Integrated Care for Pregnant Women with Type One Diabetes using Wearable Technology

Research Protocol

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Background

Type one diabetes (T1D) is an auto-immune condition resulting from the destruction of pancreatic β-cells which requires insulin to be administered for survival. It is a chronic condition for which there is currently no cure [1]. Causative factors are unknown, although probable causes are believed to be genetic susceptibility combined with viral or environmental factors [2]. The condition affects 400,000 people in the UK, more than 29,000 of whom are children. Annually the incidence of T1D is increasing by about 4%, with a 5% increase in children aged under 5 over the last two decades [3]. Since the discovery of insulin in 1921, and more recent advances in technology, this formerly fatal diagnosis has allowed those with the condition to lead long and healthy lives. This is increasingly due to education and awareness of the positive impact of 'self-management' [4]. Self-management combines the necessary individual actions performed daily to identify individual concerns and problem-solving strategies necessary to treat and manage an individual's health, either independently or in partnership with the Endocrine team and associated healthcare professionals (HCPs) [5].

In Northern Ireland, approximately 100,000 people are known to have diabetes, of whom 10,000 have T1D [6]. T1D affects 1% of all pregnancies in Northern Ireland, approximately 85 pregnancies and births annually. While the advances in insulin analogues and the development and use of wearable technologies have improved pregnancy outcomes, particularly maternal glycaemic control, pre-eclampsia, foetal malformation and mortality rates remain 2-5 times greater than for non-diabetic populations [7] [8].

The Topol Report (2019) recognises the increased use of wearable technologies, such as glucose monitors and activity monitors to collect, store, access and share medical and other health-related data [9]. The use of finger-prick blood glucose meters for self-monitoring and self-management have been central to managing T1D since the mid-1980's. Implantable sensors for continuous glucose monitoring became available on prescription in November 2017 throughout the UK. Wearables for remote vital-sign monitoring including accelerometers to track vital signs, including heart rate, respiratory rate, blood oxygen saturation and blood pressure have been accepted into daily routines. The Report asserts that sharing this data in a responsible and ethical way can benefit research. The Report also identifies the potential for improved self-management of chronic conditions through integration of

multi-modal data incorporating the disciplines of genomics, sensors and AI [9]. The use of AI techniques such as deep learning will define normality for an individual and may help them to make sense of the information available. The current challenge for pregnant women with T1D is making sense of the data available and responding accordingly. A review of the literature has identified few studies investigating the use of wearable technologies, including intermittent glucose monitors (IGM), for participation in regular physical activity (PA) to reduce blood pressure, glycaemic variability, and maternal weight gain within this population [10] [11]. The influence of IGM on PA and dietary intake on the cardio-vascular health of pregnant women with T1D using multiple daily injections [10] is an area requiring further research. Pregnancy guidelines recommend PA as an intervention to reduce the risks of venous thromboembolism and pre-eclampsia [11] [12]. The physiology of T1D impacts rates of success on safely maintaining optimal glucose levels when combining food, exercise and insulin therapy [3] [10] [11]. Activity levels also impact blood glucose levels in various ways. As a result, pregnant women with T1D have concerns around PA and hypoglycaemia [11].

Aim

The aim of this research is to identify statistically significant correlations between blood glucose, insulin, diet, PA and Heart rate (HR), and to identify the importance of these connections with pregnancy outcomes.

A potential impact of the cross-sectional analysis of the information collected from wearable technologies using computational approaches may inform pregnant women with T1D to achieve optimal physical activity and euglycaemia while reducing incidences of maternal pre-eclampsia and neonatal hyperinsulinaemia due to increasing time spent in the optimal glycaemic range for pregnancy, which is 3.5-7.8mmol/L.

Research Questions

This research will answer three questions:

1. Can the application of machine learning identify relationships between glucose levels, exogenous insulin, carbohydrate intake, activity intensity and heart rate in pregnant women with T1D?

