

MTech4U - integrated care for pregnant women with type 1 diabetes using wearable technology

Submission date 17/08/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 24/08/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 09/06/2023	Condition category Nutritional, Metabolic, Endocrine	<input checked="" type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Type 1 diabetes (T1D) is an auto-immune condition (where the immune system attacks the body) for which there is no cure. It is self-managed with insulin and regular blood glucose tests, in partnership with a specialist hospital team and other healthcare professionals. In Northern Ireland, about 10,000 people have T1D. The condition affects about 115 pregnancies and births each year. While the advances in insulin and the use of wearable technologies have improved these pregnancies, there are up to five times more problems than for non-diabetic populations. The use of wearable technologies, such as glucose sensors and activity monitors can help to improve self-management using computers and artificial intelligence. The current challenge for pregnant women with T1D is making sense of the data available and responding accordingly. Pregnancy guidelines recommend activity as an intervention to reduce the risk of blood clots. Having T1D makes it difficult to keep blood glucose levels in a safe range and activity causes pregnant women with T1D to have concerns.

The aim of this study is to identify significant patterns between blood glucose, insulin, diet, activity and heart rate and to look at how these connections affect pregnancy outcomes. This information might help pregnant women with T1D to have more normal pregnancies.

Who can participate?

Pregnant women who have had T1D for more than 1 year. They must be aged between 18-50 years old and able to read and speak English

What does the study involve?

Participants wear a glucose tracker and a fitness tracker. They will be asked to keep a diary to record periods of sickness or busy days as this may have an impact on their blood glucose levels. The women will record insulin doses and carbohydrates eaten. Photos of food eaten will help the research team to learn more about the link between food, insulin, and blood glucose. The fitness tracker will be provided by the research team but no physical activity levels will be provided. All women will follow normal pregnancy guidance around activity levels as advised by the hospital team. Blood pressure readings will be taken at each antenatal clinic visit as part of routine care. Readings from the glucose sensor and the wearable fitness tracker will be collected at the end of each fortnight's observation by the researcher.

What are the possible benefits and risks of participating?

The study is low risk with no interventions, apart from wearing a commercially available fitness tracker. There is a possibility that a participant may suffer a pregnancy loss or a poor pregnancy outcome. It is hoped that the information from this research will help to make pregnancies to women with T1D more normal. As these women use insulin, they may sometimes have low blood glucose and need help from other people. They will be asked to check their blood glucose a minimum of eight times per day and will be supported by the hospital team.

Where is the study run from?

Ulster University in association with Craigavon Area Hospital (UK)

When is the study starting and how long is it expected to run for?

March 2020 to July 2022

Who is funding the study?

Department for the Economy, Northern Ireland (UK)

Who is the main contact?

Mrs Dawn Adams

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Contact information

Type(s)

Public

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

261867

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

IRAS 261867

Study information

Scientific Title

Pregnant women with type 1 diabetes - does wearable technology improve outcomes?

Study objectives

The purpose of this study is to investigate the use of wearable technologies by pregnant women with type 1 diabetes (T1D). The study will involve collecting data from pregnant women who have T1D and are using wearable technologies, such as the FreeStyle Libre glucose monitor and commercially available fitness tracker. Wearable glucose monitors have previously been shown to improve outcomes in pregnancies complicated by Type One diabetes. Computational analysis will be used to identify statistically significant correlations between insulin, carbohydrate, heart rate, activity and blood glucose data using a Flash glucose monitor and a commercial fitness tracker, over two weeks in each trimester of the pregnancy. The study will last for approximately 18 months. All data collected will be subject to Bayesian and statistical analysis. The researchers hope to increase understanding of the benefits of time spent in the optimal range for blood glucose, which is currently 3.5-7.8 mmol/l during pregnancy, specifically among those women using multiple daily injections of insulin.

A cross-sectional analysis of information collected from wearable technologies using computational approaches may identify the impact of the data generated on pregnancy duration, maternal health in pregnancy, neonatal birth-weight and neonatal blood glucose levels.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 15/09/2020, NHSBT Newcastle Blood Donor Centre (Holland Drive, HRA Newcastle, NE2 4NQ, UK; +44 (0)2071048265; tyneandwearsouth.rec@hra.nhs.uk), REC ref: 20/NE/0193

Study design

Observational single-centre study

Primary study design

Observational

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied

Pregnant women with type 1 diabetes

Interventions

Fitness trackers will be given to consented participants by the Researcher at the start of the period of data collection, that is gestational week 9-11. Participants will be asked to wear the device on their non-dominant hand for a period of 2 weeks. After this time, data from the

interstitial glucose monitor and the fitness tracker will be analysed using support vector machine (SVM), Bayesian Networks and Gaussian Regression models to identify potential correlations between the data sets and the impact on glucose levels, specifically Time in Range.

Intervention Type

Device

Phase

Phase I

Drug/device/biological/vaccine name(s)

FreeStyle Libre Interstitial Glucose Sensor, MiBand 5 fitness tracker

Primary outcome(s)

1. Time spent in the optimum glucose range of 3.5 mmol/mol - 7.8 mmol/mol measured using the Abbott FreeStyle Libre 14-day glucose sensor as a percentage at three timepoints, i.e. weeks 9-13, 20-24 and 32-36
2. HbA1c in mmol/mol gathered from Laboratory Reports filed in the Northern Ireland Regional handheld maternity records (readings obtained from capillary blood glucose samples as part of the routine care pathway within the antenatal clinic) between weeks 9-13, 20-24 and 32-36
3. Number of hypoglycaemic/hyperglycaemic episodes in minutes per day as a percentage of time measured using the Abbott FreeStyle Libre 14-day glucose sensor between weeks 9-13, 20-24 and 32-36

Key secondary outcome(s)

The following outcome measures (except 8) are collated from written/printed records within the Northern Ireland Regional handheld maternity records. These contain NIMATS (Northern Ireland MATernity System) antenatal, intranatal, postnatal and neonatal reports as well as Lab reports for all blood results:

1. Pre-eclampsia defined as new-onset hypertension with simultaneous proteinuria developing at any point from 20 weeks' gestation
2. Mode of delivery, i.e. vaginal, instrumental - forceps or ventouse, elective caesarean section emergency caesarean section as a percentage of participant outcomes measured at the time of birth
3. Gestational age in completed weeks and days measured at the time of birth
4. Live born infants, number and percentage measured at the time of birth
5. Infant birthweight in grams, measured at the time of birth
6. Perinatal mortality, number and percentage of births measured from 20 weeks' gestation until 7 days after the birth
7. Neonatal death, in numbers and percentage measured from 7 days after birth until 28 days after birth
8. Neonatal blood glucose levels in mmol/mol, collated from the Neonatal Hypoglycaemia Pathway within each infant's neonatal chart (neonatal glucose levels measured using the Abbott FreeStyle Precision Pro glucometer) within 3 hours of birth and during the first 48 hours of life
9. Maternal weight change in kg measured at the booking visit and on admission to the delivery suite for induction of labour, or in spontaneous labour, or for elective caesarean section. Mothers undergoing emergency caesarean section will have been weighed on admission to the delivery suite as per the hospital protocol

Completion date

14/07/2022

Eligibility

Key inclusion criteria

1. Women with T1D in the first trimester of pregnancy
2. Aged 18 - 50 years old
3. Duration of diabetes >1 year
4. Using multiple daily injections or insulin pump therapy
5. Using an interstitial glucose sensor
6. BMI <40 kg/m²
7. Have undertaken a program of structured education for carbohydrate counting
8. Able to understand English

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

50 years

Sex

Female

Key exclusion criteria

1. Less than 18 years of age
2. Type 2 diabetes (T2D) or a genetic variant of diabetes
3. Diagnosed <1 year
4. Not using multiple daily injections or an insulin pump
5. Have not undertaken a program of structured education including carbohydrate counting
6. >13 weeks pregnant at the time of presenting to the antenatal clinic
7. Unable to read or understand English

Date of first enrolment

08/07/2021

Date of final enrolment

29/01/2022

Locations

Countries of recruitment

United Kingdom

Northern Ireland

Study participating centre

Craigavon Area Hospital

68 Lurgan Road

Craigavon

Portadown

United Kingdom

BT63 5QQ

Sponsor information

Organisation

University of Ulster

ROR

<https://ror.org/01yp9g959>

Funder(s)

Funder type

Government

Funder Name

Department for the Economy

Alternative Name(s)

An Roinn Geilleagair, Department for the Economy NI, Department for the Economy (Northern Ireland), Department for the Economy, Northern Ireland, Northern Ireland, Department for the Economy, DfE

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Dataset	version 2		23/08/2022	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version 2	01/06/2020	19/08/2021	No	Yes
Protocol file		28/07/2020	19/08/2022	No	No