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Care Delivery

OptimAAPP, a smartphone insulin dose calculator for carbohydrate, fat, and protein: A cross-over, randomised controlled trial in adolescents and adults with type 1 diabetes using multiple daily injection therapy

Tenele A. Smith[1,2] | **Nisha Venkatesh**[3,4] | **Kerryn Roem**[4] | **Jean C. Lu**[3,4] | **Emma Netzer**[4] | **Adrian Medioli**[5] | **Stuart Szwec**[2] | **David N. O'Neal**[3,4] | **Bruce R. King**[1,2,6] | **Carmel E. Smart**[1,2,6]

[1]College of Health, Medicine and Wellbeing, University of Newcastle, Callaghan, New South Wales, Australia

[2]Hunter Medical Research Institute, New Lambton Heights, New South Wales, Australia

[3]Department of Endocrinology, St Vincent's Hospital Melbourne, Fitzroy, Victoria, Australia

[4]Department of Medicine, University of Melbourne, Fitzroy, Victoria, Australia

[5]College of Engineering Science and Environment, University of Newcastle, Callaghan, New South Wales, Australia

[6]Department of Paediatric Endocrinology, John Hunter Children's Hospital, New Lambton Heights, New South Wales, Australia

Correspondence
Carmel E. Smart, Department of Paediatric Endocrinology, John Hunter Children's Hospital, Lookout Rd, New Lambton Heights, NSW, Australia.
Email: carmel.smart@health.nsw.gov.au

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Abstract

Aims: To (1) evaluate the efficacy of OptimAAPP, a smartphone insulin dose calculator for carbohydrate, fat, and protein in managing glycaemia compared with carbohydrate counting in adolescents and adults with type 1 diabetes using flexible multiple daily injection therapy (MDI, ≥4 injections/day) and (2) assess user acceptability of OptimAAPP.

Methods: In this free-living trial, participants aged 12–50 years were randomised to use carbohydrate counting or OptimAAPP for meal insulin dose calculation for 3 months, then use the alternate method for 3 months. The primary outcome, time-in-range (3.9–10.0 mmol/L) was measured in weeks 3–4 of each arm using continuous glucose monitoring. The acceptability of OptimAAPP was assessed at end intervention using a purpose-designed questionnaire.

Results: An intention-to-treat analysis of 41 participants, mean age 28 ± 12 years and HbA1c 56 ± 10 mmol/mol (7.3 ± 0.9%) found no significant difference in glycaemic outcomes when using OptimAAPP compared with carbohydrate counting including time-in-range (70.5 vs. 67.6%, $p = 0.102$), above range (24.5% vs. 28.0%, $p = 0.068$), below range (4.9% vs. 4.4%, $p = 0.318$), and coefficient of variation (32.2% vs. 33.3%, $p = 0.136$). There was no severe hypoglycaemia. Participants reported that OptimAAPP was easy to use (79%), and they were confident in giving the recommended doses (82%). Barriers to use were the small food database and the time associated with food entry.

Conclusions: In adolescents and adults using flexible MDI therapy, OptimAAPP use did not produce glycaemic outcomes that were significantly different from carbohydrate counting. Participant views of OptimAAPP indicate a high level of acceptability. Increasing the size of the food database will likely enhance the user experience.

This study was prospectively registered with the Australian New Zealand Clinical Trials Registry (ACTRN12619000373178p).

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KEYWORDS
blood glucose, child, continuous glucose monitoring, diabetes mellitus, nutrients, smartphone, type 1

1 | INTRODUCTION

In people living with type 1 diabetes, postprandial glycaemia has been identified as the single largest contributing factor to HbA1c[1] and therefore, is a critically important therapeutic target for the prevention of diabetes-related vascular complications. To achieve target postprandial glycaemia, research by our group[2–4] and others[5,6] supports the consideration of dietary macronutrients other than carbohydrate when calculating the meal insulin dose. Dietary fat and protein have been shown to significantly increase and delay the peak postprandial glucose excursion and cause sustained postprandial hyperglycaemia.[7] Further, the magnitude of this excursion has been shown to vary significantly between individuals despite the same meal carbohydrate content,[8] necessitating individualised titration of the insulin dose for fat and protein.