2. Can computational analysis enhance understanding of relationships between data-sets and their combined impact on pregnancy outcomes?
3. How can the data gathered from wearable technologies by pregnant women with T1D be integrated to benefit self-management of this chronic condition?

Objectives

The objectives are:

1. To identify and analyse correlations between data-sets generated by wearable technologies when used by pregnant women with T1D. These data-sets include, but may not be limited to, heartrate variability, intensity of activity measured as steps per day, insulin doses administered, carbohydrates eaten and their impact on glucose levels, specifically time spent in the prescribed target-range of 3.5-7.8mmol/L.
2. To observe the potential association of PA on blood glucose levels, particularly time spent in the target range identified above.
3. To develop learning algorithms using correlations between glucose levels, insulin, diet, PA and HR, and the cumulative effects of non-pharmacological activities on glucose management using results obtained in the first two objectives.

Methodology

Participants and Recruitment - Eligibility

Following advice from the Lead Clinician within the Southern Trust, it has been decided that all eligible women will be invited to participate in this research. Therefore, no exclusion criteria other than non-consent for inclusion within the study will be applied.

Inclusion criteria

Inclusion Criteria	
Ages Eligible for Study	18 years and older (Adult, Older Adult)
Sexes Eligible for Study	Female
Type of Diabetes	Type One
Duration of diabetes	> 1 year
Insulin administration	Multiple daily injections or pumps
Structured Diabetes Education	DAFNE*, or similar
BMI	< 40
Condition	Pregnant
Language	Able to read and understand English

Exclusion criteria

Not consenting to participation in this study will be the only exclusion criteria.

Promoting the Research

This research is taking place within Craigavon Area Hospital. Clinical staff and the Research & Development team, have been contacted and have agreed to facilitate the research. Posters informing service-users of the nature of the study and its purposes will be distributed (Appendix One).

Recruitment

The study will be undertaken during pregnancy with participant recruitment taking place in Craigavon Area Hospital, within the Southern Health and Social Care Trust (SHSCT). A meeting will be held with the Head of Midwifery and the Multi-disciplinary team prior to displaying posters to advertise the research project. A Principal Investigator will be appointed to liaise with the investigation team in accordance with The European Patients Forum general principles [13].

Participant Information Sheets (Appendix Two) will be sent to potential recruits with their booking appointment letters. The letters will be sent approximately 14 days in advance of the clinic appointment, which generally takes place at 7-9 weeks' gestation for women with T1D. This will provide detail on what the study involves, what they are required to do and how their data will be used. Any questions the participant has will be answered during their first visit to the antenatal clinic, between 7-10 weeks' gestation, the researcher will have the opportunity to discuss the study requirements and answer any questions. The researcher can be contacted directly using the number provided. Consent forms and pre-addressed stamped envelopes will be provided by the researcher, for the return of consent forms to Ulster University. Women will also be provided with the researcher's university email address and a dedicated contact number as they may have further questions before consenting. Rolling recruitment will begin following ethical approval with the final collection of datasets taking place in August 2021.

Participant numbers are anticipated to be 25 pregnant women with Type 1 Diabetes. There are approximately 19 women with T1D who receive their antenatal care in Craigavon Area Hospital annually, therefore a rolling recruitment over 18 months

should see a sufficient number of women recruited to provide enough data points for the computational analysis proposed.

Procedure

Study design

The research is an observational cross-sectional study. It comprises of the collection of datasets from participants to analyse pregnancy outcomes based on data from the most commonly used wearable technologies by people with T1D. These wearable technologies are:

- a FreeStyle Libre™ glucose monitor, prescribed by the hospital Consultant
- a FitBit™ activity tracker which will be provided by the University research team.

Participants will also use their own glucometers and insulin pens or pumps.

