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1 • **Title:** Impact of a medical mobile phone app (QUIPP) for predicting preterm birth on the
2 anxiety and decisional conflicts faced by women in threatened preterm labour.

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12 13 14 15 16 **Introduction**

17 In the United Kingdom (UK), 8% of babies are born preterm (before 37 weeks' gestation)(Office for
18 National Statistics, 2019). Babies who survive preterm birth are at high risk of short and long-term
19 health problems (Liu *et al.*, 2016; Patel, 2016), and The Department of Health is therefore aiming to
20 reduce the preterm birth rate to 6% by 2025 (Department of Health, 2017; NHS England, 2019).

21 However many women who present before 37 weeks' gestation with symptoms of labour do not do
22 on to deliver their baby early (Iams *et al.*, 2002). The difficulty in diagnosing preterm birth means
23 that triaging women who present with symptoms of threatened preterm labour (TPTL) is a challenge
24 (Carter *et al.*, 2018). Clinicians need to balance the risks of over-medicalising the majority of women

25 who will not deliver early (Iams *et al.*, 2002), with the small risk of preterm delivery for those
26 discharged home (DeFranco, Lewis and Odibo, 2013). This challenge is compounded by current UK
27 guidance which advises treating all women who present under 30 weeks' gestation in threatened
28 preterm labour (TPTL) (NICE, 2015). This is despite that most women presenting in TPTL will not have
29 delivered within seven days (Iams *et al.*, 2002), leading to psychological, economic and clinical
30 implications of unnecessary interventions (Watson and Ridout, 2015; Watson *et al.*, 2019).

31

32 For women experiencing TPTL, alongside the potential frightening consequence of delivering their
33 baby early, they describe conflicting emotions and feelings, which could affect the decisions they
34 make about their care. Women's 'decisional conflict' (defined as a "state of uncertainty about a
35 course of action" (The Ottawa Hospital Research Unit, 2003, p 2) may be increased by these
36 contradictory emotions. For example these could include, their responsibilities (not wanted to be
37 away from older children while needing to be an inpatient for their unborn child), the opposing
38 advice they may receive from different clinicians, and/or feeling tense due to preterm labour
39 symptoms while trying to stay calm for the unborn baby (Carter *et al.*, 2018). These emotions and
40 feelings could all affect how a woman makes decisions about her care and inadvertently prevent
41 joint decision making. To improve women's experiences and decisions around TPTL, clinicians need
42 to be aware of their complex emotions and what issues are important to them. This would promote
43 individualised care, shared decision-making, and reduce 'decisional conflict'. The uncertainty of TPTL
44 and the decisions around TPTL that women face, often results in increased maternal anxiety, which
45 is in itself a risk factor for premature delivery (Rich-Edwards and Grizzard, 2005; Latendresse, 2009;
46 Christian, 2012).

47

48 The QUIPP app is a free, validated mobile phone application (app) that supports clinical decision-
49 making by providing an individualised risk of delivery within clinically important time points (i.e.

50 within one, two and four weeks of testing, and before 30, 34 and 37 weeks' gestation (Kuhrt *et al.*,
51 2016; H. A. Watson *et al.*, 2017; Carter *et al.*, 2019; Watson *et al.*, 2019). The risk score is based upon
52 the woman's risk factors for preterm birth i.e. history of preterm birth or prelabour preterm
53 ruptured membranes (PPROM), invasive cervical surgery (e.g. LLETZ or cone biopsy) and multiple
54 pregnancy) and her clinical test results (fetal fibronectin; fFN) and cervical length. Alongside
55 generating a percentage risk score, the QUIPP app also provides the risk score in an infographic
56 donut chart (see Figure 1), allowing the clinician to communicate with the woman in an easy to
57 understand format. It is possible that informing women of their risk status using the QUIPP app
58 [which incorporates fFN and/or cervical length, both of which have high negative predictive values
59 (Tsoi *et al.*, 2005; Abbott *et al.*, 2013; Bruijn *et al.*, 2015)], would help to reduce anxiety in women
60 with a lower risk of imminent delivery (Carter *et al.*, 2018).

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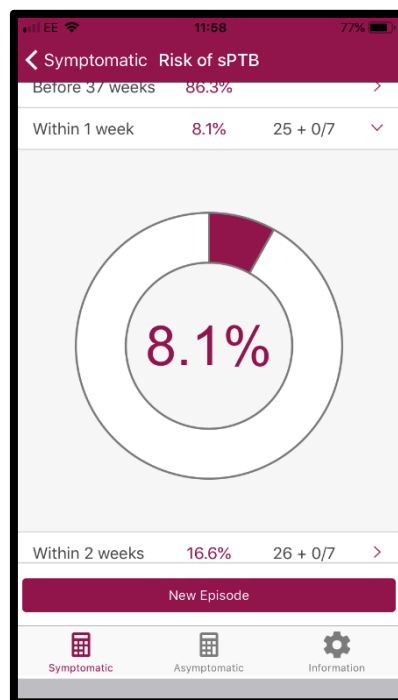


Figure 1 An image generated using the QUIPP app and knowledge of patient history, cervical length and fetal fibronectin measurement. Clicking on the numeric risk score at the top of the screen creates the associated donut risk infographic. In this example, a woman has an 8.1% risk of delivering with 1 week of the test and a 16.6% risk of delivering within 2 weeks. (Image used with consent from the QUIPP Team)

69 The importance of shared decision-making was highlighted by the 2015 Montgomery v Lanarkshire
70 case, which emphasized the need for clinicians to present information in a meaningful way to

71 patients (Chan *et al.*, 2017). With this in mind, the QUIPP app was designed in collaboration with the
72 Women's Health Academic Centre's Preterm Birth Studies Public and Patient Involvement (PPI)
73 group and women participating in a qualitative part of the PETRA study (REC Ref.14/LO/1988), the
74 findings of which are reported elsewhere (Carter *et al.*, 2018, 2019). The addition of the
75 corresponding donut chart infographic in the app provides clinicians with a visual risk illustration, in
76 addition to the % risk score, which they can use to enhance communication with women.

