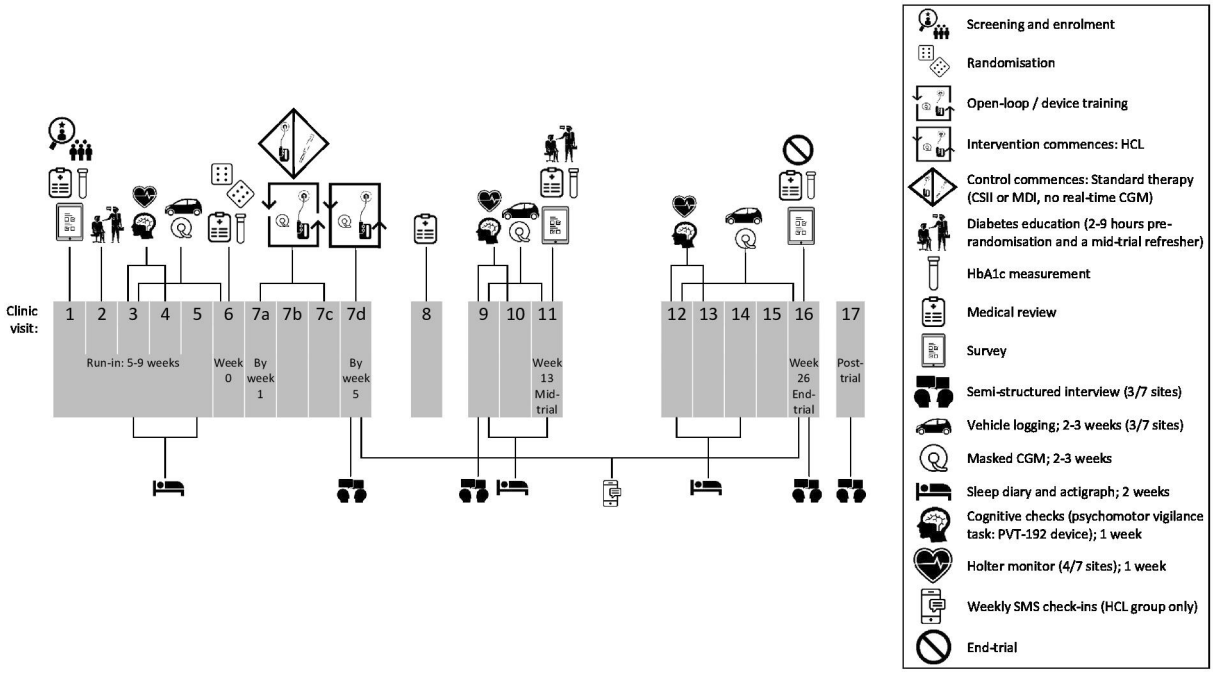


Figure 1 Study overview. CGM, continuous glucose monitor; CSII, continuous subcutaneous insulin infusion; HbA1c, glycated hemoglobin; HCL, hybrid closed-loop; MDI, multiple daily insulin injections; SMS, short messaging service.

The intervention group received training about the trial HCL (MiniMed™ 670G (Medtronic, Northridge, California, USA)). The control group continued to use their pre-trial insulin delivery modality, coupled with an insulin bolus dose calculator (for meal-related dose estimation), but had no real-time CGM access. Both groups participated in 11 further clinic visits (including "Visit 6" at which they were randomized) for clinical monitoring and support, additional diabetes education, and data collection (figure 1). Adverse events (eg, severe hypoglycemia and ketoacidosis) were monitored and are reported elsewhere.[6] There were no departures from protocol.

Psychological outcome data were collected via online (Qualtrics, Provo, Utah, USA) surveys administered on tablet computers at clinic visits at enrollment (Visit 1), mid-trial (Visit 11: week 13) and end-trial (Visit 16: week 26). These data were accessible only to the psychological substudy team who were not involved in participants' clinical care. Hard copy versions were available when online completion was not possible. Additionally, we collected demographics and characteristics from medical records (age, sex, diabetes duration, laboratory-assessed HbA1c, masked CGM, severe hypoglycemic episodes in the past 12 months, and pre-trial insulin delivery modality) and the enrollment survey (country of birth, primary language, education, and employment).

