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Why do pregnant women participate in research?

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Why do pregnant women participate in research? A patient participation investigation using Q-Methodology.

Background: Patient participation in study design is paramount to design studies that are acceptable to patients. Despite an increase in research involving pregnant women, relatively little is known about the motivational factors that govern their decision to be involved in a clinical trial, compared to other patient groups.

Objective: To better understand the viewpoints of pregnant women who take part in clinical trials

Method: We chose to use Q-Methodology, a method of exploring the structure of opinions surrounding a topic. We developed a set of 40 statements that encompassed the reasons why pregnant women might want to take part in research and 30 research participants from the PRiDE Study (an observational trial investigating the role of micronutrients in gestational diabetes) were asked to rank them in order of agreement. The finished matrices from each participant were compared and analysed to produce capturing viewpoints.

Results: 30 women aged 19-40 involved in the PRiDE study completed the questionnaire. There were two overarching motivators that emerged: a willingness to help medical research and improve our knowledge of medical science, and having a personal connection to the disease, therefore a potential fear of being affected by it. A third, less significant viewpoint, was that of a lack of inconvenience being a motivating factor.

Conclusion & Discussion: Understanding what motivates pregnant women to decide to take part in a research study is valuable and helps researchers maximise their uptake and retention rates when designing a trial involving pregnant women.

Key Words: participation, consent, patient choice, pregnancy research, Q-methodology

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Background

Historically, women of child-bearing age have been excluded from trials due to concerns over foetal safety. There have been a relative lack of therapeutic trials involving pregnant women. This had led to a deficiency in knowledge of the safety of many medicinal products in pregnancy and in children and the prescription of unlicensed medicines whereby the prescriber takes responsibility for non-intended side effects. In 1993, the FDA lifted its ban of the testing of medicinal products on women[1] and the National Institute of Health made it a legal requirement to include women in trials[2,3]. The Royal College of Physicians followed suit in 2007 and published guidelines on how to safely involve women[4]. Due to these changes in policy, we can expect that research involving pregnant women will be increasing, and yet little is known about why this specialist group would choose to take part.

A literature review of reasons why patients agree to take part in trials revealed a large number of studies investigating cancer patients and a smaller number investigating specialist groups including cardiac failure patients, elderly patients, low income groups and African-Americans as specialist populations. There were few investigating pregnant women, a unique group of patients whose reasons for participation will undoubtedly differ from those already studied as a healthy group who will be paying consideration to their unborn child. We summarise the findings of these studies in Table 1.

There were emerging themes of note that were specific to pregnant women such as the consideration of the risk to foetus[5,10], as well as potential benefit[6,8,10,12]. A theme across many of the studies was a perception that being in a trial would mean superior care to those not participating[6,7,10,12]. Pregnancy could be the first time that women have regular contact with healthcare professionals, so it is understandable that the attitude of the professionals had a great impact on the choices the women made[7,8,12]. Altruism played a part in the decision making process, as it does with all types of patients considering entering a clinical trial; women want to help others, particularly those in a similar situation to them[6,7,8,10]. There was also a convenience factor which influenced the decision making process; pregnant women do not have the time nor energy to take part in trials that require a great deal of commitment, the easier it is on their schedules and health the more likely they are to accept[5,6,7,9].

Table 1: Studies to date that have investigated why pregnant women take part in clinical trials

