

Harrogate Road Surgery 355 Harrogate Road Leeds LS17 6PZ Tel: 0113 268 0066 Harehills Community Health Centre 427 Harehills Lane Leeds LS9 6EY Tel: 0113 249 0598

Information about a clinical study for a new device for diabetes.

Eligible patients will be contacted by the study team and sent a link to this letter.

We would like to speak to you to discuss a clinical study for a new device for diabetes.

The study is assessing a new sensor for monitoring of your sugar levels.

We are looking for people who;

- Have Type 2 diabetes
- Use long-acting, background insulin once or twice a day
- Take other medications to lower blood sugar belonging to;
 - o SGLT2 inhibitor class (drugs like Empagliflozin, Dapagliflozin or Cangliflozin)
 - GLP-1 (drugs like Semaglutide, Dulaglutide)
- Are willing to wear the FreeStyle Libre 3 glucose sensor as part of a research study

We believe you may be suitable for this study and would like to discuss it in more detail with you. Below is a summary of the study;

The study will last for up to 12 months and during this time you will have reviews with a diabetes specialist to look at your diabetes management.

At the start of the study, you will wear a sensor on your arm for approximately 14 days. Then you will be randomly allocated to either continue using your current glucose monitoring method or you will be asked to wear a FreeStyle Libre 3 for 8 months.

During the study, you will also be asked to;

- Give blood samples for diabetes related laboratory tests at the start, middle and the end of the study.
- Have in-person or virtual reviews with a diabetes specialist.
- Complete questionnaires about your diabetes experience.

Any allocated to continue with their current glucose monitoring method will be offered an optional 4-month period of FreeStyle Libre 3 use after 8 months.

Participation in this study is entirely your choice and you are free to decide not to take part or to withdraw from the study at any time without having to give a reason. This will have no effect on your future medical treatment.



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Partners:

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You will be reimbursed for time and any reasonable travel costs associated with attending study visits.
Yours sincerely
Interface Clinical Services (Research Team)
On behalf of the practice