Outcomes and measures

The primary/secondary outcomes and measures of the overall trial are reported elsewhere.[6 14] This report focuses on six diabetes-specific and hypoglycemia-specific psychological outcomes, chosen to provide a broad oversight into lived experiences of HCL. Their measurements are summarized below. Various factors were considered in selecting the outcome measures, including relevance (of the scale and individual items), length (eg, to minimize burden to participants), and reliability, validity, and responsiveness (see online supplemental file: Supplement 3), which also includes a description of each psychological outcome). Scoring details and interpretation are provided in online supplemental file: Supplement 3.

Diabetes-specific distress and positive well-being were assessed, respectively, with the 20-item Problem Areas in Diabetes (PAID) scale,[15] and a 4-item subscale of the 28-item Well-being Questionnaire.[16] Diabetes-specific QoL was assessed with the 7-item DAWN Impact of Diabetes Profile.[17] Diabetes treatment satisfaction was assessed with the total score of the Diabetes Treatment Satisfaction Questionnaire status version (DTSQs; calculated by summing items 1 and 4–8).[18] At end-trial, data were collected using the changed version of the DTSQ but were not needed as enrollment DTSQ scores were<30 (ie, not at ceiling), meaning that there was room for improvement in treatment satisfaction; see online supplemental file: Supplement 3).[19] Perceived frequency of unacceptably high or low glucose levels was assessed with DTSQs items 2 and 3, respectively. Fear of hypoglycemia was assessed with the 11-item short-form of the Hypoglycemia Fear Survey (HFS-SF).[20] This includes three subscales: the "worry" subscale (six items) assessing hypoglycemia-related concerns, and two behavior subscales measuring tendencies towards "avoidance" of situations in which hypoglycemia may be a risk or difficult to manage (three

items), and a preference to "maintain high" glucose (two items). Awareness of hypoglycemia was assessed with the single-item Gold score.[21]

Analysis

We developed a statistical analysis plan a priori to conducting this secondary analysis, outlining predefined study outcomes, covariates, and analysis methods. Analyses were conducted in Stata SE V.17.0 using intention-to-treat principles. The psychological outcomes were assessed with linear mixed models using restricted maximum likelihood estimation. The effect of the intervention was assessed by a time-by-intervention interaction, adjusted for enrollment (pre-randomization) and a mid-trial score of the psychological outcome (unadjusted model). An adjusted model, with enrollment covariates added, was also assessed. Covariates included in the adjusted model were selected based on known associations, that is, age, sex, diabetes duration, HbA1c, severe hypoglycemia in the past 12 months (≥1 or <1 event), and pre-trial insulin delivery modality (MDI or CSII). Model residuals were visually assessed to ensure linear assumptions were met. Mean differences of the psychological outcome at enrollment, mid-trial, end-trial are presented with 95% CIs and p values. Significance is reported at the p<0.05 level. No interim analyses were planned or implemented.

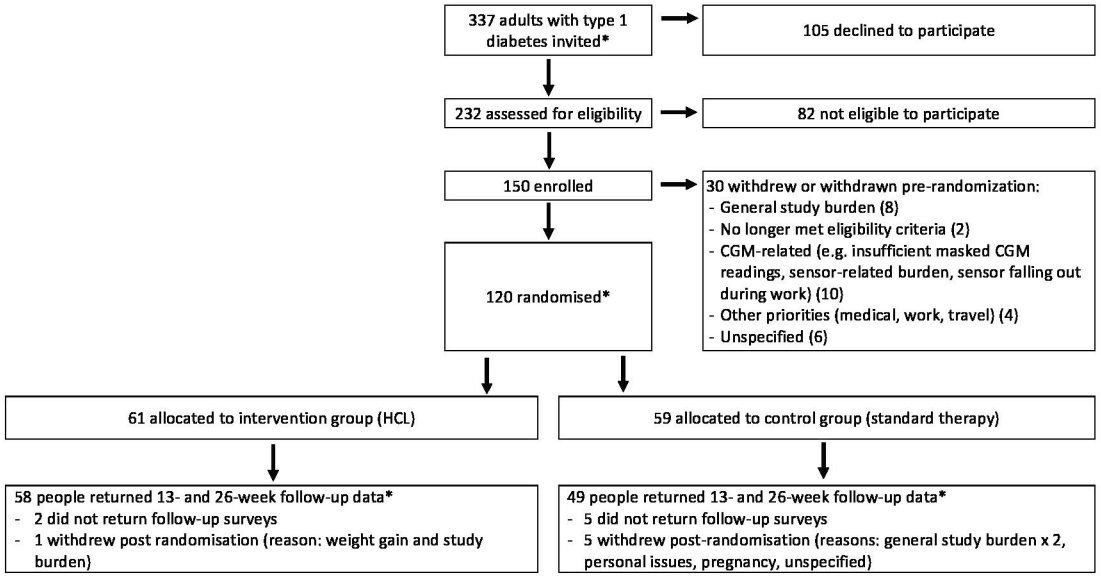
Missing data were imputed at the scale level using multivariate imputation by chained equations as specified by the RCT protocol. All imputations were performed separately for each treatment arm. Enrollment and mid-trial variables were included in the model based on their correlation with the outcome. 13 participants had missing data for Visit 11 and Visit 16. 20 imputations were conducted at the scale level for each psychological outcome.