Data from the FreeStyle Libre™ and Fitbit™ will be collected for two weeks in each trimester of pregnancy. These data sets are available electronically. Information about insulin doses administered is available from capillary blood glucose monitors or patient diaries which are provided by the hospital endocrine team. A knowledge of carbohydrate values is required for insulin administration. This information is also available from capillary blood glucose monitors or individual patient diaries. The information for insulin and carbohydrates can also be entered into the FreeStyle Libre database by users, making it available for download. Carbohydrate calculations may be validated using photographs of food eaten. As many people with T1D use a software application, 'Carbs&Cals', to calculate carbohydrate doses before administering insulin this could also potentially facilitate an electronic record of food eaten. Heart rate data is available from the FitBit app – an online resource which is populated with information generated by the wrist-worn wearable. Active minutes are also accessible from the online FitBit resource.

Computational approaches will be applied to analyse and identify correlations between glucose, diet, activity, insulin and glucose control and inform the development of algorithms to process the data collected. This has the potential for prediction of insulin requirements to facilitate glucose management during exercise in pregnancy.

Study Requirements

As this is an observational cross-sectional study, this section explains the factors for observation and wearable technology pertinent to the study.

Pregnant women with T1D will be recruited between 7-10 weeks' gestation. Gestation, HbA1c, weight and Blood Pressure will be obtained with consent at the beginning of each fortnight of observation, that is from week 7-10 in the first trimester, week 20-24 in the second trimester and week 33-37 in the third trimester. They will use standard technology for insulin administration and blood glucose monitoring as required by the SHSCT Endocrine team, following NICE Guidelines [14]. A FreeStyle Libre™ glucose sensor will be worn by the women. This is scanned a minimum of once every 8 hours, although it is usually scanned 10-20 times per day. It provides a graph of continuous interstitial glucose levels, which equates to a minimum of 96 data points over a period of 24 hours. The graph informs users of current and past glucose levels, trends after eating, before driving etc. When glucose levels are rising or falling it gives additional information on the speed of change using directional arrows. Participants will be asked to record insulin doses administered and carbohydrate intake on the FreeStyle Libre™ handset. This will provide feedback to the HSCT care team regarding insulin titration. A Fitbit™ activity tracker will be provided by the University and should be used for two weeks each trimester. This is worn on the non-dominant wrist. Among the various pieces of information recorded by the tracker those relevant to the study include steps walked, heart rate and minutes of activity per day. Participants will be asked to record all episodes of physical activity each day using the FreeStyle Libre™ "Comments" facility. No specific physical activities will be recommended as this is a free-living observational study. All participants will follow normal pregnancy guidance around activity levels [15]. They will be encouraged to record periods of activity in the blood glucose diary provided by the hospital team. Blood pressure readings will be taken at each ante-natal clinic visit. Readings from the FreeStyle Libre™ and FitBit™ wearables will also be collected at the end of each fortnight's observation. The data from the FreeStyle LibreTM and the FitbitTM will be processed and analysed as outlined above. Participants will be asked to keep a diary recording the type and duration of physical activity undertaken each day, if any. They may wish to record periods of sickness as this will have an impact on their glucose readings, and potentially on insulin doses and carbohydrate intake. A photographic record of food eaten will enable

assessments of portion size and carbohydrate intake to facilitate researcher awareness of carbohydrates consumed [16] [17] [18]. This will include treatments for low blood sugar episodes. The diary would enable participants to record their thoughts and feelings about the information provided by the wearables and personal responses to it. This would permit co-designed modifications in the research and potentially identify reasons for disengagement or compliance based on user feedback.

