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## **Title**

An integrated pre-pregnancy care programme framework theoretically modelled from the perspectives of women with Type 2 diabetes and healthcare professionals.

## **Abstract**

### **Background**

Pregnancies in women with diabetes are associated with significant additional risks for the fetus, infant and mother such as, higher risk of stillbirths or congenital anomalies. Pre-pregnancy care can attenuate these risks. However, while women with Type 2 diabetes account for half of pregnancies in women with pre-existing diabetes, they are much less likely to receive pre-pregnancy care than women with Type 1 diabetes. This discrepancy may be related to the fact that most pre-pregnancy care is located in specialist diabetes centres where women with Type 1 diabetes are managed; whereas women with Type 2 diabetes are managed in primary care and reproductive care is not a routine element of diabetes care. Therefore, to improve pre-pregnancy care among women with Type 2 diabetes strategies need to be tailored to the specific needs of this group and the context of their diabetes care.

### **Objectives**

This paper seeks to inform the development of an integrated pre-pregnancy care programme by presenting strategies identified by women with Type 2 diabetes and healthcare professionals that address some of the barriers they experience in relation to pre-pregnancy care.

### **Methods**

A qualitative study using semi-structured in-depth interviews with women of reproductive age with Type 2 diabetes (n=30) and diabetes healthcare professionals (n=22) from both primary and secondary care. Data were transcribed verbatim and analysed thematically using Framework Analysis. The identified themes were then mapped to create a theoretical intervention framework using Normalisation Process Theory and the Capabilities, Opportunity, and Motivation to perform a Behaviour model.

### **Results**

Six themes were identified expressing the need for a multimodal approach for improving the uptake of pre-pregnancy care in women with Type 2 diabetes. These themes were then mapped onto the constructs of Normalisation Process Theory as follows: coherence (enhancing understanding of reproductive needs among women and healthcare professionals); cognitive participation (constructing a positive narrative for pregnancy and Type 2 diabetes); collective action (increasing the visibility of the reproductive needs of women, integrating healthcare systems and utilising supportive technologies); and reflexive monitoring (using multi-modal approaches to support systemised care). The data were also modelled to identify target behaviours for intervention detailing what needs to be done by whom, when and where.

## **Conclusion**

Women with Type 2 diabetes account for half of pregnancies in those with pre-existing diabetes; however, they are less likely to receive pre-pregnancy care than women with Type 1 diabetes. Pre-pregnancy care can reduce the maternal and fetal risks associated with Type 2 diabetes. This study presents strategies to improve the current low uptake of pre-pregnancy care for women with Type 2 diabetes. These strategies have been tailored to the specific needs of women and healthcare professionals and support integration within the woman's routine diabetes management.

## **Keywords**

Pre-pregnancy care,

Type 2 diabetes,

Integrated care pathway,

Qualitative research,

Intervention development

## 1 Introduction

2 The number of women with Type 2 diabetes (T2DM) who become pregnant is increasing  
3 (Jovanovič et al., 2015) and in the UK they now account for over half of pregnancies in  
4 women with pre-existing diabetes (Murphy et al., 2017; NPID, 2019). This proportion will  
5 continue to rise as the age of onset for T2DM decreases in women (Royal College of  
6 Paediatrics and Child Health, 2019). Pregnancies in women with diabetes are associated  
7 with increased risk of adverse maternal, fetal and infant outcomes (Allen et al., 2018;  
8 Berry et al., 2016; Macintosh et al., 2006; Mackin et al., 2019). The risk of stillbirth and  
9 fetal death is 4-5 times greater in women with T2DM compared to those without diabetes  
10 (Mackin et al., 2018; Mackin et al., 2019). Additional risks include: congenital  
11 abnormalities; macrosomia; birth-trauma; caesarean section; and infant admissions to  
12 neonatal intensive care (Allen et al., 2018; Berry et al., 2016; Macintosh et al., 2006;  
13 Mackin et al., 2019). Many of the processes that drive these adverse risks occur in the  
14 first trimester of pregnancy, before a woman presents to antenatal services. Therefore, it  
15 is important to minimise these potential hazards prior to conception with effective pre-  
16 pregnancy care.

17  
18 Pre-pregnancy care (PPC) measures for women with T2DM, include: reducing weight;  
19 improving glycaemic control; adding high-dose folic acid; and stopping potentially  
20 teratogenic therapies (Murphy et al., 2010a; Murphy et al., 2017; Wahabi, et al., 2010;  
21 Willhoite et al., 1993). These measures can significantly reduce the risk of adverse  
22 outcomes. However, the majority of women with T2DM currently do not receive PPC, and  
23 present to services already pregnant, often late in the first trimester or in the second  
24 trimester, with preventable risk factors for adverse outcomes (Egan et al., 2016; Murphy  
25 et al., 2017; NPID, 2019). Hence, increasing the proportion of women with T2DM  
26 receiving PPC is of high importance.