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Study	Description	Findings
Mohanna et al, 1999[5]	Semi-structured interviews and thematic analysis of 18 women who had declined to take part in a prophylactic nifedipine trial for pre-term labour (27% uptake rate) 2 years later	Declined to take part in the trial because: Protection of the foetus "it will never happen to me" Presence of a placebo arm Feeling like Guinea pigs Already "felt ill in pregnancy" Not enough public knowledge of the trial
Rodger et al, 2003[6]	50 cross-sectional surveys and semi-structured interviews regarding a hypothetical trial of low molecular heparin in pregnancy	Important determining factors: Potential benefit to foetus (68%) Personal health (27%) Altruism (5%) Pregnant women may be willing to accept risk to themselves if foetus could benefit.
Baker et al, 2005[7]	Focus groups and semi-structured interviews with 17 postnatal women who had participated in a program of maternity care research, followed by thematic analysis.	Factors involved in decision making Altruism and self-protection Enhanced care Professional guidance Suitable methodology Practical inconvenience, an apparent lack of clinical equipoise, and feeling disempowered demotivated women
Kenyon et al, 2006[8]	20 qualitative interviews after involvement in a randomised controlled trial of antibiotics to prevent pre-term labour. Analysed using constant comparison.	Experiences of the recruitment process: Motivations: Better outcome for baby, helping women in the future in same situation, positive social interaction with consenting healthcare professional and high quality of information given Acuity of the situation led to perception of poor judgement of risk and understanding of trial design. Background presumption of antibiotics being safe.
Nechuta et al, 2009[9]	Cross-sectional survey in 9 prenatal clinics of 311 pregnant women about attitudes to data collection for epidemiological studies involving their children.	Phone interview preferred to face to face interviews Reluctance to allow access to medical records and infant examinations in women with post-secondary school education 34-48% would require no compensation for participating.
Lyerly et al, 2012[10]	22 semi-structured interviews of women in H1N1 vaccine trial	Motivators: Women motivated by the media: highlighted the risks of H1N1 infection in pregnancy Perceived safety advantage Early access to vaccine To improve knowledge in the area Demotivators: risk to foetus, a placebo arm, a change to plan in care
Nechuta et al, 2012[11]	311 women interviewed at first prenatal care visit about attitudes to collection and storage of biological samples (blood, placenta, cord blood).	More likely to allow collection of maternal blood (72%) than cord blood (63%) or placental tissue (64%). 68% agree with storage of samples. 25-28% would not participate even if compensated, higher in Hispanic ethnicity and primiparous women.
Smyth et al, 2012[12]	Semi-structured interviews of 16 women involved in a trial of anticonvulsants in the prevention of pre-eclampsia	Motivators: Unpredictability of pre-eclampsia Quality of information received Role of healthcare professionals and family Perceived personal benefit Perception of voluntariness of joining

Qualitative interviewing and closed questionnaires are commonly used to investigate subject matter relating to patient choice, however these have limitations. Interviews are time consuming and can cover a broad range of subject matter. The sample size must therefore be smaller and the results are

difficult to compare and apply to a wider population. In contrast, questionnaires are more practical but are binary in their responses and they lose the qualitative reasoning that the participant would be able to share in an interview. They also require validation by expert groups which is a time-consuming process. Often, people have many reasons to participate in research and both of these techniques may elucidate those reasons, but will not necessarily allow the participant to add a weighting which tells the researcher what is most to least important to them. Q-methodology addresses these problems. It is practical and captures the individual and varied views of a reasonable sized group, yet still allows for comparison in a quantitative manner. It also allows for the direct comparison by the participant of reasons to participate in research, allowing the researcher to place emphasis on these to design studies fitting for their chosen group of participants.

We carried out a study of women involved in a clinical trial investigating the role of micronutrients in the development of gestational diabetes. To draw particular focus to what motivated the women to consent, we used Q-Methodology[13], for a systematic mapping of shared viewpoints on a topic which would not arise from interviewing or standard questionnaires alone.

Method

The PRiDE study is a multi-centre observational trial funded by the Medical Research Council investigating the role of vitamin B12 in the development of diabetes in pregnancy. Our study was formally ethically approved as a sub-study PRiDE. We asked 30 women enrolled in the PRiDE study at George Eliot Hospital to take part in this questionnaire during their glucose tolerance test appointment. The inclusion criteria for the PRiDE study are same as the risk factors for gestational diabetes: BMI>30, previously given birth to a large (>4.5kg) baby, previously had gestational diabetes, 1st degree relative with diabetes, and Asian/Black Caribbean/Middle Eastern ethnic origin. In order to participate in PRiDE, the patient must have at least 1 risk factor. Women were asked to take part during glucose tolerance test clinics on 18 separate days between 2nd September 2013 and 15th January 2014. All 30 women enrolled in the PRiDE study who attended clinic on one of the 18 days were asked to take part during a 2 hour wait period and all 30 accepted.

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In Q-Methodology, the participant is asked to rank items (the Q-set) based on their viewpoint, following a condition e.g. level of agreement. The finished matrix (the Q-Sort) is correlated with all other participants, allowing a derivation of the level of agreement and disagreement between each participant. Factor analysis is used to extract inter-correlated Q-Sorts, which represents participants that have a similar viewpoint. The analysis is used to produce an ideal Q-Sort for each viewpoint that is then named and interpreted.