77

78 Aim

79 The aim of this study is to evaluate whether the use of the QUIPP app results in lowering levels of
80 anxiety and decisional conflict in women experiencing threatened preterm labour.

81

82 To determine whether QUIPP reduced decisional conflict and improved shared decision making, we
83 will investigate a subgroup of EQUIPTT trial participants' decisional conflict levels following their
84 TPTL clinical assessment and compare findings between women where had the QUIPP app had been
85 used and those where it had not been used. We will also investigate women's anxiety before and
86 after TPTL clinical assessment.

87

88 Methods

89 Study Design

90 The EQUIPTT study (The Evaluation of the QUIPP app for Triage and Transfer) was a randomised
91 cluster trial, carried out in 13 UK hospitals in London, the South East and the Midlands which aimed
92 to evaluate the impact of the QUIPP app on inappropriate management for TPTL [REC Ref.
93 17/LO/1802;(Watson *et al.*, 2019)]. For the first six weeks, all 13 sites continued their normal triage
94 practice for TPTL to allow a run-in period and collect baseline information. Seven sites were

95 randomised to the QUIPP app intervention (to use as a decision and communication tool) and six
96 sites were randomised to the control (continued their normal practice) for a 9-month period. In the
97 final 6-week period the QUIPP app intervention was established at the control sites. Ensuring the
98 QUIPP app would be established at control sites incentivised all sites to participate in the study,
99 regardless of how they were randomised. A subset of participants were asked to complete a
100 questionnaire booklet which was used to evaluate decisional conflict and anxiety (supplementary file
101 1).

102

103 For this subset, women were enrolled through convenience sampling as they attended the maternity
104 assessment centre with symptoms of TPTL between 26th March 2018 - 12th February 2019 (this
105 included the 9-month study period and final 6-week period as described above). Women were
106 recruited at all 13 sites for QUIPP app intervention as the control sites also used the app during the
107 final 6-week period of the trial.

108

109 Data Collection

110 Women presenting to the maternity assessment unit with symptoms of TPTL were provided with a
111 study patient information leaflet (supplementary file 2). If they wished to participate and complete
112 the questionnaire booklet, written informed consent was taken by local site research midwives.
113 Inclusion criteria required the women to be between 23⁺⁰ - 34⁺⁶ weeks' gestation with symptoms of
114 TPTL (i.e. abdominal pain/back pain/tightenings). Women were excluded if they had a definitive
115 diagnosis of labour (i.e. regular painful contractions with cervical change of more than 3cm on
116 speculum or digital examination), confirmed rupture of membranes (on speculum examination) or
117 significant vaginal bleeding.

118

119 Instrument

120 The 5-page questionnaire booklet comprised two sections and was designed in collaboration with
121 the King's College London/St Thomas' Hospital Preterm Birth Studies Patient and Public Involvement
122 (PPI) panel. The first section was completed before her assessment with a clinician and consisted of
123 demographic and medical information (e.g. maternal age, ethnicity, gestational age, parity, previous
124 preterm birth), symptoms, frequency of symptoms, severity of pain, and a pre-assessment anxiety
125 score. The second section was completed following clinical assessment and included questions on
126 what tests had been undertaken, whether the clinician had used the QUIPP app, the agreed care
127 plan, questionnaires to determine post-assessment anxiety and decisional conflict scores and a free
128 text comment box.

129

130 The pre and post-assessment anxiety scores utilised the Visual Analogue Scale for Anxiety (VASA)
131 (Hornblow and Kidson, 1976), which has more recently been used in other maternity studies (Hepp
132 *et al.*, 2016). The scale comprised of a 10 cm horizontal line with '*not at all anxious*' on the left-hand
133 side, and '*extremely anxious*' on the right-hand side. Women were asked to mark how anxious they
134 felt on the line. The local research midwife then measured the line with a 10 cm ruler to produce a
135 VASA score (i.e. 2.5 cm = a score of 2.5). The scores could range from 0 (low anxiety) to 10 (high
136 anxiety). For reliability, the questionnaire booklets were printed in advance for all sites to ensure
137 that the visual anxiety scale printed as 10 cm exactly.

138

139 The Decisional Conflict Scale (O'Connor, 1995) involves 16 statements about the care offered to
140 them following TPTL assessment. There are five response categories for each statement, ranging
141 from 'strongly agree' to 'strongly disagree'. The local research midwife calculated and recorded a
142 score to each response from 0 (strongly agree) to 4 (strongly disagree). The response scores for the
143 16 statements were calculated (summed, divided by 16, and multiplied by 25) as per the Decisional

144 Conflict Scale User Manual (The Ottawa Hospital Research Unit, 2003). The final calculated scores
145 ranged from 0 (no decisional conflict) to 100 (extremely high decisional conflict).

146

147 Sample Size

148 Target recruitment for the EQUIPTT questionnaire sub-study was 300 participants (approximately 25
149 recruits per site), allowing for non-compliance and missing data. Based on previous research using
150 visual analogue scale scores (Allred, Byers and Sole, 2010), a total sample size of 272 was required at
151 standard levels of significance (alpha = 0.05 two-sided) to achieve 90% power to detect a 10%
152 difference in mean VASA scores between sites with and without the intervention.

153

154 Data Analysis

155 Following completion of the questionnaire booklet, the local research midwives entered the
156 anonymised data from the booklets onto a pre-prepared Microsoft Excel spreadsheet. The research
157 midwives then cross checked the typed data with the paper copies. The spreadsheet was formatted
158 with drop-down pre-populated answer boxes to minimise error during data transfer. The original
159 paper questionnaire case report form was stored in the study folders (kept in a locked cupboard or
160 room) at each local site, while the anonymous spreadsheet was sent electronically to the study
161 coordinators. The study coordinators saved the anonymous spreadsheets on a secure King's College
162 London network which was only accessible through an individual username and password. Once
163 recruitment had finished at all sites, the study coordinators amalgamated the anonymous local
164 spreadsheets to create one spreadsheet of all sites. The data were then analysed using Stata 15
165 Statistical Software (StataCorp, 2017).