27  
28 There are a number of factors that contribute to the poor uptake of PPC in women with  
29 T2DM. These factors are evident at the individual, (women's understanding of pregnancy  
30 risks) health professional (a lack of awareness of the need for reproductive care) and  
31 system (a lack of visibility of women of reproductive age) levels (Forde et al., 2019).  
32 Previous intervention studies aimed at improving PPC in women with diabetes (Egan et  
33 al., 2016; Murphy et al., 2010a; Willhoite et al., 1993; Yamamoto et al., 2018) have tested

34 a number of different strategies, including: education for healthcare professionals; patient  
35 registries; electronic prompts on medical records; and mass-media promotion. While  
36 these studies showed some improvement in PPC among women with Type 1 diabetes  
37 (T1DM), the impact on women with T2DM was small, with modest improvements in  
38 uptake ranging from 8-16%. The studies attributed this low responsiveness to the high  
39 proportion of women with T2DM being from minority ethnic populations and/or of lower  
40 socio-economic status (Egan et al., 2016; Murphy et al., 2010a; Willhoite et al., 1993).  
41 Another factor which might explain the difference in uptake between women with T1DM  
42 and T2DM, is that the former are managed in specialist diabetes services while the latter  
43 are generally seen in primary care. As most PPC services are located in specialist  
44 diabetes centres where women with T1DM are managed by health professionals who are  
45 very aware of the need for PPC they are more likely to access this care, compared to  
46 women with T2DM who are managed in primary care. Reproductive care is not a routine  
47 element of diabetes management in primary care and accessing PPC is more complex.  
48 Studies have also indicated there is a lack of awareness of the reproductive health needs  
49 of women with T2DM in primary care settings and their reproductive intentions are not  
50 routinely elicited or responded to (Forde et al., 2016; Forde et al., 2019). Hence, a new  
51 model of care for women with T2DM of reproductive age is needed if pregnancy outcomes  
52 are to be improved in this growing population. This paper seeks to inform such a  
53 development by presenting strategies identified by women with T2DM and healthcare  
54 professionals that address some of the barriers they experience in relation to PPC.

55

## 56 **Research Design and Methods**

57 This study aimed to theoretically model a framework, to develop an integrated pre-  
58 pregnancy care programme for women living with T2DM, utilising the strategies identified  
59 by women with T2DM and healthcare professionals. We conducted an exploratory  
60 qualitative study using individual in-depth, semi-structured interviews. Women of  
61 reproductive age with T2DM (n=30) were purposively recruited via their usual diabetes  
62 healthcare settings from an urban area of the UK with high ethnic and socioeconomic  
63 diversity. Healthcare professionals from both primary and secondary care were also  
64 purposively sampled including: general practitioners (GPs), practice nurses (PN),  
65 diabetes specialist nurses (DSN), and diabetologists.

66

67 Women with T2DM were interviewed face-to-face and healthcare professional interviews  
68 were either face-to-face or via telephone, depending on the participants' preference.  
69 Separate interview guides were developed for women and healthcare professionals,  
70 although both contained similar questions on how PPC could be enhanced. The women  
71 were asked about their suggestions to increase uptake, including awareness of and/or  
72 access to PPC; while the healthcare professional interviews explored their views on how  
73 to enhance provision and access to this care for women with T2DM.

74  
75 Recognising the emotive nature of these interviews, particularly for those women with a  
76 previous unfavourable pregnancy outcome, all interviews were conducted by one  
77 researcher with expertise in counselling for people with diabetes. In addition there was  
78 direct access to psychological support if required, via the diabetes mental health service  
79 of a participating site. The interviews were digitally recorded, professionally transcribed,  
80 and transferred to NVivo version 10. Participants provided informed written consent in  
81 alignment with studies ethical approval, which was granted by the National Research  
82 Ethics Service (Reference 14/NW/1511).

83  
84 A Framework Analysis approach, which follows a structured and systematic process for  
85 analysis was used (Ritchie et al., 2014). The data from the women and the healthcare  
86 professionals were analysed as separate datasets and then synthesised to identify  
87 convergent areas relating to uptake and provision of PPC for women with T2DM. A  
88 detailed account of the study methods has been reported in a previous paper detailing  
89 the experiences of women and healthcare professionals in relation to the reproductive  
90 care of women with T2DM (blinded for peer review). This paper focuses on the  
91 participants' ideas in relation to enhancing the provision and uptake of PPC. Rigour was  
92 attended to through an audit trail of data collection and analytical processes making  
93 explicit decision-making and data interpretations (Lincoln and Guba, 1985; Polit and  
94 Beck, 2012).

