Abstract

Introduction
Lifestyle modification in the form of dietary advice and exercise programs form the foundation of Gestational Diabetes Mellitus (GDM) management. Current guidelines recommend 150 mins of moderate intensity physical activity (PA) per week throughout pregnancy. It is estimated that only 15% of pregnant women exercise at a recommended level. The aim of this research is to investigate whether adding a PA monitor would encourage an increase in PA to guideline recommendations in women with GDM.

Methods
Forty-one women with a positive oral glucose tolerance test, were recruited from outpatients’ antenatal clinics. These women received diet and exercise advice upon GDM diagnosis. One-third of the participants were randomly assigned to a wear a Fitbit™ Inspire. Participants were surveyed regarding their PA habits at two time points during the study, after GDM diagnosis and 6 weeks later. No alterations were made to the type, standard or accessibility of their antenatal care.

Results
At baseline, 8 (21%) of the women surveyed met the minimum guideline recommendations for PA. Following the intervention 18 (46%) of women were exercising at levels in accordance with these guidelines. Of those, the group assigned to wear a Fitbit™ 10 (77%) participants were compliant with PA guideline recommendations.

We demonstrated that wearing a fitness tracker (Fitbit™) increases PA in women with GDM supporting them in achieving guideline recommendations.
Introduction

Gestational diabetes (GDM) is one of the most frequent complications of pregnancy\(^1\) and can be loosely described as carbohydrate intolerance with first onset or recognition in pregnancy\(^2\) amounting to hyperglycaemia of varying severities during the gestational period.\(^3,4\) The International Diabetes Federation (IDF) now estimates that one in six live births (16.8%) are to women with some form of hyperglycaemia in pregnancy. The majority (84%) are considered to be GDM.\(^3,5\) As a consequence of increasing obesity prevalence and advancing maternal age, the incidence of both T2DM and GDM is rising globally.\(^6\)

GDM is associated with significant health risks to mother and baby. In general, excessive foetal growth and foetal macrosomia due to foetal hyperinsulinism in response to maternal hyperglycaemia\(^7,8\) remains the main perinatal concern in GDM. Consequences include birth trauma, shoulder dystocia, and neonatal hypoglycaemia.\(^4\) GDM is also associated with maternal morbidity such as hypertensive disorders including pre-eclampsia, preterm birth, and higher rates of induced labours and operative deliveries.\(^1,3,9,10\) GDM is a well-known predictor of future diabetes.\(^11\)

Pregnancy for most women is associated with greater than recommended weight gain.\(^1,12\) Excessive gestational weight gain (GWG) is a risk factor for hypertension, GDM, pre-eclampsia, caesarean delivery, macrosomia, stillbirth and perinatal complications.\(^1\) It is also independently associated with postpartum weight retention and an important contributor to increased obesity among women.\(^1,13\) By implementing lifestyle interventions such as diet and exercise to minimize excessive GWG, there is significant potential for improved health outcomes for both mother and infant.\(^14\)

The Centres for Disease Control and Prevention (CDC) The American College of Obstetricians and Gynaecologists (ACOG) recommend that healthy women should get at least 150 minutes of moderate-intensity exercise every week during pregnancy.\(^15\) It is estimated that approximately two thirds of pregnant women undertake some form of recreational physical activity\(^16\) however, only 10 to 15% of pregnant women exercise to guideline recommendation levels.\(^17,18\) Low levels of physical activity (21.5%) have been reported in an Irish cohort of pregnant women.\(^19\)

Most women (70-85%) with GDM can achieve normoglycemia with lifestyle modification alone. Lifestyle modification includes physical activity and nutritional intervention thus highlighting the importance of effective communication of information, motivation of subjects and a positive doctor-patient interaction.\(^20\) However, despite this information encouraging an active lifestyle during pregnancy remains a challenge.
It is important to understand why current antenatal and GDM care models advising to increase PA levels have, for the most part, been ineffective and how might they be improved and incorporated into women’s lives. Since pregnancy is such a unique time when health behaviours can be encouraged in order to improve both mother and baby’s health outcomes it is essential to understand facilitators to PA and to employ strategies to support women to overcome them.\textsuperscript{19}

The aim of this research is to investigate whether the advice given on exercise is enough to encourage women to follow the guideline recommendations.\textsuperscript{21,22} In addition, we aimed to assess if adding a Fitbit\textsuperscript{TM} will increase PA to guideline recommendations in women with GDM.