166

167 The demographic data, symptom data, and agreed care plan were summarised. A repeated
168 measures ANOVA (RMANOVA) undertaken for the VASA scores with time point (pre-assessment and

169 post-assessment) as the within subject variable. Planned independent sample t tests were used to
170 compare change in VASA scores between sites using the QUIPP app and sites using standard care.
171 Due to low compliance with the QUIPP app at some of the intervention sites, we also compared
172 change in VASA scores for women aware the QUIPP app was used compared to women unaware of
173 the QUIPP app used (independent sample t tests). This sub-analysis was required because if a
174 woman is not involved in the decision-making using the app, it cannot influence her experience.

175

176 For analysis purposes we performed Chi-Squared tests on the proportion of women with a decisional
177 conflict score of <25 and a score of ≥ 37.5 , both between women aware of the app being used and
178 women not aware of the app being used. These cut-offs were used as a meaningful difference
179 between low and high levels of decisional conflict (The Ottawa Hospital Research Unit, 2003). Scores
180 that are <25 are associated with implementing decisions, while scores that are high (≥ 37.5) are
181 associated with decision delay or uncertainty around implementation (The Ottawa Hospital Research
182 Unit, 2003; Kawaguchi *et al.*, 2013; Kim *et al.*, 2017).

183

184 **Findings**

185 Questionnaires were completed by 221 women from 12 of the potential 13 sites. After exclusions
186 (Figure 2), 202 questionnaires were included in the analysis.

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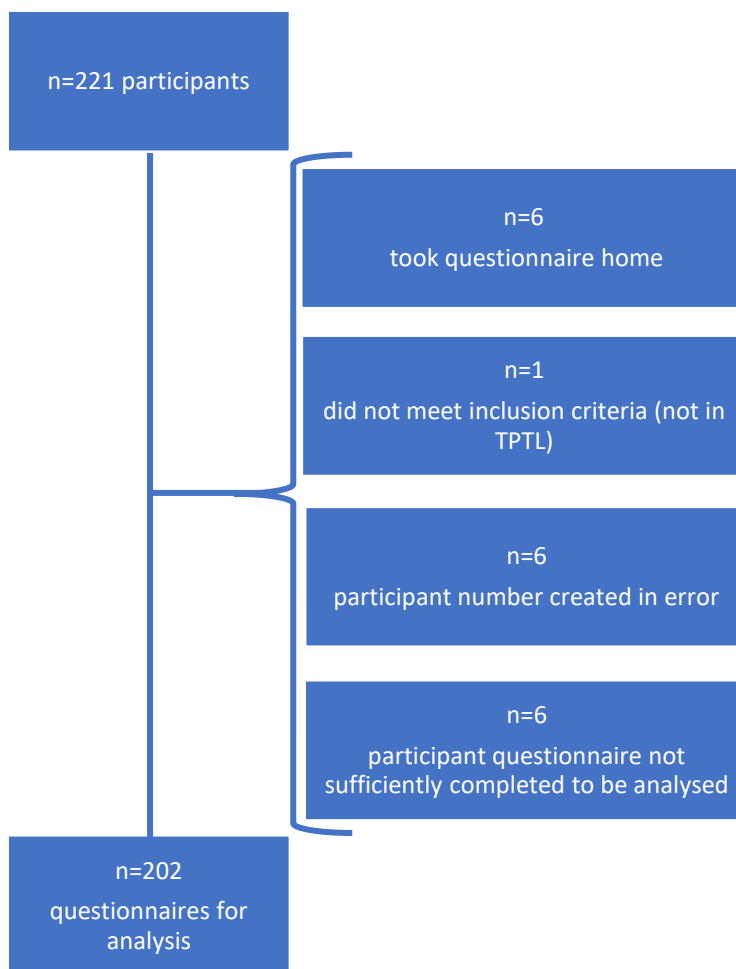


Figure 2 Flowchart of participant exclusions

Of the 202 women in threatened preterm labour completing the booklet and 81 (40%) were at sites randomised to using the app, and 121 (60%) were at sites randomised to standard care.

214

215 Baseline characteristics

216 Demographics, pregnancy characteristics, symptoms, test undertaken and care plan are described in

217 Table 1.

		Women at sites randomised to using QUIPP app	Women at sites randomised to using Standard care	All women
Total n (%)		81 (40)	121 (60)	202 (100)
Aware QUIPP App used in their care		48 (59)	11 (9)	59/202 (29)
Maternal age n (%)	Under 20 years	2 (3)	5 (4)	7/202 (4)
	21- 25 years	16 (20)	15 (12)	31/202 (15)
	26 - 30 years	24 (30)	45 (37)	69/202 (34)
	31 – 35 years	23 (28)	31 (26)	54/202 (27)
	36 – 40 years	15 (19)	20 (17)	35/202 (17)
	Over 40 years	1 (1)	5 (4)	6/202 (3)
Maternal ethnicity n (%)	White	41 (51)	74 (61)	115/201 (57)
	Asian	18 (23)	20 (17)	38/201 (19)
	Mixed	8 (10)	3 (2)	11/201 (5)
	Black	11 (14)	22 (18)	33/201 (16)
	Other	2 (3)	2 (2)	4/201 (2)
Primigravida n (%)		30 (37)	64 (53)	94/201 (47)
Symptoms present n (%)	Tightenings	63 (78)	82 (68)	145/201 (72)
	Abdominal pain	70 (86)	111 (93)	181/201(90)
	Back pain	40 (49)	73 (61)	113/200 (57)
Tests performed n (%)	Fetal heart rate	77 (95)	110 (91)	187/202 (93)
	Vaginal exam	60 (74)	81 (68)	141/201 (70)