RESULTS

Of the 120 participants who were randomized (intervention n=61 or control n=59) and completed psychological measures at enrollment, 107 (89%) completed psychological measures at weeks 13 and 26 (figure 2). At enrollment, participants were aged 44±12 (mean±SD) years and 53% were women (table 1). They had lived with T1D for an average of 24±12 years. Their mean HbA1c was 61±11 mmol/mol (7.8±1.0%). Most were born in Australia (76%), spoke English as their primary language (98%), were university educated (57%) and had full-time employment (60%).

table 2 shows modeled mean between-group differences in the psychological outcomes, in unadjusted and adjusted models, at mid-trial (13 weeks) and end-trial (26 weeks). Within the unadjusted models, a statistically significant between-group difference, favoring the intervention, was observed for diabetes-specific positive well-being at mid-trial (Δ=1.0, 95% CI (0.1, 1.9), p=0.025) and sustained at the end-trial (Δ=0.9, 95% CI (0.0, 1.8), p=0.042). Additionally, there was a between-group difference at the end-trial in the perceived frequency of unacceptably high glucose levels (DTSQ item 2), favoring the intervention (Δ=−1.1, 95% CI (−1.6, −0.6), p<0.001). No other statistically significant between-group differences were observed at either time point.

In the adjusted models, the statistically significant between-group differences, favoring the intervention, were retained for diabetes-specific positive well-being at mid-trial (Δ=1.1, 95% CI (0.2, 2.0), p=0.014) and end-trial (Δ=1.0, 95% CI (0.1, 1.9), p=0.023) and for



*Participants were recruited between 26 April 2017 and 24 January 2019, and randomised between 28 June 2017 and 2 May 2019. Data collection (26-week follow-up) was completed on 31 October 2019.

Figure 2 Study flow diagram. CGM, continuous glucose monitor; HCL, hybrid closed-loop.

perceived frequency of unacceptably high glucose levels at end-trial (Δ=−1.1, 95% CI (−1.6, −0.6), p<0.001). Additionally, statistically significant between-group differences, favoring the intervention, emerged at end-trial for diabetes distress (Δ=−6.4, 95% CI (−12.5,−0.3), p=0.039), and fear of hypoglycemia: "maintain high" (Δ=−0.8, 95% CI (−1.6 to −0.1), p=0.034) and "worry" (Δ=−1.8, 95% CI (−3.5, 0.0), p=0.048). No other statistically significant between-group differences were observed at either time point. Visual inspection of model residuals showed satisfactory assumptions of linearity and heteroscedasticity. No difference in the study conclusion was observed within either the unadjusted or adjusted models when comparing multiple imputed data to non-imputed data.

DISCUSSION

In this 26-week, open-label, RCT of HCL versus standard therapy (CSII or MDI without real-time CGM), those allocated to HCL reported significantly greater diabetes-specific positive well-being at 13-week follow-up, which was maintained at 26 weeks. At 26 weeks, the HCL group also reported significantly less frequent perceived unacceptably high glucose levels. Adjusted analyses also showed reduced diabetes distress and fear of hypoglycemia ("maintain high" and "worry" subscales) favoring HCL.

