ISRCTN25071503 https://doi.org/10.1186/ISRCTN25071503

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

Submission date
17/08/2021

Recruitment status
No longer recruiting

Registration date
24/08/2021

Overall study status
Completed

Last Edited
09/06/2023

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[X] Individual participant data
[_] 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
261867

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
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 toinvestigate 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

Secondary study design
Case series

Study setting(s)
Home, Hospital, Internet/virtual

Study type(s)
Diagnostic

Participant information sheet

See additional files

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 measure
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

Secondary outcome measures
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

Overall study start date
24/03/2020

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
50 Years

Sex
Female

Target number of participants
20

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
Northern Ireland

United Kingdom

Study participating centre
Craigavon Area Hospital
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Sponsor type
University/education

Website
https://www.ulster.ac.uk/campuses/jordanstown

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

Publication and dissemination plan
A study protocol has not been published. It can be made available on request. It is anticipated that research papers generated as a result of this study will be submitted for publication to peer-reviewed journals in the fields of computer science, midwifery/obstetrics, diabetes and potentially physical activity, as this is a multi-disciplinary PhD trial. Findings will also be made available on the Doctoral Midwifery Research Society website.

Intention to publish date
19/12/2024

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?
Participant information sheet	version 2	01/06/2020	19/08/2021	No	Yes
Protocol file		28/07/2020	19/08/2022	No	No
Dataset	version 2		23/08/2022	No	No
HRA research summary			28/06/2023	No	No