	Fetal Fibronectin	66 (81)	65 (55)	131/199 (66%) ²¹⁸
	Cervical length	12 (15)	19 (17)	31/195 (16%) ²¹⁹
	Urinalysis	70 (86)	108 (90)	178/201 (89%) ²²⁰
	Blood test	20 (25)	14 (13)	34/193 (18%)
	Don't know	0 (0)	2 (2)	2 (1%) ²²¹
Agreed care plan n (%)	Discharged home	60 (75)	88 (74)	148 (74%) ²²²
	Not discharged home	14 (18)	17 (14)	31 (16%) ²²³
	Unsure	6 (8)	14 (12)	20 (10%) ²²⁴

225 *Table 1 Baseline characteristics of participants completing the questionnaire*

226

227 The majority of participants were of White ethnicity (n=115, 57%) and within the 26-30 years age
228 category (n=69, 34%). Women presented with a range TPTL symptoms and most had multiple
229 symptoms. The majority (n=145/201, 72%) of women reported tightenings, usually described as
230 irregular (n=76/201, 38%). Nearly all women (n=181/201, 90%) women reported having lower
231 abdominal pain, with the majority (n = 95/201, 47%) describing this pain as moderate. More than
232 half of all women (n=113/200, 57%) suffered with back pain. Baseline characteristics and symptoms
233 were similar between sites that were randomised to using the app, and sites randomised to standard
234 care.

235

236 Clinical tests performed

237 Nearly all women (n=187/202, 93%) reported that the fetal heart rate was checked. The majority of
238 women reported that they had a vaginal examination (n=141/201, 70%), a cervico-vaginal swab for
239 an fFN test (either qualitative or quantitative) (n=131/199, 66%) and urinalysis (n=178/201, 89%).
240 Only 16% had a cervical length measurement, 18% a blood test and 1% of women said they did not

241 know what tests had been undertaken on them. Women in sites randomised to using the QUIPP app
242 were more likely to have an fFN test (81% vs 55%) and a blood test undertaken (25% vs 13%).

243

244 Agreed care plan

245 Following TPTL assessment, the majority (74%, 148/202) of women knew the plan was to be
246 discharged home. However, despite being seen by a clinician, 10% (20/202) reported that they were
247 unsure what the agreed care plan was.

248

249 Aware QUIPP app was being used in their care.

250 Of the 202 women who completed the booklet, 59/202 (29%) were aware the QUIPP App had been
251 used in their care. At sites randomised to using the app, 48 women [48/81 (59%)] were aware the
252 QUIPP app had been used in their care. At sites randomised to standard care, 11 women [11/121
253 (9%)] said that they were aware the clinicians had used the QUIPP app in their care. This may be
254 because clinicians at the standard care sites were aware of the app from working in other hospitals,
255 despite the fact that they were currently working at a sites where using the app was not in their
256 protocol.

257 To meet the aim of this study the research team analysed anxiety outcomes and decision conflict
258 outcomes based on the randomisation of the site the women presented at (site randomised to using
259 the app vs. site randomised to standard care) and on whether women were aware the app had been
260 used in her care. This was decided because if a woman is unaware the QUIPP app was used in her
261 care, it is unlikely to influence a woman's anxiety and/or decisional conflict.

262

263

264 Outcomes for women's perceptions of triage experience

265 *Anxiety outcomes: VASA Scores*

266 Four women did not provide a complete set of pre- and post-assessment VASA scores, leaving 198
267 participants available for analysis of anxiety levels. The outcomes are presented in Table 2.

268 A one-way RMANOVA showed a significant reduction in difference between VASA scores before and
269 after assessment. $F(1,197) = 114.6$ $p = 0.000$. An independent t-test was run to assess differences in
270 anxiety reduction between sites using and not using the QUiPP app. The results showed a greater
271 reduction in VASA scores for women in QUiPP protocol sites (2.39 ± 0.36) compared to those
272 receiving standard care (1.93 ± 0.23) but this was not statistically significant $t(196) = 1.13$, $p = 0.26$).
273 We also used an independent t-test to compare the post-assessment VASA scores of women aware
274 of QUiPP app use with to those unaware of its use. This showed a reduction that approached
275 borderline statistical significance (2.75 ± 0.49 vs. 1.91 ± 0.21 ; $t(196) = 1.84$, $p = 0.07$).

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277 *Decisional Conflict Outcomes*

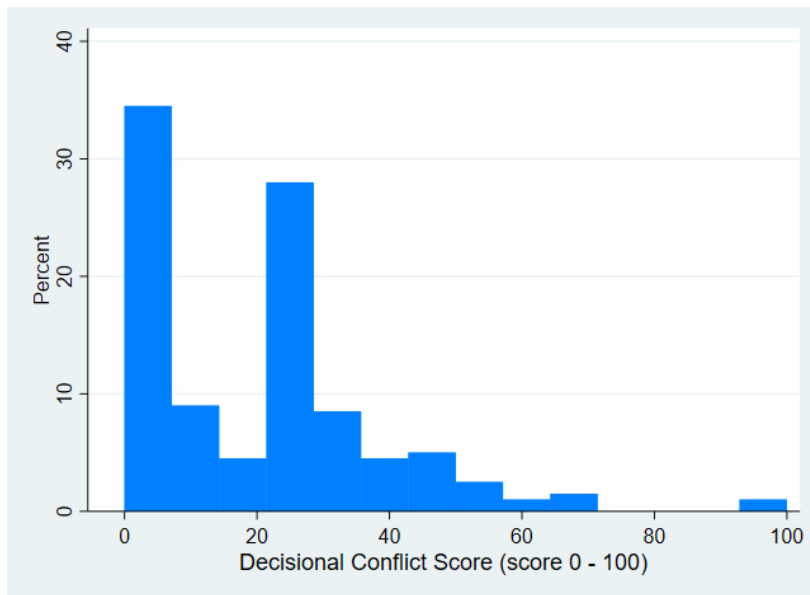
278 Of the original 202 participants, 200 completed the decisional conflict outcomes questions, the
279 results of which are shown in Figure 3.