Diabetes-specific positive well-being has not been examined in previous HCL studies and is under-researched generally. The items forming the 4-item scale refer to experiencing a sense of satisfaction from managing diabetes, feeling positive about it, and feeling able to cope with diabetes challenges.[16] Gaining this advantage early (within 13 weeks) is an important testament to HCL delivering on the universally high expectations of this advanced technology. This finding also highlights the importance of mid-trial data collection. That it was

Table 1 Participant characteristics at enrollment (visit 1)

	Randomized group					
	Intervention (n=61)		Control (n=59)		Whole sample (N=120)	
Sex						
Female	33	54.1	31	52.5	64	53.3
Male	28	45.9	28	47.5	56	46.7
Age, years	43.6	±11.6	44.5	±11.8	44.1	±11.6
Diabetes duration, years	24.0	±12.0	24.1	±12.5	24.1	±12.2
Pre-trial insulin delivery modality						
MDI	30	49.2	31	52.5	61	50.8
CSII	31	50.8	28	47.5	59	49.2
Country of birth: Australia	43	70.5	48	81.4	91	75.8
Primary language spoken at home: English	60	98.4	58	98.3	118	98.3
Highest educational qualification						
High school or lower	4	6.6	9	15.3	13	10.8
Trade/apprenticeship	4	6.6	2	3.4	6	5.0
Certificate/diploma	22	36.1	11	18.6	33	27.5
University undergraduate or postgraduate	31	50.8	37	62.7	68	56.7
Employment						
Full-time work	35	57.4	37	62.7	72	60.0
Part-time work	15	24.6	14	23.7	29	24.2
Not working (retired or other reason)	11	18.0	8	13.6	19	15.8
HbA1c						
%	7.8	±1.1	7.7	±0.9	7.8	±1.0
mmol/mol	62	±12.1	60	±10.4	61	±11.3
Severe hypoglycemic events in past 12 months: ≥1	8	13.1	6	10.2	14	11.7
Impaired awareness of hypoglycemia: Gold score≥4	21	34.4	18	30.5	39	32.5
Severe diabetes distress: PAID score≥40	15	24.6	12	20.3	27	22.5

Data are n % or mean±SD.
CSII, continuous subcutaneous insulin infusion; HbA1c, glycated hemoglobin; MDI, multiple daily insulin injections; PAID, Problem Areas in Diabetes scale.

Table 2 Diabetes-specific psychological outcome scores for HCL and standard therapy groups at enrollment, mid-trial and end-trial, with mean differences examined using both unadjusted and adjusted models

		HCL		Control		Unadjusted models*			Adjusted models†		
Outcome	Time point	Mean	SD	Mean	SD	Mean difference	95% CI	P value	Mean difference	95% CI	P value
Diabetes distress‡	Enrollment	26.6	19.4	24.1	17.3						
	Mid-trial	20.3	15.3	26.2	19.9	−4.4	(−11.0, 2.2)	0.191	−5.5	(−11.6, 0.6)	0.078
	End-trial	20.5	14.7	26.3	21.7	−5.3	(−11.9, 1.3)	0.117	−6.4	(−12.5,−0.3)	0.039
Diabetes-specific positive well-being§	Enrollment	6.5	2.4	6.9	2.4						
	Mid-trial	7.7	2.3	6.7	2.5	1.0	(0.1, 1.9)	0.025	1.1	(0.2, 2.0)	0.014
	End-trial	7.8	2.4	6.9	2.7	0.9	(0.0, 1.8)	0.042	1.0	(0.1, 1.9)	0.023
Diabetes-specific quality of life¶	Enrollment	4.7	0.8	4.7	0.7						
	Mid-trial	4.5	0.9	4.8	0.6	−0.2	(−0.5, 0.1)	0.110	−0.2	(−0.5, 0.1)	0.111
	End-trial	4.5	0.9	4.8	0.7	−0.3	(−0.6, 0.0)	0.073	−0.3	(−0.6, 0.0)	0.067
Diabetes treatment satisfaction**											
"Total satisfaction"	Enrollment	26.0	5.1	26.1	5.1						
	Mid-trial	27.7	6.1	27.1	4.7	0.6	(−1.4, 2.6)	0.537	0.6	(−1.4, 2.6)	0.549
	End-trial	28.2	5.9	27.3	5.2	0.9	(−1.1, 2.9)	0.367	0.9	(−1.0, 2.9)	0.356
"Perceived frequency of high glucose"	Enrollment	3.4	1.4	3.2	1.4						
	Mid-trial	2.6	1.3	2.9	1.3	−0.3	(−0.8, 0.2)	0.186	−0.4	(−0.8, 0.2)	0.161
	End-trial	2.3	1.2	3.4	1.3	−1.1	(−1.6, −0.6)	<0.001	−1.1	(−1.6, −0.6)	<0.001
"Perceived frequency of low glucose"	Enrollment	2.4	1.5	2.2	1.4						
	Mid-trial	1.6	1.2	2.0	1.2	−0.4	(−0.9, 0.1)	0.140	−0.4	(−0.9, 0.1)	0.099
	End-trial	1.8	1.3	1.8	1.2	−0.1	(−0.6, 0.4)	0.699	−0.1	(−0.6, 0.4)	0.582
Fear of hypoglycemia††											
"Avoidance"	Enrollment	1.3	1.9	0.9	1.8						
	Mid-trial	1.2	2.1	1.3	2.7	−0.1	(−0.8, 0.7)	0.867	−0.2	(−0.9, 0.6)	0.636
	End-trial	1.2	2.0	1.1	2.3	0.1	(−0.6, 0.9)	0.748	0.0	(−0.7, 0.7)	0.970
"Maintain high"	Enrollment	3.4	2.4	3.4	2.2						
	Mid-trial	2.4	2.2	3.0	2.0	−0.6	(−1.4, 0.2)	0.147	−0.7	(−1.4, 0.1)	0.080
	End-trial	2.4	1.9	3.1	2.1	−0.7	(−1.5, 0.1)	0.071	−0.8	(−1.6, −0.1)	0.034
"Worry"	Enrollment	8.4	5.6	7.4	5.2						
	Mid-trial	5.9	4.8	7.2	5.8	−0.9	(−2.8, 1.0)	0.364	−1.2	(−3.0, 0.5)	0.165
	End-trial	5.5	4.4	6.8	5.5	−1.4	(−3.3, 0.5)	0.150	−1.8	(−3.5, 0.0)	0.048
Hypoglycemia awareness‡‡	Enrollment	3.0	1.8	2.8	1.6						
	Mid-trial	2.6	1.7	2.7	1.6	−0.0	(−0.7, 0.6)	0.897	−0.1	(−0.7, 0.5)	0.738
	End-trial	2.5	1.5	2.5	1.7	−0.2	(−0.8, 0.4)	0.598	−0.2	(−0.8, 0.4)	0.461

*Unadjusted models: adjusted only for enrollment and mid-trial score of the psychological outcome. Reference group: control.
†Adjusted models: as per unadjusted models, with additional adjustment for age, sex, diabetes duration, HbA1c, severe hypoglycemic episodes in the past 12 months (<1 or ≥1), and previous diabetes treatment (MDI or CSII). Reference group: control.
‡Diabetes distress: PAID scale, total score 0–100, higher scores indicate more diabetes distress, and scores of ≥40 indicate severe diabetes distress.
§Diabetes-specific positive well-being: W-BQ28, total score 0–12, higher scores indicate greater diabetes-related positive well-being.
¶DIDP, composite score 1–7, higher scores indicate more negative impacts of diabetes on quality of life.
**Diabetes treatment satisfaction: DTSQs total score, scored 0–36, higher scores indicating greater diabetes treatment satisfaction. DTSQs high glucose (item 2), scored 0–6, higher scores indicating greater perceived frequency of unacceptably high glucose levels. DTSQs low glucose (item 3), scored 0–6, higher scores indicating greater perceived frequency of unacceptably low glucose levels.
††Fear of hypoglycemia: HFS-SF "avoidance" subscale, scored 0–12, higher scores indicating more behaviors to prevent hypoglycemia and its negative consequences. HFS-SF "maintain high" subscale, scored 0–8, higher scores indicating more behaviors keep glucose levels higher to prevent hypoglycemia. HFS-SF "worry" subscale, scored 0–24, higher scores indicating more worries about hypoglycemia.
‡‡Hypoglycemia awareness: Gold score, scored 1–7, scores ≥4 indicate impaired hypoglycemia awareness.
CSII, continuous subcutaneous insulin infusion (i.e. insulin pump); DIDP, DAWN Impact of Diabetes Profile; DTSQs, Diabetes Treatment Satisfaction Questionnaire status version; HbA1c, glycated hemoglobin; HCL, hybrid closed-loop; HFS-SF, Hypoglycemia Fear Survey short-form; MDI, multiple daily insulin injections; PAID, Problem Areas in Diabetes scale; W-BQ28, 28-item Well-being Questionnaire.

sustained at 26 weeks, in both unadjusted and adjusted analyses, is also important. Given the relentless nature of diabetes self-management, any improvement in diabetes-specific positive well-being needs to be valued by healthcare professionals, industry, and policymakers. Diabetes-specific positive well-being is worthy of further investigation in future diabetes technology trials.

Severe diabetes distress was experienced by about one-quarter of the sample at enrollment, similar to an Australian national survey.[22] There was a statistically significant reduction in diabetes distress in the HCL group at 26 weeks, observed only after adjusting for covariates. The fact that the reduction was not significant at 13 weeks, but became evident by 26 weeks in adjusted analyses, likely reflects the complexity of diabetes distress. It may take time or experience with a new technology before distress begins to subside, and there may be interindividual differences in the aspects of diabetes distress that are resolved or exacerbated.[23] Qualitative studies highlight that some people using HCL experience hassles, annoyance, and disruption of daily activities (eg, sleep, exercise) due to technical/connectivity problems and alarms.[8 9] It is possible that HCL reduced many aspects of diabetes distress, but HCL hassles and trial conditions (figure 1) attenuated such benefits. A 6-month RCT of HCL versus SAP and an 8-month crossover trial of HCL versus SAP both reported no reduction in diabetes distress at follow-up.[24 25] However, in our study, the control group continued with their usual management (MDI or CSII without real-time CGM). Thus, the contrast between intervention and control is much greater here, and the between-group difference may be partly attributable to greater visibility of, and improvement in, glucose levels due to HCL. Conversely, three[26–28] of four[29] 12-week single-arm prospective studies demonstrated reduced diabetes distress following HCL or advanced HCL use. Future trials need to examine the effect of HCL on aspects of diabetes distress. For example, in a trial of tubeless HCL, five of the seven subscales of the T1-Diabetes Distress Scale, contributed to lower diabetes distress (powerlessness, diabetes management, hypoglycemia, eating, and physicians), but there was no effect on distress related to negative social perceptions and friends/family.[27] We did not analyze the previously identified PAID subscales[30 31] because they lack structural validity,[30] while the validity of the total score has been replicated consistently.[15]

Adjusted analyses also show fear of hypoglycemia reduced in the HCL group, in terms of both "worry" (ie, about recognizing or negative consequences of hypoglycemia) and compensatory behaviors to "maintain high" glucose levels. In parallel, we have shown previously that time below range (TBR) was significantly reduced in the HCL group compared with control.[6] Qualitative research shows that, when HCL works well, adults with T1D feel peace of mind and less worry about hypoglycemia.[8] Therefore, it is possible that the HCL safeguards (eg, warning alarms and insulin delivery modification to reduce severe hypoglycemia risk) likely contributed to reductions in hypoglycemia-related worries and compensatory behaviors to "maintain high" glucose levels. Another 6-month trial showed that HCL reduced such behaviors, but not worries, compared with SAP.[24] However, most studies (smaller: N≤58 participants; and shorter: ≤3 months) have reported mixed findings. For example, three single-arm prospective studies observed reductions in fear of hypoglycemia following HCL or advanced HCL,[26 28 29] while four crossover trials comparing HCL or advanced HCL to SAP observed no between-group differences.[9 25 32 33] The lack of difference may be attributable to the use of CGM in the SAP group. The wider CSII and CGM literature also reports mixed findings regarding the effects of diabetes technologies on the fear of hypoglycemia.[11 34]

In our study, there were no between-group differences at either follow-up in the HFS-SF "avoidance" subscale, suggesting that HCL did not enable participants to re-engage with activities that may feel risky to them if hypoglycemia occurred. That there was also no improvement in awareness of hypoglycemia symptoms (see below) is of interest, as a recent cluster analysis of the HFS-II has shown that "avoidance" (renamed "restricted activity") is associated with impaired awareness of hypoglycemia (IAH).[35] Our RCT found no significant between-group differences in awareness of hypoglycemia at mid-trial or end-trial. At enrollment, one-third of participants had a score indicative of impaired awareness, which may suggest limited scope for demonstrating population-level improvement. However, we acknowledge this rate is somewhat higher than the average 20–25% reported in most population-based studies.[36] Similarly, a crossover trial, also with one-third of participants with impaired awareness, found no differences in awareness between HCL and SAP (across two 4-month periods).[25] A 3-month observational study of advanced HCL, including 21% with IAH at baseline, showed significant improvement in hypoglycemia awareness (using the Clarke score) but the reduction in the proportion above the cut-point for IAH (Clarke>3: 21–15%) was not significant.[28] Two single-arm prospective studies, conducted primarily with adults, also used the Clarke score, and reported improved hypoglycemia awareness following HCL or advanced HCL.[26 29] However, they included a higher proportion of people with impaired awareness at baseline. Further, the Clarke score,[37] is known to confound impaired awareness with severe hypoglycemia.[38] Thus, score changes may reflect a reduction in severe hypoglycemia rather than an improvement in awareness of symptoms. There is no evidence that technologies (involving some form of CGM) improve awareness of hypoglycemia symptoms, rather, they provide "technological awareness" only while the sensor is worn.[39] Thus, restoration of hypoglycemic symptoms may be reliant on psychoeducational approaches, which have shown benefits.[40–42]

There were no significant between-group differences in total satisfaction with diabetes treatment at either time point in the unadjusted or adjusted models, despite

baseline scores not being at the ceiling (ie, scope to indicate increased satisfaction at follow-up). While no previous trials investigating treatment satisfaction have compared HCL to standard therapy among adults, three crossover trials have used DTSQ to examine satisfaction with HCL or advanced HCL versus SAP therapy over 4, 8 or 12 weeks,[9 13 32] and two observational studies of advanced HCL have used the DTSQc.[43 44] Treatment satisfaction increased only with advanced HCL,[32 43 44] suggesting that advanced HCL has improved on earlier iterations of HCL in ways that are meaningful to those using the technologies every day. The DTSQ has also shown greater treatment satisfaction at follow-up in two[26 27] out of three single-arm prospective HCL or advanced HCL studies.[29] Additionally, we found that HCL participants perceived unacceptably high glucose less frequently at 26 weeks. Relatedly, a prospective study of tubeless HCL (Omnipod 5) has reported less frequency of both unacceptably low and high blood glucose following 3 months of HCL.[27]

Finally, we also assessed the impact of diabetes on QoL. Our models showed no significant between-group differences at either time point in unadjusted or adjusted models. Three real-world prospective studies, with predominantly adult participants, found improved diabetes-specific QoL following 12 weeks of HCL or advanced HCL, but the lack of control groups are limitations.[26 28 29] Conversely, a crossover study among older adults comparing 4 months of HCL and SAP reported no between-group differences in diabetes-specific QoL.[25] Above, we have noted the lack of positive impact of HCL on "avoidance" of situations in which hypoglycemia may feel risky, which may be contributing to this lack of benefit for diabetes-specific QoL. In addition, it may be explained by the counterbalancing effect of the potential benefits of HCL against the potential burdens of the uptake of a new diabetes technology combined with the intensive participation requirements of the trial (figure 1).[8 9] Importantly, preferences for diabetes technologies are highly personal, thus catering to individual needs and preferences is paramount to optimized and sustainable diabetes self-management.[2]

Uptake of HCL may improve well-being, treatment satisfaction or diabetes-specific QoL for some people and worsen them for others, depending on their priorities and preferences. Randomization can hide these individual differences. Furthermore, the meaningful effects of HCL on diabetes distress and fear of hypoglycemia after adjusting for known covariates, suggest that the effects were confounded by certain characteristics, and the randomization may not have held for these psychological outcomes.[45] For example, fear of hypoglycemia is predicted by prior experience of severe hypoglycemia with traumatic experiences having long-term impacts which may not be fully mitigated by relatively brief access to advanced technologies.[41] Therefore, the unadjusted effect estimates for these constructs should be interpreted with caution.

There are noteworthy differences between our former[6] and current reports, due to different aims and therefore, different analyses of the data set. First, in the former analyses, treatment satisfaction, and diabetes-specific positive well-being, diabetes-specific QoL, and diabetes distress were secondary outcomes, explored per protocol,[14] with adjustment only for score at enrollment. In the current analyses, the models controlled for enrollment and mid-trial scores, and covariates. Second, the current analyses investigated fear of, and impaired awareness of, hypoglycemia, and perceived frequency of unacceptably high and low glucose levels, which were not included in the former report. Third, instead of using log-transformed PAID scores, the current paper presents mean PAID percentage scores. Finally, due to the differing approaches, some results differ. For instance, the current analysis identified improvement in diabetes distress and no change in diabetes-specific QoL at 26 weeks due to HCL. In contrast, the former reported no improvement in diabetes distress and a small improvement in diabetes-specific QoL at 26-week follow-up.