Research sample

Study Type	Observational cross-sectional study
Estimated Enrolment	20 participants
Allocation	Not randomised
Primary Purpose	Investigative
Official Title	Integrated Care for Pregnant Women with Type One Diabetes using Wearable Technology
Study Start Date	Summer 2020
Estimated Primary Completion Date	Autumn 2021
Estimated Study Completion Date	November 2021

Participant Requirements

Access to:	***Use***	***Data Collection***
Normal daily activity	Capillary glucose monitoring as per HSCT Protocol.	BG monitor downloads
	Use of MDI and insulins as prescribed and identified by the MDT within the HSCT.	BG diary & glucometer
	Self-reporting of dietary intake.	Photo log of foods eaten
	Self-reporting of daily activity.	
FreeStyle Libre intermittent glucose monitoring system	Use of FreeStyle Libre intermittent glucose monitoring system to record:	Libre and software
	- Carbohydrate intake	Fitbit dashboard/API
Fitbit Activity Tracker	- Insulin doses	
	- Activity type & duration	Diary of - thoughts and
	Use of Fitbit activity tracker to record:	feelings about the
	- Heart rate	information provided by
	- Steps	the wearables and
	- Active minutes	personal responses

Outcome measures

Primary Outcome	***Time Frame***	***Recorded data***
Time spent in the target glucose range of 3.5-7.8mmols/L and HbA1c <40mmol/mol	After gestational week 10 to last planned measurement at gestational week 37 or prior to birth.	Measured in % Proportion of subjects
Birth weight	At birth	Measured in kg
Secondary outcomes		
Number of hypoglycaemic episodes	During the pregnancy period (from first day of randomisation to birth)	Count of episodes
Pre-eclampsia defined as new-onset hypertension occurring from gestational week 20 to birth with simultaneous proteinuria or presence of eclampsia	Occurring from gestational week 20 to delivery	Number of combined events
Change in body weight	From early pregnancy baseline to last planned recording before giving birth)	Measured in kg and/or %
Mode of delivery, e.g. vaginal, operative vaginal, planned caesarean section or unplanned caesarean section, induced or spontaneous delivery	At birth	%
Pre-term delivery (delivery before 37 completed gestational weeks)	At birth	Number of events
Live born infants	At birth	Number of children
Early foetal death (delivery before 20 completed GWs)	At birth	Number of events
Perinatal mortality (death of foetus/infant)	Between at least 20 completed GWs before delivery and before 7 completed days after delivery	Number of children
Neonatal mortality (death of infant)	Between at least 7 completed days after delivery and before 28 completed days after delivery	Number of children

Data Collection

It is intended that data collection will commence in June 2020 and continue until October 2021. This should allow sufficient time to collect a substantive number of datasets, facilitating the recruitment of a sufficient number of women into the project.

Data sets

The following data sets will be collected over the period of two weeks in each trimester.

Glucose levels:

- Collect data from participants using the FreeStyle Libre™ flash glucose monitor. The monitor is provided by the NHS and is available on prescription from GP surgeries on the recommendation of the Endocrine consultant. It is applied by the user and worn on the upper arm. Data is collected every 15 minutes for 14 days and stored in a database.

Physical activity:

- Collect data on steps taken, HR and minutes of activity per day from participants using an identified wearable fitness tracker provided by the researcher. The data is stored in a database.

Data analysis

The data collected will be analysed using linear and non-linear regression methods, and clustering to identify the strength of relationships between glucose, insulin, diet, activity and heart-rate. The intention is to develop algorithms to facilitate blood glucose management, specifically time spent in the target glucose range of 3.5-7.8mmols/L.

Storage

The information collected from participant information sheets and any written information pertaining to participants will be stored in a locked cabinet in Block 16. Access will only be available to members of the research team.
https://www.ulster.ac.uk/__data/assets/pdf_file/0003/75639/DataHandling.pdf

Electronic datasets will be stored on a secure, password encrypted server with Ulster University. Each participant's datasets will have a Unique Participant Identifier to maintain anonymity, minimising the potential for identification.

Ethical approval

The study will be peer reviewed by a member of academic staff of Ulster University prior to seeking ethical approval from the Ulster University Research Ethics Filter

Committee. Once ethical approval has been received, and following amendments, an application will be made to ORECNI.

Ethical considerations

The population for observation are a vulnerable group with specific requirements requiring support and input from the multi-disciplinary team of endocrinologists, obstetricians, midwives and Diabetes Specialist Nurses.

