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# Determining variation in glucose levels in people with impaired glucose tolerance (prediabetes)

**Submission date**
03/05/2019

**Recruitment status**
No longer recruiting

**Registration date**
22/05/2019

**Overall study status**
Completed

**Last Edited**
10/06/2024

**Condition category**
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background & study aims
The number of people with diabetes continues to rise throughout the world. In addition, there has been a similar rise in impaired glucose tolerance or prediabetes, which is a risk factor for developing type 2 diabetes. The aim of this pilot study is to collect glucose data using the FreeStyle Libre Pro Flash Glucose Monitoring System from adults with impaired glucose tolerance.

Who can participate?
Patients aged 18 and over with an HbA1c of 5.7-6.4% (39-47 mmol/mol).

What does the study involve?
Participants will wear two FreeStyle Libre Pro Sensors for up to 14 days (glucose data is not visible during this time). Participants will also be supplied with a fitness tracker and a tablet; an app will be pre-installed on the tablet and participants will be requested to record dietary intake for three days.
Participants will return to clinic for Sensor removal and data upload (Sensor and tracker), they will then wear a FreeStyle Libre Sensor for up to 14 days (glucose data will be visible during this time). Participants will be requested to complete a questionnaire at the end of the study.

What are the possible benefits & risks of participating?
The study gives participants with impaired glucose tolerance the opportunity to experience sensor technology using the FreeStyle Libre Pro and FreeStyle Libre Systems. The only risks associated with the study are from obtaining venous blood samples, these are small but could include pain, bruising, local infection and fainting. Data collected may be used to inform future pivotal clinical study designs in this population.

Where is the study run from?
1. Hathaway Medical Centre, Chippenham
2. Claremont Medial Practice, Exmouth
3. Albany House Medical Centre, Wellingborough

4. The Adam Practice, Hamworthy
5. Atherstone Surgery, Atherstone

When is the study starting and how long is it expected to run for?
28/05/2019 to 31/07/2019

Who is funding the study?
The study is funded by Abbott Diabetes Care Ltd

Who is the main contact?
Dr Pamela Reid

# Contact information

### Type(s)
Public

### Contact name
Dr Pamela Reid

### Contact details
Abbott Diabetes Care
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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
ADC-UK-PMS-19041

# Study information

### Scientific Title
A pilot study to determine glycaemic variability in people with impaired glucose tolerance (prediabetes)

### Acronym
SAGE

## Study objectives
This pilot study is being conducted to determine the amount of glycaemic variability (measured by %CV glucose) in people with impaired glucose tolerance (prediabetes).

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 17/05/2019, NRES Committee: South West – Cornwall and Plymouth Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT; +44 (0)207 104 8048; nrescommittee.southwest-cornwall-plymouth@nhs.net), ref: 19/SW/0087

## Study design
Prospective multi-centre single-arm pilot study

## Primary study design
Interventional

## Secondary study design
Single-arm pilot study

## Study setting(s)
GP practice

## Study type(s)
Other

## Participant information sheet
No participant information sheet available

## Health condition(s) or problem(s) studied
Impaired glucose tolerance

## Interventions
Participants will wear two FreeStyle Libre Pro Flash Glucose Monitoring Sensors for up to 14 days, followed by FreeStyle Libre for up to 14 days. During the Libre Pro sensor wear, participants will wear a fitness tracker (throughout the two weeks) and record dietary intake (for three days).

There is no follow-up period unless the participant experiences an unanticipated adverse device effect (ADE).

## Intervention Type
Device

## Phase
Not Applicable

## Drug/device/biological/vaccine name(s)
FreeStyle Libre Pro Flash Glucose Monitoring Sensor, FreeStyle Libre

### Primary outcome measure
Glycaemic variability (%CV glucose), measured using sensor glucose data collected by the FreeStyle Libre Pro Flash Glucose Monitoring System during the first two-weeks of the study.

### Secondary outcome measures
Other glycaemic measures such as time in range (3.9-10.0 mmol/L [70-180 mg/dL]), measured using sensor glucose data collected by the FreeStyle Libre Pro Flash Glucose Monitoring System during the first two-weeks of the study.

### Overall study start date
01/01/2019

### Completion date
31/08/2019

## Eligibility

### Key inclusion criteria
1. Aged 18 years or over.
2. Most recent HbA1c 5.7-6.4% (39-47 mmol/mol), recorded in medical notes in last 12 months.

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
40

### Total final enrolment
43

### Key exclusion criteria
1. Recorded diagnosis of diabetes.
2. Concomitant disease or condition that may compromise patient safety including and not limited to; cystic fibrosis, severe mental illness, a diagnosed or suspected eating disorder or any uncontrolled long term medical condition.
3. Has a pacemaker or any other neurostimulators.
4. Currently receiving dialysis treatment or planning to receive dialysis during the study.
5. Women who are pregnant, plan to become pregnant or become pregnant during the study.
6. Participating in another study of a glucose monitoring device or drug that could affect glucose measurements or management.

7. Known (or suspected) allergy to medical grade adhesives.
8. In the investigator's opinion, unsuitable to participate due to any other cause/reason.

**Date of first enrolment**
28/05/2019

**Date of final enrolment**
27/07/2019

# Locations

**Countries of recruitment**
England

United Kingdom

**Study participating centre**
**Hathaway Medical Centre**
United Kingdom
SN14 6GT

**Study participating centre**
**Claremont Medial Practice**
United Kingdom
EX8 2JF

**Study participating centre**
**Albany House Medical Centre**
United Kingdom
NN8 4RW

**Study participating centre**
**The Adam Practice**
United Kingdom
BH15 4JQ

**Study participating centre**
**Atherstone Surgery**
United Kingdom
CV9 1EU

# Sponsor information

**Organisation**
Abbott Diabetes Care Ltd

**Sponsor details**
Range Road
Witney
United Kingdom
OX29 0YL
+44 1993 863164
Joe.Bugler@abbott.com

**Sponsor type**
Industry

**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

**Publication and dissemination plan**

Possible presentation at a diabetes conference, and/or publication in a peer-reviewed journal. Estimated timeline is one year from trial end date.

## Intention to publish date
31/07/2020

## Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Pamela Reid.

## IPD sharing plan summary
Data sharing statement to be made available at a later date

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Abstract results | | 01/06/2020 | 01/07/2022 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Abstract results | | 25/08/2020 | 10/06/2024 | No | No |