95  
96 **Theoretical modelling**

97 This paper is aligned to the modelling stage of the Medical Research Council (MRC)'s  
98 framework for complex interventions, hence the study findings were used to explicate  
99 potential areas for intervention (MRC, 2006). *Normalisation Process Theory* (NPT) was  
100 used to translate the findings to inform intervention implementation strategies (Murray et

101 al.,2010). This analysis involved mapping the study findings onto the core NPT  
102 constructs (and sub-components), which are: coherence (differentiation, specification  
103 and internalisation); cognitive participation (initiation, enrolment and activation); collective  
104 action (workability and integration); and reflexive monitoring (systematisation and  
105 appraisal). The mapping was conducted following an approach utilised in previous  
106 complex intervention development studies (Mair et al.,2008; Ross et al.,2019). While our  
107 data presents a synthesis of the suggestions of both healthcare professionals and women  
108 living with T2DM, NPT targets healthcare professionals' practices and ways of working,  
109 to support embedding an intervention into clinical care (May et al.,2009). Therefore, we  
110 also modelled the findings using the *Capabilities, Opportunity and Motivation to perform*  
111 *a Behaviour* (COM-B) model (Michie et al.,2014), to identify target behaviours for  
112 intervention from the data.

113

## 114 **Findings**

115 Thirty women with T2DM participated in this study. The mean age was  $36.6\pm 5.1$  years  
116 and the mean duration of diabetes was  $6.2\pm 4.5$  years. The majority of women were  
117 overweight or obese (mean BMI of  $32.5\pm 6.6$  kg/m<sup>2</sup>). Most women (n=19) had no  
118 exposure to PPC, including those who were pregnant at the time of the study (n=8) (Table  
119 1) (blinded for peer review). Individual interviews were also conducted with 22 healthcare  
120 professionals including GPs (n=6), PNs (n=8); DSNs (n=6) and diabetologists (n=2).

121

122 (Table 1 about here)

123

## 124 **Themes**

125 The women and healthcare professionals identified several strategies for improving  
126 provision and uptake of PPC for women with T2DM. These strategies were organised  
127 thematically and aligned with the core NPT constructs, they are outlined below and  
128 summarised in table 2, with linkage to source data. The source data are identified with  
129 codes and detail whether the woman had received care (PPC) or not (no PPC) or was  
130 pregnant at the time of their participation in the study.

131

132 (Table 2 about here)

133

134 **Coherence**

135 This relates to how women with T2DM and healthcare professionals understand the  
136 elements and purpose of PPC (*individual specification*); how they develop a shared  
137 understanding of these (*communal specification*); and identify with them, such as,  
138 highlighting the need for care or providing PPC (*differentiation*); and how women and  
139 healthcare professionals understand the benefits and value of investing in PPC  
140 (*internalised meaning*). The findings for this construct were expressed in one theme,  
141 outlined below.

142

143 *Understanding the reproductive needs of women with Type 2 diabetes*

144 A lack of understanding about the relationship between diabetes and pregnancy was  
145 expressed by the women and healthcare professionals (blinded for peer review). To  
146 address this, the women with T2DM identified the need for information about PPC during  
147 their initial education following diagnosis and at subsequent reviews, as one suggested:  
148 “*Put it in their minds, women need to know they should talk about it when they’re Type 2*”  
149 (*B06 PPC*). They recommended that information provided should include the rationale  
150 and importance of the different steps to take in preparing for pregnancy, rather than just  
151 telling them to lose weight or improve their glucose levels, as highlighted in the following  
152 extract; “*You need to tell us why, why it is important, not just, do this, ... I would have tried*  
153 *harder if I’d known beforehand [current pregnancy] but now I have to wait and see what*  
154 *I’ve done*” (*C08, no PPC, pregnant*).

155

156 Healthcare professionals revealed they did not always associate T2DM with pregnancy,  
157 many viewed it as a condition of older age. The primary care participants identified that  
158 they need further education and training on reproductive care for women with T2DM.  
159 They commented that most current professional reproductive health training tends to  
160 consider women with T1DM rather than T2DM. While some of the primary care  
161 professionals believed that PPC was the remit of specialist services, others indicated that  
162 with appropriate training they could address some aspects of it in their routine diabetes  
163 care provision, as a GP highlighted: “*It’s not something that comes to the top of your mind*  
164 *when you’re talking to a Type 2 diabetic, often it’s about poor control or other issues Type*  
165 *2’s usually have, but we could do things like adding folic acid*” (*GP02*).



166  
167 Both the women and healthcare professionals indicated that reproductive issues were  
168 not discussed in an optimal way. The women often felt that their questions were not  
169 addressed, or their reproductive needs were a low priority for healthcare professionals  
170 who focussed on their glucose levels and weight-loss. Healthcare professionals also  
171 recognised that they did not always interact well with women in respect of their  
172 reproductive health, and that they would like training in how to address reproductive  
173 issues more constructively in consultations, a specialist nurse highlighted: "*Professionals*  
174 *need further training about preconception including how to communicate with the women*  
175 *about it*" (DSN PC01).

176

### 177 **Cognitive participation**

178 This relates to the shared approach to develop and sustain an intervention to enhance  
179 PPC. Cognitive participation expresses the extent to which stakeholders feel their role is  
180 recognised by others, and that they can make and sustain a valid contribution  
181 (*legitimation*). In the context of an intervention to enhance PPC for women with T2DM,  
182 the data from the women and healthcare professionals suggest the need for promoting  
183 positive messages on pregnancy and T2DM, to encourage and activate both groups.

