GENERAL PRACTICE OPTIMISING STRUCTURED MONITORING TO IMPROVE CLINICAL OUTCOMES IN TYPE 2 DIABETES: THE GP-OSMOTIC STUDY PROTOCOL

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Introduction

Achieving glycaemic targets is associated with long-term micro and macrovascular benefits. Achieving glycaemic targets in primary care, where the majority of people with type 2 diabetes (T2D) receive their care, is challenging.

Collecting meaningful blood glucose data to guide rational lifestyle and therapy changes to achieve glycaemic targets has been shown to be effective but raises a number of challenges.

New technologies of continuous glucose monitoring offer the opportunity to overcome barriers to collecting meaningful real-time glucose data in a real-world clinical setting. Evidence of their effectiveness in primary care and in people with T2D is limited.

Our aim is to assess the (cost) effectiveness of retrospective continuous glucose monitoring (rCGM) in an inclusive population of adults with T2D in primary care. A further aim is to gather robust hypoglycaemia prevalence and glycaemic variability data in this population.

Materials and Methods I

GP-OSMOTIC is an individually randomised controlled trial set in General Practices in Victoria, Australia, testing the effect of the FreeStyle Libre Pro® Flash Glucose Monitoring System (Abbott) applied for 14 days, on 4 occasions per year, compared with usual care.

A collaborative educational consult with a Credentialed Diabetes Educator – Registered Nurse (CDE-RN) will be provided to all participants.

Eligible patients: T2D (> 12 months), aged 18-80 years, diabetes duration >1 - <20 years and most recent HbA1c (in the previous 6 months) >7mmol/mol (0.5%) above their individualised target on maximum oral therapy and/or injectable therapy (insulin and/or GLP1 agonists).

All participating health professionals will take part in a 2 hour training session, with a focus on how to interpret the Ambulatory Glucose Profile (AGP) reports generated by the device. No clinical guidance will be given as patients will be managed according to standard clinical practice.

Materials and Methods II

Evaluation at baseline and 12 months will include:
1. HbA1c (primary outcome), measured as absolute difference in mean change in HbA1c at 12 months between the intervention and control arm;
2. time in target (4-10mmol/L), assessed from data downloaded from the rCGM device worn at baseline and 12 months (blind to the control group participants); and
3. diabetes distress (Problem Areas in Diabetes (PAID) scale).

We will also measure hypoglycaemia, glycaemic variability, additional patient-reported outcomes, acceptability to health professionals and patients, and cost-effectiveness (informed by EQSD, the resources used to administer the intervention and health service utilisation data).

Conclusion

The OSMOTIC Study will generate cost effectiveness evidence about the potential of Flash rCGM technology to drive personalised treatment intensification to achieve glycaemic targets, with important implications for clinical practice and health policy.

References


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