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285 *Figure 3 Histogram of women's decisional conflict scores (n=200). Decisional conflict score can be between 0-100, with a*
 286 *higher score indicating more decisional conflict.*

287

288 Our cohort had low decisional conflict which was not normally distributed (Figure 3). Most women in
 289 our cohort had low decisional conflict (the median decisional conflict score in did not go above 23),
 290 which reinforced our analysis plan to divide decisional conflict scores into those <25 and those ≥
 291 37.5.

292 For women who were aware of the QUiPP app, 23% had high decisional conflict (a decisional conflict
 293 score ≥ 37.5) compared to 77% high decisional conflict in women who were not aware of the QUiPP
 294 app being used. A Chi-squared test found that this was not statistically significant. Full results are
 295 presented in Table 3.

	Women at EQUIPTT study site			Women aware of QUiPP use during their visit			Total	
	Site randomised to using QUiPP	Site randomised to using standard care	P value	Yes	No	P value	Mean VASA score *	n
Number of women with VASA scores (n)	78	120	-	47	151	-		198

Pre-assessment anxiety*	5.39 (4.82-5.95)	5.47 (5.05-5.90)	0.818	5.69 (4.90 - 6.48)	5.36 (4.98 - 5.74)	0.161	5.44 (5.10 - 5.78)	
Post-assessment anxiety*	3.00 (2.39 - 3.61)	3.54 (2.39-3.61)	0.161	2.94 (2.11 - 3.76)	3.45 (3.04- 3.87)	0.244	3.33 (2.96 - 3.70)	
Difference in anxiety*	2.39 (1.67 - 3.10)	1.93 (1.48 - 2.38)	t(196) = 1.13, p = 0.26	2.75 (1.76 - 3.74)	1.91 (1.50 - 2.32)	t(196) = 1.84, p = 0.07	2.11 (1.72 - 2.50)	

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Table 2 Women's perception of outcomes: Visual Analogue Scale for Anxiety

**Data are presented as mean with 95% confidence intervals in brackets*

Difference in anxiety P values reported as: the observed t-value, (degrees of freedom), and significance level

	Women at EQUIPTT study site			Women aware of QUIPP use during their visit			Median decisional conflict score for all women	Total
	Site randomised to using QUIPP	Site randomised to using standard care	P value	Yes	No	P value		
Total number of women with decisional conflict scores (n)	79	121	-	58	142	-	-	200
Median decisional conflict score	16	23	-	11	23	-	23	-
Decisional conflict scores < 25 n (%)	47 (43)	62 (57)	0.252	37 (34)	72 (66)	0.092	-	109
Decisional conflict scores ≥ 37.5 n (%)	8 (27)	22 (73)	0.119	7 (23)	23 (77)	0.458	-	30

302
303

Table 3 Women's perception of outcomes: Decisional Conflict Scores

304 *Free text comments*

305 Of the 202 questionnaires, 47 women provided written comments in a free text box. Full thematic
306 analysis including coding of the data was not undertaken as most of the written comprised a few
307 words or one sentence. Two researchers read the comments and assigned them into appropriate
308 'theme' categories. The final theme categories were agreed by consensus. Of the 47 comments, the
309 majority (43/47) could be assigned into one of the five final categories which are described below:

- 310 1. Positive comments describing reassurance, good care and friendly staff (n=30).
- 311 2. Complaints about waiting times and its contribution to anxiety (n=3). One participant
312 wrote that "the wait made me more anxious than I was before I arrived."
- 313 3. How having a history of preterm birth increases their anxiety when in threatened
314 preterm labour (n=1).
- 315 4. Clinicians did not always involve women in the decision-making, so women did not feel
316 they had options about their care (n=4).
- 317 5. Unclear communication and care plans (n=5). One woman was not sure why she was
318 being admitted and another said "I was anxious when the neonatologist spoke to me as
319 they said I was going into labour, and I started crying. There was a lack of
320 communication, I haven't seen a senior doctor". Another respondent said that she
321 "came here to find answers about the pain I am experiencing. No answers were given
322 but thankfully I'm not in labour".

323

324 Of the remaining comments (4/47) that were not assigned into categories, 3 women used the
325 comment box to write down their clinical diagnosis, and 1 woman used it to advocate for plastic
326 speculums.

327

328

329 **Discussion**

330 This study assessed anxiety and decisional conflict in a large sample of women across 12 different
331 hospital sites. Despite the fact our cohort is slightly younger than the UK average maternal age
332 (Office for National Statistics, 2019), and is more ethnically diverse (Office for National Statistics,
333 2018), our findings are likely to be generalisable to the South of England, if not a wider UK pregnant
334 population.

335

336 For all women presenting in threatened preterm labour in this study, anxiety was significantly
337 reduced following clinical assessment compared to how they felt when they first arrived at the
338 maternity assessment unit. This demonstrates that seeing a clinician, regardless of how they assess
339 the woman, has a positive effect on reducing maternal anxiety. As most women in this study
340 underwent fFN testing, our findings suggest that increased maternal anxiety is not associated with
341 fFN use. Although this contrasts with previous reports (Shennan *et al.*, 2005), our findings align with
342 a previous Canadian study where fFN testing was associated with maternal reassurance, even when
343 women received a 'positive' fFN result (Peterson *et al.*, 2014).

