FreeStyle Libre

FreeDM2 Randomised Controlled Trial (RCT) Results.

CONTENTS:

RCT=randomised controlled trial; T2D=type 2 diabetes; TIR=Time in Range.
Images are for illustrative purposes only. Not actual patient.

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Most basal insulin-treated T2D remains uncontrolled,[1] pointing to the need for more actionable data.

In the UK,

~70%[1]

of PWD treated with basal insulin have an HbA1c ≥58 mmol/mol

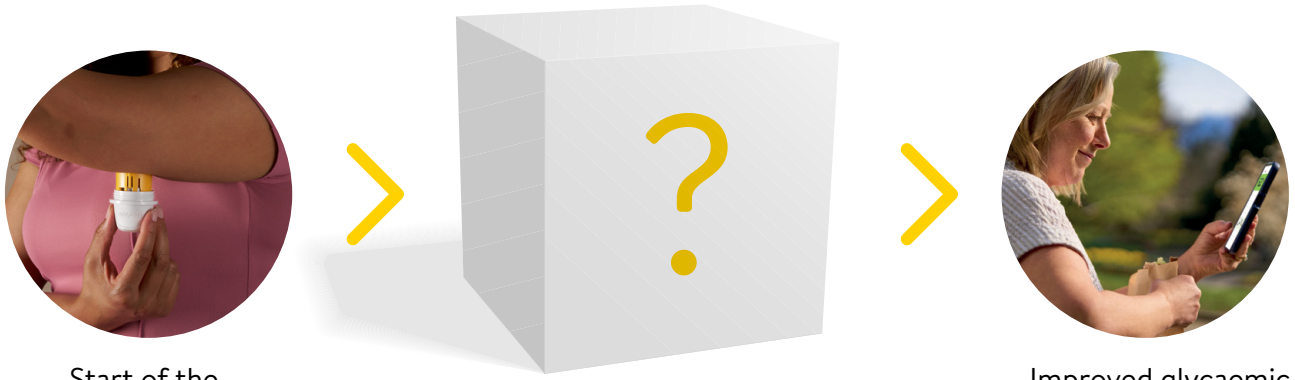
Use of Libre systems is associated with an average HbA1c reduction of 0.32–1.4% in populations treated with basal insulin[2–5]

PWD=people with diabetes; T2D=type 2 diabetes.

1. Interface audit data analysis, data held on file at Abbott. **2.** Elliott, T. *Diabetes Vasc Dis Res* (2021): https://doi.org/10.1177/14791641211021374. **3.** Carlson, A. L. *BMJ Open Diabetes Res Care* (2022): https://doi.org/10.1136/bmjdrc-2021-002590. **4.** Wright, E. E. *Diabetes Spectr* (2021): https://doi.org/10.2337/ds20-0069. **5.** Nathanson, D. *Diabetologia* (2025): https://doi.org/10.1007/s00125-024-06289-z.

FreeDM2: unboxing the behavioural impact of using the Libre 3 system.

A rigorous landmark RCT to evaluate glycaemic and behavioural improvements in adults with T2D on basal insulin regimens with suboptimal HbA1c and TIR[1]



Start of the Libre 3 system

Improved glycaemic management

A key strength of this study lies in its objective of understanding the mechanisms by which the Libre 3 system influences change in glycaemia without therapy intervention[1]

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1. Wilmot, E. G. *Lancet Diabetes Endocrinol* (2026): https://doi.org/10.1016/S2213-8587(26)00076-8.