Informed consent

Research participants will be fully informed in writing about the purpose, methods and intended uses of the research, what their participation in the research entails and what risks, if any, are involved. Participants will have this information prior to consenting to inclusion in the study. They will be advised of their right to withdraw from the study at any time if they wish to do so. Consent will be obtained to use any data collected prior to their withdrawal as consent for this cannot be assumed. Independent completion of the consent form will imply voluntary consent.
The study information page (Appendix 1) will be made accessible in the form of a hard copy to all potential recruits.
Anonymised data and randomised identification numbers will be used [13].

Risk Assessment

The research is observational in nature. It is low risk without any interventions, apart from the wearing of a fitness tracker. There is a possibility that a participant may suffer a pregnancy loss or a poor outcome. The SHSCT have bereavement midwives whose services are available to those women experiencing pregnancy loss at any gestation. The hospital multi-disciplinary team will provide access to the service if or when appropriate. Due to the necessary use of insulin participants may experience episodes of hypoglycaemia, low blood glucose, requiring treatment from others. The NICE [14] and SHSCT requirements for regular capillary glucose monitoring will be supported for all participant adherence.

Right to Withdraw

As part of the consent process participants will be made aware that participation is voluntary and that they can withdraw at any time without subsequent effect to them

or the care they receive. All participants will be made aware of their right to withdraw from the study at any stage for any reason. Consent will be obtained to include anonymised data generated by them for inclusion in computational analysis.

Confidentiality and anonymity

Access to all records, paper and electronic, will only be available to identified research team members in accordance with GDPR legislation. The confidentiality of participants will be maintained at all times. All paper documents will be stored in a locked filing cabinet in Ulster University for 10 years and then confidentially destroyed. Great care will be taken when quoting results in publications to ensure no individual party can be identified.

IP addresses and datasets from the FreeStyle Libre™ and Fitbit™ technology will be held on a secure Ulster University database for analysis. All electronic information will be stored on a password protected computer kept in a locked room on Ulster University premises for 10 years and then confidentially destroyed in line with Ulster University policy:
https://www.ulster.ac.uk/__data/assets/pdf_file/0003/75639/DataHandling.pdf

Protection of the participants

Those who wish to participate will be asked to give their name and contact details so the researcher can contact them. Participants will have access to the DSN/Endocrine Consultant responsible for their care. Adverse Event forms will be completed as appropriate. The GDPR guidance for Ulster University can be found here:
https://www.ulster.ac.uk/__data/assets/pdf_file/0006/286008/GDPR-Policy-clean-final-version-14-Jan-20-.pdf

Dissemination

Dissemination and outcomes of findings from the study will be submitted for publication in a peer-reviewed journal. Oral and poster presentations will be submitted to relevant national/international conferences. The study will be written up as part of a doctoral thesis.

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Glossary

1) DAFNE – Dose Adjustment for Normal Eating. This is a structured education programme for people living with Type One Diabetes. DAFNE is a way of managing diabetes which provides people with the skills necessary to estimate the carbohydrate in each meal and to inject the appropriate dose of insulin.
2) FreeStyle Libre™ Flash Glucose Monitor - This is a factory-calibrated sensor worn on the upper arm for a period of 14 days, clinically proven to be accurate and consistent. Glucose readings are obtained by scanning the sensor at least once every 8 hours. The reader displays glucose data as a line graph with a “trend arrow” showing if glucose is rising or falling. The Libre is water-resistant and can be worn while showering, swimming and exercising. It reads glucose levels from interstitial fluid (ISF), a thin layer of fluid that surrounds the cells of tissues below the skin, rather than blood. There is a 5-10minute delay in ISF glucose response to changes in blood glucose. Glucose readings on ISF have been proven to reliably reflect glucose levels. The sensor is approved for use before driving and in pregnancy.

Appendix One

mTech4U

Ulster University

Faculty of Computing, Engineering and the Built Environment

Can you help us with our mTech4U Pregnancy Study?

