Glucose variability in Type 1 Diabetes & glycaemic responses to food composition

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Ethics approval: NHS, Invasive or Clinical Research (NICR) Panel, University of Stirling and the West of Scotland Research Ethics Service (WoSRES) REC 5 (20/WS/0123). IRAS ID 273640

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Glucose variability in Type 1 Diabetes & glycaemic responses to food composition

- Study Protocol
- Ethics
- Recruitment

Study Protocol

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Rationale

- Limited published data on glucose variability & postprandial hyperglycaemia after breakfast

Aim

- To describe distribution & dispersion of glucose variability & postprandial hyperglycaemia following breakfast

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Main objectives

- Determine glycaemic variability
- Determine the variability of glucose excursion in the 4-hr postprandial breakfast period
- Describe comparisons between measurements & variables

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Study design

- Enroll Paediatric Diabetes Dietitians to recruit participants
- Collection of Dexcom CGM data
- Collection of data on breakfast meal & postprandial period

Main inclusion criteria

- Age between 1-17 years
- Diagnosis of T1D for a minimum of one year
- Using MDI (with carbohydrate counting) or CSII
- Using Dexcom CGM on a regular basis.
- Access to internet and email

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Methodology

- Baseline data: Sex, DOB, anthropometrics, HbA1c, date of diagnosis, insulin doses, regimen
- Glucose measurements: Dexcom CGM data
- Survey questionnaires & photo food diaries:
  - Morning questionnaire - breakfast meal & insulin management.
  - Photo of breakfast
  - Evening questionnaire - 4-hr postprandial activities, intake & adjustments
- Amendment - recruitment for CGM data only

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Outcome measures

- Primary measure - mean glucose in the four-hour postprandial breakfast period
- Secondary outcome measures for glucose variability: TIR, TBR and TAR
- Secondary outcome measures for the 4-hr postprandial period:
  - Mean of peak, time to peak, time to recover. TIR, TBR, TAR
  - Comparisons of the above between cohorts & variables

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Data analysis

- Descriptive statistical analysis to describe, summarise and visualise data
- Outputs will include the distribution of glucose levels and diurnal, nocturnal and post-breakfast variability to determine the spread and dispersion of the data.

Ethics process

- University ethics
- IRAS application
- REC - West of Scotland Research Ethics Service (WoSRES) REC 5
- Health Research Authority & Health & Care Research Wales (HRA & HCRW); NRS Permissions CC Team
- Individual NHS sites – R&D
- Issue of the UK Local Information Pack

Recruitment

- Enroll RDs
- UK Local Information Pack
- R&D - capacity and capability
- RDs - role of Principal Investigator (PI) & recruit
- Investigator – Dexcom sharing data invite, arranges completion of questionnaires

Recruitment - NHS sites:

- Scotland: Fife (PI: Julie Nicol), Greater Glasgow & Clyde (PI: Kirsty Maclean
- Wales: Betsi Cadwaladr (PI: Sophie Lennon), Swansea (PI: Kevin Miller)
- Midlands: Birmingham Women's & Children's (PI: John Pemberton), Leeds (PI: Frances Hanson), Leicester (PI: Sue Roach)
- South-West: Royal Devon & Exeter (PI: Maria Leveridge)
- South-East: Epsom & St Helier (PI: Kate Keen), Lewisham & Greenwich (PI: Adele Swart), Surrey & Sussex (PI: Vanessa Phillipson)

Recruitment - to date

- *n* = 95
- 46% female
- Mean age 9.9 years
- 76% on insulin pump therapy
- CGM data - *n* = 87
- CGM data & completed questionnaires - *n* = 71
- Morning questionnaires - *n* = 437
- Evening questionnaires - *n* = 384

What next…

- Analyse data
- Write up protocol for second phase
- Submit second phase to ethics
- Write up results of first phase
- Enroll RD’s for next phase

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Thank you for listening

Any Questions?

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