Clinical consensus guidelines now acknowledge the significant contribution of fat and protein to postprandial glycaemia. These guidelines recommend that in addition to carbohydrate, people with type 1 diabetes receive education on the glycaemic impact of fat and protein and increase the insulin dose to compensate for their prolonged glycaemic effect, with an emphasis on titration based on the individual response.[9] In this population, reducing the complexity of meal insulin dose calculations via integration of standard (based on carbohydrate) automated bolus calculator (ABC) algorithms into glucose meters and insulin pumps has been shown to reduce treatment burden[10] and improve the accuracy[11] and subsequently, the effectiveness and safety of meal insulin dosing. This is demonstrated by improvements in glycaemic control[12] and reductions in the frequency and fear[13] of hypoglycaemia. With the rise in smartphone use globally, mobile applications have emerged as an ideal platform for ABC algorithm integration.

To date, several smartphone-based calculators for fat and protein have been described.[14,15] Whilst these calculators have demonstrated reductions in postprandial glucose, trials of their efficacy have been limited to French and Polish-speaking populations, and have been short in duration (4–7 days). This has thus far prevented broader translation.

To permit the implementation of best-practice guidelines into routine care, there is a need for a tool to guide the calculation of the insulin dose for mixed meals of varying composition. This tool must be able to be feasibly employed by people living with type 1 diabetes without adding substantially to the complexity and burden of management. OptimAAPP is a novel, smartphone insulin dose calculator that considers the carbohydrate, fat, and protein content of the meal and individual sensitivities to each of these macronutrients.

What's new?

- OptimAAPP is a smartphone insulin dose calculator designed to facilitate the implementation of guideline-recommended carbohydrate, fat, and protein dosing.
- OptimAAPP aided people using flexible multiple-daily injection therapy in achieving recommended targets; time-in-range >70%, time above range <25% and coefficient of variation ≤36% without a significant increase in time below range or severe hypoglycaemia.
- Use was also associated with increased efficiency and accuracy and reduced mental burden of dose calculation.
- Findings suggest OptimAAPP is an effective tool for dosing for all macronutrients that assists in achieving target glycaemia whilst reducing the burden of insulin management.

The principle aims of this study were to (1) evaluate the efficacy of OptimAAPP in managing glycaemia compared with carbohydrate counting and (2) assess the acceptability of OptimAAPP to adolescents and adults with type 1 diabetes using multiple daily injection (MDI) therapy.

2 | PARTICIPANTS AND METHODS

2.1 | Study design and Participants

This was a randomised controlled, cross-over trial conducted under free-living conditions at two Australian tertiary sites, John Hunter Children's Hospital, Newcastle (adolescents) and St Vincent's Hospital, Melbourne (adults). Adolescents and adults with type 1 diabetes for ≥1 year, using flexible MDI therapy (≥4 injections/day) were recruited. Inclusion criteria were age 12–50 years

and HbA1c ≤64 mmol/mol (≤10.0%). Individuals with complications of diabetes, non-English speaking or who had any other major medical condition were excluded. This study was conducted in accordance with the National Statement on Ethical Conduct in Human Research (2007) and the Declaration of Helsinki (2013). Ethical approval was granted by the Hunter New England Research Ethics Committee (2019/ETH00068) and prospectively registered with the Australian New Zealand Clinical Trials Registry (ACTRN12619000373178p). Informed, written consent was sought from all participants and for participants <18 years, a parent prior to study enrolment.

2.2 | Study procedure

The study had two arms. Participants were stratified by age group (paediatric or adult) and each participant was randomised in a 1:1 ratio according to a computer-generated randomisation schedule (generated and allocated by statistician) to use carbohydrate counting (control arm) or OptimAAPP (intervention arm) for meal insulin dose calculation for an initial 3-months and cross-over to the alternate study arm for a further 3 months. There was a 2-week period before each study arm where insulin-to-carbohydrate ratios were optimised.

2.3 | Intervention: OptimAAPP, smartphone insulin dose calculator

The OptimAAPP algorithm considers the carbohydrate, fat, and protein content of the meal, the individual's sensitivity to these macronutrients, the pre-meal blood glucose level, sensitivity to insulin, and active insulin on-board. Determination of the meal macronutrient content (g) is supported by an integrated, customisable database of 695 commonly eaten foods in the Western diet.