344

345 For women with abdominal pain in pregnancy, anxiety is not just linked to her risk of preterm birth.
346 While the QUIPP app provides reassurance to women who are less likely to be in preterm labour, if a
347 woman is not provided with an acceptable alternative reason for her pain her anxiety may not be
348 relieved. This represents a divide between a clinician's priorities (e.g. excluding the most severe
349 pathology) and women's motivations for seeking help and need to 'make sense of the symptoms'
350 (Carter *et al.*, 2018). This emphasises that the QUIPP app should be used as a decision support tool,
351 helping clinicians and women to decide on the nature and timing of the most appropriate
352 management, given the risk, rather than a simple rule in/rule out tool. Clinician's still need to
353 communicate effectively with the woman regardless of her QUIPP score.

354

355 While the majority (30/47, 65%) of written comments spoke positively about their care, the
356 remaining comments highlighted negative aspects of care which may have contributed to anxiety
357 levels and decisional uncertainty. In some cases, women were unclear as to what occurred during
358 their assessment either reporting that they were unsure of what the agreed care plan was or unsure
359 what tests had been undertaken. This, again, highlights the divide between a clinician's priorities and
360 women's motivations for seeking help. Clinicians need to ensure that they communicate effectively
361 with women, understanding the importance of effective clinical explanation and counselling,
362 including using clear language and checking that they have been understood (Ali, 2017).

363

364 While we used the recommended cut-offs when analysing decisional conflict scores (The Ottawa
365 Hospital Research Unit, 2003) other researchers have used alternative thresholds (e.g. ≥ 25)
366 (Thompson-Leduc *et al.*, 2016). As a score of 25 can be gained by answering 'neither agree nor
367 disagree' for all questions, we felt that using the higher cut-off of ≥ 37.5 was more appropriate as an
368 accurate measure of women with meaningful decisional conflict.

369

370 Limitations

371 Many additional factors (not just concerns about TPTL or awareness of QUIPP app use) may have
372 affected a woman's anxiety which were not revealed by the questionnaire. This could include events
373 that occurred prior to seeing a clinician, such as longer waiting times highlighted in our respondents
374 written comments. Indeed, this is a factor known to increase anxiety (Thu *et al.*, 2015).

375 Unfortunately, a limitation is that waiting times were not recorded as part of the study and would
376 have been informative. Maternity services could explore waiting room interventions that have

377 shown promise elsewhere in reducing anxiety, such as music and visual art (Holm and Fitzmaurice,
378 2008) (Nanda *et al.*, 2012).

379

380 While there were reductions in anxiety and decisional conflict for women who were aware of the
381 QUiPP app use, this failed to reach statistical significance. Clinicians at all sites were trained in the
382 use of the QUiPP app and a training plan was developed to reinforce the guidance (Watson *et al.*,
383 2019). However, a limitation is that some women at the intervention sites were not aware of the
384 QUiPP app being used. For example, of the 30 women in this study with high decisional conflict
385 scores (≥ 37.5) only 23% (7/30) were aware of the QUiPP had been used, compared to 77% (23/30)
386 who were not aware. The proportion of women with high decisional conflict was reduced in women
387 who were aware the QUiPP app was used, compared to those unaware ($p=0.458$). Although this
388 finding was not statistically significant it is possible that clinicians who discussed QUiPP scores with
389 the women were more effective at communicating and involving women in their care. Our power
390 calculation did not adequately allow for poor compliance with QUiPP app use, so a larger sample size
391 may have resulted in findings reaching statistical significance

392

393 Enabling patients to understand risks can be a challenge but is crucial for clinicians when making
394 shared decisions (Say, Robson and Thomson, 2003). Given working pressures, staff changeover and
395 unfamiliarity with the app, it is possible that some staff were not confident in using the app as a
396 communication tool, or using the donut chart infographic to visually represent risk (Figure 1).

397 Greater reductions in women's anxiety or decisional conflict may be possible as clinicians' familiarity
398 and confidence in the reliability of the prediction algorithms increases, along with enhanced
399 dissemination and future roll-out of the QUiPP app (such as producing a QUiPP Implementation
400 Toolkit for hospital sites to utilise). . While QUiPP may have potential to reduce anxiety and

401 decisional conflict for women experiencing TPTL, further research is needed to support generalised
402 use of the tool.

403

404 While not all women were aware the QUIPP app was used in the sites randomised to using the
405 QUIPP app, another limitation is that some women were aware of the QUIPP app being used despite
406 presenting at sites randomised to standard care. Any potential affect on the results was minimised
407 by analysing anxiety outcomes and decisional conflict outcomes by both site randomisation and
408 women's awareness (Table 2 and Table 3).

409

410 Although the DCS has been used in several studies of decision making in pregnancy (Say, Robson and
411 Thomson, 2003, 2011), we are not aware that it has been validated for research with pregnant
412 women. While the DCS is sensitive to change and reliable (O'Connor, 1995), some argue its clinical
413 applicability is limited as it does not incorporate the concept of pairing the choice of a patient with
414 their values and preferences (Say, Robson and Thomson, 2011).

415

416 Whilst 221 women entered data into the questionnaire booklets, after exclusions only 202 were
417 analysed. Of the included 202 booklets, not all were complete meaning overall numbers were less
418 than the target recruitment of 300 questionnaire booklets that specified pre-study power for primary
419 outcomes. Recruitment was challenging due to several factors. Local research midwives often work
420 office hours when women in TPTL can arrive at any time. The study design meant women were
421 required to complete the first section of the booklet before TPTL assessment, and the second
422 section afterwards. Often by the time the research midwives arrived to explain the study and
423 undertake consent, the women had already been assessed. Some women also took the
424 questionnaire booklet home with them in error. On reflection we believe that recruitment could

425 have been improved in numerous ways including identifying a local study clinical champion who is
426 known to the maternity staff. Additionally, recruitment could have been increased if more clinical
427 staff were trained to take consent rather than relying solely on research midwives who are often
428 committed to several projects at the same time. Both refinements could have resulted in women in
429 TPTL arriving during the night or at weekends being consented to the study.

