

# HYPOGLYCAEMIA FEAR IN ADULTS WITH TYPE 1 DIABETES AT HIGH RISK OF HYPOGLYCAEMIA: THE IMPACT OF SWITCHING FROM FLASH GLUCOSE MONITORING TO CONTINUOUS GLUCOSE MONITORING

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## Background

- Hypoglycaemia in people with Type 1 Diabetes Mellitus (T1DM) is associated with increased mortality and morbidity.
- Fear of hypoglycaemia and diabetes related emotional distress can influence quality of life, psychological well-being, and may be an important deterrent to diabetes management.
- Real-Time Continuous Glucose Monitoring (RT-CGM) devices display a continuous estimate of blood glucose, along with real-time alerts and alarms. The flash glucose monitoring system (Abbot Freestyle Libre) allows patients to review estimated blood glucose and 8-hours of retrospective data when the reader is swiped over the sensor.
- In phase 1 of the I HART CGM study we showed that RT-CGM (Dexcom G5) has a greater beneficial impact on hypoglycaemia outcomes and fear of hypoglycaemia compared to flash glucose monitoring at 8 weeks (1). Both intervention groups were then given an opportunity to use RT-CGM for another 8 weeks and here we present the data from phase 2.

## Objectives & Aims

- To evaluate the impact of extending the use of RT-CGM in the RT-CGM cohort and switching to RT-CGM in the flash glucose monitoring cohort in the I HART CGM study on fear of hypoglycaemia, diabetes related emotional distress and hypoglycaemia awareness.

## Methods

### Study design

- This was a prospective randomized parallel group study with an open extension phase.
- After a two-week run in with blinded CGM participants were randomized to either RT-CGM or flash glucose monitoring for 8 weeks. Participants were then given an opportunity to continue with RT-CGM in the RT-CGM group or switch to RT-CGM in the flash glucose monitoring group for another 8 weeks.

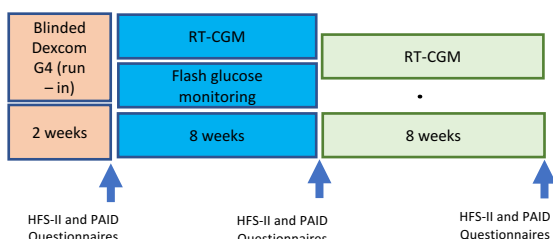
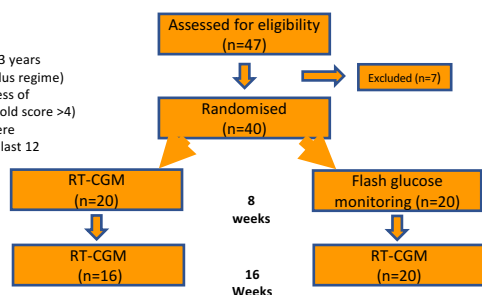


Figure 1. Study design

### Study population

#### Inclusion criteria:

- Age >18 years
- Type 1 diabetes >3 years
- On MDI (Basal-bolus regime)
- Impaired awareness of hypoglycaemia (Gold score >4) or episode of severe hypoglycaemia in last 12 months



### Intervention devices

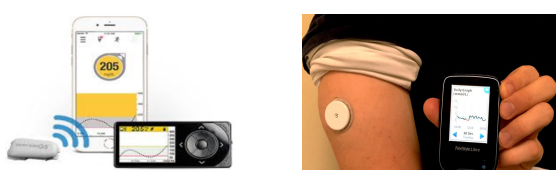


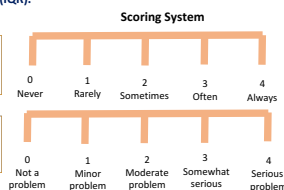
Figure 3. Dexcom G5 CGM (left) and Abbott Freestyle Libre (right)

## Results

	RT-CGM (n=20)	Flash glucose monitoring (n=20)	P-value
Gender (male/female)	12/8	24/16	-
Age (years)	50.5 (45.0 - 64.5)	48.5 (34.0 - 63.0)	0.45
Duration of diabetes (years)	30.0 (25.0 - 36.0)	28.0 (16.5 - 36.5)	0.47
Gold score	5 (5 - 6)	5 (4 - 5)	0.14
HbA1c (mmol/mol)	57 (49 - 62)	55 (48 - 65)	0.80
(HbA1c (%))	7.4 (6.6 - 7.8)	7.2 (6.5 - 8.1)	7.3 (6.5 - 7.8)

Table 1. Baseline demographics (n=40). Results are expressed as median (IQR).

- HFS-II:** Looks at how hypoglycaemia makes people feel and behave
  - Section one: Behaviour
  - Section two: Worry



- PAID:** Looks at issues related to diabetes that can be a problem to patients

### HFS-II Questionnaire

Maximum score = 132  
Minimum score = 0  
Higher score indicates worse outcome

### PAID Questionnaire

Maximum score = 100  
Minimum score = 0  
Higher score indicates worse outcome

Table 2. HFS-II and PAID Scoring

Type of questionnaire	RT-CGM group				Flash glucose monitoring group				RT-CGM vs Flash	
	At 8 weeks	Endpoint at 16 weeks	Δ	P value	At 8 weeks	Endpoint at 16 weeks	Δ	P value	Δ	P value
<b>HFS-II Q</b>	53.6 (24.9)	50.1 (23.7)	-3.6	0.10	50.4 (26.7)	45.7 (27.7)	-4.8	0.11	-1.2	0.75
<b>Behaviour Section</b>	20.4 (10.2)	19.5 (9.9)	-0.9	0.40	18.7 (10.7)	18.8 (10.4)	0.05	0.96	0.9	0.50
<b>Worry Section</b>	33.2 (16.5)	30.6 (16.7)	-2.6	0.17	31.7 (17.4)	26.9 (18.5)	-4.8	<b>0.04</b>	-2.1	0.47
<b>PAID Q</b>	33.4 (20.8)	29.5 (17.2)	-3.8	0.14	33.9 (21.7)	29.6 (20.2)	-4.3	0.09	-0.5	0.89
<b>Gold Q</b>	4.1 (1.5)	4.3 (1.4)	0.2	0.68	4.6 (1.3)	4.2 (1.5)	-0.4	<b>0.04</b>	-0.6	0.17

Table 3. Comparison of questionnaire outcomes as 8 week and 16 weeks. Results are expressed as mean (SD)

## Conclusions

- The improvement in fear of hypoglycaemia previously seen with RT-CGM after the first 8 weeks is maintained at the 16-week study endpoint in this group.
- At the 16 week endpoint there was significant reduction in the HFS-II worry sub-score (31.7 vs 26.9, p=0.04) and Gold score (4.65 vs 4.20, p=0.04) when switched from flash glucose monitoring to RT-CGM
- Diabetes related emotional distress (PAID score) did not change significantly in either group.
- The between-group difference did not reach statistical significance for the outcomes at 16-week study endpoint.
- These findings suggest that switching from flash glucose monitoring to RT-CGM reduces worry associated with hypoglycaemia fear. Interestingly the gold score fell significantly but remained above 4.

### References

- Reddy, M., Jugnee, N et al., A randomized controlled pilot study of continuous glucose monitoring and flash glucose monitoring in people with type 1 diabetes and impaired awareness of hypoglycaemia. Diabetic Medicine. (2017); 1-8. Contact for any questions: n.jugnee@imperial.ac.uk