184

#### 185 *Constructing a more positive narrative for Type 2 diabetes and pregnancy*

186 The women identified that the common stigmatising constructs associated with T2DM  
187 reduced their confidence in discussing their reproductive intentions. Perceptions such as  
188 T2DM being self-induced due to obesity, or a condition of older age, made them  
189 embarrassed or uncomfortable about raising the issue of pregnancy, as the following  
190 extract illustrates: "*I was told by my GP that I was too fat to get pregnant - I was so hurt*  
191 *by what she'd said, so you can imagine my response with her in the consultation after*  
192 *that – I wasn't very responsive at all*" (C02,no PPC).

193

194 This perception was compounded by healthcare professionals who reported they did not  
195 consider the reproductive potential of these women, with a contribution from a healthcare  
196 professional reinforcing this: "*Type 2's are often older than childbearing age, aren't*  
197 *they?... I've got to remember that this person is of childbearing age*" (DSN PC02). To  
198 counter this barrier, the women suggested that PPC should be highlighted more positively

199 for them, and the prevailing stereotypes of T2DM as a lifestyle condition associated with  
200 obesity and old age need to be challenged, both in the healthcare system and in the wider  
201 community.

202

### 203 **Collective action**

204 Collective action relates to how women living with T2DM, and healthcare professionals  
205 work together within the healthcare system to amplify awareness and uptake of PPC.  
206 This includes how women and healthcare professionals engage with the different  
207 elements necessary for delivering PPC (*interactional workability*). Incorporating it as part  
208 of a team approach (*relational integration*) and having the capacity and resources within  
209 teams to support care delivery (*skill-set workability*). Ultimately there is need for an  
210 intervention to be embedded in practice (*contextual integration*), therefore, a recognised  
211 care-pathway within the healthcare system, with defined responsibilities for all  
212 stakeholders in respect of PPC. The following themes relating to the constructs of  
213 collective action were generated from the suggestions of women living with T2DM and  
214 healthcare professionals.

215

#### 216 *Enhancing the visibility of pre-pregnancy care*

217 Women with T2DM and healthcare professionals proposed different strategies for  
218 increasing the visibility and prominence of diabetes and pregnancy in primary care  
219 settings. One suggested strategy was that posters and/or leaflets should be made  
220 available in healthcare settings accessed by women with T2DM. Women said that such  
221 promotional materials would help to nudge them to ask about pregnancy within  
222 consultations, as one participant stated: “GPs surgeries need more posters, having  
223 something there that brings people’s awareness to it, even if it’s subliminally, it might later  
224 trigger something” (B06, PPC). In addition to primary care settings, it was suggested that  
225 these materials could also be promoted through diabetes eye screening services, as  
226 another woman recommended: “Put pictures giving information about diabetes and  
227 pregnancy on the walls in health places, like when waiting for your eye test, or even post  
228 them to the people” (E07, no PPC). Healthcare professionals were in agreement that  
229 there was a need for clear and visible messaging about pregnancy for women with T2DM,  
230 as a community-based diabetes specialist nurse shared: “I was in GPs surgery today and

231 *I don't think I've seen anything that hit me in the face about it, so, maybe they need to*  
232 *broadcast pre-pregnancy more” (DSN PC02).*

233

234 *Integrated healthcare systems*

235 Provision of, and/or access to PPC was described as unclear, by both the women and  
236 healthcare professionals. Some women reported that their primary care professionals  
237 would not refer them for PPC until they had improved their glucose control or lost weight.  
238 Healthcare professionals in primary care expressed their uncertainty about PPC for  
239 women with T2DM and were not always clear about when or where to refer them.

240

241 There was concordance between women and healthcare professionals as to how this  
242 problem should be addressed. Both groups recommended that PPC needs to be  
243 integrated into the routine care of women with T2DM, from diagnosis onwards. They  
244 suggested that pregnancy and reproductive health need to be included in routine  
245 structured education programmes for people with T2DM, as a woman who had previously  
246 attended PPC shared: *“Really it’s about triggering the information cascade. Put it into*  
247 *the course you go to when you’re first diagnosed to learn about diabetes; then ask about*  
248 *it when doing the annual reviews” (B04, PPC).* While healthcare professionals  
249 highlighted that they face multiple pressures in delivering the core elements of diabetes  
250 care, they suggested pre-pregnancy and reproductive care need to be a more central  
251 part of diabetes care provision in primary care, as a GP highlighted *“We’re generalists,*  
252 *so when you're thinking about diabetes and pre-conceptual care, it’s easily missed”*  
253 *(GP01).*