OptimAAPP initialisation requires the health care professional to enter the user's individual mealtime insulin-to-carbohydrate ratios, insulin sensitivity factors, and the average amount of carbohydrate (g), fat (g), and protein (g) consumed at main meals. The OptimAAPP algorithm has been designed using evidence-based clinical research undertaken by our group over the previous 12 years.[2–4,7,16,17] OptimAAPP uses the average meal carbohydrate, fat, and protein intake and the meal insulin-to-carbohydrate ratio inputted by the user to determine a revised insulin-to-carbohydrate ratio as well as a meal insulin-to-fat ratio and insulin-to-protein ratio for the individual. OptimAAPP provides a recommended total dose only. It does not provide advice regarding the number of doses, the timing of dosing, or type of mealtime insulin. Our previous published work has demonstrated that in this population, splitting the insulin dose or replacing rapid-acting meal insulin with regular insulin provides no additional benefit over a single dose of rapid-acting insulin prior to the meal. Hence, all participants were instructed to use rapid-acting insulin and give the total recommended insulin dose before eating.

OptimAAPP meal insulin dose calculation requires the user to enter their pre-meal blood glucose level and select both the type of food/s and quantity of food/s to be consumed. Screenshots of the application interface including the meal builder screen are shown in Figure S1.

2.4 | Study visits

The study was divided into six visits. The activities undertaken, measures, and the time allocated to each visit are summarised in Table 1 and Figure 1. All visits for participants 1–4 (paediatric) and 1–9 (adults) were conducted face-to-face in the clinic setting, all visits for the remaining participants were conducted virtually to comply with government-imposed lock-down restrictions associated with the COVID-19 pandemic.

3 | DATA ANALYSIS

3.1 | Study outcomes

The primary outcome measure was the proportion of time spent in the glucose target range [TIR (3.9–10 mmol/L)] for OptimAAPP compared with carbohydrate counting. Secondary outcome measures included glycaemic metrics including time spent above glucose target range [TAR (>10.0 mmol/L)] and below glucose target range [TBR (>3.9 mmol/L and >3.0 mmol/L)], postprandial TIR, TAR and TBR, and overnight (24:00–06:00 h) TIR, TAR, and TBR, glycaemic variability (coefficient of variation, CV), and change in HbA1c from baseline (study entry). Patient-reported measures included participant acceptability of OptimAAPP and ability to quantify fat and protein pre- and post-intervention.

The timeline of study measures is presented in Figure 1. TIR, TAR, TBR, postprandial TIR, TAR, and TBR, overnight TIR, TAR, and TBR and glycaemic variability were measured in weeks 3 and 4 of each study arm using the Dexcom G5® Mobile (Dexcom Inc., San Diego, CA, USA) continuous glucose monitoring system. HbA1c was measured at three timepoints: entry into the study, end control arm, and end intervention arm using a capillary or venous blood sample. Fat and protein quantification was assessed at two timepoints: entry into intervention arm and end intervention arm

TABLE 1 Sample study flow for participants' randomised control > intervention.

Usual care, carbohydrate counting (control arm)			
Visit	**Week**	**Activities**	**Duration (h)**
1	−2	Start control arm run-in period • Assess carbohydrate counting (questionnaire +3-day food diary) • Educate on carbohydrate counting (if required)	0.5–1
2	+3	• Educate on CGM insertion and use • Insert CGM	0.5
-	+4	Insert CGM	0.25
-	+6	Monitoring phone call-check compliance, troubleshooting	0.25
-	+8	Monitoring phone call-check compliance, troubleshooting	0.25
-	+10	Monitoring phone call-check compliance, troubleshooting	0.25
3	+12	End control arm Measure HbA1c	0.25
-	+13–14	Washout	-
OptimAAPP (Intervention Arm)			
4	+15	Start intervention arm run-in period • Assess carbohydrate counting (questionnaire) (0.25 h) • Educate on carbohydrate counting (if required) (0.5 h) • Assess fat and protein knowledge (questionnaire) (0.25 h) • Educate on glycaemic impact of fat and protein (0.5 h) • Initiate OptimAAPP and educate on use (0.5–1 h)	2–2.5
5	+18	• Provide refresher education on CGM insertion and use • Insert CGM	0.5
-	+19	Insert CGM	0.25
-	+21	Monitoring phone call-check compliance, troubleshooting	0.25
-	+23	Monitoring phone call-check compliance, troubleshooting	0.25
-	+25	Monitoring phone call-check compliance, troubleshooting	0.25
6	+27	End intervention arm • Measure HbA1c • Assess fat and protein knowledge (questionnaire) • Evaluate OptimAAPP user experience (questionnaire)	0.5