A Q-Set of 40 statements of why pregnant women may decide to participate in the PRiDE study was derived by aliterature review and informal semi-structured interviewing. In order to capture as wide a range of statements as possible, the literature review involved all studies exploring motivational factors for involvement in research, including in non-pregnant participants, although statements that would not apply to our population were excluded (i.e. those involving life-saving therapy and having 'nothing to lose' as life expectancy was short). We identified 105 unique reasons why pregnant patients may choose to participate in trials. This was supplemented with 20 unique reasons which were derived from informal, semi-structured interviewing of PRiDE researchers (including doctors, midwives, nurses and administrators) and PRiDE participants. The 125 statements were grouped into emerging themes and 40 key statements, which best exemplified the themes, were chosen to include in the Q-Set. This was done so that participants could work with a manageable number of items that were thorough, covered a broad range of opinions and were different enough for the participants to be able to rank. Figures 1 shows a flow chart of the methodology.

Figure 1: A flowchart depicting the process of collecting appropriate statements, asking participants to rank these statements, and analysing the responses.

Q-Sorts can be administered in a number of ways, including paper cards. We chose to use an iPad which was more user friendly, allowed the participant to carry out the ranking in stages, and enabled streamlined data collection and analysis. The participants were asked to rank the 40 items using an iPad and the Poet-Q platform[14]. This allowed them to systematically choose the statements they

agreed with most from the pool of items to form a finished Q-Sort. The participants were then given the opportunity to explain their reasoning for the items they agreed with most and least. The questionnaire took an average of 20 minutes to complete. The Poet-Q platform[15] makes the ranking of statements user-friendly by asking the participants firstly to group the statements into 'agree most' and 'agree least' categories, then asks the participant, in stages, to further delineate between the statements in each category. The participants were all able to complete the Q-Sort using Poet-Q and the only issues encountered were with the loss of a wireless connection and with holding the iPad in the correct orientation. There was a data collector present in the department to resolve these issues. In a Q-Sort, each statement is given a score depending on its position in the matrix. Pearson's formula is used to calculate the correlation between each finished Q-Sort. A level of significance of $p<0.01$ is used to flag up significant correlations in a correlation table. This was done by the PQ Method program[16].

PQ Method highlighted emerging 'factors' by identifying participants that had Q-Sorts with a high level of correlation. Each participant is compared against a 'factor ideal' to identify how much their ideas correlate with the standard. After the identification of the first factor, the communality they share is extracted from the matrix in order to find the second factor. This is done until there are no more factors left to derive. The factors were then subjected to a Varimax rotation with the intention to maximise the number of Sorts showing preference for one given factor. In Q-Methodology, the factors derived equate to statistically derived, shared viewpoints on the subject matter at hand. The terms 'factor' and 'viewpoint' are used interchangeably in the remainder of this study.

Results

Our population included 30 women from the PRiDE study who attended their glucose tolerance test between 2nd September 2013 and 15th January 2014 (Table 2). Ages ranged from 19-40, with 60% aged between 21 and 30. The majority (80%) of our population was Caucasian. The women had a variety of occupations, almost half in the public sector industries (Healthcare = 4, Community = 5, Education = 4) and more than a quarter were housewives/unemployed.

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A 3 factor solution was accepted from Centroid analysis using PQ Method based on an explanation variance of 57% and eigenvalues of 14.6, 1.7 and 0.9 for factors 1,2 and 3, respectively. A 5,6 and 7 factor solution were ruled out. A 4 factor solution was considered but ruled out as there was insufficient loading on the 4th factor. Sorts that were representative of one factor more than the others (also known as "loading" on factor) with statistical significance ($p<0.01$) were flagged as 'factor determining sorts'. The number of sorts loading on each factor 1, 2 and 3 were 6, 9 and 2, respectively: a total of 17 participants were significantly loading on one of the three factors. Using the sorts that were loading on each of the three factors, PQ Method was used to create a factor array: an exemplary Q Sort for each factor that showed the ideal positioning of each of the statements for a participant with the viewpoint in question. An example of a factor arrays is shown in Figure 2. PQ Method was also used to calculate the correlation between each of the factors (table 3) and differences between them and identified distinguishing and consensual statements.Table 2: Demographics of the 30 pregnant women involved in PRiDE who participated in this study.