254

255 The primary care healthcare professionals highlighted that the current electronic  
256 templates they use to inform their diabetes management do not include any assessment  
257 of reproductive intention. As these templates direct the focus of their consultations, it was  
258 suggested these should be modified to identify women of reproductive age with T2DM  
259 and ensure appropriate reproductive care is provided, illustrated by a GP in the following  
260 extract *“It would be helpful to have it on a template somewhere to make sure you’ve*  
261 *covered it, and it would probably be useful if it flashes up in just females, because if it’s*  
262 *coming up in everyone, then you’ll soon switch off to it” (GP02).*

263

264 Healthcare professionals from primary and secondary care highlighted the importance of  
265 having a distinct care-pathway across the healthcare system, addressing the  
266 reproductive health of women with T2DM. Such pathways would need to make explicit  
267 the responsibilities of primary care professionals and specialist diabetes services to  
268 correct the current confusion reported by healthcare professionals on who does what in  
269 respect of reproductive health and pre-pregnancy management. As one GP indicated:  
270 *“Our role is in referring, but I suppose we could take some action ourselves I guess, it’s*  
271 *sort of working side-by-side with the hospital, the pre-pregnancy clinics, reiterating the*  
272 *same messages and then knowing when to refer on”* (GP05).

273

#### 274 *Supportive technologies*

275 The increasing role of the internet and mobile technologies were highlighted as important  
276 by both healthcare professionals and the women. Many identified the potential role that  
277 these technologies could play in providing information on reproductive health and  
278 pregnancy planning in T2DM, while more interactive technologies could help them with  
279 decision-making and in activating their pregnancy planning (goal-setting), as this woman  
280 stated *“Apps are the way to go really, you can work through things with them, and people*  
281 *use their phones a lot, because it’s handy”* (B03, PPC). It was also emphasised that the  
282 information provided should be clear and reliable with links to local services and  
283 resources. The women emphasised that information should be easily understood and  
284 linked to active websites specifically targeting all women of reproductive age. They also  
285 identified text prompts as a means of sending information; or to support their self-  
286 management with motivational messages between consultations.

287

#### 288 **Reflexive monitoring**

289 Incorporating and acknowledging mechanisms to understand and monitor the way(s) an  
290 intervention influences practice, underpins reflective monitoring. This recognises  
291 opportunities for healthcare professionals and women to monitor their goals in respect of  
292 their pregnancy intentions; and the perceived utility and effectiveness of the intervention  
293 (*systematisation*). It involves monitoring concordance with care-pathways, as well as  
294 providing practice and community level feedback on performance in providing PPC  
295 delivery, recognising the team perspectives on the value of their intervention (*communal*  
296 *appraisal*). The inclusion of individual perspectives on the outcomes and value of the

297 intervention (*individual appraisal*) are also important, as these may identify contextual  
298 factors influencing the adoption and activation of PPC measures, leading to adjustments  
299 in care delivery (*reconfiguration*). This NPT construct and its components were expressed  
300 in the theme outlined below.

301

### 302 *A multi-modal approach*

303 The collective suggestions of the women with T2DM and the healthcare professionals  
304 indicated that multiple strategies focussing on the women, healthcare professionals and  
305 healthcare systems are required if the uptake of PPC is to be improved. It was advocated  
306 that this should include an integrated educational programme targeting both women with  
307 T2DM and healthcare professionals regarding pregnancy and reproductive health in the  
308 context of T2DM. Allied with the sub-theme *Integrated Healthcare Systems* within the  
309 Collective Action construct, it was also recommended that the intervention needs  
310 embedding in the healthcare system, with some GPs suggesting that it would be more  
311 attended to if it was adopted within the primary care incentive payment scheme for  
312 diabetes. The following accounts from a woman with diabetes and a GP illustrate the  
313 need for a multimodal approach:

314

315 *“If you really wanted to get the information out there to the right people, you’ve got to use*  
316 *a multi-pronged approach. It wouldn’t be enough just to say, ‘let’s leave it with the GP,*  
317 *let’s produce some posters. It’s not enough to say, ‘well, let’s leave it with the consultants*  
318 *or diabetic nurses in hospitals.’ If you’re going to capture people, particularly people who*  
319 *don’t really realise that pregnancy is an issue when you’re diabetic, you have to use*  
320 *multiple approaches”* (B06, PPC).

321

322 *“I think you’d have to do it in lots of different ways. I mean posters are quite good in*  
323 *reception areas. People are there quite a lot waiting around for something or other.*  
324 *Perhaps if it was QOF [Quality Outcome Framework] target, that would make a*  
325 *difference, you know, because everything else that’s evidenced-based is on there, but*  
326 *preconception care isn’t for Type 2 diabetes, and our education updates”* (GP02).

327

328 It was also evident from both groups that a feedback mechanism would have the potential  
329 to provide reinforcing messages for both the women and the healthcare professionals.

