Study protocol for the MobilE artificial Intelligence Solution for diabeteS Adapted Care - MELISSA trial

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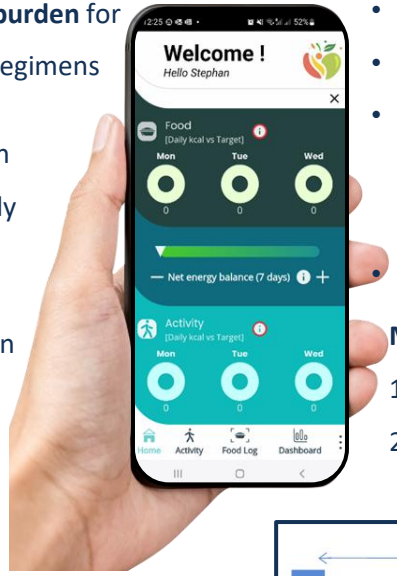
Background

- Achieving **optimal glycaemic control** remains a **burden** for many people with diabetes on intensive insulin regimens
- **Current digital solutions** are **restricted** to certain treatment modalities and populations, potentially **contributing** to **health disparities**
- **Multiple factors affect glucose** levels, e.g., insulin dose, carbohydrate content meal, stress, illness, exercise and sleep
- **Digital tools** based on artificial intelligence (**AI**) that consider these factors can **benefit** daily decision making on **insulin therapy** and improve **glycaemic** control



Aim

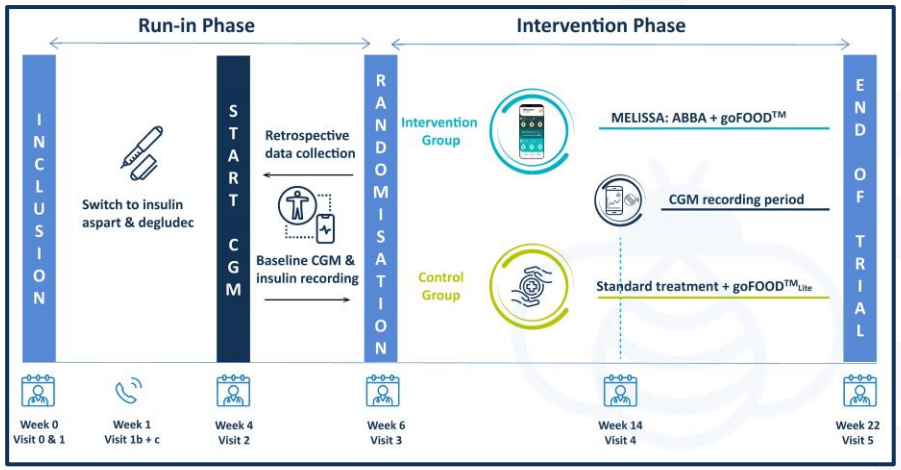
To **develop** and clinically **validate** the **MELISSA application** to support people with diabetes on multiple daily insulin injections (MDI) in their daily glucose management by providing individualised basal and bolus insulin suggestions

Methods

- **Randomised** (1:1) controlled parallel-group **trial**
- Study duration **22 weeks**
- **Participants**: people with **type 1** (n = 382) and **type 2** (n = 90) **diabetes,** age 16-80 years, on MDI and who have a HbA1c value of 49-86 mmol/mol (6,6%-10%)
- Four countries

MELISSA application introduces **two AI**-driven **features:**

1. Adaptive basal-bolus advisor (**ABBA**) algorithm
2. Image-based automatic dietary assessment system, **goFOOD™**



Study design: a **6-week run-in phase** & a **16-week intervention phase** during which **ABBA and goFOOD™** (providing continuous-scaled energy and macronutrient information) is tested **against continuation** of **standard treatment**.

Outcomes

- **Primary outcome**: time spent in target range (**TIR, 3.9-10.0 mmol/L**) based on blinded CGM.
- **Secondary outcomes**: hypoglycaemia, glucose metrics, patient-reported outcomes (e.g., quality of life) and MELISSA usage & safety

Conclusion

MELISSA has the **potential** to **improve glycaemic control** and **support** people with diabetes in their **self-management by** providing **AI**-driven **individualised insulin** dose **suggestions.** This digital solution is **independent** of currently available **diabetes management** devices.

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