Characteristic		n	%total
Age	<20	1	3%
	21-30	18	60%
	>30	11	37%
Ethnicity	White	24	80%
	Mixed	1	3%
	Asian	4	13%
	Caribbean	1	3%
Marital Status	Single	5	17%
	Divorced/Separated	2	7%
	Married	15	50%
	Common Law	6	20%
	Other	2	7%
Occupation	Healthcare	4	13%
	Sales	1	3%
	Education	4	13%
	IT	1	3%
	Community	5	17%
	Arts	2	7%
	Administration	3	10%
	Maintenance	1	3%
	Housewife	8	27%
	Legal	1	3%

Table 3 Correlation between viewpoints

Viewpoint	1	2	3
1	1.00	0.61	0.42
2	0.61	1.00	0.55
3	0.42	0.55	1.00

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Table 4: High and low scoring statements

	High scoring statements	Low scoring statements
Viewpoint 1	It might help someone else in the future	I might get more attention from healthcare professionals if I take part
	I would not take part in the study if there was any risk to my baby	I know someone who has been affected by diabetes in pregnancy
	I would like to support medical science	I did not want to disappoint the person who asked me
	It is an important area of research	I am scared of declining in case it effects my care later on
	The benefits of taking part outweigh the risks	I might get better or faster access to care
Viewpoint 2	I know someone who has been affected by diabetes in pregnancy	I might get more attention from healthcare professionals if I take part
	It might help someone else in the future	I would prefer to leave it to someone else to take part
	I know someone who has been affected by diabetes	I am scared of declining in case it effects my care later on
	I am interested in finding out the results of this study	I might get better or faster access to care
	The benefits of taking part outweigh the risks	I do not like the time commitment required
Viewpoint 3	I know someone who has been affected by diabetes	I would prefer to leave it to someone else to take part
	Taking part is the right thing to do	I am scared of developing diabetes because of what I have heard in the media
	I do not mind giving a DNA sample	The study might be big in the media
	The appointments are at the same time as my scans	I want to be part of a study that involves a large number of people
	It is an important area of research	I want to learn more about the condition

Figure 2: An example of a factor array (depicting viewpoint 1 in this case). A participant that loaded heavily on viewpoint 1 strongly agreed with the statements on the right and disagreed with statements on the left.

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Table 5: Consensual statements. All 3 types of participant agree that the area of research is an important one, that declining would not affect future care, and that they did not agree to take part to avoid disappointing the person who asked them.

Statement	Viewpoint 1 position	Viewpoint 2 position	Viewpoint 3 position
It is an important area of research	+3	+2	+3
I am scared of declining in case it effects my care later on	-3	-3	-2
I did not want to disappoint the person that asked me	-3	-3	-2

Table 4 summaries the high and low scoring statements for each of the derived factors. Table 5 summarises the consensual statements between the three factors. All 3 types of participant were in agreement that the area of research is an important one, and that there is trust in the healthcare professionals looking after them that their decision to take part bears no relation to the type of care they will receive. This was highlighted to them during the consenting process.

Viewpoint 1: 'Helping the future of medicine': This viewpoint is to take part because she supports medical research the future of medicine. These participants believe that PRiDE is an important study that will help future generations. Below are example statements given by the participants.

"Cures and treatments arise when people agree to be part of medical studies so it is important that I take part to help provide answers and treatments. I am part of a healthcare team and understand how important research is to finding treatments so I feel I should help in any way I can." Participant L5FYP2ZR is a 25 year old British nurse.

"[I chose to take part] because there is no risk to me or my baby, but taking part in this study may help". Participant SENYHCMG is a 28 year old British married housewife.

These participants agree to take part for the greater good, rather than personal gain: they do not believe that it will get them more attention from healthcare professionals or that their access to care will be any better. There is also no evidence of a personal connection to the disease.

"I tend to think about the generation of the future and the impact society has on them." Participant 7F0XALGH is a 26 year old Asian youth worker.

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Participants loading on viewpoint 1 were aged 25-39, 67% were British and 50% were married. Interestingly, 67% were public sector workers, with 75% of these working in healthcare.

Viewpoint 2: 'My responsibility': In contrast to viewpoint 1, viewpoint 2 participants have a personal connection to diabetes and may feel that it is their responsibility to help the research to help those affected in the future. Comparing to viewpoint 1, these participants have a specific interest in diabetes, rather than medical research in general.

"Research is also key to my future so being part of this study may help doctors to develop a cure for diabetes sooner than hoped.Research is key to future developments in medicine and care and I am more than happy to participate in any study that will benefit my children/our future generations in years to come." Participant 4ZX0Q6UE is a 34 year old single administration assistant.

Due to the personal experience, there is a sense of fear amongst these participants that they may be affected.

"A friend recently had a baby and she developed diabetes during pregnancy. Before pregnancy she was fine and healthy." Participant GAKHWRZX is a 25 year old British common-law warehouse worker.

"My auntie has severe diabetes that began at pregnancy many years ago. She is facing losing her toes this year.I used to be scared of diabetes but the amount of information now available is reassuring." Participant E2ZJS9VF is a 31 year old, married, British housing officer.

Similarly to factor 1 participants, these participants are not interested in personal benefits of taking part in the study. Statements involving personal benefits were ranked low, as seen in factor 1.

"It doesn't matter to me if I get more care or not. I just wanted to help." Participant CQ0YIHGD is a 29 year old general assistant.

"I don't think it is right to take part in a trial to get better health care. That's the wrong reason to do it." Participant E2ZJS9VF (as above).

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Participants loading on viewpoint 2 were also 67% British and aged between 25-39. 78% were married (compared to 50% of viewpoint 1 participants). Once more, a significant proportion were public sector workers (56%), however only 29% of these worked in healthcare.

Viewpoint 3: 'No skin off my nose'. Viewpoints in this group were more difficult to interpret about distinctive reasons that attracted them to the study, however they did not mind taking part because they did not feel inconvenienced by it. Had it been a more invasive study, they may have opted out.

"The commitment has been manageable and as my mum had diabetes I thought I might be an interesting candidate for the research.I think if one can help one should especially if the commitment is low and manageable, e.g, all extra blood tests etc have been taken at the same time as the normal pregnancy blood tests." Participant ZN2IRWEY is a 29 year old married British housewife.

They lie somewhere between factors 1 and 2, whereby they may know someone affected by diabetes and they also think it is an important area of research, however do not seem to as feel personally responsible as factor 2 participants, or as interested in the research as factor 1 participants. They are not particularly drawn to diabetes, but their participation is not an inconvenience.

Heavy loading Viewpoint 3 participants were aged between 29-34, all were British and 50% were married. Once again, the proportion of healthcare workers was more than expected (50%).

Four statements that factor 1 participants disagreed with and factor 2 participants agreed with highlight their differing reasons for taking part:

1. I am scared of developing diabetes because of what I have heard in the media
2. I think I might be affected by diabetes in my pregnancy
3. I know someone who has been affected by diabetes
4. I know someone who has been affected by diabetes in pregnancy.

It is clear that fear and personal experience have influenced the factor 2 participants.

Discussion

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We conducted a study using a methodology ideal for examining subjectivity in order to elucidate the opinions of women involved in an observational trial in those at risk of diabetes in pregnancy. The majority of the 30 women aged 19-40 were Caucasian and either employed in the public sector, or were housewives. We found 3 distinct opinions as to why pregnant women choose to participate in research: an interest in helping medical research advancement, a personal connection to the disease and the lack of inconvenience. All three groups agreed that it was an important area of research, benefits outweighed risks, and that personal gain did not influence their decision.

As highlighted by Lylerly et al [10] there are a group of women in whom the fear of contracting a disease motivates them to take part in research. Similarly, one group of the women interviewed by Mohanna et al[17] who had *declined* to take part in a clinical trial had done so because of a lack of belief that the disease would affect them. In our study, women who feared developing diabetes were the women who knew someone effected by the disease. It is interesting to note that these women agreed to take part, despite knowing that the PRiDE study would not help them personally. In fact, no statements relating to a benefit to personal health featured in the high ranking statements of any groups, unlike previous studies [6,7,10]. Also in contrast to studies who noted a better outcome for the baby being a strong motivational factor[6,8] and a potential risk being a demotivator[5,10], our study participants agreed to take part in the trial knowing that their baby would not be harmed nor helped. Interestingly, as demonstrated by Nechuta et al[11], there was a preconception amongst the study team that cord and tissue collection and storage may be unpopular amongst pregnant women and demotivate them to take part. Our participants across all three viewpoints were indifferent about this; the collection and storage of samples did not affect their decision to participate. We postulate that including women who declined to take part in PRiDE would have brought forward this issue.

One weakness of this study is that some participants may have found the process of completing a Q Sort arduous, and they would have had to fill a number of other questionnaires during the same appointment. To avoid the temptation for the participants to sort statements at random, we chose to have the questionnaire administered during the 2 hour wait at the glucose tolerance test appointment; a time that the participants were asked to sit in a waiting room with minimal distractions. We hoped

that these measures would ensure participants paid attention to the task. The fact that there were correlations between Sorts is reassuring that the participants engaged in the process.

Another difficulty with a Q-Methodology study is that in order to create a conclusive Q-Set of statements, all current opinions on the matter need to be evaluated. We reviewed all literature to date, although this was limited, therefore our Q-Set may not be as broad and inclusive of all opinions as we would hope. At the end of the questionnaire we included a free text section for participants to write about anything else they would have liked included. This did not reveal any further possible statements.

As evident from the demographics of the study, a large number of our participants were Caucasian, married and either worked in the public sector or were housewives. This may represent the type of participant who would agree to take part in the PRiDE study. It is possible that housewives are able to be more flexible with their time, and are therefore more open-minded when being asked to take part in research. Public sector workers, particularly those in healthcare, may be more aware of the need for research in medical advancement and more eager to help. It would have been interesting to involve women who declined to take part in the study, as done by Mohanna et al[5], however we decided against this as some women may have felt harassed if they had been asked to complete a questionnaire on involvement in research having declined to take part. It may also true that participants who consented to take part in the Q-Study are a group who are already more likely to want to participate in research.

In conclusion, this study has provided insight into the field of pregnant women participation in trials. The information can be used in research development for trials involving this specialist group of patients who differ from usual trial participants because they are not unwell and they consider their unborn child when consenting to trials. We have shown that in order for a pregnant woman to consider trial participation, the study should: have the potential to make a difference; be relevant to the participant; and be minimally invasive in terms of time and tests. It is important to note that these women were involved in a non-interventional trial and so their reasons may differ to those in an interventional randomized controlled trial. Further work should include investigation across socio-

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economic groups and ethnicities as well as investigating the women who have declined participation to better understand their barriers.

We have shown that Q-Methodology is a practical way to gain an objective view early on in a medical trial on what is drawing the participants to take part. It allows for allows for fine-tuning of the recruitment process to present to potential participants the reasons that they may find attractive when making the decision to consent.

References

1. Bush JK, The industry perspective on the inclusion of women in trials. *Academic Medicine* 1994; 69:708-15
2. US congress. *National Institutes of Health Revitilisation Amendment. Public law*. 1993; 103-43.
3. Hilts P. FDA ends ban on women in drug testing. *New York Times.* 1993; B8
4. Royal College of Physicians. *Guidelines on the practice of ethics committees in medical research with human participants*. 2007; London.
5. Mohanna K; Tunna K, Witholding consent to participate in clinical trials: decisions of pregnant women. *British Journal of Obstetrics and* Gynaecology. 1999; 106: 892-7
6. Rodger MA; Makropoulos D; Walker M; Keely E; Karovitch A et al, Participation of pregnant women in clinical trials: will they participate and why? *American Journal of Perinatology*. 2003; 20: 69-76
7. Baker L; Lavender T; Tincello D. Factors that influence women's decisions about whether to participate in research: an exploratory study. *Birth* 2005; 32: 60-6
8. Kenyon S; Dixon-Woods M; Jackon CJ; Windridge K; Pitchforth E, Participating in a trial in a critical situation: a qualitative study in pregnancy. *Quality & Safety in Healthcare* 2006; 15: 98-101
9. Nechuta S; Mudd LM; Biery L; Elliott MR; Lepkowski JM et al, Attitudes of pregnant women towards participation in perinatal epidemiological research. *Paediatric Perinatal Epidemiology* 2009; 23: 424-30
10. Lyerly AD; Namey EE; Gray B; Swamy G; Faden RR, Women's views about participating in research. *IRB Ethics and Human Research* 2012; 34: 1-8.
11. Nechuta S; Mudd LM; Elliott MR; Lepkowski JM; Paneth N et al, Attitudes of pregnant women towards the collection of biological specimens during pregnancy and at birth. *Paediatric Perinatal Epidemiology* 2012; 26: 272-5
12. Smyth RM; Jacoby A; Elbourne D, Deciding to join a perinatal randomised control trial: experiences and views of pregnant women enroled in the Magpie Trial. *Midwifery* 2012 28 478-85
13. Stephenson W, *The study of behaviour; Q-technique and its methodology*. Chicago: University of Chicago Press; 1953
14. Jeffares, S. Dickinson, H. And Hughes,G. (2012) iPOETQ (version 1.1). Available at http://poetqblog.blogspot.co.uk/ (accessed 11/08/2015)
15. Jeffares. S. and Dickinson, H. (2016, forthcoming). Evaluating Collaboration: The Creation of an online tool employing Q methodology, Evaluation. DOI: 10.1177/1356389015624195
16. Schmolk P. PQMethod 2014. Available at http://schmolck.userweb.mwn.de/qmethod/ (accessed 11/08/2015)