330 These messages could signal areas of practice that were working well or those that  
331 required improvement. One participant indicated that feedback between healthcare  
332 professionals in different settings could be beneficial for women with T2DM: “So, from  
333 what the doctor here [PPC clinic] told me, my GP done a very good job on the before  
334 care, just that initial information, so if that’s true, then they should tell my GP, so that other  
335 women can be helped before they get to the specialists, because my GP said it wasn’t  
336 his area” (A01, PPC). Healthcare professionals indicated that a system for notifying them  
337 about positive or adverse care outcomes may support their continued professional  
338 education and care provision for women living with T2DM in their reproductive years, as  
339 one GP described: “If there was some way to hear back from the hospital about when a  
340 woman first goes, like had we made the right changes to the medications and stuff like  
341 that, and later what happened during pregnancy, that would be good, and would help us  
342 when we have other women thinking about pregnancy, we would know what are the best  
343 things to do for them, or not” (GP 01).

344

#### 345 **Framework for target behaviours**

346 As outlined in the theoretical modelling section, the COM-B model was used to translate  
347 the participant accounts into target behaviours and provide a framework for potential  
348 interventions in respect of those behaviours. This framework details specific activities and  
349 how they could be actioned in the healthcare system. In-so-doing we have developed a  
350 structure for intervention and potential intervention components detailing what needs to  
351 be done by whom, when and where. The COM-B framework is presented in Table 3.

352

353 (Table 3 about here)

354

#### 355 **Discussion**

356 This study sought to identify strategies to improve the current low provision/uptake of  
357 PPC for women with T2DM. Improving the uptake of this care is a high priority to reduce  
358 negative pregnancy outcomes and healthcare costs, in this growing population (National  
359 Institute for Health and Care Excellence (NICE) 2015a; NICE 2015b) The strategies  
360 identified by participants target many of the current barriers to the uptake of PPC (Forde  
361 et al., 2019). Some of the identified strategies are similar to those proposed in previous

362 interventions: the use of leafleting to promote PPC (Egan et al., 2016; Murphy et al.,  
363 2010a; Willhoite et al., 1993); education on PPC (Egan et al., 2016; Murphy et al., 2010a;  
364 Willhoite et al., 1993); and integration between primary and secondary care (Egan et al.,  
365 2016; Yamamoto et al., 2018). An important difference in the strategies proposed by this  
366 study is that they specifically focus on women with T2DM in primary care where women  
367 receive their diabetes care. Hence, they are integrated within the women's routine care  
368 context with an explicit care-pathway for either planning, or prevention of an unplanned  
369 pregnancy. In addition, this study identified a range of intervention foci for mediating  
370 women's reproductive behaviour, including: improving the understanding of women and  
371 healthcare professionals in relation to reproductive health; making PPC more visible in  
372 the care system; integrating specialist and primary care delivery; and the need to create  
373 a more positive narrative about being a woman of reproductive age living with T2DM. The  
374 data also suggest that underpinning these barriers are several important behavioural  
375 regulators affecting both women and healthcare professionals, related to awareness and  
376 understanding; motivation and activation; system regulation; and performance feedback.  
377 We have incorporated these insights into a model of implementational science to provide  
378 a theoretical framework for intervention, making explicit the underpinning mechanisms  
379 and target behaviours for intervention and potential of embedding PPC within routine  
380 diabetes management for people living with T2DM.

381  
382 Positioning PPC in the context of routine primary care diabetes management, was an  
383 important emphasis within the study findings. The ideas provided by both the healthcare  
384 professionals and women revealed some useful strategies to enable this, as well as some  
385 of the associated challenges to be addressed. The participants accounts were congruent  
386 with a Dutch survey of primary care professionals on improving access to PPC, which  
387 also advocated: integration of PPC within routine care; the use of decision support tools;  
388 addressing women's preferences in consultations (van Voorst, Plasschaert, de Jong-  
389 Potjer, Steegers, & Denktas, 2016); and reducing negative perceptions about pregnancy  
390 in women with T2DM (Lavender et al., 2010; Murphy et al., 2010b). This latter point, was  
391 also evident in our data with some healthcare professionals acknowledging that they did  
392 not consider women with T2DM in relation to their reproductive behaviours; and the  
393 women felt they were stigmatised which inhibited them in raising their reproductive  
394 intentions in consultations (Forde et al., 2016; Forde et al., 2019). Therefore, it will be  
395 necessary to address these negative associations within the intervention and promote a

396 more positive narrative in relation to the reproductive potential of women with T2DM. One  
397 opportunity for doing this, suggested by participants, would be to incorporate information  
398 on pregnancy and diabetes in established programmes of self-management education  
399 (Chatterjee, Davies, Stribling, Farooqi, & Khunti, 2018).