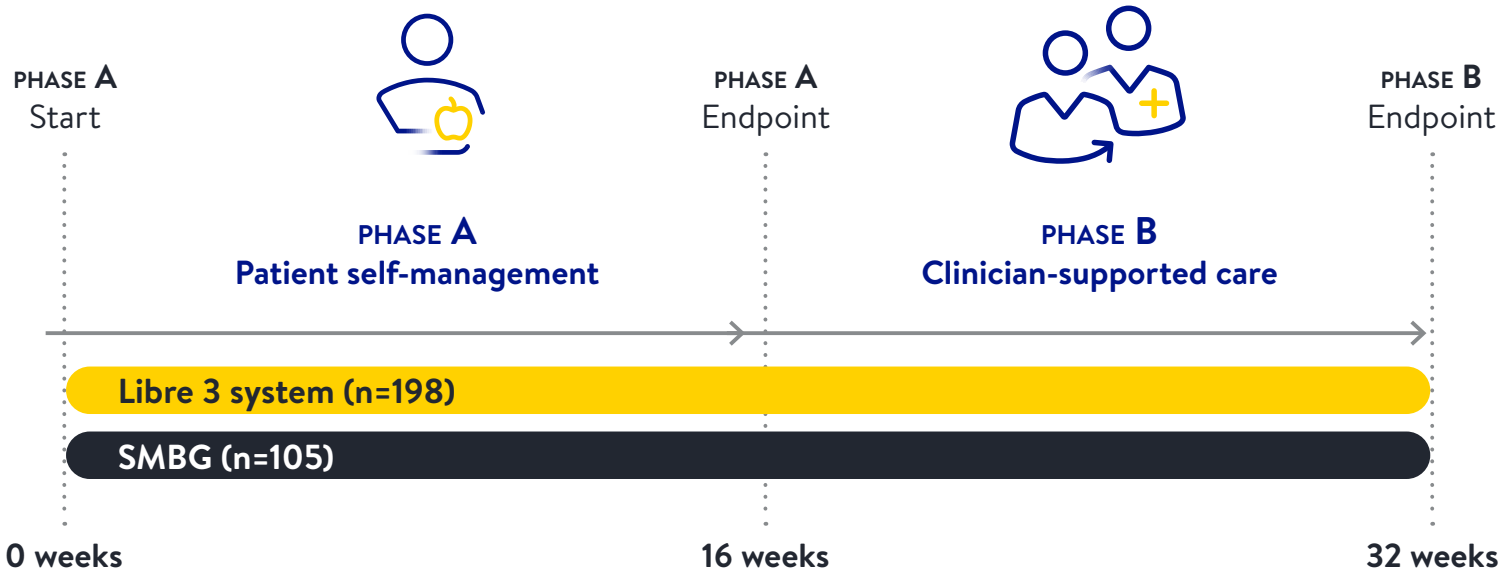
FreeDM2 RCT study design and endpoints.[1]

Methodology:

- 24 centres
- 2:1 randomisation

Population:

- Mean age: 60.7 ± 9.8
- HbA1c: 7.5–11.0% (59–97 mmol/mol)
- Mean HbA1c: 8.8% (73 mmol/mol)
- Mean daily finger pricks: ~2
- T2D on basal insulin plus SGLT2i or GLP-1 or dual GIP/GLP-1 RA



PRIMARY ENDPOINT

- HbA1c change at 16 weeks

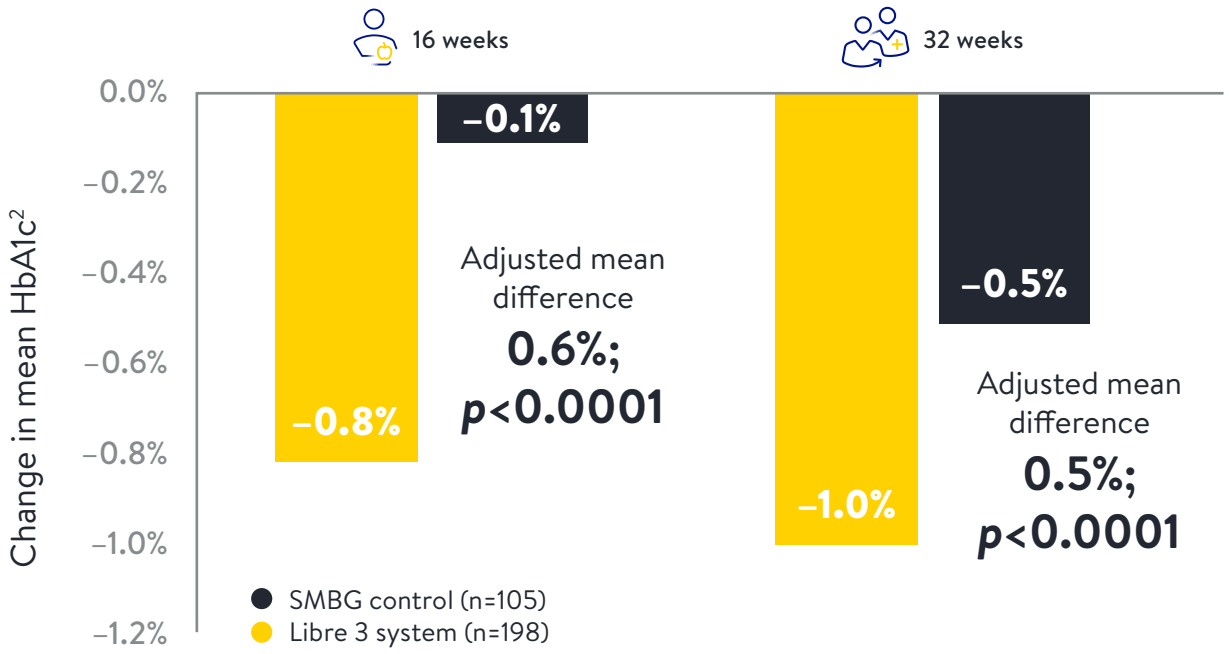
SECONDARY ENDPOINT

- HbA1c change at 32 weeks
- CGM metrics
- Accelerometer data
- Changes to insulin doses & non-insulin medications
- Qualitative interviews
- Safety
- PROMs (including EQ-5D-5L, GMSS, UKDDQ, HCS, HFS-II)