If you have Type One diabetes and

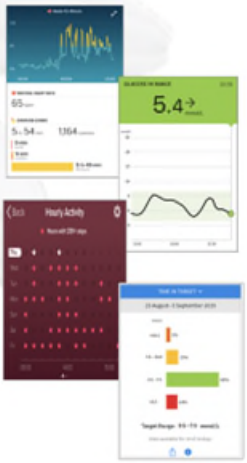
- you are in the first trimester of pregnancy
- use insulin pens or a pump
- use a FreeStyle Libre
- are aged between 18-50 years old
- are willing to wear a fitness tracker

then we need your help

We want to see how your:

- insulin
- food eaten
- daily activity levels
- heart rate
- glucose levels

affect your health in pregnancy.



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Appendix Two

Participant Information sheet for Use of Wearable Technology in Pregnancy by Women with Type One Diabetes – mTech4U

As a pregnant woman with Type One diabetes, you are invited to participate in a research project investigating the use of the FreeStyle Libre glucose monitor and a fitness tracker. Before you decide whether or not to take part, it is important that you understand what the research is for and what you will be asked to do. Please read the following information and ask questions about anything that might not be clear to you.

Project title
Use of Wearable Technology in Pregnancy by Women with Type One Diabetes.

What is the purpose of this study?
We would like to know more about the link between activity levels, heart rate patterns, carbohydrate intake, insulin and glucose levels during pregnancy. We will look at the length of your pregnancy, the birthweight of your baby and their risk of hypoglycaemia after they are born.

Why have I been asked to take part?
You are being invited to take part in this research as you:

- are aged between 18 years of age or older
- have had Type one diabetes for more than 1 year
- have had additional training around managing your condition, i.e. DAFNE or similar
- are using multiple daily injections of insulin
- have no health complications.

What will I be asked to do if I decide to take part?
We will ask you to wear the following devices for a period of two weeks between 7-12 weeks, 18-24 weeks and 30-38 weeks

- a fitness tracker, which will be provided by the research team, to monitor your heart rate, active minutes and number of steps taken each day.
- FreeStyle Libre glucose monitor to record glucose levels, carbohydrate intake & insulin doses taken and any notes e.g. activity, illness etc. We will ask you to email information from your FreeStyle Libre to provide the team with information collected.

We would also like you to photograph the food you eat each day over the two-week period. You can email or WhatsApp these photos to us. Information from the Libre and Fitbit will be collected at the end of each fortnight's use for analysis. The information may help us to better understand blood glucose changes. We would also like you to keep a diary to write about how you feel about taking part in this study.

Do I have to take part?
You do not have to take part in this study, your participation is entirely voluntary. You can choose to stop taking part in the study at any time, but we will use data we have already collected from you for analysis.

Are there any risks to taking part?
No additional risks have been identified. If you have any worries, you are advised to contact your Consultant for further advice. They are responsible for the care of you and your baby. Your agreement to take part in this research will not affect the you or your baby receive.

Benefits
Benefits of this research include increased monitoring during your pregnancy. The results may help women with Type One diabetes and their babies in the future.

What if something goes wrong?
This study has been carefully planned, approved and reviewed by Ulster University and Southern Health and Social Care Trust. As this study is only about the information from your Libre, the food you eat, insulin you take and the Fitbit, no additional risks have been identified.

Will my details be kept confidential?
If you agree to take part in this research your details will be kept confidential. All information collected will be securely stored within Ulster University. It will only be available to the research team. None of your personal details will be available to anyone outside the research team.

What will happen to the results from this study?
The knowledge we gain from this research will be made publicly available through research papers and information posters. No information which could possibly identify you will be available.

Who is organising the study?
This study has been organised by Ulster University in conjunction with the Southern Health and Social Care Trust. It is funded by The Department for the Economy leading to a PhD qualification.

Who can I contact about this study?
If you would like to take part in the study or you would like to speak to someone about this research project, please contact:

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What if I wish to make a complaint about the study?
If you want to make a complaint about this study, or the way it is completed, you can do so using the complaints procedure of Ulster University, which is available here:
https://www.ulster.ac.uk/__data/assets/pdf_file/0011/75638/Complaints.pdf

If you want to know more about the Research Governance process, please contact:

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Appendix Three

For research use only	
ID	

The Use of Wearable Technology in Pregnancy by Women with Type One Diabetes – consent form for participants

Investigators: Dawn Adams, Prof Huiru Zheng, Prof Marlene Sinclair, Prof Marie Murphy, Dr. Julie McCullough

Please initial each box to indicate that you understand and agree to each statement:

I have read and understood the information sheet for this study.	☐
I have had the chance to ask questions about the study and am satisfied with the answers I have been given.	☐
I agree to wear the activity monitor and allow the information from it to be used by the research team.	☐
I agree to provide access to data collected on the FreeStyle Libre, including food intake and insulin given.	☐
I agree to provide access to my maternity records for the research team to access information about blood pressure, HbA1c and weight	☐
I agree to provide photographs of all food eaten to help the research team to learn more about my carbohydrate intake.	☐
I agree to record my thoughts and opinions about my involvement in the diary provided and allow the research team access to this.	☐
I agree to the research team being able to record how and when my baby is born, and knowing the weight, gender and blood glucose levels of my baby.	☐
I know that I can stop taking part in the study at any time without my care being affected.	☐
If I stop taking part in the study at any time all data previously gathered may be used by the research team.	☐
I wish to receive a copy of the study findings and agree to my name and address being retained by the research team for this purpose.	☐
My consent has been given freely and voluntarily.	☐

Name of Researcher accepting consent: _____

Signature: _____ Date: _____ /_____ /_____

Name of Participant: _____

Signature: _____ Date: _____ /_____ /_____

Appendix Four

For research use only	
ID	

Personal Information Trimester 1 (to be completed by the Researcher)

1. Age: ☐

2. Gestation:
   - ❍ 7-8 weeks
   - ❍ 9-10 weeks
   - ❍ 11-12 weeks

3. HbA1c: ☐ mg/dL

4. Height in cm: ☐ cm

5. Weight in Kg: ☐ Kg

6. BMI: ☐ Kg/m^2

7. Pregnancy no: ☐

8. Duration of Diabetes: ☐ years

9. BP /

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ID	

Trimester 2

10. Gestation:
    - ❍ 18-20 weeks
    - ❍ 20-22 weeks
    - ❍ 22-24 weeks

11. HbA1c: [ ] mg/dL

12. Weight in Kg: [ ] Kg

13. BP [ ] / [ ]

Trimester 3

14. Gestation:
    - ❍ 30-32 weeks
    - ❍ 32-34 weeks
    - ❍ 34-36 weeks

15. HbA1c: [ ] mg/dL

16. Weight in Kg: [ ] Kg

17. BMI: [ ] Kg/m^2

18. BP [ ] / [ ]

Appendix Five

GP Notification Letter

Title of Study: Pregnancy, Diabetes and Wearable Technology

ORECNI ref:

Name of PhD Researcher: Mrs Dawn Adams

Email address: adams-d10@ulster.ac.uk

Details of Participant:

(affix hospital label here)

Dear Dr

Your patient has consented to participate in a research project. Please see the enclosed information leaflet for more details on the study. They will receive a Fitbit® wearable fitness tracker to use alongside their FreeStyle Libre® glucose monitor. Your patient will continue to be reviewed regularly by the joint Obstetric and Endocrine team at CAH.

This is a cross-sectional observational mixed methods trial that follows usual practice.

If you have any questions please contact the Researcher or Principal Researcher, Professor Huiru 'Jane' Zheng, whose details are below.

Yours sincerely,

Telephone: +44 7933453808

ulster.ac.uk