using a 16-item multiple-choice questionnaire in which participants were asked to classify six foods as low, medium, or high in fat (6-items), 6 foods as low, medium or high in protein (6-items) and determine the amount of fat and protein in a packaged product using the nutrition panel (4-items). Participant acceptability of OptimAAPP was assessed at a single timepoint, end intervention arm using a 15-item questionnaire comprised of multiple choice, open-ended and closed questions focusing on the attributes of learnability, satisfaction, trust, efficiency,

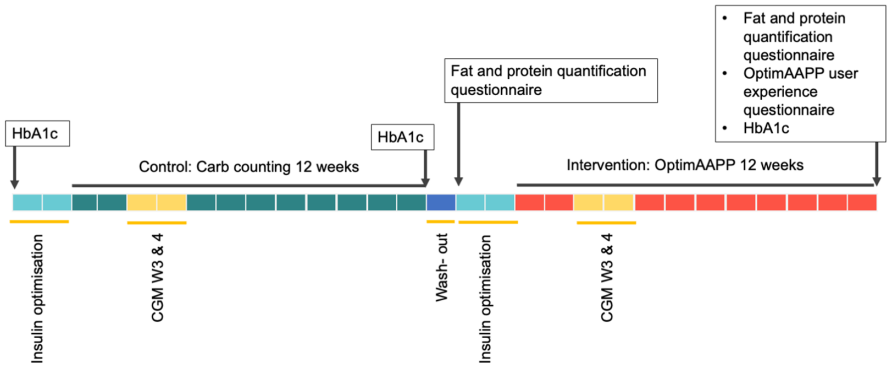

FIGURE 1 Timeline of study measures.

TABLE 2 Clinical characteristics of 41 children and adults using multiple daily injection therapy.

	All participants	Children (<18 years)	Adults (≥18–50 years)
Sample size	41	18	23
Age (years)	27.3 ± 12.4	15.2 ± 1.8 (12.6–17.9)	36.7 ± 8.0 (22.7–50.2)
Gender (male: female)	15:26	7:11	8:15
Duration of diabetes (years)	8.5 ± 7.5	5.9 ± 3.3	10.6 ± 9.2
HbA1c [mmol/mol (%)]	56 ± 10 (7.3 ± 0.9)	56 ± 11 (7.3 ± 1.0)	56 ± 10 (7.3 ± 0.9)
BMI (kg/m^2)	NA	23.8 ± 4.4 (17.3–36.4)	25.6 ± 4.1 (18.1–34.7)
Total daily insulin dose[a] (U/kg/day)	0.9 ± 0.3	0.8 ± 0.3 (0.6–1.4)	0.5 ± 0.2 (0.2–1.0)

Note: Data are presented as numbers, means ± SD, or means ± SD (range).

[a]Reported as a 5-day average.

and future improvements. Both questionnaires were piloted with adolescents ($n = 3$) and adults ($n = 3$) living with type 1 diabetes (not included as participants) and were designed to take less than 10 minutes to complete.

On completion of weeks 3 and 4 in each study arm, participant' continuous glucose monitoring data were downloaded using Dexcom CLARITY® software (Dexcom Inc., San Diego, CA, USA).

3.2 | Postprandial analysis

Postprandial periods were defined using 4-h time-blocks that have been previously validated in a population of Australian adults living with type 1 diabetes.[18] Breakfast was defined as 06:00–10:00 h, lunch 11:00–15:00 h, and dinner 17:00–21:00 h.

