

# Retrospective chart review of FreeStyle Libre in adults with type 2 diabetes

<b>Submission date</b> 09/09/2022	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 03/10/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 24/06/2025	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background & study aims

Diabetes is a lifelong condition where the amount of sugar in the blood is too high. The aim of this study is to review the effectiveness of the FreeStyle Libre Glucose Monitoring System in adults with type 2 diabetes using insulin.

### Who can participate?

Anyone aged 18 years old and over with type 2 diabetes

### What does the study involve?

For each medical record, HbA1c levels will be collected after 3 to 6 months of use of the FreeStyle Libre sensor and will be compared with their HbA1c levels before starting FreeStyle Libre.

### What are the possible benefits & risks of participating?

There are no direct benefits or risks to patients whose medical records are included.

### Where is the study run from?

Abbott Diabetes Care (UK)

### When is the study starting and how long is it expected to run for?

February 2022 to January 2024

### Who is funding the study?

Abbott Diabetes Care (UK)

### Who is the main contact?

Dr Pamela Reid (UK)  
pamela.reid@abbott.com

## Contact information

Type(s)

Public

**Contact name**

Dr Pamela Reid

**Contact details**

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## **Additional identifiers**

**Integrated Research Application System (IRAS)**

312330

**Central Portfolio Management System (CPMS)**

52369

**Protocol serial number**

ADC-UK-PMS-22054

## **Study information**

**Scientific Title**

A retrospective, non-interventional, chart review study of the effectiveness of FreeStyle Libre in adults with type 2 diabetes

**Acronym**

REFER-UK

**Study objectives**

Effectiveness of FreeStyle Libre flash glucose monitoring system on glycaemic control versus standard of care measured by HbA1c, using patient records

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 02/08/2022, this is a retrospective observational study reviewing medical charts, which does not require ethics approval under the UK's law, ref: 22/NRS/0022

**Study design**

Retrospective non-interventional chart review study

**Primary study design**

Observational

**Study type(s)**

Prevention

**Health condition(s) or problem(s) studied**

Diabetes mellitus (diabetes)

**Interventions**

Patient HbA1c levels that were collected 3 to 6 months after the start of FreeStyle Libre are compared to HbA1c levels collected prior to starting Libre.

**Intervention Type**

Device

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

FreeStyle Libre sensor

**Primary outcome(s)**

Hemoglobin A1c (HbA1c) level measured using the FreeStyle Libre sensor and recorded in medical charts at baseline and 3 to 6 months after initiation

**Key secondary outcome(s)**

There are no secondary outcome measures

**Completion date**

31/01/2024

**Eligibility****Key inclusion criteria**

1. Age 18 years or over
2. Has type 2 diabetes using basal-bolus insulin regimen for at least 1 year
3. Has used FreeStyle Libre/Libre 2 regularly for at least 3 months
4. HbA1c recorded in medical notes between 8.0% and 12.0% (64 to 108 mmol/mol) in the 3 months prior to starting FreeStyle Libre/Libre 2
5. HbA1c recorded in medical notes 3 to 6 months after starting FreeStyle Libre/Libre 2

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

87

**Key exclusion criteria**

1. Female participant who was pregnant during the data collection period
2. Received dialysis treatment during the data collection period
3. Participated in another device or drug study that could have affected glucose measurements or management during the data collection period

**Date of first enrolment**

04/10/2022

**Date of final enrolment**

11/09/2023

## **Locations**

**Countries of recruitment**

United Kingdom

England

Northern Ireland

Scotland

Wales

**Study participating centre**

**St John's Hospital**

Livingston

United Kingdom

EH54 6PP

**Study participating centre**

**Royal Infirmary of Edinburgh**

Edinburgh

United Kingdom

EH16 4SA

**Study participating centre**  
**Western General Hospital**  
Edinburgh  
United Kingdom  
EH4 2XU

**Study participating centre**  
**University Hospital Wishaw**  
Wishaw  
United Kingdom  
ML2 0DP

**Study participating centre**  
**Neath Port Talbot Hospital**  
Port Talbot  
United Kingdom  
SA12 7BX

**Study participating centre**  
**Morrison Hospital**  
Swansea  
United Kingdom  
SA6 6NL

**Study participating centre**  
**Singleton Hospital**  
Swansea  
United Kingdom  
SA2 8QA

**Study participating centre**  
**Antrim Area Hospital**  
Antrim  
United Kingdom  
BT41 2RL

**Study participating centre**  
**Northampton General Hospital**  
Northampton

United Kingdom  
NN1 5BD

**Study participating centre**

**Southern Health**  
Southampton  
United Kingdom  
SO40 2RZ

**Study participating centre**

**University Hospitals Coventry and Warwickshire NHS Trust**  
Coventry  
United Kingdom  
CV2 2DV

## **Sponsor information**

**Organisation**

Abbott (United Kingdom) Diabetes Care Ltd

**ROR**

<https://ror.org/03wnay029>

## **Funder(s)**

**Funder type**

Industry

**Funder Name**

Abbott Diabetes Care

**Alternative Name(s)**

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

For-profit companies (industry)

**Location**

United States of America

## Results and Publications

### Individual participant data (IPD) sharing plan

All study data sourced for this study comes directly from data recorded in medical charts, so can be obtained from original source via appropriate approval, rather than from the sponsor.

### IPD sharing plan summary

Not expected to be made available

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		04/08/2024	24/06/2025	Yes	No