400  
401 The findings also related to other studies which suggest that a lack of awareness of PPC  
402 inhibits utilisation (Morrison et al., 2018). In this study, lack of awareness was evident in  
403 both the women and healthcare professionals and was underpinned by a lack of clarity  
404 over when women should be referred. In the UK this uncertainty is underpinned by the  
405 location of pre-pregnancy clinics within specialist diabetes services (Mortagy, Kielmann,  
406 Baldeweg, Modder & Pierce, 2010). Healthcare professionals from primary and specialist  
407 care agreed that primary care staff should play a bigger role in delivering PPC. They also  
408 reported that this required integration with diabetes specialists and that it should be  
409 incorporated into primary care electronic records with prompts and reminders. These  
410 points were also identified in our data, with the addition that: primary care professionals  
411 would need ongoing training to undertake this work; and care-pathways to provide clarity  
412 in relation to the roles and responsibilities of the primary care and specialist diabetes  
413 teams, thus integrated at a health system level. It was also suggested that it may be  
414 necessary to incentivise primary care to undertake this work, as they are already overly  
415 committed.

416  
417 Finally, the study identified strategies for behavioural reinforcement. For women, the  
418 emphasis was on motivating them to activate enhanced self-management by  
419 emphasising the benefits of planning a pregnancy and the risks of having an unplanned  
420 pregnancy for them and their offspring. It was suggested that this should be reinforced  
421 through collaborative goal setting. For healthcare professionals, behavioural prompts in  
422 the form of reminders within the electronic patient record were proposed; together with  
423 performance monitoring at the system level giving feedback on the number of  
424 planned/unplanned pregnancies. It was also suggested to incorporate reproductive  
425 assessments into primary care incentivisation programmes for diabetes (in the UK the  
426 Quality-Outcome-Framework) (Department of Health, 2004; Doran, Kontopantelis,  
427 Reeves, Sutton, & Ryan, 2014). The inclusion of the COM-B model has framed the  
428 identification of factors that both inform and involve women living with T2DM to enhance  
429 awareness raising and uptake of PPC, and the competing and contributory factors that



430 mediate healthcare professionals' practices and behaviours (Michie, Atkins, & West  
431 2014). A further consideration reported in the data, was the potential application of  
432 supportive technologies use of E-health systems, such as digital and mobile health  
433 interventions. While such technologies have been used to enhance care during  
434 pregnancy (Mackillop, Hirst, Bartlett, Birks, Clifton, Farmer et al., 2018), they have not  
435 yet been considered for pre-pregnancy care, hence it would be useful to consider how  
436 supportive technologies could be applied in this context.

437

#### 438 *Limitations*

439 This study has some important limitations to consider. As the study was conducted in one  
440 geographical location, an inner-city area with high ethnic diversity and socio-economic  
441 disadvantage, this potentially limits the transferability of the findings as the experiences  
442 captured may be less applicable to more suburban, rural, or affluent areas. However,  
443 this geographical focus was also a strength, as the concentration of high-risk populations  
444 for T2DM means that there were many women in this area with diabetes and in their  
445 reproductive years. This enabled the study to consider the phenomena associated with  
446 PPC uptake in a high prevalence setting that could inform reproductive healthcare  
447 delivery, compared with areas with smaller diabetes populations. It was also important  
448 that this study included women from a diversity of ethnic and socio-economic  
449 backgrounds, as these have been cited by previous studies as factors that may explain  
450 poor uptake of this care in women with T2DM (Murphy et al., 2010a; Murphy et al., 2017).

451

452 Additionally, neither NPT nor COM-B model underpinned the study approach, rather they  
453 have been used as tools to frame potential areas for a future intervention from our study  
454 data. Nevertheless, we have shown how our study data mapped onto the constructs of  
455 NPT effectively and explained factors that could be targeted to enhance the provision  
456 and uptake of PPC. We have also used these data to identify a strategy of who will  
457 perform some of the specific target behaviours, including where and when these could  
458 be addressed and by whom. In-so-doing we have identified explicit intervention  
459 specifications from the suggestions of the women with T2DM and healthcare professional  
460 who participated in this study about how to improve the provision and uptake of PPC for  
461 this group. Finally, it is important to recognise that the findings and intervention elements  
462 identified are not exhaustive. For example, some of the social factors that can mediate

463 women's reproductive behaviours, such as cultural and family factors were not fully  
464 explicated. So, an additional consideration in identifying strategies to improve PPC  
465 uptake in women with T2DM could be community or family level interventions.

466

## 467 **Conclusion**

468 This study has highlighted some important factors to be considered in the development  
469 of pre-pregnancy interventions for women living with T2DM. The findings emphasise the  
470 need for a multi-modal approach that enables healthcare professions to identify and  
471 respond to the reproductive needs of women living with T2DM. There is also a need to  
472 create a more positive narrative around women of reproductive age living with T2DM, to  
473 challenge the stigmatising and erroneous assumptions that impede women's  
474 engagement with their reproductive health. Following the MRC framework for complex  
475 intervention (MRC, 2006), the study has developed a theoretical framework for  
476 intervention detailing the structural, process and behavioural changes needed for  
477 improving PPC uptake and reducing the number of women living with T2DM unprepared  
478 for pregnancy. The next step will be to use the framework to develop detailed  
479 specifications for the intervention components.