Strengths and limitations

Our RCT represents the largest, longest, and most comprehensive psychological study of HCL compared with standard therapy (without real-time CGM) to date. The strengths and limitations of the overall trial are described elsewhere.[6] Many previous quantitative examinations of the psychological impacts of HCL have been limited by small samples, short follow-up, lack of a control group, or lack of adjustment for covariates.[3 4 11] Additionally, participants in previous HCL trials are likely to have been "early adopters" of technology, with prior experience with diabetes technologies (eg, CSII or CGM).[4] This limits the generalizability of those study findings, as they are unlikely to provide insights into the experiences of people with less access to, or familiarity with, advanced diabetes technologies. Our study has overcome some of these earlier limitations in three ways. First, our study enrolled people whose pre-trial insulin delivery modality was MDI or CSII, (1:1 ratio) and the control group continued with their standard therapy (including no real-time CGM access or allocation to another advanced technology). Second, our large sample allowed for robust analyses controlling for covariates. Finally, our 13 and 26-week follow-ups allowed time for participants to adjust to the HCL and for experiences to be consolidated. Our study compared HCL against standard care (without real-time CGM). At the time of this RCT, only 23% of Australian adults with T1D used CGM.[46] Therefore, a non-CGM control group was a justifiable comparator and an appropriate reflection of standard care. While CGM has become the standard of care in the past year, it will continue to be beyond reach for many people with T1D across the world for several years to come.[47] Government subsidies can reduce financial inequities to access.[48] However, at the time of this RCT, CGM subsidies were not universally available to all Australian adults with T1D. Personal

preferences also remain important considerations for the uptake and sustained use of diabetes technologies.[49]

A potential limitation is that our analyses adjusted for HbA1c, but not time in range (TIR) or TBR, which were excluded from the models due to the data collection timings (figure 1); this would be an interesting area for future research. Psychological data were collected prior to brief diabetes education (provided equally to all participants), while TIR/TBR data were collected after diabetes education. The direct impact of diabetes education was not measured, but at follow-up, glycemic and psychological benefits were observed only in the HCL arm, suggesting technology had a stronger impact than brief education.[6] The findings may not be generalizable to all people with diabetes (eg, people attending non-specialist tertiary diabetes clinics). Most participants had a university degree, which is higher than the national average education level,[50] higher socioeconomic status,[6] and spoke English as their primary language, and the mean HbA1c was near the recommended target (7.8%) at baseline.

The rapid speed at which diabetes technologies are advancing makes conducting and timely reporting of comprehensive evaluations of the latest technology in a RCT setting challenging, as technology is upgraded by the time findings are reported.[51] However, our trial provides important and novel insights into the ways in which HCL can affect psychological outcomes. This study focused on a first-generation commercially available HCL device. The translation of these findings remains to be confirmed and further research with other HCL systems (eg, advanced, next-generation, bihormonal, and open-source systems) will increase insights into the fast-growing options available to support T1D self-management.

CONCLUSIONS

In this RCT, adults with T1D using HCL experienced improvements in diabetes-specific positive well-being, apparent from 13 weeks, and sustained at 26 weeks, as well as a reduction in perceived frequency of unacceptably high glucose levels at 26 weeks. Significant reductions in diabetes distress and fear of hypoglycemia were apparent at 26 weeks, in adjusted models only, suggesting interindividual differences in these outcomes. These novel findings demonstrate that HCL offers important psychological benefits over standard therapy to adults with T1D. There was no significant change in awareness of hypoglycemia, diabetes treatment satisfaction, perceived frequency of unacceptably low glucose levels, or diabetes-specific QoL. Similar comprehensive evaluations of psychological outcomes are desirable in future clinical trials and real-world studies of rapidly evolving diabetes technologies to ensure that psychological benefits are achieved in parallel with biomedical benefits.

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Contributors DO led the overall trial, which was co-designed by EAD, AJJ, TWJ, ACK, SAM, DO, JS, VS, and ST, and refined with input from LAB, MGB, NDC, PGC, DJH-W, JK, SNS, GW, CH, and JAH. Participant screening and enrollment, collection of informed consent, and provision of medical care were led by SAM, BP, MHL, DO, LAB, MGB, NDC, PGC, DJH-W, JK, RWM, SNS, and GW. The psychological substudy was designed by JS, CH, ST, and JAH. The Qualtrics survey was prepared by JAH and SR-G. Data cleaning was completed by JAH and SR-G, overseen by CH. The research question was devised by JAH, CH, and JS. The statistical analysis plan was prepared by JAH, CH, and BL, and reviewed by JS, DO, AJJ, TWJ, PGC, and ACK. BL analyzed the data, with support from JAH. JAH, CH, JS, and BL interpreted the results. JAH prepared the first draft of the paper and subsequent revisions, with input from CH and JS, and from BL for the analysis section. All authors reviewed the paper for critical content and approved the final version. DO and CH are the guarantors of this work and, as such, had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analyses.

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