3.3 | Sample size

It was determined that a sample size of 48 would provide 80% power at the 5% significance level, to detect an absolute difference of 10% in the mean percentage time spent with glucose levels within the target range (3.9–10.0 mmol/L) between conditions, assuming the standard deviation of the percentage time in target is 20.

3.4 | Statistical analyses

An intention-to-treat approach was used for analyses. The intention-to-treat population was defined as all participants who were randomised and had completed at least one, 2-week continuous glucose monitoring wear period. Mixed-effects linear regression models were used to assess the difference in TIR, TAR, TBR, postprandial TIR, TAR, TBR, overnight TIR, TAR, TBR, glycaemic variability, and the mean change in HbA1c from baseline between treatment arms. As study participants were measured twice, a random effect for the participant was included to adjust for the correlation of outcomes within study participants. All statistical analyses were programmed using SAS v9.4 (SAS Institute Inc. Cary, NC, USA). Statistical significance was set a priori at $p < 0.05$.

4 | RESULTS

Twenty-three adolescents and 28 adults with type 1 diabetes were enrolled in the study with a total of 51 participants. All paediatric participants ($n = 18$) used the EzyBicc bolus calculator, a small number ($n = 3$, 13%) of adult participants used a bolus calculator integrated into their glucometer. The remaining adult participants ($n = 20$, 87%) used their own method/s of dose calculation based on their years of lived experience.

Fifteen participants withdrew from the study (8 adults and 7 adolescents). Of these, 10 did not complete at least one, 2-week continuous glucose monitoring wear period and were excluded from the final analysis (Figure S2). In total, data from 41 participants (18 adolescents, 23 adults) were included in the final analysis, the baseline characteristics of these participants are presented in Table 2. Of these, five completed only one of the two-week continuous glucose monitoring periods ($n = 1$ intervention arm only, $n = 4$ control arm only).

4.1 | Glycaemic outcomes

Glycaemic outcomes for each insulin dosing method are presented in Table 3 and Table 4. There were no significant differences in TIR, TAR, TBR, overnight TIR, TAR, TBR, glycaemic variability, or change in HbA1c from baseline when using OptimAAPP compared with carbohydrate counting. There were no episodes of severe hypoglycaemia (cognitive impairment requiring external assistance) or any other adverse event recorded in the study.

Compared with carbohydrate counting, there was no significant difference in postprandial TIR, and TAR when using OptimAAPP for meal insulin dose calculation at breakfast, lunch, and dinner. There was a significant increase in postprandial TBR when using OptimAAPP for meal insulin dose calculation at dinner, but not at breakfast and lunch (Table 4).

The average number and distribution of bolus events and carbohydrate, fat, and protein intake, recorded at breakfast, lunch, and dinner when using OptimAAPP is presented in Table 5. Compared with breakfast, there was a significant increase in the mean intake of protein at lunch ($p = 0.03$) and both fat ($p = 0.001$) and protein ($p < 0.001$) at dinner.

4.2 | Fat and protein counting

Compared with baseline, after 3 months of using OptimAAPP, there was no change in the ability of participants to correctly classify the fat and/protein content of foods [mean score 10.3 (range; 7–15) vs. 10.6 (range; 8–13)].

4.3 | User acceptability of OptimAAPP

In total, 34 of 37 participants (92%) who completed the intervention arm also completed the OptimAAPP user experience questionnaire.

All participants agreed (47% strongly agreed) that the initial clinician-led session where the app was configured with the personal insulin settings and education on app functionality and use was provided was sufficient to get them started with using OptimAAPP. Participants found the insulin on-board feature useful (77%), The majority of participants felt confident giving the insulin doses that OptimAAPP recommended (82%) and that overall,

TABLE 3 A comparison of glycaemic outcomes when using carbohydrate counting versus OptimAAPP for meal insulin dose calculation.

