UNIVERSITY OF CAMBRIDGE

IMS Institute of Metabolic Science

CLOSED-LOOP FROM ONSET IN CHILDHOOD TYPE-1 DIABETES (CLOUD): A RANDOMISED CONTROLLED TRIAL TO ASSESS THE EFFECT OF CLOSED-LOOP INSULIN DELIVERY ON RESIDUAL BETA-CELL FUNCTION

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Background

- Retention of beta-cell function in type 1 diabetes (T1D) is associated with reductions in short- and long-term complications
- The impact of continued intensive metabolic control on beta-cell function using closed-loop insulin delivery following diagnosis is unknown

Objective

- The CLOuD study aims to assess the effectiveness of hybrid closed-loop initiated at T1D diagnosis on the preservation of beta-cell function compared to standard multiple daily injection therapy

Methods

- CLOuD adopts an open-label, multi-centre, randomised, single-period, two-arm parallel group study design (see Figure 1)
- We aim to recruit 96 randomised participants over 2 years
- Eligible patients (youths with T1D aged 10 to 16 years) are approached at 5 UK sites within 2 weeks of diagnosis
- In closed-loop participants, the FlorenceM hybrid closed-loop system is initiated within 6 weeks of diagnoses and applied over a 2-year period (see Figure 2, Figure 7)
- The primary outcome is C-peptide concentration (AUC) during mixed-meal-tolerance-test (MMTT) at 12 months post diagnosis
- Secondary outcomes include residual beta-cell function at 6 and 24 months, glycaemic control and insulin requirements
- Participants' and their families' cognitive, emotional, and behavioural characteristics and their response to trial participation will be evaluated; a cost-utility analysis will be performed.

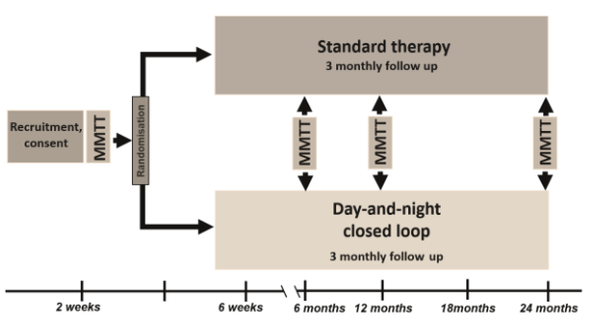

Figure 1. Study design for CLOuD study

Abbreviations

AUC	Area under the curve	MMTT	Mixed meal tolerance test
DKA	Diabetic ketoacidosis	T1D	Type 1 diabetes

Figure 2. FlorenceM closed-loop system

Results

- Recruitment started in January 2017
- Between January and October 2017, 25 participants were recruited, of whom 14 were randomised to closed-loop intervention (see Figures 3 to 6 for participants' characteristics)
- Over this period, there were no dropouts, and none of the subjects starting closed-loop had discontinued treatment

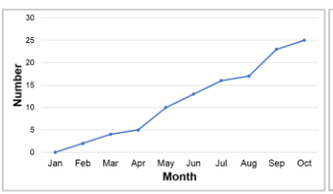

Figure 3. Accumulated recruitment

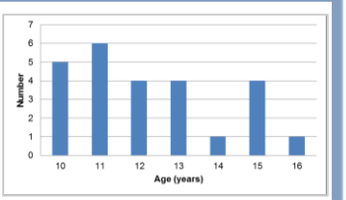

Figure 4. Age of study participants

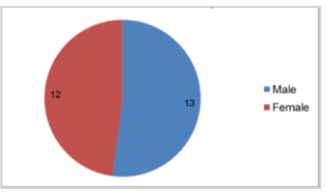

Figure 5. Gender of study participants

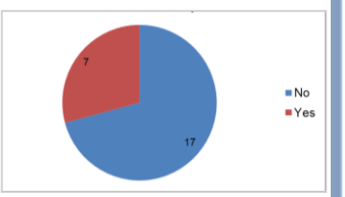

Figure 6. Presence of DKA at diagnosis

Conclusions

- Preliminary findings suggest that starting closed-loop shortly after diagnosis of T1D is feasible
- CLOuD study will generate evidence about safety, efficacy, utility, user-acceptance and cost-effectiveness of closed-loop in new onset diabetes

Acknowledgements

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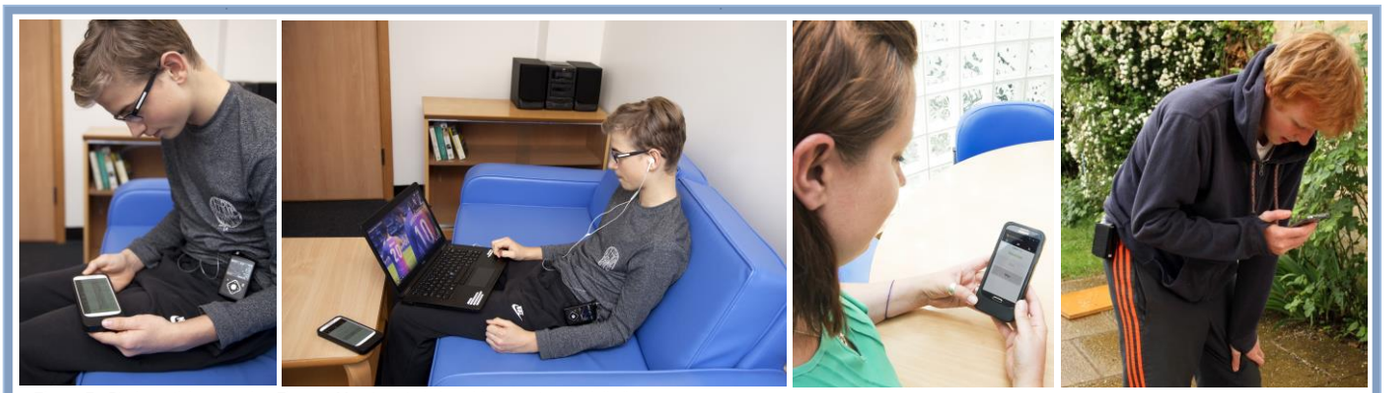

Figure 7. Study participants using FlorenceM automated closed-loop system in daily living