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Table 1. Participant Characteristics (women with Type 2 diabetes)

<b>Characteristic</b>	<b>All (n=30)</b>	<b><sup>†</sup>PPC exposure (n=11)</b>	<b>No <sup>†</sup>PPC exposure (n=19)</b>
Age (years)			
Median (range)	37 (25-44)	40 (32-43)	36 (25-44)
Duration of diabetes (years)			
Median (range)	5.5 (1-15)	8 (1-15)	4 (1-13)
HbA1c (mmol/mol)			
Median (range)	57 (40-108)	58 (40-91)	70 (70-108)
HbA1c (%)			
Median (range)	7.4 (5.8-12)	7.5 (5.8-10.5)	8.6 (7.3-12)
<sup>‡</sup> BMI (Kg/m <sup>2</sup> )			
Median (range)	34.9 (20.4-47.9)	34.2 (20.4-43.6)	35.3 (21.1-47.9)
Reproductive status (n, %)			
Pregnant	8 (27%)	0	8 (100%)
No contraception	14 (46%)	6 (43%)	8 (57%)
Contraception	8 (27%)	5 (63%)	3 (37%)
Adverse obstetric events (n, %)			
Spontaneous abortion	8 (27%)	3 (37.5%)	5 (62.5%)
Stillborn at term	3 (10%)	2 (67%)	1 (33%)
Ectopic pregnancy	2 (7%)	0	2 (100%)
Relationship status (n, %)			
Single	7 (23%)	1 (14%)	6 (86%)
In a relationship	23 (77%)	10 (43.5%)	13 (56.5%)
Ethnicity (n, %)			
Asian	8 (27%)	4 (50%)	4 (50%)
Black	16 (53%)	6 (37.5%)	10 (62.5%)
White	6 (20%)	1 (17%)	5 (83%)
Highest education attainment (n, %)			
Secondary school	15 (50%)	3 (20%)	12 (80%)
Higher Education award	15 (50%)	8 (53%)	7 (47%)
<sup>§</sup> IMD (quintiles) (n, %)			
1 (least deprived)	0	0	0
2	3 (10%)	1 (33%)	2 (67%)
3	6 (20%)	3 (50%)	3 (50%)
4	14 (47%)	5 (36%)	9 (64%)
5 (most deprived)	7 (23%)	2 (29%)	5 (71%)

<sup>†</sup>PPC, pre-pregnancy care

<sup>‡</sup>BMI (kg/m<sup>2</sup>), Body Mass Index - Healthy weight 18.5–24.9; Overweight 25–29.9; Obesity I 30–34.9; Obesity II 35–39.9; Obesity III 40 or more

<sup>§</sup>IMD, Index of Multiple Deprivation score range quintile groups, 1 (Least deprived) - 5 (most deprived)

Table 2: Mapping themes to Normalisation Process Theory components

Component	Theme	Context
Coherence	<i>Understanding the reproductive needs of women with Type 2 diabetes</i>	Making pre-pregnancy care for women, and the benefits of addressing this, more explicit both for the women and healthcare professionals; and integrating reproductive support into the current routine care contexts of women with Type 2 diabetes.
Cognitive participation	<i>Constructing a more positive narrative for Type 2 diabetes and pregnancy</i>	Proactively identify women with Type 2 diabetes women in the care system for supportive intervention and activate this with prompts.
Collective action	<i>Enhancing the visibility of pre-pregnancy care Integrated healthcare systems Supportive technologies</i>	Ensuring the workability and integration of the intervention by embedding it within the current care system and with linkage between primary and specialist care.
Reflexive monitoring	<i>A multi-modal approach</i>	Create opportunities for information and performance feedback at the individual (goal attainment) and system levels (process adherence and pregnancy outcomes).

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Table 3 Target behaviours for the uptake of pre-pregnancy care specifications

Target behaviour	Who	What	When	Where
Increase the visibility of pre-pregnancy care within healthcare settings	Healthcare professionals and organisations	Information and visual representations of diabetes and pregnancy with key messages using multi-media	Ongoing promotion of message	Primary care; diabetes outpatients; eye screening; sexual health; fertility clinics; early pregnancy units
Improve women's understanding of their pre-pregnancy care needs and pregnancy planning	Women living with Type 2 diabetes	Clear information resources Constructive education by healthcare professionals- with care planning Integrate pregnancy within structured education programmes	During routine diabetes reviews with healthcare professionals Group education sessions	Healthcare consultations and education sessions (primary and secondary care)
Improve healthcare professionals understanding of the reproductive healthcare needs of this population	Healthcare professionals working with women with Type 2 diabetes	A targeted professional education programme on pre-pregnancy care and how it is communicated, detailing their responsibilities and its benefits, and promoting a positive narrative	Ongoing programme with regular updates	Primary and secondary care (electronic delivery)
Integrate pre-pregnancy care into the routine management of women with Type 2 diabetes in primary care	Primary healthcare professionals	Integrate reproductive health and pre-pregnancy care into clinic templates and within consultations, with active prompting Explicit care-pathway for pre-pregnancy care and prevention of unplanned pregnancy	During healthcare consultations	Primary care consultations

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