	Carbohydrate counting	OptimAAPP	Difference	*p*-value
Time-in-range [3.9–10.0 mmol/L] (%)	67.6 (2.2)	70.5 (2.3)	2.9 (1.7)	0.102
Time above range [>10.0 mmol/L] (%)	28.0 (2.2)	24.5 (2.3)	−3.5 (1.9)	0.068
Time below range [<3.9 mmol/L] (%)	4.4 (0.5)	4.9 (0.5)	0.5 (0.5)	0.318
Time below range [<3.0 mmol/L] (%)	1.4 (0.2)	1.5 (0.2)	0.1 (0.2)	0.318
Glycaemic variability [CV] (%)	33.3 (1.4)	32.2 (1.4)	−1.1 (0.7)	0.136
Change in HbA1c from baseline (%)	0.01 (0.09)	0.01 (0.07)	0.01 (0.07)	0.907

Note: Data are presented as means (SE) or numbers. P-values compare OptimAAPP to the reference insulin dosing method, carbohydrate counting.

it was easy to get OptimAAPP to do what they wanted it to do (79%); the OptimAAPP screen layouts were simple to follow (85%), and it was easy to add new foods to the OptimAAPP database (65%). Whilst all participants (100%) reported that they would recommend OptimAAPP to other people living with type 1 diabetes and most participants (65%) responded that they wanted to keep using the app beyond the study, only half (50%) preferred OptimAAPP to their usual method of meal insulin dose calculation.

TABLE 4 A comparison of postprandial and overnight glycaemic outcomes when using carbohydrate counting versus OptimAAPP for meal insulin dose calculation.

	Carbohydrate counting	OptimAAPP	*p*-value
Postprandial time-in-range [3.9–10.0 mmol/L] (%)			
Breakfast	78.5 (29.0)	77.0 (31.0)	0.355
Lunch	71.4 (31.0)	67.5 (31.1)	0.052
Dinner	67.7 (30.9)	68.6 (30.0)	0.655
Overnight	70.6 (34.2)	70.6 (32.5)	0.912
Postprandial time above range [>10.0 mmol/L] (%)			
Breakfast	17.7 (28.4)	18.7 (31.4)	0.435
Lunch	23.2 (31.7)	26.3 (32.5)	0.086
Dinner	27.6 (32.2)	24.5 (31.2)	0.171
Overnight	24.8 (35.1)	23.4 (33.4)	0.603
Postprandial time below range [<3.9 mmol/L] (%)			
Breakfast	3.8 (11.2)	4.4 (11.1)	0.710
Lunch	5.4 (11.6)	6.2 (12.0)	0.567
Dinner	4.8 (10.6)	6.9 (13.7)	0.014*
Overnight	4.5 (11.4)	6.0 (13.5)	0.094
Postprandial time below range [<3.0 mmol/L] (%)			
Breakfast	0.9 (5.1)	1.0 (4.9)	0.946
Lunch	1.2 (4.8)	1.7 (5.5)	0.195
Dinner	1.1 (4.3)	1.9 (6.6)	0.016*
Overnight	0.9 (3.9)	1.3 (5.0)	0.285

Note: Data presented as means (SD) or numbers. *p*-values compare OptimAAPP to the reference insulin dosing method, carbohydrate counting.
*$p < 0.05$.

4.3.1 | Benefits and challenges of OptimAAPP use

Participant reported key benefits and challenges of OptimAAPP use are presented in Table 6. Overall, two key benefits were identified; reduced mental burden (32%), and improved efficiency in insulin dose calculation (24%).

Participants universally (100%) reported the limited number of foods in the database and the time involved in food/meal entry as the primary challenge associated with OptimAAPP use.

4.3.2 | Recommendations to increase acceptability of OptimAAPP

Overall, 65% of respondents provided additional feedback on how OptimAAPP could be further improved. Most comments focused on increasing the number and searchability of foods in the OptimAAPP database via integration with existing food databases and incorporating food pictures/technology for food photography recognition respectively. Participants suggested that OptimAAPP insulin dose recommendations consider a broader range of factors that affect blood glucose levels including physical activity, hormonal changes associated with the menstrual cycle, and sickness. Bluetooth connectivity with commercially available CGM systems and blood glucose meters and enhanced recording-keeping features that enable exercise and dietary intake to be tracked and exported as a user-friendly report for analysis were also proposed.