430

431 Conclusions

432 The QUIPP app has potential to reduce anxiety and decisional conflict in women who are aware that
433 it is being used in their care, however further research is needed to support this. Clinicians could
434 consider use of QUIPP as both a decision support and communication tool to appropriately target
435 care where it is needed and to reassure women whose risk of preterm birth is low. Additional work is
436 required to ensure clinicians are aware of the QUIPP app and optimise using it as a communication
437 tool when counselling women.

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448 **References**

449 Abbott, D. S. *et al.* (2013) 'Evaluation of a quantitative fetal fibronectin test for spontaneous preterm
450 birth in symptomatic women', *American journal of obstetrics and gynecology*. Elsevier, 208(2), pp.
451 122-e1. doi: 10.1016/j.ajog.2012.10.890.

452 Ali, M. (2017) 'Communication skills 1: benefits of effective communication for patients', *Nursing*
453 *Times*, 113(12), pp. 18–19.

454 Allred, K. D., Byers, J. F. and Sole, M. Lou (2010) 'The Effect of Music on Postoperative Pain and
455 Anxiety', *Pain Management Nursing*. W.B. Saunders, 11(1), pp. 15–25. doi:
456 10.1016/J.PMN.2008.12.002.

457 Bruijn, M. M. C. *et al.* (2015) 'Quantitative fetal fibronectin testing in combination with cervical
458 length measurement in the prediction of spontaneous preterm delivery in symptomatic women',
459 *BJOG: An International Journal of Obstetrics & Gynaecology*. Wiley Online Library.

460 Carter, J. *et al.* (2018) 'Threatened preterm labour: Women's experiences of risk and care
461 management: A qualitative study', *Midwifery*. doi: 10.1016/j.midw.2018.06.001.

462 Carter, J. *et al.* (2019) 'Development and validation of prediction models for the QUIPP App v.2: a
463 tool for predicting preterm birth in women with symptoms of threatened preterm labor', *Ultrasound*
464 *in Obstetrics & Gynecology*. John Wiley & Sons, Ltd, 0(ja). doi: 10.1002/uog.20422.

465 Chan, S. W. *et al.* (2017) 'Montgomery and informed consent: where are we now?', *BMJ*, 357, p.
466 j2224. doi: 10.1136/bmj.j2224.

467 Christian, L. M. (2012) 'Psychoneuroimmunology in pregnancy: Immune pathways linking stress with
468 maternal health, adverse birth outcomes, and fetal development', *Neuroscience and Biobehavioral*
469 *Reviews*. doi: 10.1016/j.neubiorev.2011.07.005.

470 DeFranco, E. A., Lewis, D. F. and Odibo, A. O. (2013) 'Improving the screening accuracy for preterm
471 labor: is the combination of fetal fibronectin and cervical length in symptomatic patients a useful
472 predictor of preterm birth? A systematic review', *American Journal of Obstetrics and Gynecology*.
473 Mosby, 208(3), p. 233.e1-233.e6. doi: 10.1016/J.AJOG.2012.12.015.

474 Department of Health (2017) *Safer Maternity Care - The National Maternity Safety Strategy -*
475 *Progress and Next Steps*. Available at:
476 [http://www.euro.who.int/__data/assets/pdf_file/0004/277735/Born-too-soon_preterm-birth-in-](http://www.euro.who.int/__data/assets/pdf_file/0004/277735/Born-too-soon_preterm-birth-in-Europe-trends,-causes-and-prevention.pdf?ua=1)
477 [Europe-trends,-causes-and-prevention.pdf?ua=1](http://www.euro.who.int/__data/assets/pdf_file/0004/277735/Born-too-soon_preterm-birth-in-Europe-trends,-causes-and-prevention.pdf?ua=1).

478 Hepp, P. *et al.* (2016) 'Measuring the course of anxiety in women giving birth by caesarean section: a
479 prospective study', *BMC Pregnancy and Childbirth*, 16(1), p. 113. doi: 10.1186/s12884-016-0906-z.

480 Holm, L. and Fitzmaurice, L. (2008) 'Emergency department waiting room stress: Can music or
481 aromatherapy improve anxiety scores?', *Pediatric Emergency Care*. doi:
482 10.1097/PEC.0b013e31818ea04c.

483 Hornblow, A. R. and Kidson, M. A. (1976) 'The Visual Analogue Scale for Anxiety: A Validation Study',
484 *Australian & New Zealand Journal of Psychiatry*. SAGE PublicationsSage UK: London, England, 10(4),
485 pp. 339–341. doi: 10.3109/00048677609159523.

486 Iams, J. D. *et al.* (2002) 'Frequency of Uterine Contractions and the Risk of Spontaneous Preterm
487 Delivery', *New England Journal of Medicine*. Massachusetts Medical Society, 346(4), pp. 250–255.
488 doi: 10.1056/NEJMoa002868.

489 Kawaguchi, T. *et al.* (2013) 'Development and validation of the Japanese version of the Decisional
490 Conflict Scale to investigate the value of pharmacists' information: a before and after study', *BMC*
491 *Medical Informatics and Decision Making*, 13(1), p. 50. doi: 10.1186/1472-6947-13-50.

492 Kim, J. *et al.* (2017) 'Validation of the Decisional Conflict Scale for Evaluating Advance Care Decision
493 Conflict in Community-dwelling Older Adults', *Asian Nursing Research*. Elsevier, 11(4), pp. 297–303.

494 doi: 10.1016/J.ANR.2017.11.004.

495 Kuhrt, K. *et al.* (2016) 'Development and validation of a tool incorporating cervical length and
496 quantitative fetal fibronectin to predict spontaneous preterm birth in asymptomatic high-risk
497 women', *Ultrasound in Obstetrics and Gynecology*, 47(1), pp. 104–109. doi: 10.1002/uog.14865.

498 Latendresse, G. (2009) 'The Interaction Between Chronic Stress and Pregnancy: Preterm Birth from A
499 Biobehavioral Perspective', *Journal of Midwifery and Women's Health*. doi:
500 10.1016/j.jmwh.2008.08.001.

501 Liu, L. *et al.* (2016) 'Global, regional, and national causes of under-5 mortality in 2000–15: an
502 updated systematic analysis with implications for the Sustainable Development Goals', *The Lancet*.
503 doi: 10.1016/S0140-6736(16)31593-8.

504 Nanda, U. *et al.* (2012) 'Impact of visual art on patient behavior in the emergency department
505 waiting room', *Journal of Emergency Medicine*. doi: 10.1016/j.jemermed.2011.06.138.

506 NHS England (2019) *NHS Long Term Plan » Overview and summary*, NHS England. Available at:
507 <https://www.longtermplan.nhs.uk/online-version/overview-and-summary/>.

508 NICE (2015) 'Preterm Labour and Birth', *National Institute for Health and Care Excellence*. London:
509 National Institute for Health and Care Excellence (UK) (National Institute for Health and Care
510 Excellence: Clinical Guidelines), (November).

511 O'Connor, A. M. (1995) 'Validation of a Decisional Conflict Scale', *Medical Decision Making*. Sage
512 PublicationsSage CA: Thousand Oaks, CA, 15(1), pp. 25–30. doi: 10.1177/0272989X9501500105.

513 Office for National Statistics (2018) 'Regional ethnic diversity'. Available at: [https://www.ethnicity-
514 facts-figures.service.gov.uk/uk-population-by-ethnicity/national-and-regional-populations/regional-
515 ethnic-diversity/latest](https://www.ethnicity-facts-figures.service.gov.uk/uk-population-by-ethnicity/national-and-regional-populations/regional-ethnic-diversity/latest).

516 Office for National Statistics (2019) *Birth characteristics in England and Wales: 2018*. Available at:

517 <https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/livebirths/datasets/birthcharacteristicsinenglandandwales>.

518

519 Patel, R. M. (2016) 'Short- and Long-Term Outcomes for Extremely Preterm Infants.', *American*

520 *journal of perinatology*. United States, 33(3), pp. 318–328. doi: 10.1055/s-0035-1571202.

521 Peterson, W. E. *et al.* (2014) 'Women's perspectives of the fetal fibronectin testing process: a

522 qualitative descriptive study', *BMC Pregnancy and Childbirth*, 14(1), p. 190. doi: 10.1186/1471-2393-

523 14-190.

524 Rich-Edwards, J. W. and Grizzard, T. A. (2005) 'Psychosocial stress and neuroendocrine mechanisms

525 in preterm delivery', in *American Journal of Obstetrics and Gynecology*. doi:

526 10.1016/j.ajog.2005.01.072.

527 Say, R. E., Robson, S. and Thomson, R. (2003) 'The importance of patient preferences in treatment

528 decisions—challenges for doctors', *BMJ : British Medical Journal*, 327. doi:

529 <https://doi.org/10.1136/bmj.327.7414.542>.

530 Say, R., Robson, S. and Thomson, R. (2011) 'Helping pregnant women make better decisions: a

531 systematic review of the benefits of patient decision aids in obstetrics.', *BMJ open*. British Medical

532 Journal Publishing Group, 1(2), p. e000261. doi: 10.1136/bmjopen-2011-000261.

533 Shennan, A. *et al.* (2005) 'Fetal fibronectin test predicts delivery before 30 weeks of gestation in high

534 risk women, but increases anxiety', *BJOG: An International Journal of Obstetrics & Gynaecology*,

535 112(3), pp. 293–298. doi: 10.1111/j.1471-0528.2004.00420.x.

536 StataCorp (2017) 'Stata Statistical Software: Release 15'. College Station, TX: StataCorp LLC.

537 The Ottawa Hospital Research Unit (2003) *Decisional Conflict Scale User Manual*. Available at:

538 https://decisionaid.ohri.ca/docs/develop/User_Manuals/UM_Decisional_Conflict.pdf.

539 Thompson-Leduc, P. *et al.* (2016) 'Prevalence of clinically significant decisional conflict: an analysis of

540 five studies on decision-making in primary care.', *BMJ open*. British Medical Journal Publishing
541 Group, 6(6), p. e011490. doi: 10.1136/bmjopen-2016-011490.

542 Thu, H. *et al.* (2015) 'Factors Associated With Increased Anxiety in the MRI Waiting Room', *Journal of*
543 *Radiology Nursing*. doi: 10.1016/j.jradnu.2015.04.009.

544 Tsoi, E. *et al.* (2005) 'Sonographic measurement of cervical length in threatened preterm labor in
545 singleton pregnancies with intact membranes', *Ultrasound in Obstetrics & Gynecology*. John Wiley &
546 Sons, Ltd., 25(4), pp. 353–356. doi: 10.1002/uog.1809.

547 Watson, H. . *et al.* (2017) 'Pregnancy Outcome Poster Abstracts', *BJOG: An International Journal of*
548 *Obstetrics & Gynaecology*, 124, pp. 122–154. doi: 10.1111/1471-0528.14589.

549 Watson, H. . and Ridout, A. (2015) 'Re: Preterm labour: summary of NICE guidance', *BMJ : British*
550 *Medical Journal*. Available at: <https://www.bmj.com/content/351/bmj.h6283/rr>.

551 Watson, H. A. *et al.* (2017) 'The QUIPP app: a safe alternative to a treat-all strategy for threatened
552 preterm labour', *Ultrasound in Obstetrics & Gynecology*. Wiley Online Library, 50(3), pp. 342–346.
553 doi: 10.1002/uog.17499.

554 Watson, H. A. *et al.* (2019) 'EQUIPTT: The Evaluation of the QUIPP app for Triage and Transfer
555 protocol for a cluster randomised trial to evaluate the impact of the QUIPP app on inappropriate
556 management for threatened preterm labour', *BMC Pregnancy and Childbirth*, 19(1), p. 68. doi:
557 10.1186/s12884-019-2210-1.

558