**Methods**

This was a single-centre, randomized, controlled intervention study aimed at assessing if the addition of a Fitbit\textsuperscript{TM} device might increase physical activity levels in women with Gestational Diabetes Mellitus (GDM). The study was conducted between February and June 2020 in the Obstetric Department of Portiuncula University Hospital, Saolta group. Approval for this study was obtained from the Human Research Ethics Committee of University Hospital Galway on 27\textsuperscript{th} January 2020.

The International Association of Diabetes Pregnancy Groups (IADPSG) criteria were used for the diagnosis of GDM. 41 women with a diagnosis of GDM were enrolled in this study between 20 and 28 weeks of gestation. They were randomly allocated to either the Fitbit\textsuperscript{TM} intervention group (n=13) or the control group (n=28).

In all study participants, baseline data was collected at diagnosis of GDM, prior to receiving any of the GDM care, this included clinical information including obstetric history, family history of diabetes, and previous history of GDM or foetal macrosomia and data on exercise habits, using the IPAQ long form questionnaire.\textsuperscript{23}

Standard GDM care followed for all study participants (n=39). In addition, the intervention group (n=13) received a Fitbit\textsuperscript{TM} device but no extra advice, exercise prescription or deviation from the standard of care for GDM. Weekly Met minutes were calculated from the IPAQ to determine whether the women met current PA guideline recommendations.

All participants were then resurveyed after 6 weeks. At this stage, PA was reassessed using the IPAQ and met.mins\textsuperscript{-1} per week were calculated. The Fitbit\textsuperscript{TM} software was also accessed weekly to measure the wearers PA i.e. active minutes/day and step counts.
Graphpad Prism was used for statistical analysis. Data was tested for normal distribution. Wilcoxon matched-pairs sign ranked tests were used to examine physical activity data from the IPAQ questionnaires - before and after the intervention within each group. Mann-Whitney tests were used to compare the physical activity assessed by the IPAQ of the control vs the intervention group at baseline and again at the end of the intervention. Effect size (\( \Theta \)) was calculated based on the standardized mean difference between the population or timepoint using the formula \( \Theta = (\mu_1 - \mu_2)/\sigma \). Where \( \mu \) is equal to the mean for one population and \( \sigma \) is the standard deviation based on both populations. Fitbit data was collected weekly for time active and step counts. \( P<0.05 \) was considered statically significant. Data are presented as mean +/- standard deviation or as individual data.

Results

In all, forty-one women with GDM consented to participate in this study. Two withdrew prior to completion of the intervention period, one woman from each study group. There were no adverse events reported and all who completed were fully compliant with wearing the activity tracker daily. See Table 1 for baseline characteristics of the group studied. There were no significant differences in the baseline characteristics of the 2 study populations.

**Table 1. Baseline Characteristics of the Study Population**

<table>
<thead>
<tr>
<th></th>
<th>All Participants (n=39)</th>
<th>No Device (n=26)</th>
<th>Fitbit(\oplus) (n=13)</th>
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</thead>
<tbody>
<tr>
<td>Age</td>
<td>33 +/- 5</td>
<td>33 +/- 5</td>
<td>34 +/- 5</td>
</tr>
<tr>
<td>Parity</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>0</td>
<td>21% (n=8)</td>
<td>15% (n=4)</td>
<td>23% (n=3)</td>
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<tr>
<td>1</td>
<td>38% (n=15)</td>
<td>31% (n=8)</td>
<td>54% (n=7)</td>
</tr>
<tr>
<td>2 or more</td>
<td>44% (n=17)</td>
<td>54% (n=14)</td>
<td>23% (n=3)</td>
</tr>
<tr>
<td>4 or more</td>
<td>10% (n=4)</td>
<td>8% (n=2)</td>
<td>8% (n=1)</td>
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<td>History of GDM</td>
<td>33.33% (n=13)</td>
<td>38% (n=10)</td>
<td>23% (n=3)</td>
</tr>
<tr>
<td>Family History of Diabetes</td>
<td>33.33% (n=13)</td>
<td>31% (n=8)</td>
<td>38% (n=5)</td>
</tr>
<tr>
<td>BMI (\leq30 \text{ Kg/m}^2)</td>
<td>49% (n=19)</td>
<td>50% (n=13)</td>
<td>46% (n=6)</td>
</tr>
</tbody>
</table>