5 | DISCUSSION

Smartphone insulin dose calculators promise to simplify mealtime insulin dosing, reduce treatment burden, and improve the accuracy of insulin dose calculation translating to improvements in glycaemic control. This free-living study demonstrated that in adolescents and adults using MDI therapy and proficient in carbohydrate counting, OptimAAPP assists users to achieve target glycaemia, similar to carbohydrate counting. Participants' views

TABLE 5 Average carbohydrate, fat, and protein intake, number, and distribution of bolus events at breakfast, lunch, and dinner when using OptimAAPP over a 3-month period.

	Carbohydrate (g)	Fat (g)	Protein (g)	Bolus events	Bolus distribution (%)
Breakfast	36 (20) [1–78]	13 (5) [2–26]	14 (6) [5–26]	54 (30) [2–84]	34.9
Lunch	41 (19) [7–78]	16 (5) [11–29]	19 (6)* [12–32]	59 (25) [26–123]	29.7
Dinner	45 (16) [12–81]	19 (7)* [11–33]	26 (9)** [15–46]	60 (20) [26–101]	35.4

Note: Data are presented as means (SD) [range] or numbers (SD) [range] or (%). *p*-values compare lunch and dinner to breakfast.
*$p < 0.05$. **$p < 0.001$.

TABLE 6 Participant reported benefits and challenges of OptimAAPP use.

Benefits	Illustrative participant responses
Perceived improvement in glycaemic control	I definitely felt that it gave better-suggested doses than I did! Particularly when eating protein and fat which I really didn't know I should be calculating. I believe that the app helped me keep my sugar level when using it.
	Heavier meals whilst still not as well controlled as lighter meals seem to be better controlled than prior to app use.
Perceived reduction in insulin dosing errors	It was able to do the calculations for me and I knew it was going to be correct.
Perceived improvement in insulin dose accuracy	Getting more accurate doses.
	Easy way to calculate exact doses without having to do too many calculations.
Reduced mental burden	Database was helpful. Don't have to mentally remember.
	Not having to think about dosage.
Improved efficiency in insulin dose calculation	Didn't have to look up foods that I regularly eat over and over again.
	Once I had my meals loaded it was quick to calculate my bolus without having to perform any mathematics.
Improved knowledge	Helped me work out how protein affects me with meals.
	Learning more about carb quantities.
Challenge	Illustrative participant responses
Limited number of foods in food database, entry of new foods time-consuming	The *time taken* to add menu items whilst preparing a meal in addition to preparing doses and preparing family meals.
	Insufficient database, if too difficult to enter a food I tended not to use the app for that meal.
	Burdensome to be constantly adding foods due to small database especially when eating out or making a meal/ recipe up.
	It took a bit of time to load up foods and meals. Building a larger food database would have been useful, particularly for brands and take-out/café meals.
	The database. It was tedious to add all my meals in however, if you could leverage an app like calorie king or my fitness pal it was ok.

of OptimAAPP indicated a high level of acceptability. Reduced mental burden alongside perceived improvements in efficiency and accuracy of dose calculation, were cited as benefits of system use.

Consistent with the clinical targets for TIR of >70%, TAR of <25%, and CV ≤36%, recommended by international consensus statement,[19] and best-practice guidelines,[20,21] in the present study participants on MDI therapy using OptimAAPP over a 3-month period achieved an average TIR of 70.5%, TAR of 24.5%, and CV of 32.2%. Whilst this was not significantly different to that observed with carbohydrate counting (TIR:67.6%, TAR:28.0, CV:33.3%), the average TIR, TAR, and CV recorded in both the OptimAAPP and carbohydrate counting arms was comparable to, or better than that reported in free-living trials of children and adolescents (TIR:57.0–67.2%, TAR:25.6–39.1%, CV:25.0%–48.0%)[22–24] and adults (TIR:67.8%–68.5%, TAR:29.5%–30.0%, CV:31.0%–34.7%)[25,26] using hybrid closed loop systems for the same 3-month duration.