CGM=continuous glucose monitoring; EQ-5D-5L=EuroQol 5-Dimension 5-Level questionnaire; GIP=glucose-dependent insulinotropic polypeptide; GLP-1 RA=glucagon-like peptide-1 receptor agonist; GMSS=Glucose Monitoring Satisfaction Survey; HCS=Hypoglycaemic Confidence Scale; HFS-II=Hypoglycaemia Fear Survey-II; PROMs=patient-reported outcome measures; SGLT2i=sodium-glucose cotransporter-2 inhibitor; SMBG=self-monitoring of blood glucose; UKDDQ=UK Diabetes and Diet Questionnaire.

1. Wilmot, E. G. *Lancet Diabetes Endocrinol* (2026): https://doi.org/10.1016/S2213-8587(26)00076-8.

The use of the Libre 3 system resulted in clinically and statistically significant HbA1c changes at 16 weeks, sustained through 32 weeks.[1]



Patients achieving ≥0.5% reduction in HbA1c

16 weeks:

Libre 3 system	SMBG
65%	27%

p<0.0001

32 weeks:

Libre 3 system	SMBG
70%	49%

p=0.0006

SMBG=self-monitoring of blood glucose.

1. Wilmot, E. G. *Lancet Diabetes Endocrinol* (2026): https://doi.org/10.1016/S2213-8587(26)00076-8. **2.** Baseline HbA1c for study population was 8.81%.

The Libre 3 system users experienced increased Time in Range (TIR).[1]

TIR improvements occurred with no increase in hypoglycaemia[1]

	16 weeks	32 weeks
Overall TIR	**+2.5 hours** total TIR per day[1] +10.4% difference compared to control ($p<0.0001$)[1]	**+2.5 hours** total TIR per day[1] +10.6% difference compared to control ($p=0.0004$)[1]
Waking hours 6 a.m. to midnight	**+1.6 hours** +8.7% difference compared to control ($p=0.0009$)[1]	**+1.5 hours** +8.2% difference compared to control ($p=0.0064$)[1]
Sleeping hours midnight to 6 a.m.	**+0.9 hours** +15.7% difference compared to control ($p<0.0001$)[1]	**+1.1 hours** +17.7% difference compared to control ($p<0.0001$)[1]

T2D=type 2 diabetes.

1. Wilmot, E. G. *Lancet Diabetes Endocrinol* (2026): https://doi.org/10.1016/S2213-8587(26)00076-8.

Real-time biofeedback helps people with T2D make behaviour changes that drive long-term glycaemic benefits.[1]

Increases in overall daily and light physical activity[2]
Accelerometer data

Improved hypoglycaemic confidence
Hypoglycaemic Confidence Scale

Better dietary choices[2]
UK Diabetes and Diet Questionnaire

Reduced emotional burden
Glucose Monitoring Satisfaction Survey

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1. Wilmot, E. G. *Lancet Diabetes Endocrinol* (2026): https://doi.org/10.1016/S2213-8587(26)00076-8. **2.** This effect was recorded at 16 weeks (Phase A, self-management); no statistically significant difference at 32 weeks (Phase B, clinician-supported care).

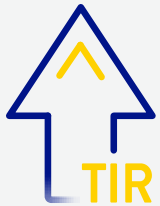
FreeDM2 demonstrated improvement in glycaemic management and behavioural changes in adults with T2D on basal insulin regimens.[1]

Libre

Most glycaemic improvements were achieved by patient behaviour changes rather than by medication changes and provider interventions[1]

Significant reduction in HbA1c

- 1.0% for Libre 3 system at 32 weeks vs. 0.5% for SMBG at 32 weeks



Significant increase in TIR

- +2.5 hour total TIR improvement at 16 and 32 weeks

Proactive behavioural changes

- Healthier dietary choices[2]
- Increased light physical activity[2]

Psychosocial improvements

- Improved hypoglycaemia confidence
- Reduced emotional burden

SMBG=self-monitoring of blood glucose; T2D=type 2 diabetes; TIR=Time in Range.
Target glucose range: 3.9–10.0 mmol/L.

1. Wilmot, E. G. *Lancet Diabetes Endocrinol* (2026): https://doi.org/10.1016/S2213-8587(26)00076-8. **2.** This effect was recorded at 16 weeks (Phase A, self-management); no statistically significant difference at 32 weeks (Phase B, clinician-supported care).

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