GDM: Gestational Diabetes Mellitus,

At baseline 21% (n=8) of the women surveyed via the IPAQ questionnaire met the minimum guideline recommendations of 30 minutes of physical activity on 5 or more days of the week, however, following the intervention, 46% (n=18) of women were exercising at levels in accordance with these guidelines, figure 1. Overall, 51% (n= 20) of the participants increased PA levels while 31% (n=12) decreased PA levels. Moreover, 18% (n=7) maintained their current activity but of those whom maintained their PA levels only 1 participant was guideline compliant.
**Figure 1a & b:** The Percentage of Study Participants Meeting Physical Activity Guidelines Before and After the Study period (n = 39). The blue portion of the pie chart depicts the proportion of women in this study who exercised to guideline recommended levels of physical activity. The orange portion represents the proportion of women who did not meet guideline recommendations pertaining to PA in pregnancy. This data is based on the answers in the IPAQ questionnaire.

Average weekly MET minutes for the recreational PA were 315 +/- 289 MET.mins^{-1}.week^{-1} at baseline and increased to 508 +/- 502 MET.mins^{-1}.week^{-1} following the intervention ($P = 0.045$). Although overall MET.mins^{-1}.week^{-1} as reported on the IPAQ questionnaire did not change in the group as a whole ($P = NS$), see table 2.
Table 2. Physical Activity (MET.mins⁻¹.week⁻¹) data. Physical activity as surveyed from the IPAQ questionnaire before and after the intervention in the whole group (n = 39), control group (n = 26) and Fitbit™ group (n = 13). Data represented as Mean +/- SD.

Upon enrolment in the study six of control participants were meeting guideline recommendations for PA, at the six week follow up, 7 women in the control group were meeting recommendations for PA in pregnancy. 27% (n=7) of those in receipt of standard GDM care increased recreational levels of physical activity from 90 +/- 183 to 589 +/- 458 MET.mins⁻¹.week⁻¹ (P= 0.0267, θ = 1.433692). Four of those participants achieving guideline recommendations. At the same time 50% (n=13) actually decreased recreational PA from baseline activity levels from 420 +/- 190 to 133 +/- 161 MET.mins⁻¹.week⁻¹ (P=0.002, θ= 1.629744) despite receiving standard GDM care including advice to increase PA levels. Two of these thirteen women were in fact guideline compliant prior to the study period, however after the six weeks no longer met guideline recommendations for PA in pregnancy. Four of the 26 women in this control group who were meeting guideline recommendations prior to the GDM diagnosis continued to meet guideline recommendations during the study period.

All of the participants (n=13) in receipt of a Fitbit™ device significantly increased overall PA levels from 1015 +/- 488 to 1613 +/- 858 MET.mins⁻¹.week⁻¹ (P=0.001) see table 2. In addition, 77% (n=10) increased PA to guideline recommended levels, figure 2b. Following the intervention, recreational PA levels in the Fitbit™ group were significantly higher when compared to that of the GDM standard care group (915 +/- 425, vs. 305 +/- 411, P=0.0001, θ= 1.459162), and total PA in the Fitbit™ group was also higher with a weekly average of 1613 +/- 858 vs. 934 +/- 850 MET.mins⁻¹ (P=0.003, θ = 1.002833), Fitbit™ vs standard care group respectively, table 2.
Following routine standard of care, at the end of the six-week period, 27% (n=7) of participants were reaching guideline recommended PA levels. The group assigned to wear a Fitbit® in addition to GDM standard of care, had a similar baseline PA level, with 15% reaching the guideline recommendations, figure 2a. However, the Fitbit® group increased PA guideline compliance from 15% to 77% by the end of the intervention, see figure 2b.

![Pie charts showing PA compliance before and after Fitbit usage.](image)

**Figure 2a and 2b:** The Percentage of Participants in Fitbit® Group Meeting Physical Activity Guidelines, Before and After the Addition of a Fitbit Device. The blue portion of the pie chart depicts the proportion of women who exercised to guideline recommendations. The orange portion represents the proportion of women within this group who did not meet guideline recommendations.

The average daily active minutes in Fitbit® wearers over the course of this study was 41 +/- 3 active minutes/day. Therefore, overall, the women who were given a Fitbit® met guideline recommendations of 30 minutes moderate intensity PA on 5 or more days each week during the study period. The average daily step-count in Fitbit® wearers observed in this study was 8490 +/- 3412 steps/day, figure 3.
Figure 3: Average Daily Step Count in Fitbit® Wearers Over the Last Week of the Trail Period (Week 6). Each solid bar depicts an individual within the study group wearing a Fitbit® device (n=13). The hashed bar depicts the average daily step count of the Fitbit™ group during the last week of the intervention.