Although OptimAAPP use was associated with participants meeting most targets for CGM metrics, consistent with Foltynski et al[14] the clinical targets for TBR of <4% (<3.9 mmol/L) and TBR of <1% (3.0 mmol/L)[20] were not met in this trial. Further, the use of OptimAAPP for meal insulin dose calculation at dinner; the meal with the highest mean intake of fat and protein, was associated with a significant increase in the TBR (+2.1%) compared with carbohydrate counting. This was not associated with severe hypoglycaemia or a significant increase in the TBR overnight, however, may point to the need for ongoing titration of the insulin dose for fat and protein based on the individual response. Previous controlled studies evaluating dosing algorithms for fat and protein including the Pankowska Equation[5,6,17] and Food Insulin Index[17,27] have universally reported higher rates of postprandial hypoglycaemia (25%–48%), compared with carbohydrate counting (0%–33%).

With the focus primarily on carbohydrates in type 1 diabetes management, the importance of maintaining a balanced diet which includes other dietary macronutrients, particularly lean protein and monounsaturated fats may be lost. We did not find OptimAAPP use was associated with a significant change in the ability of participants

to correctly classify foods as low, medium, or high in fat or protein. Participants tended to underestimate high-fat foods and high-protein foods and overestimate low-fat foods. Previously, we have shown that carbohydrate in snacks also tend to be over-estimated[28] suggesting targets for improvement in macronutrient education. At present, there is no evidence which defines how accurately fat, and protein needs to be estimated to optimise postprandial glycaemia. The authors however suggest that successful implementation of meal insulin dose decision support tools in practice requires some fat and protein awareness to minimise errors in insulin dosing and facilitate ongoing dose adjustment.

In contrast to other existing insulin dose calculators for fat and protein which report significant time spent on multiple and/lengthy training sessions,[14,29] a brief, 0.5–1 h. education and training session on OptimAAPP functionality and use was sufficient for participants to get started with using the app. Despite 100% of participants reporting that the number of foods in the database (695 foods) was insufficient and that the extra time needed to enter foods was a major barrier to app use, 65% of participants reported that they would like to continue using OptimAAPP beyond the study. Mazurczak et al.[30] reported similar findings in the first trial of the VoiceDiab application which includes 900 foods suggesting that if the utility of such applications is found to be acceptable, users may be able to tolerate some lack of usability.

The present study has strengths and limitations. The primary strength of the study was the design. Randomisation ensured allocation bias was minimised, furthermore, it is known that glycaemic control can improve owing to increased contact time with health care professionals. To reduce bias, in both the control and intervention arms, participants attended the same number of visits which were of similar duration, received the same number of telephone/email follow-ups, and were offered access to the same level of telephone and email support throughout the study. A limitation of the study is that it was conducted in a sample of adolescents and adults with a mean HbA1c of 56 mmol/mol (7.3%) who demonstrated proficiency in carbohydrate counting and therefore, results may not be generalisable to all populations with type 1 diabetes. Further, it could be reasoned that a population with a higher mean HbA1c would have more 'room for improvement' in glycaemic control and potentially a greater need for a tool that supports optimal meal insulin dosing. Additionally, whilst the sample was similar to,[14] or larger than[15] that used in all existing trials of similar meal insulin dose calculators, the study was conducted during the COVID-19 pandemic when government imposed lockdowns and it's effects severely impacted participant recruitment and retention, and hence, overall, the study was underpowered. We were also not statistically powered to detect differences in glycaemic outcomes between paediatric and adult sub-populations. Finally, the study measured insulin doses and dietary intake in the OptimAAPP arm only. It is possible that variations in macronutrient intake and/insulin dosing behaviours between study arms may have impacted glycaemic outcomes.

6 | CONCLUSIONS

In this free-living study of adolescents and adults using flexible MDI therapy, our findings indicate that the use of OptimAAPP does not produce glycaemic outcomes as measured by TIR, TAR, TBR, CV, and HbA1c that are significantly different than carbohydrate counting. Whilst overall, participant' views of OptimAAPP indicated a high level of acceptability, the small number of foods in the food database is a limitation that needs to be addressed prior to future studies.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

ORCID

Tenele A. Smith https://orcid.org/0000-0002-9403-4679
Nisha Venkatesh https://orcid.org/0000-0001-5270-0250
Stuart Szwec https://orcid.org/0000-0001-8549-1934
David N. O'Neal https://orcid.org/0000-0002-0870-4032
Bruce R. King https://orcid.org/0000-0002-8958-7404
Carmel E. Smart https://orcid.org/0000-0003-3104-8800

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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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