Discussion

This is one of the first studies to explore the relationship between the use of a commercially available fitness trackers and success in a physical activity (PA) intervention in gestational diabetes (GDM). This was a single centre randomized controlled intervention study aimed at assessing if the addition of a Fitbit™ device might increase PA levels in women with GDM. This study revealed that following 6 weeks of intervention, recreational PA levels were significantly higher when a Fitbit™ device was added to the normal GDM standard of care (915 +/- 425, vs. 508 +/- 411 met.mins⁻¹ per week, p=0.0001).

At present, the demographic factors influencing physical activity level in pregnancy are not fully understood. As outlined in table 1, within this study, both groups of participants were closely matched at baseline with regard to age, risk factors and current PA levels. All of the women in this study received the same hospital based GDM care. Exercise recommendations given by clinicians at outpatient appointments are a key part of this care. The only difference between the two groups was the addition of a Fitbit™ device. The women who received a Fitbit™ did not obtain any extra exercise prescription, advice or care, nor did they have any additional healthcare contact. This group experienced increased guideline compliance over the six weeks from 15% to 77%.
The control group in this study was made up of 26 women obtaining standard GDM care. Notably, only 2 of these women substantially increased their PA levels whereas 20 of these participants actually decreased their overall PA levels. Additionally, six of these women actually decreased the amount of time they participated in recreational PA, over the course of the intervention. Within this group, 3 women did not perform any recreational PA either before or after intervention despite obtaining the combined lifestyle advice with exercise prescription as part of the GDM care. This is similar to research by Sytsma et al, 2018 who noted that women who were active prior to pregnancy reported that PA levels decrease on becoming pregnant, and these levels tend to continue to decrease during pregnancy as gestation progresses.15

There has been a rapid increase in the use of technology-based activity trackers to promote healthier behaviours. Wearable fitness technology was ranked the top fitness trend of 2019 by the American College of Sports Medicine’s Health and Fitness Journal.24 Women have previously emphasised that walking was the most helpful and practical form of PA and recreational walking is associated with a 70% decreased risk of adverse neonatal outcomes.25 Measurement of steps has a number of additional advantages e.g. steps are intuitive, readily relatable to the lay person and have the potential to be useful in translating scientific results into public health messages.26 In cross sectional studies, steps/day have strong associations with physical health variables e.g. BMI, hypertension, T2DM and metabolic syndrome.27 Different types of PA trackers and pedometers including Fitbit™ devices are increasingly being utilised, both by the general public and within the field of research. They enable the accumulative measurement of daily activities and provide an estimate of total volume of ambulatory activity. They tend to be affordable, acceptable in size and simple to use with smart phone software. The standardized steps per day unit of measurement has become universally accepted and interpreted facilitating reliable cross population comparisons.28 Strong associations between steps/day and health variables have been documented, therefore there is considerable potential for integrating daily step count into medical practice as an overall index to PA levels.

Participants wearing a Fitbit™ in this study showed significant (p=0.0059) increases in their overall PA levels. In relation to recreational PA levels specifically, wearing a Fitbit™ over the course of the intervention saw participants significantly (p=0.0002) increase their exercise levels meaning that 77% (n=10) of these women managed to exercise to guideline recommended levels whilst having the exact same hospital-based care as the control group. Average recreational PA improved from 305+/- 411 to 915 +/- 425 met.mins⁻¹ PA.
Pregnancy is a unique period to implement changes in lifestyle habits. When pregnant, women tend to be highly motivated to improve unhealthy behaviours and have frequent interactions with healthcare practitioners, which facilitates counselling, support and supervision.29

This study was done to further research into the normal clinical care given to pregnant women diagnosed with GDM in regards to achieving guideline levels of PA. The addition of the PA monitors (Fitbit™ Inspire) to the normal GDM standard of care significantly increased total and recreational PA levels. The use of technology including fitness trackers and smartphone apps have shown huge potential for motivating behaviour change among sedentary adults whilst measuring and boosting PA levels.30 As shown in this study the addition of a Fitbit™ device to standard GDM care in an Irish cohort significantly improved total and recreational PA levels.

Declarations of Conflicts of Interest:

None declared.

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References: