

**Research Project Report
(PSY9188)**

University of Lincoln
Faculty of Health and Life Sciences



**Doctorate in Clinical Psychology
2009**

**Treatment choice for miscarriage: An evaluation
of the psychological impact for women and their
partners**

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Submitted in part fulfilment of the requirements for
the Doctorate in Clinical Psychology

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Abstract

Background: Currently, standard practice is to allocate women to a particular treatment for miscarriage; most commonly surgical. The alternative of offering women a choice in their treatment is controversial due to pre-conceptions around their potential for distress. However, exploration of the psychological outcomes of women and their partners when given a choice may offer new insights into the validity of existing ideas.

Methods: A non-randomised longitudinal design was used. Eighty-one women attending an Early Pregnancy Assessment Unit completed a 14-day diary following their miscarriage, including factors contributing to their treatment choice, the General Health Questionnaire (GHQ-12), the Spielberger Trait Anxiety Inventory (STAI), and rating scales for pain and bleeding. Women and their partners were also sent follow-up questionnaires at six weeks, including the GHQ-12, the Impact of Events Scale (IES) and evaluation of their treatment. Quantitative data was analysed using non-parametric analysis due to data not conforming to gaussian distributions and unequal sample sizes across treatment groups. Analyses included Wilcoxon Signed Rank tests to explore changes over time on specific measures, Kruskal Wallis tests to explore differences between treatment groups, Mann Whitney Tests to locate specific post-hoc group differences, and chi-square tests to examine treatment choices and factors affecting choice. This analysis was complimentary to further qualitative theme analysis of additional factors women freely described as important when making their choice in treatment.

Results: 43.2% of women chose surgical treatment, with choice being influenced by being frightened of seeing the miscarriage. Different factors were influential to women's choices across the other treatment options. Women expressed a range of factors that contributed to their choice, including desire for a speedy return to normality, past experience, desire for the most natural option, family and home support, impact on family, staff advice, fear of pain, bleeding and complications, wanting to avoid hospital, wanting control, and seeking an explanation for their miscarriage. STAI and GHQ-12 scores did not significantly differ according to treatment choice. Levels of pain also failed to discriminate between the treatment groups. However, women receiving expectant treatment reported greater amounts of bleeding across days one to four compared to those receiving surgical treatment. Furthermore, scores on the IES were significantly different across groups, with the medical outpatient group reporting lower scores than all others, and the surgical group reporting lower scores compared to the medical inpatient group. Scores across all measures were not significantly different when women and their partners were compared, although a significantly greater proportion of partners reached "caseness" on the GHQ-12 in the group of women receiving surgical treatment,

Conclusions: The largest proportion of women chose surgical as their preferred treatment, with different choices being influenced by different factors. Whilst anxiety and non-psychotic symptoms do not appear to differ depending on the treatment women received, results suggest those women choosing medical outpatient experienced less trauma as a result compared to

all other treatment groups. This was also true but to a lesser extent for women choosing surgical treatment (who also reported lower levels of bleeding compared to those receiving expectant treatment). Across measures, whilst the level of psychological distress was comparable between women and their partners, men appeared to experience greater distress when their partner had received surgical treatment.

Statement of contribution

The work presented in this thesis was carried out by Zoë Amelia Kyte, with exceptions to this being stated below.

At the time of joining the project (January 2007), initial ethical approval had been obtained and recruitment initiated by Dr Judith Moore (project lead, Consultant in Obstetrics and Gynaecology, City Hospital, Nottingham), Professor Cris Glazebrook (Professor of Health Psychology, Department of Behavioural Sciences, Queen's Medical Centre, Nottingham), Dr Charlotte Sheard (Dr in Health Psychology, Department of Behavioural Sciences, Queen's Medical Centre, Nottingham) and Dr Sara Cox (Associate Professor in Health, Institute of Work, Health and Organisations, Nottingham University). The process of recruitment was facilitated throughout by the nursing staff within the Early Pregnancy Assessment Unit (EPAU), City Hospital, Nottingham, particularly Linda Ahmed and Nicky Lindley, and was co-ordinated initially by Rosemary Homer, medical student, University of Nottingham.

Following Rosemary's completion of her involvement in the project (January 2007), my role was to take over co-ordination of recruitment, in addition to being responsible for data collection, data inputting and analysis, and the writing up of the study for publication. At the time of joining the project, I was also responsible for submitting minor amendments to the ethics committee with regard to desirable changes to the content of the study (inclusion of an

additional measure, involvement of an additional researcher, and extension to the project end date).

Data collected by Rosemary Homer and myself was pooled for the purposes of this thesis and journal submissions.

Research paper

Treatment choice for miscarriage: an evaluation of the psychological impact for women and their partners

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Abstract

Background: Offering women choice in their miscarriage treatment is controversial due to preconceptions around the potential for varying degrees of distress. Exploration of psychological outcomes when given a choice may offer new insights into the validity of these ideas. **Methods:** A non-randomised longitudinal design was used. Eighty-one women attending an Early Pregnancy Assessment Unit completed a 14-day diary following their miscarriage, including factors contributing to their choice, the General Health Questionnaire (GHQ-12), the Spielberger Trait Anxiety Inventory (STAI), and rating scales for pain and bleeding. Women and partners were also sent follow-up questionnaires at six weeks, including the GHQ-12, the Impact of Events Scale (IES) and evaluation of their treatment. **Results:** Surgical treatment was chosen by 43.2% of women, compared to 22.2% for expectant, 18.5% for medical outpatient, and 16.1% for medical inpatient. Significant differences between treatment groups were found for wanting to avoid hospital, an operation and an anaesthetic, being scared of bleeding heavily, seeing the miscarriage, choosing the most natural and least painful treatment. STAI, GHQ-12 scores and pain ratings did not differ significantly across treatment groups. However, IES scores were significantly lower for the medical outpatient group compared to others (as were scores for the surgical compared to medical inpatient group). Bleeding levels were higher on days one to four in the expectant compared to surgical group. Scores on all measures were not significantly different between women and partners, although partners scored higher on the GHQ-12 when women had received surgical treatment. **Conclusions:** The largest proportion of women chose

surgical as their preferred treatment, with different factors influencing the different choices. Anxiety and non-psychotic symptom levels did not significantly differ according to treatment choice, although results suggest medical outpatient (and to a lesser extent surgical) may be less traumatic for women. Women and partners experienced equivalent levels of psychological well-being, with men experiencing greater distress when their partners had received surgical treatment, Small samples sizes support the need for replication with larger numbers.

Word count: 326

Keywords: Miscarriage, treatment, choice, psychological, impact

Introduction

Miscarriage, or the spontaneous and unintended termination of pregnancy prior to 24 weeks gestation, is one of the most frequent complications of early pregnancy. It is estimated to affect around 15-20% of women (Government Statistical Service, 2005) (see appendix 1.1 for additional background information). Historically, the standard treatment of miscarriage has been surgical evacuation of the retained products of conception (ERPOC; Royal College of Obstetrics and Gynaecology, 2006), and has been recommended since the late 1800's to reduce potential complications such as blood loss and infection (Hemminki, 1998). Whilst clinical practice has changed little over time, there has been a shift in the understanding of the possible complications associated with ERPOC, which has led to the questioning of its use as a routine treatment (Ballagh et al., 1998). Complications may include cervical trauma, uterine perforation, haemorrhage, infection and complications of anaesthesia, and may result in infertility, pelvic pain and an increased chance of ectopic pregnancy (Chung et al., 1982). With between 4 and 10% of women experiencing such complications (Farell et al., 1982; Hesisterberg et al., 1986), alternative non-surgical treatment options have more recently been considered. These include expectant treatment, which is the natural resolution of the miscarriage assisted by bed rest, ultrasound examinations and antibiotics, and medical treatment, which uses agents such as misoprostol or the progesterone antagonist mifepristone administered as either an inpatient or outpatient (Chung et al., 1999; Nielsen et al., 1999). Currently, the treatment women receive for their miscarriage is predominantly governed by the recommendations of the medical professionals caring for them, rather

than individual choices of the women themselves. Consequently, hospital statistics (Royal College of Obstetrics and Gynaecology, 2006) have indicated that the majority of professionals continue to recommend surgical treatment to avoid the uncertainty around the passage of tissue with other forms of treatment, and based on the assumption that psychological distress will be less with surgical treatment (Sharma, 1993) and greater when at home (Lewis, 2007).

Since their introduction into clinical practice, however, randomised controlled trials comparing these different treatments in relation to their success rates (as defined by achieving a complete miscarriage, infection rates, bleeding time and time taken to resume normal activities: Royal College of Obstetrics and Gynaecology, 2006) have failed to provide medical evidence indicating any one as superior (Demetroulis et al., 2001; Wieranga-de Waard et al., 2002; Shelly et al., 2005; Trinder et al., 2006) (see appendix 1.2 for further information). Although fewer studies have been conducted overall, those that exist comparing the different treatments in relation to their psychological impact also support the notion that no one treatment is superior (Nielson et al., 1996; Lee et al., 2001) (see appendix 1.3 – 1.6 for further information on miscarriage and psychological impact). In the absence of apparent clinical and psychological differences between treatment options, alternative factors such as women's preferences may be a valid consideration in determining the treatment they receive.

It is well established that miscarriage can be a profound and traumatic event that leads to psychological symptoms including anxiety, depression and post-traumatic stress in both women (Lee & Slade, 1996; Lee et al., 1997; Engelhard et al., 2001; Lok & Neugebauer, 2007) and their partners (Speraw, 1994; Puddifoot & Johnson, 1997; Samuelsson et al., 2001) (see appendix 1.7 for further studies on male partners and miscarriage). However, given that previous studies have used a randomised design of allocating women to the different treatments, the role of allowing women a choice in their treatment and how this impacts on both medical and psychological outcome has not been thoroughly explored.

One study using a partially non-randomised design compared women who expressed a preference in choice of treatment to those who were randomly assigned to expectant or surgical treatment (Wieringa-de Waard et al., 2002). The authors reported that those who had been treated according to choice, and chose surgical treatment) had significantly better mental health, as measured by the State-Trait Anxiety Inventory (Spielberger, 1983) and the Perinatal Grief Scale (Toedter et al., 1988), compared to women who had been randomised to surgical treatment. Overall, women who received expectant treatment demonstrated better mental health according to the measures used in this study compared to those receiving surgical treatment. This result was maintained at three months and 12 weeks and suggests a differential impact on the mental health of women when they are given a choice in treatment. Furthermore, the study indicates results are not an artefact of the treatment per se, but rather of being given a choice. In support

of this, when given the opportunity, women have been shown to express strong preferences with regard to their treatment, which has been associated with a higher level of acceptance of their treatment at 12 weeks post-treatment (Wieringa-de Waard et al., 2004).

With this in mind, Ogden & Maker (2004) explored factors contributing to treatment choice in women experiencing first trimester miscarriage. Using a qualitative interview-based design delivered at five weeks post miscarriage diagnosis, they reported women who chose expectant management (n = 5), did so out of the desire for what they believed to be the most natural approach, and of fearing an operation. This compared to women who chose surgery (n = 5), who did so as a result of wanting the quickest resolution to their miscarriage and greater support from hospital staff. Regardless of treatment choice, all the women in this study reported feeling they had been insufficiently informed about the treatment process and neglected in relation to their emotional needs. Women also expressed the need for more time to make their decision (see appendix 1.8 for further information on services and satisfaction with care). Although this study was based on a small sample, it emphasises the need for informed decision-making for women if choice is to be considered as a determinant of treatment of miscarriage. It also offers an important foundation on which to build important theoretical and clinical studies; the results of which may be used to inform services and the women that use them.

Out of such explorations of the role of choice, Smith and colleagues (2006) have suggested that, given the diversity in women's experiences and beliefs according to the different treatment options available, there is a real need to emphasise the role of individual, informed choice in treatment. Supporting the idea of a shared decisions model in miscarriage treatment (Ankum et al., 2001), this would mean medical staff providing women with accurate, timely and comprehensive information about the potential medical *and* psychological consequences of each treatment option (according to the knowledge available to them) and allowing them the option of choosing, should they wish to, accordingly. This would be a deviation from standard practice not only in terms of explicitly being offering a choice in the first instance, but also informing women of the psychological as well as medical impact of miscarriage.

Furthermore, it raises an important question in terms of why it is important to offer women a choice and why offering a choice may affect the psychological impact of miscarriage. Existing studies do not put forward any particular hypotheses in relation to these ideas. However, studies have implied that offering choice is a way of accommodating diversity (in terms of cultures, belief systems, personal circumstances such as existing family and other commitments), and as such may suggest that a better match with women's individuals circumstances may contribute to improved psychological well-being following such an event. In addition, it may be that being offered a choice makes women feel more in control of what is happening to them, at a time when otherwise they may feel very out of control of what is happening.

This may further contribute to improved outcomes. If so, it may be that the treatment per se women receive has less influence on their experience post-miscarriage than having been given a choice in that treatment.

Psychological theories that have been considered in relation to the outcomes associated with miscarriage also offer some support to the idea of belief systems and need for control being possible moderating factors in the psychological well-being of women. In particular, Seligman's (1975) "Learned Helplessness Theory" viewed depression as the result of the expectation of future helplessness. Furthermore, helplessness is viewed as arising from the perception of uncontrollability, with an emphasis on the type and the importance of the event experienced in conjunction with the explanation that the individual attributes to the cause of the event. With this in mind, the reformulated version of this theory (Abramson, Seligman & Teasdale, 1978) proposed that the emotional, motivational and cognitive deficits seen in depression are accounted for by a particular set of attributions following the occurrence of a negative event, with the crucial attribution type being internal-stable-global. In the current context, this suggests that women who perceive the cause of their miscarriage to be due to something about themselves, something that will happen again in the future, and something that will produce failure in wide variety of circumstances (i.e. difficulty to conceive again or carry a baby to full term), will be those most vulnerable to depression.

Similarly, cognitive theories of anxiety emphasise the importance of an individual's expectations and interpretations of events in relation to perceived physical or psychosocial danger. Beck (1976) argues that, when anxious, individuals overestimate the danger inherent in a given context, in turn activating a set of responses evolutionarily designed to protect us. In their model of generalized anxiety, Beck and colleagues (Beck, Emery & Greenberg, 1985) proposed that individuals experience pervasive anxiety as a result of being prone to interpret a variety of situations as threatening, combined with developing cognitions about the self and how to behave (i.e. around acceptance, competence, responsibility and control). Biases in attention and behavioural expression are thought to further maintain anxiety symptoms through focusing on aspects of the environment that may be salient to one's cognitions, or through engaging in avoidance behaviours. In the case of miscarriage, anxieties about what the future holds in terms of reproduction and physical health may well be perceived of as threatening and out of control. Developing beliefs that one is responsible for the miscarriage or has been a failure as a consequence of it may cause greater distress and heighten anxiety symptoms further.

Perception of threat and response to stress are also inherent in theories of post-traumatic stress disorder (Horowitz, 1997; Janoff-Bulman, 1992). Within such models, individuals may experience intrusions, denial/avoidance or hyperarousal as a result of their assumptions about themselves and the world around them being challenged by the miscarriage. Rather than seeing themselves as perhaps competent, worthy and invulnerable, and the world as

predictable and comprehensible, they are faced with an event which they must make sense of but which is entirely counter to their beliefs. If such negative appraisals then lead to the event being perceived of as a continued threat (i.e. on the future possibility of having a successful pregnancy), symptoms of PTSD are thought to be maintained (Ehlers & Clark, 2000).

Based on existing literature and psychological theory, this study is designed to examine the issues raised in further detail, with a particular emphasis on exploring whether women value being given a choice in their treatment, and if so, what factors are important to them when making such a choice and how does choice impact on their psychological well-being. Whilst prior medical evidence (i.e. Lewis, 2007) suggesting greater psychological distress is experienced by women being treated at home (i.e. expectant and medical outpatient group) has led to a preference for inpatient treatments, research evidence to date suggests women may benefit from having greater involvement in their decisions which may lead to alternative choices in treatment. Based on this, the research questions for this study are as follows:

- 1) When given the opportunity to choose, what factors contribute to women's choices in miscarriage treatment?
- 2) Do women's psychological outcomes vary according to treatment when given a choice in the treatment they receive?
- 3) Do the psychological outcomes of partners differ according to the treatment women chose for their miscarriage?
- 4) Are there differences in the psychological outcomes of women and their partners?

(See appendix 1.9 for further discussion of attachment theory and miscarriage).

Materials and methods

(See appendix 2.1 on methodological issues and 2.2 on more detailed study aims)

Design:

A non-randomised, longitudinal study was conducted over a six-week period following miscarriage. Women were asked to complete measures initially over a two-week period immediately following their miscarriage. At six weeks post-miscarriage, both women and their partners (if appropriate) were invited to complete additional follow-up measures. Across both time points, measures used were both standardised (i.e. STAI, GHQ-12, IES) and constructed specifically for use in this study (i.e. qualitative sections of the diary – see measures section). The women participating were not randomised into treatment groups due to a specific interest of the study being around women's choice with regard to treatment.

Participants:

Participants were recruited into the study at an Early Pregnancy Assessment Unit (EPAU) in Nottingham (see appendix 2.3 for further information on participants). All women attending the unit with a confirmed diagnosis of non-viable pregnancy (i.e. foetal demise) were eligible for participation in the study. Women were excluded from participating in the study if they: i) had been diagnosed with an incomplete miscarriage; ii) were being managed

expectantly because a definitive diagnosis had not yet been established (although they could be invited to participate once a diagnosis of miscarriage had been confirmed); iii) were considered unable to provide consent in their own right (i.e. all women under the age of 16 years); or iv) did not speak English. These criteria were established based on existing literature, the nature of the research questions of the study, and ethical considerations appropriate to the population being recruited. EPAU nursing staff were responsible for approaching women who were eligible to take part in the study.

Over the course of the study (03.10.2006 to 23.09.2008), 1146 women were identified as being eligible to participate on the basis of their diagnosis (i.e. non-viable pregnancy). Of these, 165 (14.4%) were approached about the study on the basis of additional exclusion criteria being applied and due to clinical constraints on nurses to approach all eligible women due to making judgements of them being in extreme levels of distress (see discussion for further considerations).

Measures:

Participation in the study involved completion of a number of measures across two time points: i) the 14 days following their diagnosis of miscarriage, and ii) six-weeks post-miscarriage (see appendix 2.4 for further information). At the same time as consenting to participate, women were asked to complete a demographics questionnaire including details on age, marital, ethnic and

educational status, previous experience of miscarriage, and number of children.

i) Women were invited to complete a miscarriage diary over the 14 days following their diagnosis of miscarriage (and beginning at the same time as any treatment option they chose). Fourteen days was chosen as a suitable time period over which to complete the diary as this coincided with the period of time over which treatments would be administered and an expected complete miscarriage would take place. This diary included both qualitative and quantitative elements, as follows:

a) Potential factors that may have affected treatment choice were presented and women were asked to rate each one in relation to their importance in their own decision-making. Each of the 12 factors could be rated on a four-point likert scale as follows: “major factor” (1), “strong factor” (2), “minor factor” (3) and “not a factor” (4). This list was constructed by the research team based on observations made by the clinical staff at the EPAU and also included factors that had been identified as significant in previous research (i.e. Ogden & Maker 2004). Examples of factors included “*Advice from family*”, “*I was frightened of seeing the miscarriage*”, “*Scared of miscarrying on my own*”, and “*I chose what seemed the most natural approach*”.

b) The Spielberger State-Trait Anxiety Inventory (STAI; Spielberger, 1983) was used as a measure of state or current feelings, some of which correspond to the experience of anxiety. This 6-item self-report version, constructed from the original 20-item measure (Marteau & Bekker, 1992),

includes items corresponding to feeling calm, tense, upset, relaxed, content and worried. Responses could be made on a four-point likert scale where (1) = “not at all”, (2) = “somewhat”, (3) = “moderately”, and (4) = “very much”. Total scores can range between 6 (no anxiety) and 24 (very anxious). Psychometric properties of the 6-item measure include Cronbach’s alpha of 0.78 and a correlation of 0.92 with the original 20-item version (Chlan et al., 2003). This measure was completed on each of the 14 days in order to ascertain the trajectory of anxiety scores over this time period. This measure was not included in the six week follow up due to the anticipation that anxiety scores would be elevated initially as a result of the miscarriage, and although may remain high at six weeks, levels are likely to be distorted by other influential factors not specific to the miscarriage and may therefore distort results.

c) Visual Analogue Scales (VAS) were used to measure the intensity of pain and amount of bleeding along two separate horizontal 10cm lines. On each of these scales, “0” represented “no pain/bleeding”, and “10” represented “extreme pain/bleeding”, with women being invited to indicate along any of the 1cm interval points that were marked between each of these extremes. These ratings were completed on each of the 14 days as well as the six-week follow up to again ascertain the trajectory of ratings over this time period.

d) The General Health Questionnaire (GHQ-12; Goldberg & Hillier, 1979) was used to detect diagnosable non-psychotic psychiatric disorder in participants. This 12-item self-report questionnaire asks about the prevalence of particular

symptoms or behaviours over recent weeks using a four-point likert scale where (0) = better than usual, (1) = the same as usual, (2) = slightly worse than usual, and (3) = much worse than usual. Total scores range from 0 to 36 with a higher score indicating greater disorder. Using the “case-scoring” system (where raw scores of 0 or 1 are assigned a case score of “0”, and scores of 2 and 3 are assigned a case score of “1”), scores can range from 0 to 12. In this study, a cut-off case score of 4 was used, where scores of 4 and above indicate “caseness” (Johnson et al., 1995). Scores lower than 3 represented the normal range. Although it is common practice to use a lower cut off of 3, it has been recommended that a higher cut-off may be necessary for use with populations with somatic symptoms which can inflate scores (Johnson et al., 1995). Good internal consistency, test re-test reliability and validation sensitivity and specificity have been reported, including Cronbach’s alpha ranging from 0.82 to 0.90 (Johnson et al., 1995). Participants are asked to complete this measure on day seven of their miscarriage diary to allow time for initial adjustments to the miscarriage diagnosis. It was not felt to be necessary to complete this measure on each day of the diary (as with the STAI), as subjective changes across days were not expected and it was of greater interest to compare early scores with those achieved at follow up. In addition, the length of the questionnaire would have significantly increased the demands on women during this time, which was felt inappropriate and may have reduced willingness to participate in the study.

ii) Six-weeks from the date of the first diary entry, women were sent a collection of follow-up measures. Six weeks was selected as a suitable follow-

up date for two reasons. Firstly, treatment programmes, regardless of which option women selected, should be complete by this time, accounting for any complications or readmissions. Secondly, six weeks was considered an appropriate amount of time to allow women to reflect on their miscarriage. At this stage, women were offered the opportunity to invite their partners to also complete some measures. Women were invited to complete:

a) The GHQ-12 as in the original diary.

b) The two VAS relating to pain and bleeding as completed in the original diary.

c) Questions relating to their satisfaction with treatment. A list of 8 statements was constructed with existing literature and the development of the service in mind. These statements were designed to explore whether or not women would be likely to recommend the same treatment to a friend, whether they found treatment choice an easy decision to make, and whether they felt supported by the unit in making their decision. Responses could be made on a four-point likert scale, where (0) = “strongly disagree”, (1) = “disagree”, (2) = “unsure”, (3) = “agree”, and (4) = “strongly agree”.

d) The Impact of Events Scale (IES; Horowitz et al., 1979) was used as a measure of current subjective distress after a traumatic event. This 15-item self-report measure is composed of two subscales: 1) intrusions (i.e. flashbacks, bad dreams, strong feelings relating to the event); and 2)

avoidance of thoughts and feelings relating to the event. Participants are asked to indicate, according to four options, how frequently they had experienced a given stress reaction, with options including: “not at all” (0), “rarely” (1), “sometimes” (3) and “often” (5). Total scores range from 0 to 75, with subscale scores ranging from 0 to 35 for intrusions and 0 to 40 for avoidance. Total scores can be considered according to the following degrees of post-traumatic stress symptoms: 0 to 8 (subclinical), 9 to 25 (mild), 26 to 43 (moderate) and 44+ (severe) (Sterling, 2008). Horowitz and colleagues (1979) reported satisfactory reliability (split half reliability for the total score = 0.86). Internal consistency of the subscales has been reported as high with Cronbach’s Alpha for intrusion being 0.78, and for avoidance being 0.82. Test re-test reliability has also been reported as satisfactory (intrusion: $r = 0.89$; avoidance: 0.79; total score: 0.87). Other research has confirmed similar figures of internal reliability and factor loadings for a revised version of the measure based around diagnostic symptoms to increase content validity (Weiss & Marmar, 1997; Joseph, 2000). However, this revised version was not used as it is longer (to include a hyperarousal subscale), is more difficult to interpret, and does not have cut-off scores available (Sterling, 2008). This measure was completed at the six week follow up as immediate response would be expected to be high, and existing research indicates that scores recorded some time following the traumatic event (rather than immediately following) are more predictive of later outcomes (Sterling, 2008).

Partners were also invited to complete the following at six weeks:

- a) The GHQ-12.
- b) Questions relating to their satisfaction with treatment (as for women).
- c) The IES.

Procedure:

Women were invited to participate in the study providing they fulfilled the inclusion criteria and did not meet exclusion criteria. This was determined when women came to the unit on their first visit suspecting a miscarriage. On day one at the unit, women were provided with information sheets, consent forms and demographic questionnaires by EPAU staff. On this same occasion, they were given information about the different treatment options available to them and asked to return the next day to begin their treatment of choice. If women consented to participate in the study, they were then asked to complete the diary, starting immediately (on the second day of attending the unit and day one of treatment). Participation in the study in no way affected or interfered with the treatment women received. At the end of the 14-day period, women were asked to return their completed diaries in a freepost envelope to the research team.

Six weeks after entry into the study (taken from day one of the completed diaries), women were sent an additional follow-up questionnaire pack. These packs were distributed by a member of the research team who obtained postal addresses from the nursing staff on the EPAU. At the six-week follow-up, women were offered the opportunity to pass questionnaires on to their partners (if applicable). It was decided that women should be able in a

position to decide whether or not to involve their partners as in some cases partners may not be the fathers of the lost pregnancy. As with the diaries, women (and their partners, if applicable), were requested to return their completed measures in one freepost envelope to the research team (see appendix 2.5 for further information on procedures).

Ethical approval for the study was obtained from the North Nottinghamshire Local Research Ethics Committee (see appendix 2.6 for further information) and University of Lincoln Ethics Committee.

Results

Data was analysed using SPSS version 14.0. Non-parametric analyses were used due to data not conforming to standard Gaussian distribution and unequal sample sizes within the different treatment groups (see appendix 3.2 for normality test results). In examples where multiple comparisons have been conducted, p-values have been adjusted according to Bonferroni adjustment calculations. Non-parametric analyses were used appropriately given the conditions of the data, but at the expense of being able to explore possible interactions between variables through the use of parametric analyses such as Multivariate Analysis of Variance (MANOVA).

Patient characteristics

Of the 165 women approached to participate in the study, 121 (73.3%) provided their consent. Of these, 81 (66.9%) returned initial study measures.

At the six-week follow-up, 56 women (46.3%) and 37 partners (30.6%) returned completed measures.

The 81 women ranged in age from 21 to 47 years (mean = 33.28; IQR = 8.5). According to a Kruskal-Wallis test, women's age did not vary according to their choice of treatment [$H = 2.15$, $df = 3$, $p = 0.54$]. Of the 81, 71 (87.7%) were married or living with a partner. For the remainder, women were either single ($n = 2$, 2.5%), divorced ($n = 1$, 1.2%) or data was missing ($n = 7$, 8.6%). Ethnicity of the population was predominantly white European ($n = 66$, 81.5%), although other groups included Asian ($n = 2$, 2.5%); Black ($n = 3$, 3.7%); and Chinese ($n = 1$, 1.2%). There were 35 women (43.2%) working full time, with a further 28 (34.6%) working part time and 10 (12.3%) unemployed. Of the 81 women, 40 (49.4%) had other children and 34 (42.0%) had experienced a previous miscarriage (one or more). All partners included in the study were male.

Treatment choices

Of the 81 women participating in the study, 35 (43.2%) chose surgical treatment. This compared to 18 (22.2%) who chose expectant, 15 (18.5%) who chose medical outpatient, and 13 (16.0%) who chose medical inpatient treatment. According to a chi-square analysis, the proportion choosing surgical was significantly greater than other treatments [$\chi^2 = 14.95$, $df = 3$, $p < 0.01$] (see appendix 3.3 for further information on diagnoses, treatment choices and outcomes).

Factors underlining treatment choice

For the purposes of analysis, factors were only looked at in relation to those rated as major or strong factors (not those rated as minor or not a factor). Results of the frequency with which women endorsed the individual factors as either major or strong influences with regard to treatment choice can be seen in table i (see also appendix 3.4 for additional data). Analysis of the factors underpinning treatment choices made by women using a chi-square analysis revealed significant differences between the different treatment groups for some of the factors offered to women. These included a) *wanted to avoid staying in hospital* [$\chi^2 = 21.99$, $df = 3$, $p < 0.00001$], b) *chose what seemed the most natural treatment* [$\chi^2 = 10.12$, $df = 3$, $p < 0.025$], c) *wanted to avoid an operation* [$\chi^2 = 43.60$, $df = 3$, $p < 0.00001$], d) *wanted to avoid an anaesthetic* [$\chi^2 = 33.87$, $df = 3$, $p < 0.00001$], e) *was frightened of seeing the miscarriage* [$\chi^2 = 17.29$, $df = 3$, $p < 0.001$], f) *thought this would be the least painful* [$\chi^2 = 14.76$, $df = 3$, $p < 0.025$] and g) *was scared of bleeding heavily* [$\chi^2 = 9.46$, $df = 3$, $p < 0.025$]. Scrutiny of the percentages shown in table i suggest that for women choosing expectant management, the most important factors were avoiding a stay in hospital and an operation. Similarly, for the medical groups (inpatient and outpatient), wanting to avoid an operation and having an anaesthetic seemed to be the most important factors. For women choosing surgical management, being scared of bleeding and opting for the least painful management appeared more important than for the other groups. While being frightened of seeing the miscarriage was more important to women choosing hospital-based managements (i.e. surgical and medical

inpatient), and choosing the most natural treatment was most important to women in the medical groups (inpatient and outpatient).

----- Insert Table i here -----

Psychological impact on women

----- Insert Table ii here -----

a) Anxiety: STAI

STAI scores decreased significantly between day one and fourteen for all treatment groups (see table iia), with the exception of medical inpatient treatment (with adjusted p-value set at 0.0125 according to multiple comparisons) [Wilcoxon Signed Ranks Tests: expectant: $z = -2.83$, $p < 0.0125$; medical outpatient: $z = -3.07$, $p < 0.0125$; surgical: $z = -3.97$, $p < 0.0001$]. Women in all treatment groups reported initially moderate levels of anxiety, with a reduction to more mild levels by day 14.

According to Kruskal Wallis tests, STAI scores did not vary significantly according to treatment group for any of the time points analysed (see appendix 3.5a for additional analysis and details of non-significant results).

b) Non-psychotic psychiatric symptoms (GHQ-12)

Results of Wilcoxon Signed Ranks Tests showed a significant decrease in GHQ-12 scores between day seven and six weeks for all treatment groups (see table iib), with the exception of those receiving expectant management

(according to the adjusted p-value) [medical inpatient: $z = -2.55$, $p < 0.0125$; medical outpatient: $z = -2.53$, $p < 0.0125$; surgical: $z = -4.11$, $p < 0.0001$].

According to a series of Kruskal Wallis tests, GHQ raw scores did not significantly differ according to treatment group for either day seven or six weeks. Within the group of women who obtained scores indicative of being a “case”, there were no significant differences in terms of which treatment option they had chosen according to chi-square analysis (see appendix 3.5b for additional analysis and details of non-significant results). Similarly, there were no significant differences within each treatment group for the number of women being cases at day 7 compared to six weeks.

c) Post-traumatic stress response to trauma (IES)

Comparisons using Kruskal Wallis tests to examine whether IES scores varied according to treatment group showed women’s scores to be significantly different in total [$H = 15.99$, $df = 3$, $p < 0.01$] and on both subscales of the measure: intrusions [$H = 11.63$, $df = 3$, $p < 0.01$] and avoidance [$H = 10.84$, $df = 3$, $p < 0.025$] (see table ii)

Post-hoc Mann-Whitney analysis indicated total scores for the medical outpatient group were significantly lower than all other groups: expectant [$z = -2.68$, $p < 0.008$], medical inpatient [$z = -2.74$, $p < 0.008$], and surgical [$z = -3.21$, $p < 0.008$]. Additionally, total scores for the surgical group were significantly lower than those for the medical inpatient group [$z = -2.81$, $p < 0.008$]. Scores for the medical outpatient group were within the mild range.

Scores for the expectant and surgical groups were within the moderate range, and within the severe range for the medical inpatient group. Chi-Square analysis indicated a significant difference across treatment groups in the number of women obtaining scores within the moderate-severe range on the IES measure, with significantly fewer in the medical outpatient group [$\chi^2 = 24.38$, $df = 9$, $p < 0.01$].

More specifically, further Mann-Whitney tests showed medical outpatient scores were lower compared to the medical inpatient scores on the intrusion [$z = -2.73$, $p < 0.008$] and avoidance subscales [$z = 2.75$, $p < 0.008$]. Surgical scores were significantly lower than medical inpatient scores on the avoidance subscale only [$z = -1.94$, $p < 0.008$] (p-value adjusted to 0.008 according to multiple comparisons) (see appendix 3.5c for additional analysis and details of non-significant results).

Pain and bleeding

Figure i illustrates pain and bleeding ratings over the 14 days following women's miscarriages and at six weeks (day 42).

---- Insert Figure i ----

Due to the delayed peak in ratings and differential variations in ratings over the initial two-week period as seen in figure i, analysis has been conducted on three new ratings constructed from averaging across days 1 to 4, days 5 to 10, and days 11 to 14 individually for both pain and bleeding (see table iii).

----- Insert Table iii -----

Analysis of women's ratings of pain using Wilcoxon Signed Ranks tests indicated a significant reduction over time between the average for days 1-4 and 6 weeks for all treatment groups: expectant [$z = 2.70$, $p < 0.0125$]; medical inpatient [$z = -2.70$, $p < 0.0125$]; medical outpatient [$z = -2.67$, $p < 0.0125$]; and surgical treatment [$z = -4.80$, $p < 0.0001$]. Amount of bleeding also reduced over time for all women but this was only significant for those women receiving expectant [$z = -2.80$, $p < 0.0125$] and surgical treatment [$z = -4.46$, $p < 0.0001$] (with p-value adjusted to 0.0125).

Despite trends observable within the data (i.e. a peak in ratings for expectant group days 5-10; figure i), according to Kruskal Wallis tests, pain ratings did not differ significantly according to the treatment choice women made at any of the times points analysed (i.e. days 1-4; days 5-10; days 11-14 and 6 weeks). The same comparisons for bleeding resulted in a significant group difference for the average of days 1-4 only [$H = 8.59$, $df = 3$, $p < 0.05$]. Post hoc analysis indicated this difference to lie specifically between women receiving expectant and surgical treatment [$z = -2.19$, $p < 0.05$] (see appendix 3.6 for additional analysis and details of non-significant results).

Psychological impact on partners

Table iv details scores on the GHQ-12 and IES for the male partners of women, obtained at the six-week follow-up.

----- Insert Table iv -----

On the GHQ-12, scores did not significantly differ for partners according to the treatment group. Scores obtained for women and their partners were also not significantly different according to Wilcoxon Signed Ranks test results. Within the group of partners who obtained scores indicative of being a “case” on the GHQ-12, a significantly greater proportion were those whose partner’s had chosen surgical treatment [Chi-square: $x^2 = 12.18$, $df = 3$, $p < 0.01$].

On the IES, Kruskal Wallis analysis indicated scores did not significantly differ for partners according to the treatment group. Scores obtained for women and their partners were also not significantly different according to Wilcoxon Signed Ranks test results. Compared to women, chi-square analysis failed to report significant differences in the number of partners in the moderate to severe range of scores across treatment groups.

Evaluation of treatments

Responses provided at the six-week follow up indicated that both women and partners were in high agreement with statements relating to satisfaction with treatment. For women (see figure iia), there was a significant difference for whether they would advise the same treatment they had received to a friend [Chi-square: $x^2 = 15.21$, $df = 3$, $p < 0.01$], with the expectant group reporting a lower agreement percentage. There were no significant group differences

across the remaining statements. Nor were there significant group differences across statements for partners (see figure iib).

-----Insert Figure ii here-----

Conclusions

The results presented in this paper contribute to the literature on women's choices in treatment for miscarriage and the psychological impact that occurs subsequently. Of the 81 women participating in this study, the largest proportion chose to have surgical treatment. When provided with the opportunity to express a preference and exert a choice, women demonstrated that they are able to do so with 60-79% believing it to have been an easy decision to make. Given some of the factors women described as being influential in their choice of treatment, it appears they may hold pre-existing beliefs and attitudes relating to each option (i.e. whether it is more natural, whether it will be painful). Consequently, women opted for treatment options across the range of those available. Furthermore, factors that were shown to be important in making their treatment choice varied according to the different options. For those women choosing to have expectant treatment, it appeared the most important factors were avoiding a stay in hospital and opting for the treatment they believed would be the most natural resolution of their miscarriage. Alternatively, women choosing either of the medical treatments (i.e. inpatient and outpatient) reported the most important factors to be avoiding an operation and an anaesthetic. Finally, those women choosing surgical reported the most important contributing factors to their decision were feeling frightened about seeing the miscarriage, a belief that this option would

be the least painful and being scared of bleeding heavily. Preference for surgical treatment is in line with previously published data on women's preferences for surgical treatment and professional preference (Ryan & Hughes, 1997). Factors identified as influential are also consistent with qualitative and quantitative studies outlined previously (i.e. Ogden & Maker, 2004; Smith et al., 2006; Petrou & McIntosh, 2008). Along with these studies, current findings provide further support for the rationale of introducing a shift in responsibility for decisions around miscarriage treatment away from professionals (unless deemed necessary for medical reasons) and towards women and their partners.

Under conditions in which women are given a choice in their treatment, the current study suggests that on some measures of psychological outcome, there is no differential impact on women or their partners across treatment groups. This is certainly true for anxiety and non-psychotic symptoms levels for women across all four treatment groups and is consistent with medical literature which fails to advocate one treatment as being more superior in its success rate, as well as previous studies in which women were randomly assigned to treatment groups (Nielson et al., 1996; Lee et al., 2001). However, interestingly on the measure of non-psychotic symptoms, partners were significantly more likely to report scores indicating "caseness" if their partners had received surgical treatment. Whilst this was not the case in terms of being significantly so for women, inspection of the percentages reported suggest a trend in favour of an association between surgical treatment and greater presence of psychological distress. Rates of women

reaching “case” level of symptomatology according to the GHQ-12 at six weeks are consistent with reports of a prolonged psychological impact of miscarriage (Thapar & Thapar, 1992; Janssen et al., 1996). Whilst current results do not provide any insight into why exactly there may be such an association, results are consistent with previous research documenting high levels of psychological distress in men (i.e. Puddifoot & Johnson, 1997), which offers some possible insights. For example, despite being more physically “removed” from the event, partners may experience symptomatology on the basis of concerns and anxieties they may have about the woman’s treatment and their well being, as is discussed by some (Miron & Chapman, 1994; Murphy, 1998), or more directly from their own perception and emotional experience of the event. In the current example, the finding for partners may initially be surprising, as it may be expected that surgical treatment may “protect” partners from the experience of the miscarriage, as they are not present during the procedure. However, what this result suggests is that perhaps not being exposed to the actual event triggers other vulnerabilities for men that may include increased worry about their partner, increased anxiety over the procedure, and more opportunity to speculate and reflect on the event and what it means for themselves, their family and their future. Thus, it may be some combination of this range of factors, which results in partners experiencing miscarriage in the manner in which they appear to do. In light of this, it may be necessary to revise attitudes and provision of services, with a greater emphasis on partner’s, as well as women’s, responses to miscarriage (see appendix 4.3 for further discussion on the psychological impact of miscarriage for partners). Although similar

results for women were not significant, the same trend can be seen in the data, which may be explained by similar factors. In this sense, women may share anxieties around the procedure, their safety and the future implications of the procedure on their reproductive health. However, in addition, the finding that women appear to value having support from family and being in an environment they can control and feel familiar with, which perhaps they do not experience to such an extent in hospital, may further contribute to their experience of psychological distress.

In light of these findings, it is also interesting to observe that a group difference was reported on the measure of post-traumatic symptoms following miscarriage. In this example, those women who chose medical outpatient treatment appeared to experience significantly less severe distress following their miscarriage, suggesting either that this treatment group (and to a lesser extent surgical) may benefit in some way from having their treatment at home, or that women having medical treatment in hospital (the most severely traumatised group) are in some way disadvantaged in terms of psychological trauma. Although at this stage it is speculation as to explanations for the differences between the treatment groups, qualitative results imply that women may experience better psychological well-being as a result of being in a familiar, safe, supportive and comforting environment at home, as opposed to the hospital environment. Women experiencing treatment at home may also feel it is a more natural option and one they are more in control of (i.e. where they are, who they are with etc.). Although these conditions are present whether the treatment is medical outpatient or expectant, the latter may suffer

from a more unexpected duration, in addition to the potential for greater bleeding and therefore distress.

It is not possible to state from these results what proportion of women would meet diagnostic criteria for PTSD, as the IES is not considered valid in terms of diagnosing PTSD (Joseph, 2000). However, as an indication, using a different scale of post-traumatic symptoms, Engelhard et al. (2001) reported rates of 25% of women meeting diagnostic criteria for PTSD one month following a miscarriage (not explored in the context of specific treatments for miscarriage). Current IES scores compared to studies also using the IES measure in the same and different traumatised populations, suggest levels of symptoms reported in this study are comparable. For example, Broen et al. (2005) reported similar scores for women in a study examining the course of mental health following miscarriage (mean intrusion scores of 17.6 and 10.6 for 10 days and 6 months following miscarriage respectively; mean avoidance scores of 7.0 and 5.9 respectively). Such levels have also been reported in populations of women diagnosed with breast cancer (Koopman et al., 2002) and those experiencing serious injury (Richmond et al., 2000). What these results support is the notion that miscarriage is indeed experienced as a traumatic event in perhaps the same way that physical illness and injury can be, and that it can be associated with significant psychological distress (Lee & Slade, 1996). What remains unclear are the specific factors that contribute most significantly to these reports of post-traumatic stress responses. Potential candidates that may be relevant in the current study include unplanned pregnancy, experiencing anxiety or depression during the

pregnancy, previous pregnancy loss, prior mental health problems, and physical/sexual abuse (Born et al., 2006). Additional factors with regard to the lost pregnancy and future pregnancies may also be pertinent, including gestational age of the foetus, understanding of reason for the miscarriage, and concerns over the success of future pregnancies. Considering psychological theories of PTSD, it may be those women who have pre-conceived ideas around their ability to reproduce, whose beliefs and assumptions were then challenged by the experience of miscarriage, are those who are most vulnerable.

Whilst it was not a specific aim of the current study and therefore it has not been possible to conclude from it whether women had better or worse outcomes as a direct result of being given a choice, current findings do support the body of existing literature documenting the experience of miscarriage as a distressing, anxiety-provoking and traumatic event for both women and their partners. This is evidenced by current reports of increased levels of anxiety and other non-psychotic symptoms, and is consistent with similar reports following miscarriage (Geller et al., 2004; Walker & Davidson, 2001). Furthermore, the finding that women who receive medical treatment at home experience a less traumatic reaction to the miscarriage goes against recent opinion that greater distress is associated with treatments delivered at home for women (Lewis, 2007). However, it is appreciated that caution is needed with regard to all home treatments, given the finding of increased bleeding experienced by women receiving expectant treatment at home.

Further to the implication that treatment at home may not be as distressing as first believed, and that women may benefit from being involved in decisions made around their care, current results lend themselves to additional recommendations in relation to the treatment of miscarriage. Firstly, they may suggest important areas of information to be provided to women at the time of making their decisions. This may include highlighting factors that other women have previously found useful to consider when making a choice (i.e. consideration of impact on family, views on being in / out of hospital etc), as well as informing women of both the medical and psychological outcomes associated with the different options (i.e. elevated levels of bleeding associated with expectant treatment, lower levels of trauma symptoms possible with medical outpatient treatment) Further, results raise the issue of whether, at this stage, assessment should take place of vulnerability to psychological distress (i.e. high levels of trait anxiety, negative cognitions / maladaptive attributional styles etc.) (i.e. as a screening tool; Lee et al., 1997). In this sense, obtaining such information at an early stage in the treatment of miscarriage may be valuable in signposting women and their partners to appropriate support services (i.e. counselling) before their levels of distress reach a more damaging level post miscarriage.

Given the prevalence of elevated levels of psychological symptomatology, results also raise the question of follow-up provision of services to women and their partners following miscarriage. As such, it may be appropriate to consider inclusion of more comprehensive support services within early pregnancy services that may include offering women follow up services

including access to psychological therapies or counselling. Services may benefit from offering support to women who may be experiencing high levels of anxiety or depression, or reactions such as re-experiencing intrusive memories, avoiding feelings associated with the miscarriage, and denial of the event. With this in mind, offering vulnerable women follow-up services including counselling and psychotherapy may validate women's experiences and offer them much needed therapeutic input (see appendix 4.2 for further discussion on the psychological impact of miscarriage for women).

Despite recommendations for improvements to existing services, both women and their partners expressed a generally high level of satisfaction with the treatment they received. Furthermore, they felt that making the choice was easy (60-79% of women and 40-70% of men, with range being across treatments), and was made with all the necessary information and support, which in turn facilitated their decision-making. It is suggested within results that women receiving expectant management may be less likely to recommend the same treatment to others compared to other treatments. Although the reasons for this are not clear, it can be speculated that this may be due to the treatment not meeting women's expectations with regard to its benefits (i.e. avoiding hospital and being the most natural option), or as a consequence of the greater extent of bleeding experienced in this treatment group. According to the clinic statistics on outcomes, women receiving expectant management may be more likely to require further interventions (i.e. surgery) in order to complete their miscarriage. In the current population, these figures were 38.9% of the expectant group compared to 15.4% and

13.3% of the medical inpatient and outpatient groups respectively. Although women reported feeling fully informed, this highlights that more information may be needed for women, particularly those considering expectant treatment, to ensure their expectations are realistic and evidence-based. Due to the design of the study and data collected from only one unit, it is not possible to speculate whether these evaluations are specific to this particular service, or whether they can be generalised to units across the country adopting the same or different treatment protocols.

Whilst it is clear that using a non-randomised design to explore the role of choice in the experience of miscarriage treatment has produced some very interesting and informative results, this study is not without its limitations. A significant restriction in terms of the generalizability of the results comes from the recruitment process into the study, which resulted in small numbers of participants within each of the four treatment groups. Given that the rate of women agreeing to participate in the study was reasonable at the point of being approached, the problem appears to lie more in the discrepancy between the number of women being eligible for participation on the basis of their diagnosis ($n = 1146$) and the number approached about the study ($n = 165$). There are a number of reasons that may account for this low rate of approach, including women meeting one or more of the exclusion criteria and time/staffing demands within the EPAU, which made approaching all possible women difficult whilst concurrently managing a busy clinic. Anecdotal reports from the nursing staff also indicated that a proportion of women who may have otherwise been eligible, were not approached due to the levels of

distress they were experiencing at the time. Whilst it was an aim of the study to recruit women indiscriminately with regard to distress levels, it is appreciated that practically and ethically, this is more challenging to nursing staff who, based on their experience and knowledge, reported finding it very difficult to introduce the idea of a research study at such a time. For this reason, it may have been appropriate in hindsight to include extreme distress as an exclusion criterion to formalise the naturally occurring pattern of recruitment. Despite staff inadvertently excluding these women, it is noteworthy that the women who did get approached about the study were clearly still experiencing reasonably high levels of distress, as evidenced in their scores on the STAI, GHQ-12 and IES. Therefore, although the current study may not have picked up the more extreme cases, it remains valuable in documenting the experiences of women and their partners who nonetheless remained profoundly affected. It is worth considering, however, that future studies might benefit from considering alternative methods of recruitment including sending women information about the study in the post or via researchers rather than clinical staff who are further involved with women and their care.

A further reduction in the numbers involved in the study at the six-week follow-up may have been a result of women not wishing to reflect further on their experiences and the desire to put the event in the past and focus on the future. Similarly, lower numbers of partners participating may be explained by women not choosing to invite them into the study, partners not being present, or their own decision not to participate.

A further restriction in terms of the applicability of the results relates to comparison groups within the study. Whilst the aims of the study were to explore the impact of choice on treatment and psychological outcome, it would be of interest to include comparison groups, which allow for conclusions to be drawn with regard to whether there is a direct impact of choice on outcome (i.e. a comparison group where women were randomly assigned to treatment). This would have allowed for the hypothesis to be further explored that treatment choice per se impacts on psychological outcome. Whilst attempts have been made within this paper, the alternative approach of comparing current results with existing studies is made difficult by the use of different methodologies and study measures (see appendix 4.4 on further strengths and limitations of the study).

In relation to developing a better understanding of the factors women consider when making a choice in their treatment, whilst the current study offers a relatively comprehensive list of factors (due to the use of both quantitative and qualitative means of exploring this question), there are additional pre-miscarriage factors that may also have contributed but haven't been measured in the study and thus limit the discussion of results. These predominantly derive from consideration of the psychological theories outlined previously, particularly in relation to women's cognitions, beliefs and attributions and feelings of control over their miscarriage, which may have contributed to women's vulnerability for psychological symptoms following their miscarriage. Measurement of these factors may also benefit the unit in

terms of identifying those women who may be more likely to experience distress following their miscarriage.

With results and study limitations in mind, further research would benefit from addressing these limitations and from exploring treatment choice further with larger populations of women and their partners (male and female), with a greater representation of a wider range of cultures and healthcare systems (i.e. recruiting from multiple units across the country). It may also be of interest to examine the trajectory of results over a longer period of time in order to examine the duration of psychological impact (i.e. six months to one year, based on the existing literature and proposed trajectory of effects over time, remission rates in the first year for PTSD). Furthermore, obtaining additional qualitative data may provide further evidence to assist practitioners in establishing clear and realistic descriptions of the experiences of women receiving each of the different treatment options that may be then used in services to better inform future patients (see appendix 3.4 for qualitative analysis results).

Word count: 9.016

Declaration of interest:

The author reports no conflicts of interest. The author alone is responsible for the content and writing of the paper.

Acknowledgements:

The author would like to thank the staff of the EPAU, City Hospital, Nottingham for their assistance in recruitment into this study. Thanks also go to Dr Judith Moore, Professor Cris Glazebrook, Dr Charlotte Sheard and Dr Sara Cox for their valuable contributions and support with this project. Most importantly, thanks go to all the women and their partners who took the time at such a distressing point in their lives, to participate in the study. It is hoped they found the experience beneficial.

Funding:

This research was funded by a training grant awarded to Zoë Kyte as part of funds available for the doctorate in Clinical Psychology Training, Lincolnshire Partnership NHS Trust.

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Table i: Factors influencing treatment choice

Factors influencing treatment choice	Frequency and (%) of treatment group describing factor as strong or major influence				
	Expectant (N = 18)	Medical inpatient (N = 13)	Medical outpatient (N = 15)	Surgical (N = 35)	P
1. Wanted to get back to work as quickly as possible	5 (27.8)	3 (23.1)	2 (13.3)	7 (20.6) ¹	NS
2. Have no-one to help look after my other children	1 (5.9) ¹	2 (15.4)	0 (0.0)	2 (6.1) ²	NS
3. Wanted to avoid staying in hospital	13 (72.2)	6 (46.2)	11 (78.6) ¹	6 (17.6) ¹	<0.001
4. Wanted to avoid an operation	9 (50.0)	11 (84.6)	14 (93.3)	2 (5.9) ¹	<0.001
5. Wanted to avoid having an anaesthetic	8 (44.4)	11 (84.6)	12 (80.0)	3 (8.8) ¹	<0.001
6. Advice from family	2 (11.1)	3 (23.1)	2 (13.3)	8 (22.9) ³	NS
7. Advice from EPAU staff	6 (33.3)	4 (30.8)	4 (26.7)	14 (41.2) ¹	NS
8. Was scared of miscarrying on my own	3 (16.7)	5 (38.5)	4 (26.7) ¹	18 (51.4)	NS
9. Was scared of bleeding heavily	4 (22.2)	6 (46.2)	2 (14.3) ¹	19 (54.3)	0.024
10. Was frightened of seeing the miscarriage	3 (16.7)	5 (38.5)	1 (7.1) ¹	21 (61.8) ¹	0.001
11. Chose what seemed the most natural treatment	6 (33.3)	8 (61.5)	10 (66.7)	10 (29.4) ¹	0.018
12. Thought this would be the least painful treatment	7 (38.9)	2 (15.4)	3 (20.0)	23 (65.7)	0.002

¹ = 1 case missing; ² = 2 cases missing; ³ = 3 cases missing

Table ii (a): Mean scores (sd) on the STAI measure

Time	Management group			
	Surgical	Expectant	Medical outpatient	Medical inpatient
Day 1	16.06 (4.28)	17.50 (3.73)	18.47 (3.20)	18.00 (2.83)
Day 14	11.76 (3.64)	10.87 (4.94)	10.54 (4.20)	14.58 (5.16)
N	29	15	13	12

STAI: Minimum score possible = 6; maximum score possible = 24

Table ii (b): Mean scores (sd) on the GHQ-12 measure

Time	Management group			
	Surgical	Expectant	Medical outpatient	Medical inpatient
Day 7	18.81 (6.89)	17.22 (7.71)	19.93 (6.73)	20.62 (7.02)
N	31	18	14	13
6 weeks	13.32 (5.21)	15.56 (8.06)	11.22 (5.31)	16.70 (6.08)
N	28	9	9	10
"Cases" (n / %)				
Day 7	23 (38.3)	13 (21.7)	12 (20.0)	12 (20.0)
6 weeks	12 (52.2)	5 (21.7)	2 (8.7)	4 (17.4)

GHQ-12: Minimum score possible = 0, maximum score possible = 36

Table ii (c): Mean scores (sd) on the IES measure (at 6 weeks)

Measure	Management group			
	Surgical	Expectant	Medical outpatient	Medical inpatient
Total	33.23 (8.40)	38.43 (15.67)	13.20 (7.16)	47.67 (6.06)
Intrusions	16.08 (3.88)	18.86 (9.87)	6.60 (6.43)	23.67 (7.53)
Avoidance	17.15 (7.36)	19.57 (6.66)	6.60 (7.02)	24.00 (4.73)
N	13	7	5	6

IES: Total scores: 0-8 = sub clinical; 9-25 = mild; 26-43 = moderate; 44+ = severe

Table iii: Pain and bleeding ratings

Measure	Time	Treatment group			
		Expectant	Medical inpatient	Medical outpatient	Surgical
Pain VAS	Average days 1-4	22.48 (15.35)	17.47 (12.23)	24.82 (13.65)	16.99 (18.08)
	N	18	12	15	35
	Average days 5-10	12.51 (13.45)	8.10 (8.60)	7.46 (14.04)	9.54 (12.91)
	N	15	11	14	33
	Average days 11-14	6.63 (11.40)	7.14 (14.18)	4.58 (9.10)	4.84 (12.14)
	N	16	12	14	30
	6 wks	1.40 (3.13)	0.80 (1.14)	0.00 (0.00)	1.77 (5.09)
N	10	10	9	27	
Bleeding VAS	Average days 1-7	34.60 (22.51)	24.39 (21.74)	34.88 (18.66)	19.31 (18.45)
	N	18	12	15	35
	Average days 5-10	19.58 (14.47)	9.72 (10.39)	14.49 (15.14)	10.24 (13.62)
	N	16	11	14	33
	Average days 11-14	9.12 (11.76)	11.24 (14.91)	9.58 (12.01)	5.43 (9.64)
	N	17	11	14	29
	6 wks	3.50 (7.75)	2.00 (4.00)	4.33 (13.00)	1.17 (2.54)
N	10	10	9	27	

Table iv: Partner's mean scores (sd)

Measure	Management group			
	Surgical	Expectant	Medical outpatient	Medical inpatient
GHQ-12 @ 6 weeks	14.90 (6.67)	10.29 (2.87)	13.20 (3.77)	17.00 (3.81)
GHQ-12 "Cases"	11 (52.4)	0 (0.0)	2 (40.0)	5 (100)
N	21	7	5	5
IES total @ 6 weeks	26.90 (11.47)	24.40 (11.17)	38.00 (-)	40.25 (14.03)
Intrusions @ 6 weeks	12.80 (6.41)	10.40 (4.56)	16.00 (-)	22.75 (8.96)
Avoidance @ 6 weeks	14.10 (5.82)	14.00 (8.34)	22.00 (-)	17.50 (5.80)
N	10	5	1	4

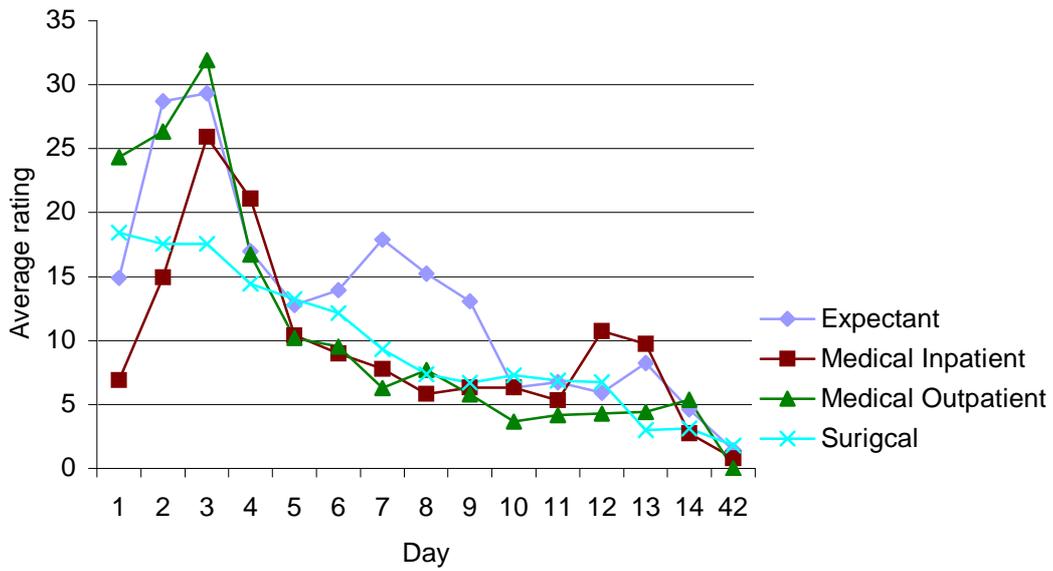


Figure i (a): Average pain ratings over time

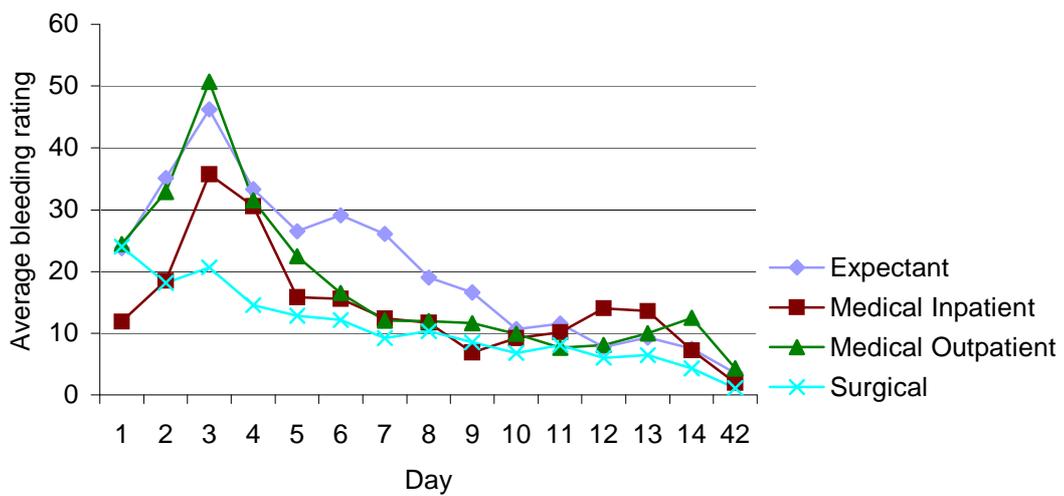


Figure i (b): Average bleeding ratings over time

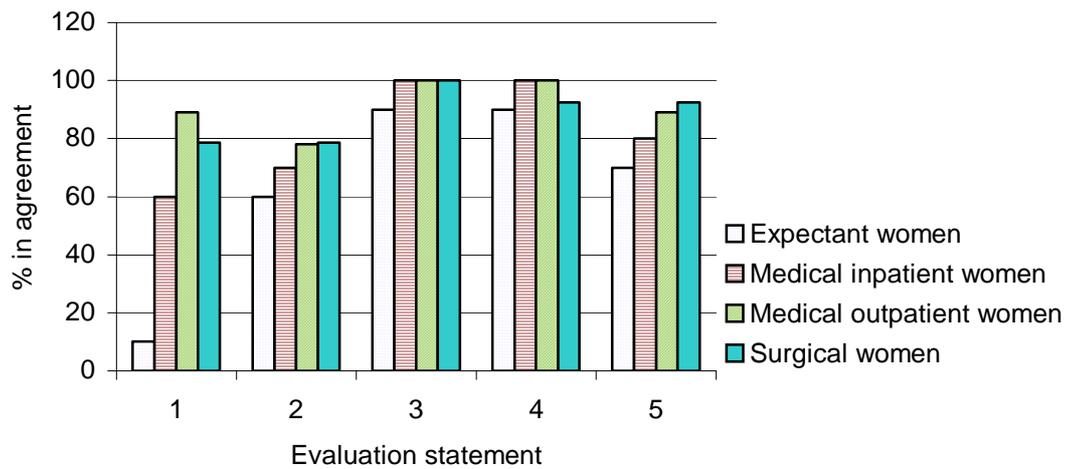


Figure ii (a): Percentage of women in agreement with evaluation statements

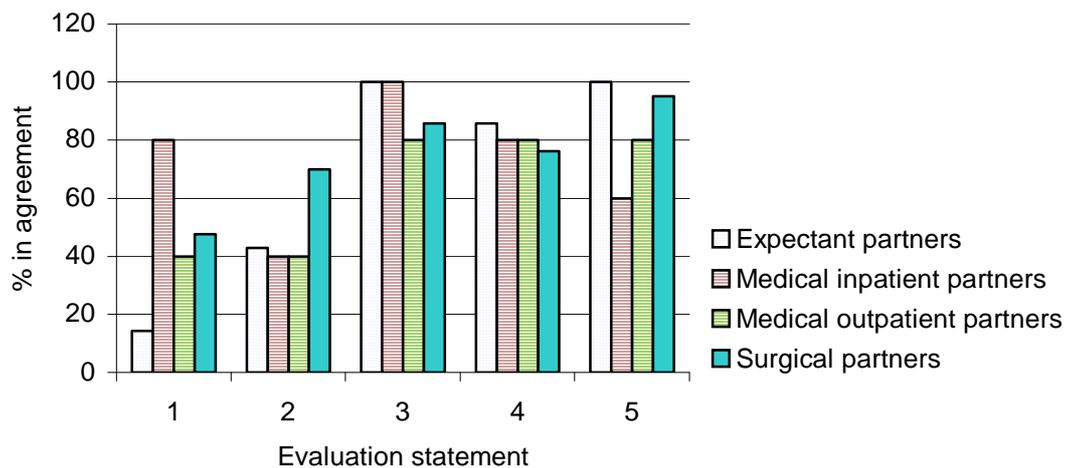


Figure ii (b): Percentage of partners in agreement with evaluation statements

Key:

- 1 = Would advise the same treatment
- 2 = Found it a easy decision to make
- 3 = Felt fully informed when making the choice in treatment
- 4 = Felt fully supported in the choice
- 5 = Feel I / my partner made the right decision

Journal guidelines for authors: Human Reproduction

(Relevant sections taken from:

http://www.oxfordjournals.org/our_journals/humrep/for_authors/index.html, date: 17th November 2008)

SCOPE

Human Reproduction publishes full length, peer reviewed papers reporting original research, as well as opinions, debates and clinical case reports of outstanding originality and importance. Mini-reviews forming part of the 'Developments in Reproductive Biology and Medicine' series are also occasionally published. These articles aim at summarizing concisely particularly important and rapidly-developing areas of reproductive medicine for which not enough has been published to enable more substantive reviews to be written. The majority of 'Developments' reviews will originate from the journal's Associate Editors but uninvited contributions are also welcomed.

Papers should be within the recognized broad scope of human reproductive biology and reproductive medicine. This includes relevant scientific and clinical aspects of reproductive physiology and pathology, reproductive endocrinology and endocrine therapies. It also includes andrology, contraception, **early pregnancy**, embryo development, **ethical issues**, fertilization, gametogenesis, genetic screening (first trimester) , genetic diagnosis (pre-implantation), gonadal function, implantation, infectious diseases, menstrual disorders, **psycho-social issues**, reproductive genetics, reproductive surgery, reproductive oncology, reproductive epidemiology, and

stem cell research. Research which would be classified as clearly in the fields of obstetrics or gynaecological oncology will not normally be published.

GUIDELINES FOR PREPARATION OF MANUSCRIPT

Manuscript length

Papers should be of a length appropriate for the amount of information they contain. Failure to restrict the length of manuscripts, especially Introduction and Discussion sections, can negatively influence the reviewers' and the editor's decisions.

Style

Manuscripts should be written using clear and concise English, with English standard spelling and conventions.

Units of measurement and abbreviations

Units of measurement should be in Système International (SI) units and those recommended by the IUPAC should be used wherever possible. Standard units of measurements and chemical symbols of elements may be used without definition in the body of the paper. Abbreviations should be given in brackets after their first mention in the text, and used thereafter. For centrifugation rates give g values rather than rpm, as this will vary according to rotor diameter.

Format

Double spacing on one side of the paper only. Number each page top right.

Number lines. Avoid underlining. Differentiate clearly letters O, I and numbers 0, 1. Ensure unusual symbols are written clearly.

Structure (listed in order of appearance in the published manuscript)

Title

Should not exceed 25 words and should be specific and informative.

Running title

Should not exceed 50 characters.

Authors

Give initials and family name of all authors. Declaration of Authors' roles is required at submission and this information will be listed for each author on the title page of the paper (refer to the section 'To accompany manuscript at submission' above for more details regarding authorship).

Address

The department, institution, city and country should be given with postal code for each author. An e mail address will be published for the corresponding author, who should be clearly identified. Current addresses should be provided for all authors.

Abstract

The abstract should be a single paragraph of not more than 250 words which clearly summarizes the findings of the manuscript. Note that online abstracts

are published for viewing in isolation to the main body of the manuscript and should be self explanatory. The following structured headings should be used to divide the text of abstracts: BACKGROUND, METHODS, RESULTS and CONCLUSIONS. All papers should clearly describe within the BACKGROUND section the background and objective of the study and within the METHODS section the design, setting, patients, interventions and main outcome measures should be described. Where multiple methodologies have been used, these and the results obtained can be presented in sequence in a combined METHODS and RESULTS section. Mention of the study's single most important limitation should be made in the CONCLUSION section of the abstract. Citations should not appear in the abstract.

Key words

Up to five key words must be supplied by the author. The key words, together with the title and abstract, are used for online searches. They should therefore be specific and relevant to the paper.

Introduction

The introduction should be limited to the specific background necessary to show the importance and context of the current study. The objective of the study should be clearly stated in the final paragraph of the Introduction.

Materials and methods

The names, town and country of origin of all suppliers should be included.

Results

Unnecessary overlap between tables, figures and text should be avoided.

Discussion

The discussion should begin with a succinct statement of the principal findings, outline the strengths and weaknesses of the study, discuss the findings in relation to other studies, provide possible explanations and indicate questions which remain to be answered in future research.

Acknowledgements

Personal acknowledgements should precede those of institutions or agencies.

Funding

With respect to funding of research, in line with the World Association of Medical Editors (WAME) guidelines,

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the journal considers it the responsibility of the author to protect the integrity of the research record from bias related to the source of funding by fully declaring all sponsorships, the roles played by sponsors in the research as well as institutional affiliations and relevant financial ties. These should be listed in the manuscript after the 'Acknowledgements'.

Reference citations within the text

Authors are responsible for the accuracy of the references. Each reference should be cited by author and date. If there are two authors please list both, if

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Please use the following style. Note that correct punctuation and journal abbreviations must be used in order to run the search programs used to edit the manuscript. Incorrectly typed references take a lot of time to correct, for which we reserve the right to charge. Up to 10 authors should be included after which et al. should be used. Refer to the following examples. Abbreviate scientific journals according to established publications.

Biggers JD and McGinnis LK (2001) Evidence that glucose is not always an inhibitor of mouse preimplantation development in vitro. Hum Reprod 16,153-163.

Gekas J, Thepot F, Turleau C, Siffroi JP, Dadaoune JP, Briault S, Rio M, Bourouillou G, Carre Pigeon F, Wasels R et al. (2001) Chromosomal factors

of infertility in candidate couples for ICSI: an equal risk of constitutional aberrations in women and men Hum Reprod 16, 82-90.

Elliot WH and Elliot DC (2001) Biochemistry and Molecular Biology. 2nd edn, Oxford University Press, Oxford, UK.

Warren MA, Li TC and Klentzeris D (1994) Cell biology of the endometrium: histology, cell types and menstrual changes. In Chard T and Grudzinski JG (eds) The Uterus. Press Syndicate of the University of Cambridge, Cambridge, UK, pp.94-125.

Tables

Each table should be numbered consecutively with Roman numerals. Please avoid complex constructions. Each item of data should be in a separate cell and should be produced using Word or Excel format. Each table should be self-explanatory and include a brief descriptive title. Footnotes to the table indicated by superscript lowercase letters are acceptable but should not include extensive experimental detail. Reference to the tables in the text should be sequential (ie Table I, II etc).

Do not include more tables than is absolutely necessary - non-essential tables may be judged as being suitable for online-only publication.

Figure legends

Each legend must be self contained, with all symbols and abbreviations used in the figure defined.

Figures

Full instructions on preparing the figures are available as part of the online submission instructions. Please follow these instructions carefully as failure to do so will delay publication of your manuscript (please note: the editors reserve the right to charge for extensive changes). In preparing graphs authors should avoid background tints and 3D effects and maintain a consistent label size and aspect ratio (the x/y axis ratio) throughout a paper. Figure and axes titles should be clear and NOT in bold text. Do not include more figures than is absolutely necessary - non-essential figures may be judged as being suitable for online-only publication.

Ethics approval letter:

North Nottinghamshire Local Research Ethics Committee
1 Standard Court
Park Row
Nottingham
NG1 6GN

Tel: 0115 9123344 ext 39368
Fax: 0115 9123300

12 December 2007

Dr Judith Moore
Consultant Obstetrician and Gynaecologist
Early Pregnancy Assessment Unit
Nottingham City Hospital
Hucknall Road
Nottingham
NG5 1PB

Dear Dr Moore

Study title: **The outcomes and experiences of women with a diagnosis of miscarriage - comparison of outpatient and inpatient medical management, surgical and expectant management**
REC reference: **06/Q2402/58**

Amendment number: **4**

Amendment date: **09 November 2007**

The above amendment was reviewed at the meeting of the Sub-Committee of the REC held on 16 November 2007.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

EA2

Ethical Approval Form: Human Research Projects

Please word-process this form, handwritten applications will not be accepted



This form must be completed for each piece of research activity whether conducted by academic staff, research staff, graduate students or undergraduates. The completed form must be approved by the designated authority within the Faculty.

Please complete all sections. If a section is not applicable, write N/A.

1 Name of Applicant	Dr Zoë Kyte	
	Department: Clinical Psychology	Faculty: Health, Life and Social Science
2 Position in the University	Trainee clinical psychologist	
3 Role in relation to this research	Student researcher	
4 Brief statement of main Research Question	<p>To compare different miscarriage management options in terms of the factors that influence choice in treatment, and the psychological effects of each treatment option. The study will specifically assess:</p> <ol style="list-style-type: none"> 1. To evaluate factors affecting women's choice of treatment for miscarriage. 2. To explore the relationship between choice of treatment and psychological outcome in women both immediately and six weeks post-miscarriage. 3. To explore how the experiences of the women's partners differ depending on the choice of treatment. 4. To investigate what follow-up services women and their partners would find beneficial following their miscarriage. 	
5 Brief Description of Project	<p>The study will recruit women and their partners, where applicable, from the Early Pregnancy Assessment Unit, Nottingham City Hospital. After making their choice in miscarriage treatment, women who participate in the study will be asked to complete a questionnaire including demographic and medical information, and a miscarriage diary. The diary contains questions about factors influencing choice in treatment, as well as the Spielberger State-Trait Anxiety Inventory and rating scales for extent of pain and bleeding experienced. This diary is completed over 14 consecutive days with day one being the day they make their treatment choice. On day seven, women and their partners are also asked to complete the General Health Questionnaire. Six weeks after entry into the study, women and their partners are sent a follow-up questionnaire including the General Health Questionnaire, pain and bleeding rating scales and some questions about their satisfaction with their treatment. Women and their partners will also be asked to complete the Impact of Events Scale at this stage.</p>	
	Approximate Start Date: 1 st September 2007	Approximate End Date: 31 st December 2010
6 Name of Principal Investigator or Supervisor	Dr Judith Moore, Consultant Obstetrician and Gynaecologist	
	Email address: Judith.a.moore@nuh.nhs.uk	Telephone: 0115 9691169 ext. 45284

7 Names of other researchers or student investigators involved	1. Dr C. Glazebrook, 2. Mrs C. Sheard, Dr S Cox
8 Location(s) at which project is to be carried out	Early Pregnancy Assessment Unit, Nottingham City Hospital, Nottingham.

9 Statement of the ethical issues involved and how they are to be addressed –including a risk assessment of the project based on the vulnerability of participants, the extent to which it is likely to be harmful and whether there will be significant discomfort. (This will normally cover such issues as whether the risks/adverse effects associated with the project have been dealt with and whether the benefits of research outweigh the risks)	<p>Miscarriage is a sensitive area and most women (and their partners) will experience some kind of grief reaction after the diagnosis has been made. Participation in this study, although not physically detrimental, may exacerbate the emotional impact of the miscarriage. Equally, it may help the process. In any circumstance where participants experience difficulties, emotionally or otherwise, they are encouraged to contact the Early Pregnancy Assessment Unit for support when needed. This will be made very clear to participants. In addition, the GP's of all participants will be informed of their participation in the study. Consequently, should it be necessary, individuals are able to seek alternative forms of support and assistance via their GP.</p> <p>Although the benefits of participating in this study are more significant for women experiencing miscarriage in the future, individuals may find completing the questionnaires and interview therapeutic and results may highlight those individuals experiencing an abnormal grief reaction to the miscarriage so that appropriate support can be sought.</p>
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Ethical Approval From Other Bodies

10 Does this research require the approval of an external body ?	<p>Yes <input checked="" type="checkbox"/> No <input type="checkbox"/></p> <p>If "Yes", please state which body:- North Nottinghamshire Local Research Ethics Committee</p>
11 Has ethical approval already been obtained from that body?	<p>Yes <input checked="" type="checkbox"/> Please append documentary evidence to this form.</p> <p>No <input type="checkbox"/></p> <p>If "No", please state why not:- Not applicable</p> <p>Please note that any such approvals must be obtained and documented before the project begins.</p>

APPLICANT SIGNATURE

I hereby request ethical approval for the research as described above.
I certify that I have read the University's ETHICAL PRINCIPLES FOR CONDUCTING RESEARCH WITH HUMANS AND OTHER ANIMALS.



Applicant Signature

Date 10th September 2007

PRINT NAME ZOE KYTE

FOR COMPLETION BY THE CHAIR OF THE FACULTY RESEARCH COMMITTEE

Please select ONE of A, B, C or D below:

A. The Faculty Research Committee gives ethical approval to this research.

B. The Faculty Research Committee gives conditional ethical approval to this research.

12 Please state the condition
(inc. date by which condition
must be satisfied if applicable)

C. The Faculty Research Committee cannot give ethical approval to this research but refers the application to the University Research Ethics Committee for higher level consideration.

13 Please state the reason

D. The Faculty Research Committee cannot give ethical approval to this research and recommends that the research should not proceed.

14 Please state the reason

Signature of Chair of Faculty Research Committee (or nominee)

Kan Guo

18-09-2007

Signed

Date

Research and Development letter

Nottingham University Hospitals NHS Trust
Research and Development Department
Hucknall Road
Nottingham
NG5 1PB

Ref: 06OB002

Date: 12 September 2006

Direct dial: 0115 9627913
Tel: 0115 969 1169 ext 46913
Minicom: 0115 962 7749
www.nuh.nhs.uk/nch/randd

Dr J Moore
Consultant Obstetrician and Gynaecologist
Maternity Unit
City Hospital Campus

Dear Dr Moore,

Re: The outcomes and experiences of women with a diagnosis of miscarriage – comparison of outpatient and inpatient medical management, surgical and expectant management

R&D Reference: 06OB002

Ethics Reference: 06/Q2402/58

The R&D Department have considered the following documents:

- NHS REC application form
- R&D Application form
- Protocol version 1, dated May 2006
- Participant Information Sheet, version 3, dated August 2006
- Participant Consent Form, version 3, dated August 2006
- Letter of invitation to patient, dated June 2006
- Letter of invitation to partner, dated June 2006
- Letter to GP
- Questionnaire (women)
- Questionnaire (partner)
- Diary

The study now has R&D approval subject to the conditions set out below:

That you:

- Abide by the Clinical Trial/Research agreement (as applicable)
- Abide by the terms of your substantive employment/honorary contract with the Trust (where applicable)
- Ensure that all study personnel, not employed by the Nottingham University Hospitals Trust, hold Honorary contracts with this Trust, before they have access to any facilities, patients, staff, their identifiable data, tissues or organs.
- Conduct all Clinical Trials under the jurisdiction of the EU Directive 2001/20/EC in accordance with The Medicines for Human Use (Clinical Trials) Regulations 2004
- Comply with the current Research Governance Framework for Health and Social Care, (Copies of the Research Governance Framework for Health and Social Care can be found at www.doh.gov.uk or via the R&D office)
- Report all research, which is discontinued temporarily or permanently, to the R&D Department in a timely manner
- Provide information for R&D reporting purposes including publications, Serious Adverse Events and progress reports as requested/required
- Request written approval from the R&D Department for any changes to the project protocol including amendments, study personnel and study documentation you propose to implement
- Notify the R&D Department as soon as you are made aware of any study inspection/audit by an external organisation
- Must not start your project until you have received all relevant written regulatory approvals/authorisations

In addition:

- All projects are liable to be monitored by the Trust
- Unless you have indicated otherwise on the R&D application form the project details will be uploaded to the National Research Register (NRR) database (The NRR can be accessed on www.nrr.nhs.uk)

Yours sincerely

Dr B Thomson
Research & Development Director

Cc NHS Research Ethics Committee

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10 December 2007

Dr Judith Moore
Hucknall Road
Nottingham
NG5 1PB

Dear Dr Moore

**ID: 06OB002 The outcomes and experiences of women with a
 diagnosis of miscarriage – comparison of outpatient
 and inpatient medical management, surgical and
 expectant management.**

Thank you for informing R&D of the following amendments:

- Additional investigator Dr Zoe Kyte
- Extension until 31/12/08

The amendment has been given R&D approval, however, please contact Graeme Docherty in this department to discuss whether there are additional costs attached to the study

Yours sincerely,

Richard Hart

R&D Projects and Data Manager

cc East Midlands Research Ethics Committee

Appendix 1

Introduction

1.1 Additional background information

For at least 50% of women, the cause of their miscarriage is never known (Regan & Rai, 2000). However, where explanations have been provided they have tended to originate from genetic, endocrinological, anatomical, immunological or microbiological factors. Environmental factors including drug use (from caffeine to cocaine; Ness et al., 1999) and exposure to stressful life events (Neugebauer, Kline, Stein, Shrout, Warburton & Susser, 1996) are examples of potential contributory factors.

Current standard practice is for investigations to take place as to the possible cause of a miscarriage once the woman has experienced three or more miscarriages (“recurrent miscarriage”) (Royal College of Obstetricians and Gynaecologists, 2004).

1.2 Medical outcome and patient satisfaction

A number of studies have reported an increase in patient satisfaction with medical compared to surgical treatment, despite the greater medical success rate of the latter (with success defined as in the research paper) (Demetroulis, Saridogan, Kunde & Naftalin, 2001; Lee, Cheung, Haines, Chan & Chung, 2001; Zhang et al., 2005). Trinder et al. (2006) reported that unplanned admissions following incomplete or unsuccessful treatment, or medical complications were most common for those women opting for expectant management and least common for surgical. Others have reported no

significant differences between the different treatment options with regard to rates of infection, bleeding time, and time taken for women to resume normal activity levels following their miscarriage (Ngai, Chan, Tang & Ho, 2001; Weeks & Danielsson, 2006).

1.3 Miscarriage and psychological distress

Whilst the degree of distress experienced is likely to vary considerably across women, it is widely understood that many will experience miscarriage as a profound and traumatic event (Lee & Slade, 1996; Engelhard et al., 2001). Indeed, up to 51% are thought to experience some form of psychological morbidity following their loss, including symptoms of anxiety, depression and post-traumatic stress (Lee et al., 1997; Engelhard et al., 2001; Lok & Neugebauer, 2007). Despite this, the significance and impact of miscarriage for many women is often not acknowledged by professionals (Wong et al., 2003).

Studies report between 20-50% of women who miscarry experience symptoms of depression following their loss, with rates varying depending on the methodologies and measures used (Slade, 1994; Geller, Kerns & Klier, 2004). Neugebauer et al. (1992a) reported levels of depressive symptoms 3.4 times higher in women who had miscarried compared to pregnant women, and 4.3 times higher compared to community women who had not recently been pregnant. This figure reduced marginally to 3 times greater than community women by six weeks. Furthermore, Neugebauer et al. (1992a) identified risk for depression as being substantially higher for those women

who did not have children already (relative risk of 5.0 versus 1.3 for women with and without children respectively). The finding that women may be experiencing levels of depression over and above those reported for similar groups of women and that such symptoms may not be transient but rather may persist for some time following their loss has been consistently reported (Thapar & Thapar, 1992; Janssen, Cuisinier, Hoogduin & De Graauw, 1996). In some studies, symptoms have persisted for up to 12 months post-miscarriage (Beutel, Deckardt, Von Rad & Weiner, 1995). Furthermore, use of appropriate comparison groups in the study by Neugebauer et al (1992a) indicates that it is something specific to the experience of miscarriage results in elevated levels of depressive symptomatology in women.

Similarly, high rates of anxiety have also been reported in up to 40% of this population (Prettyman, Cordle & Cook, 1993; Lee, Slade & Lygo, 1996; Nikcevic, Kuczmierczyk & Nicolaidis, 1998), reducing slightly to 32% at 12 weeks post-miscarriage (Prettyman et al., 1993). In particular, women report anxiety relating to possible physical complications following the miscarriage, explanations for the miscarriage and future pregnancies. Longitudinal studies report persistence of elevated anxiety for up to six months post-miscarriage (Cordle & Prettyman, 1994; Walker & Davidson, 2001), and confirm levels of anxiety are higher in women who have miscarried compared to a range of appropriate comparison groups (i.e. pregnant women, new mothers, community cohorts) (Thapar & Thapar, 1992; Beutel et al., 1995; Janssen et al., 1996). In one study (Nikcevic, Tunkel, Kuczmierczyk & Nicolaidis, 1999), the focus was to examine whether awareness of the cause of the miscarriage

influenced the anxiety experienced. They reported that all women, regardless of their level of knowledge as to the cause of their miscarriage displayed elevated levels of anxiety four-weeks post miscarriage, although this was more common in those unaware of the cause.

In addition to more generalised anxiety, Geller, Klier and Neugebauer (2002) reported rates of 3.5% compared to 0.4% for Obsessive Compulsive Disorder (OCD) in women who had miscarried and non-pregnant community controls respectively. They were unable to demonstrate increased rates of panic disorder and phobic disorders six months post-miscarriage but concluded that miscarriage may constitute a significant risk factor for an initial or recurrent episode of OCD. Further studies are required, however, with adequate comparison groups in order to determine the relationship, if any, with other anxiety disorders.

Consideration of PTSD as a consequence of miscarriage is one of the latest additions to the literature. Salvesen, Oyen, Schmidt, Malt and Eik-Nes (1997) were the first to report a case of PTSD in a woman following miscarriage. Since that time, others have gone on to cite evidence of Acute Stress Disorder (ASD) in approximately 10-15% of women during the four weeks post-miscarriage (Bowles et al., 2000; Walker & Davidson, 2001), and of PTSD in 25% of women a month after the loss and 7% after four months (Engelhard et al., 2001). In this latter study, severity of symptoms at one month was equivalent to those seen in other traumatized populations. Women reported experiencing intrusive recollections, distress when exposed to

reminders of the miscarriage, flashbacks, and feelings of helplessness. Many of these studies, however, suffer the common limitation in that they fail to include a suitable comparison group perhaps, in this case, owing to confusion over the most appropriate groups for such investigations (i.e. women who have experienced trauma unrelated to reproduction, women experiencing miscarriage at different stages of the pregnancy, women experiencing loss postpartum).

1.4 Miscarriage and grief

Differentiating grief from depression is a clinical challenge due to similarities in presentation. Recent advances in thinking have made attempts to formally distinguish grief in the context of a life event such as miscarriage from that of depression. “Traumatic grief” (Prigerson et al., 1999) describes a phenomenon distinct from normal grief or PTSD, whereby the stressor is explicitly identified as being the loss of an attachment figure (Prigerson et al., 1995). Thus, despite looking clinically similar in presentation, traumatic grief can be differentiated from depression on the basis of being characterised by a yearning for the deceased and feeling “stunned” (Prigerson et al., 1995). Studies examining the concept of traumatic grief have yet to be incorporated into the literature on miscarriage, but it offers an interesting new opportunity for examining attachment concepts in this field.

Beutel et al. (1995) made their distinction based on phenomenological criteria and theoretical considerations. They reported that grief, compared to depressive reactions, were higher immediately following miscarriage (20%

versus 12% respectively). However, depression was associated with longer term psychological, social, and health status changes. They concluded that detrimental psychological consequences occur only when the miscarriage is not mourned and women fail to experience a grief reaction.

The link between grief and miscarriage is perhaps not surprising when what is lost through miscarriage is examined. Not only does a miscarriage represent the loss of pregnancy, but also the loss of the baby, the future child and of the individual they may become. There is also the loss of parenthood, of self-esteem and of confidence in one's ability to reproduce. Frost & Condon (1996) describe aspects of grief that are unique to miscarriage sufferers, including high levels of guilt (believing that the miscarriage has occurred as a consequence of something they had done; Adolfsson, Larsson, Wijma & Berterö, 2004; Hale, 2007), loss of part of the self, and a significant impact on personal identity. These components of grief may be experienced by as many as 40% of women who miscarry (Lok & Neugebauer, 2007), although may only emerge some time after the miscarriage (Lasker & Toedter, 1991) and may be more intense the later on in the pregnancy the miscarriage occurs (Goldbach, Dunn, Toedter & Lasker, 1991). Grief has also been hypothesized as having an impact on other aspects of functioning, not least physical health (see Bonanno & Kaltman, 2001 for review). This may be particularly significant as problems with sleeping and eating, and possible somatic difficulties, for example, may prolong the physical recovery from miscarriage, which may in turn have implications for the mental recovery.

An interesting addition to the argument relating to grief and miscarriage is the effect of subsequent pregnancy on the mourning process. A common initial reaction to miscarriage is for parents to wish to become pregnant again immediately. In one report, approximately 85% of women who had miscarried fell pregnant again within 18 months of their initial loss (Cuisinier, Janssen, De Graauw, Bakker, & Hoogduin, 1996). Often, medical recommendations suggest delaying subsequent pregnancies until the psychological impact of the loss has been overcome. However, recent studies have placed a significant amount of doubt over the validity and productivity of such a recommendation due to speculations as to whether subsequent pregnancy interrupts the process of mourning, which in turn can lead to problems in forming attachments to the subsequent child (Bourne & Lewis, 1984; Armstrong & Hutti, 1998). Others have argued that parents may become overly protective of the subsequent child; a phenomenon dubbed the “vulnerable child syndrome” (Green & Solnit, 1964), or may view the subsequent child as a replacement of the lost baby, suffering from “replacement child syndrome” (Cain & Cain, 1964). Studies have also shown that prior experience of miscarriage can make women feel more emotionally guarded and anxious about subsequent pregnancies (including being hypervigilant and seeking reassurance; Côte-Arsenault & Mahlangu, 1999; Côte- Arsenault, Donato & Earl, 2006; Tsartsara & Johnson, 2006) and are more likely to appraise the subsequent pregnancy as a threat (Côte-Arsenault, 2007). This has also been shown to be true for the male partners of women who have a history of miscarriage (Conway & Russell, 2000; Armstrong, 2002).

The elevated levels of depression (Franche & Mikail, 1999) and anxiety (Thapar & Thapar, 1992; Janssen et al., 1996; Armstrong & Hutti, 1998) that have been reported in women with a history of reproductive loss have been shown to be significantly associated with high levels of self-criticism (personal responsibility), low levels of dependency and a higher number of previous losses (Franche & Mikail, 1999). Self-critical thinking has also been shown to be an important predictor of the intensity of grief experienced by both women and their male partners during subsequent pregnancy (Franche, 2001) affecting not only levels of despair but also ability to cope.

Contrary to these studies, and far from being detrimental to the process of grieving, are a number of studies suggesting that subsequent pregnancy may actually have a positive effect on mourning. Theut, Pedersen, Zaslow, Rabinovich (1988) suggest that becoming pregnant again may assist in the resolution of mourning by improving a woman's self-concept. This may also be true for the partners of these women (Theut, Pedersen, Zaslow, Cain, Rabinovich & Morihisa, 1989) and has been shown to have longitudinal effects up to 2 years post-loss (Cuisinier et al., 1996; Lin & Lasker, 1996). Franche and Barlow (1999) studied the specific components of grief and emotional adjustment in pregnancy following previous miscarriage. They found lower levels of self-reported despair and difficulty coping with grief in those women who had become pregnant following a perinatal loss, compared to those women who had not subsequently become pregnant. There was no difference in levels of grief intensity, anxiety or depression between groups of fathers. Overall, levels of active grief, difficulty coping with the grief, anxiety,

and depression were higher in women compared to men. What these studies suggest is that pregnancy following miscarriage may be associated with restorative effects on both women and their partners, and that the grieving process is able to continue despite the subsequent pregnancy.

1.5 Risk factors for psychological distress following miscarriage

Studies aimed at exploring risk factors for psychological distress following miscarriage are sparse but have identified certain demographic factors such as age (Neugebauer, 2003), previous psychiatric history (Franche, 2001), and reproductive history (Brier, 1999) as potential candidates. A number of risk studies have also alluded to the fact that male partners of women may also be at risk for psychological distress following miscarriage, including grief and stress (Lasker & Toedter, 1991; Johnson & Puddifoot, 1996; Murphy, 1998; Conway & Russell, 2000), loss and anger (Miron & Chapman, 1994) and anxiety (Daly & Harte, 1996) (with symptoms persisting for up to two months post-miscarriage: Vance, Boyle, Najman & Thearle, 1995). Despite these studies, as a field of research in its own right, it remains one of the most significantly neglected areas to date.

Further information on risk factors:

Demographic factors: Studies are inconsistent in ascertaining whether certain demographic variables such as age, occupational or educational status, or social class have a role to play in mediating the relationship between miscarriage and psychological difficulties. Neugebauer (2003) reported higher risk in younger women with a history of reproductive loss, but claimed that risk

level did not vary according to the number of living children, marital status, ethnicity or educational level. Others, however, have reported the psychological effects of miscarriage to be substantially worse in those women who do not have prior children (Neugebauer, et al., 1992b, 1997; Janssen, Cuisinier, De Graauw & Hoogduin, 1997). Variations across studies may be due to differences in methodologies and measures used.

Personal psychiatric history: Prior contact with health care services for the presence of psychological symptoms has been a more reliable risk factor identified in the literature (Slade, 1994; Hunfeld Wladimiroff, Verhage & Passchier, 1995;). In one example, Neugebauer et al (1997) described how 54% of a population of women who had miscarried, who also had a history of major depression, experienced a recurrence of the disorder following their miscarriage. This emphasises the importance not only of assessment of current psychological well being but also past histories of women presenting with miscarriage.

Reproductive history: Within this category fall potential risk factors including a strong desire for the pregnancy, taking a long time to conceive, experiencing few warning signs of the loss, and a loss later in the pregnancy (Brier, 1999). Gestational age is emerging as a particularly controversial risk factor. Whilst some have reported a positive association to risk of depression (Janssen et al., 1996; Neugebauer et al., 1992b), others have reported a negative association (Thapar & Thapar, 1992). Others still have reported no association whatsoever (Neugebauer et al., 1997; Klier et al., 2000). Where a

link has been made, suggestions are around greater gestational age being associated with stronger attachments to the foetus and more pregnancy symptoms. Similarly inconsistent are studies examining maternal attitudes towards pregnancy and the miscarriage. Higher feelings of personal responsibility and lower personal resources (i.e. self-esteem and self-efficacy) have been linked to higher levels of anxiety and depression (Nikcevic et al., 1998). In turn, this study showed a link between higher self-esteem and lower personal responsibility. Others, however, have failed to establish any such associations (Neugebauer et al., 1997). Such variation in results makes it difficult to draw any firm conclusions with regard to risk factors associated with reproductive history. However, it remains a thought-provoking area of research, with interesting links to psychological / attachment theory (see appendix 1.9).

Risk factors for psychological distress associated with subsequent pregnancy are also interesting in making links with reproductive variables, particularly time since the miscarriage. Hughes, Turton and Evans (1999) studied women who had prior experience of miscarriage compared to those without such a reproductive history. Not only did they report a higher incidence of depressive symptomatology and state-anxiety in those women with a history, as measured by the Beck Depression Inventory (BDI: Beck, Ward, Mendelson, Mock & Erbaugh, 1961), Edinburgh Postnatal Depression Scale (Cox, Holden & Sagovsky, 1987) and the State and Trait Anxiety Inventories (Spielberger, 1983), particularly during the third trimester of pregnancy and for the year following the birth, but also that it was women who had conceived within the

first year post-miscarriage that accounted for the difference between groups. Those who conceived at some time point after the first year had comparable levels of symptomatology to controls, restoring faith in the argument to recommend couples to wait before entering into subsequent pregnancies. The debate continues, however, until more thorough and conclusive research is conducted.

1.6 Variations in the psychological impact of miscarriage according to different treatment options

The majority of the literature in this area is presented in the research paper. Nielson and colleagues (1996) have been amongst the first to examine whether psychological impact of miscarriage varies according to the treatment option chosen by women. Using the State-Trait Anxiety Inventory (Spielberger, 1983), they reported no significant differences in anxiety levels between women randomly assigned to either expectant or surgical treatment 14 days after miscarriage. Furthermore, Lee and colleagues (2001) reported that, at a two-week and six-week follow-up, there were no significant differences between groups of women randomly assigned to either surgical or medical treatment in terms of social functioning (as measured by the Social Performance Schedule; Hurry, Bebbington & Tentoni, 1987), psychological well-being (as measured by the General Health Questionnaire; GHQ-30 Goldberg, 1978), depression (as measured by the BDI; Beck et al., 1961), or levels of fatigue (as measured by the Fatigue Scale; Chalder, Berelowitz, Pawlikowska, Watts, & Wessely, 1993). Comparable GHQ-30 and Fatigue

Scale scores between groups were also obtained at a 6-month follow-up (data not available on the other measures used in previous follow-ups).

1.7 Miscarriage and male partners

Of the limited studies available, male responses to miscarriage have been described as ranging from desperate sadness to feeling personally unaffected, and from empathetic concern for their partner to resentment (Puddifoot & Johnson, 1997). Reports also include an increased awareness of mortality, loss of hopes and aspirations for family life, feeling vulnerable and powerless and fearful of partner's physical well being (Speraw, 1994; Samuelsson, Rådestad & Segesten, 2001). Despite these reports, there is generally a lower expectation of intense emotional response to miscarriage in men which often results in neglected needs and failure to provide support and understanding (Murphy, 1998; Conway & Russell, 2000). A consequence of this may be that men are placed at increased risk for a more adverse psychological outcome than may occur if they are offered comparable levels of support as the women themselves (Lasker & Toedter, 1991).

Studies have alluded to the potential for male partners to experience equivalent psychological distress to women following miscarriage (Puddifoot & Johnson, 1997). Although existing research into this phenomenon is currently limited, what does exist has focussed more intently on the differential impact or expression of psychological distress between men and women. Attachment theory offers interesting insights into this, which will be discussed in more detail in appendix 1.9. However, alternative explanations have been proposed

with more social origins. For example, whereas women may respond by wishing to talk openly about their experiences, men reportedly appear to prefer dealing with their psychological distress internally (De Frain, Millspaugh & Xie, 1996) and may consequently experience a less intense and extended grief reaction compared to their partners (Beutel, Willner, Deckardt, Von Rad, & Weiner, 1996; Serrano & Lima, 2006). Men reportedly also have a tendency to suppress or deny their feelings of grief (Zeanah, 1989), possibly more so in the presence of their partner if they are concerned about their well being over and above their own. There are a few commentaries documenting specifically how, to men, the baby feels less real prior to birth and therefore their greatest concern during pregnancy is towards the well being of their partner (Miron & Chapman, 1994; Murphy, 1998). Consequently, their own emotional response is often thought to be influenced by that of their partner's.

In relation to expression of grief, Tudehope, Iredell, Rodgers & Gunn (1986) reported women's symptoms to include sleep problems, depression, anorexia, weight loss, social withdrawal, guilt, anger and hostility, a morbid preoccupation with the baby, and psychosomatic symptoms. In comparison, symptoms for fathers included an inability to work, guilt, anger and hostility, denial of the death, alcohol abuse and social withdrawal (see also Vance et al., 1995). Despite different presentations, Hunfeld, Mourik, Passchier & Tibboel (1996) reported no significant differences in intensity of grief between mothers and fathers.

No studies exist to date examining alternative configurations of partner (i.e. female partners in lesbian relationships).

1.8 Existing services and satisfaction with care

As it stands, hospital services in response to miscarriage have undergone significant changes in recent years, with the introduction of alternative means of treatment (i.e. medical outpatient). However, these changes have occurred with little research being conducted alongside them to assess levels of patient satisfaction. Indeed, examination of services as they currently exist provides little evidence that their management reflects enough of the existing clinical and academic literature pertaining to the psychological consequences of miscarriage. Some of the main complaints expressed by women attending clinics revolve around physician insensitivity and lack of opportunity to discuss the personal significance of their loss (Brier, 1999).

Conway & Russell (2000) found that support from health professionals was less than optimal according to the majority of women and their partners. Only one-third of women, and even fewer partners (18%) were asked how they were coping by health professionals. This compared to 70% and 46% of women and partners respectively wanting to be asked. Furthermore, only 34% of women and 29% of partners were provided with an explanation of their miscarriage. No explanation was provided to 26% of women and 39% of partners. For the remainder, no explanation was possible. This has led some to suggest that psychiatrists, psychologists, nurses and social workers should be available to assist general practitioners and obstetricians to understand

and be sensitive to the impact of miscarriage (Rosenfeld, 1991; Conway, 1995). It also further highlights the neglect of partners in the management of miscarriage from a health professional perspective. This dissatisfaction has been reported with respect to both primary level and hospital services (Lee & Slade, 1995).

In the report by Brier (1999), levels of satisfaction were highest when women were offered follow-ups with a focus on answering their questions and giving them time to focus on their feelings. Being given this opportunity may allow women to better regulate their distress and ameliorate the psychological distress encountered. It may also allow women to develop an understanding of why the miscarriage occurred, which has been shown to facilitate a sense of control (Epstein, 1991), decrease blaming behaviours (James & Kristianson, 1995), and lessen the experience of intrusive thoughts surrounding the loss (Tunaley, Slade & Duncan, 1993). Furthermore, follow-up appointments may be useful to clarify much of what women felt confused and uninformed about during their initial hospital contact. In one study (Wong, Crawford, Gask & Grinyer, 2003), women described the need for more information and specific answers regarding the possible implications of their miscarriage as well as normalisation of the miscarriage from health professionals. More effective communication overall was thought to be important in assisting women who were experiencing guilt and false assumptions about the cause of their miscarriage.

Preliminary results suggest that psychological debriefing (crisis intervention) or, at the very least, more thorough assessment of emotional adaptation to miscarriage may not only be desired by women (Lok & Neugebauer, 2007), but may also be useful as an integral part of medical services in order to support women through this difficult time (Lee et al., 1996). This may be as simple as incorporating routine application of screening measures six to eight weeks after miscarriage to identify women who may require psychological intervention (Lee et al., 1997). Similarly, offering a caring-based counselling approach has been shown to have a positive and significant effect on the impact of miscarriage and enhancement of well being in the first year following a loss by miscarriage (Swanson, 1999).

What these studies highlight is that, despite recent changes, there remains a gap in services where women's (and men's) needs are not being met. Furthermore, development of services does not appear to take into account an evidence-base of literature emphasising the need for follow-ups focussed on assessment of psychological as well as physical health.

1.9 Attachment theory and miscarriage

One means of examining the psychological impact of miscarriage is to consider the framework provided by attachment theory (Bowlby, 1969). Derived from psychoanalytical principles, this theory introduced the concept of biologically determined attachment behaviours that develop between an infant and their primary caregiver and which function to regulate proximity to an attachment figure for the purposes of survival. Although much of the work

born out of this theory concentrates on the neonatal period (birth onwards) (Bowlby, 1969; Sugarman, 1977), more recent considerations have evolved to include the prenatal period (before birth) (Muller, 1992). Peppers & Knapp (1980) documented how the development of attachments prior to birth occurs through experience of the following events: 1) planning the pregnancy, 2) confirming the pregnancy, 3) accepting the pregnancy, 4) feeling fetal movement, 5) accepting the fetus as an individual, 6) giving birth, 7) seeing the baby, 8) touching the baby, and 9) caring for the baby. Rubin (1975) also states that: “the bond between a mother and her child that is so apparent immediately at the birth of her child is developed and structured during pregnancy. At birth there is already a sense of knowing the child....of shared experiences, shared history, and shared time on an intimate and exclusive plane” (p.149).

Within his original theoretical standpoint, Bowlby discussed how attachments could be potentially disrupted in the context of loss. However, this again emphasised the process occurring in the post-natal period. Others have integrated independent theories to support the proposition that the extent of attachment to the *unborn* child may moderate the experience of women who miscarry (Klaus & Kennell, 1976). Accordingly, when a miscarriage is experienced, development of potential attachment bonds are interrupted and lost. Given that the scope and intensity of attachments developed during pregnancy are likely to vary across women, due to differences in social circumstances, acceptance and expectations of pregnancy, and implications of having a child (Robinson, Baker & Nackerud, 1999), there is likely to be

corresponding variations in the experience of loss. This suggests it would be beneficial to assess attachments that parents may have developed during pregnancy in order to establish risk for detrimental psychological consequences of miscarriage.

With regard to attachment theory and the experience of miscarriage from the partner's perspective, it has been proposed that the attachment a father develops during pregnancy lags slightly behind that of the mother, most notably at the beginning of the pregnancy, and less so as the birth approaches (Goldbach, Dunn, Toedter & Lasker, 1991). May (1982) attributes this to the noticeable physical changes in the mother occurring towards the end of pregnancy. Given that the majority of miscarriages occur in early stages of pregnancy, this may account for any discrepancies in attitudes towards pregnancy and the unborn fetus. Studies have also commented on how fathers are more separate (both physically and psychologically) from the baby prior to birth compared to the mother (Leon, 1992). Comparatively, mothers view the baby as part of themselves (Furman, 1978) and so may be more likely to experience more intense emotional reactions as a consequence of miscarriage.

Word count: 4, 601

Appendix two

Methods

2.1 Methodological issues in studies of the psychological impact of miscarriage

A comprehensive review of the available literature on the psychological impact of miscarriage is complicated by the fact that available studies, limited as they are, suffer from wide variations in the methodology they apply. Despite some consistencies, many use different measures to define and assess the presence or absence of mental health difficulties. This prevents direct comparisons in data being made and elicits caution when drawing conclusions. In addition, symptomatology is often assessed at different time points following miscarriage, ranging from within the first two weeks up until two years post-loss (with some measuring symptoms longitudinally at a selection of time points during this period). Although this again complicates making comparisons and drawing conclusions, it also highlights that any psychological impact of miscarriage on women is potentially both short and long-term. Probably one of the most pervasive methodological criticisms, however, comes from studies using either inappropriate or non-existence control groups. When evaluating the consequences of an event such as miscarriage, it would be ideal for the purposes of interpretation and generalisability to include control groups that allow for establishing whether observed phenomenon are directly related to the miscarriage itself or whether they are, for example, characteristic of women of reproductive age in general. Many of the existing studies can be criticised for this reason, as they are restricted to recruiting a single cohort of women who have recently

experienced a miscarriage, with no comparison group. The previous review of existing literature contains studies that are based on this methodology, but where possible also includes the few studies that have included suitable comparison groups (i.e. otherwise similar women who have not experienced miscarriage).

Despite being the ideal, there are a number of methodological and practical complications to including appropriate control groups. Firstly, it is not always clear what the most appropriate control group would be (i.e. women who have miscarried later in pregnancy / post-birth, women who have terminated their pregnancy, women who have experienced trauma unrelated to reproduction). Secondly, such populations are not always easy to recruit into research studies due to ethical considerations and women's own experiences and distress levels. For the purposes of the current study, a control group was not recruited due to some of these difficulties and as a result of the nature of the study being exploratory and due to being a preliminary investigation into treatment choice and psychological impact. As will be observed, discussion of possible future directions of this study includes consideration of possible future control groups. With this in mind, discussion of current results therefore takes place with any conclusions being drawn in the context of the aforementioned caveats.

2.2 Study aims

The current study is designed to address some of the existing gaps in the literature by primarily addressing the question of whether offering a choice in

miscarriage treatment has implications in terms of the psychological well being thereafter of both women and their male partners. Through doing this, information will be obtained on the psychological factors that underpin women's choices in treatment, and how experiences vary accordingly.

The study is aimed at developing a greater understanding of the implications of offering women a choice in their miscarriage treatment in order to consider results in the context of service development and potential changes to the standard treatment approaches adopted by medical professionals. It is also designed to complement existing medical information given to women about the different treatment options and to inform services with regard to the information that women need on the potential psychological consequences of their treatment. This will allow for a more comprehensive and evidence-based pool of information on which women can make their treatment choice.

Given the limited amount of available literature in this specific area, this research was driven less by specific hypotheses (i.e. predictions with regard to the direction of the results) and more by specific research questions and the interests and needs of the existing service. These questions were set out in the research paper.

2.3 Participants

According to standard procedures of the unit, women arriving at the Early Pregnancy Assessment Unit with a suspected miscarriage are informed by nursing staff about the different treatment options available to them on their

first visit to the EPAU (day one). Having been informed of the different options, they are then asked to return to the unit on the following day to inform staff of their decision and to initiate their chosen treatment programme (surgical, medical treatment as an inpatient, medical treatment as an out-patient, or expectant treatment). On this occasion (day two), all women meeting inclusion criteria were provided with details of the study, including a consent form and information sheet informing women of the aims, purpose and procedures of the study. This information was distributed by nursing staff on the unit. Any questions specifically about the study that women had before providing their consent were addressed either by the nursing staff at the EPAU if possible, or the consultant gynaecologist leading the study. Women who signed the consent form were then provided with a diary to complete over the following two weeks (see appendix 2.4), along with a demographics form (see measures section) to also take away and complete. These items were also distributed by the EPAU nursing staff. Women were requested to return completed diaries and demographic forms to the research team, based within the Behavioural Sciences Department of the Queen's Medical Centre, Nottingham.

Women who had medical reasons to be recommended one treatment option over another, according to their consultant gynaecologist, were included, but with the reasons for treatment recommendation noted and taken into account during the data analysis and interpretation of the study.

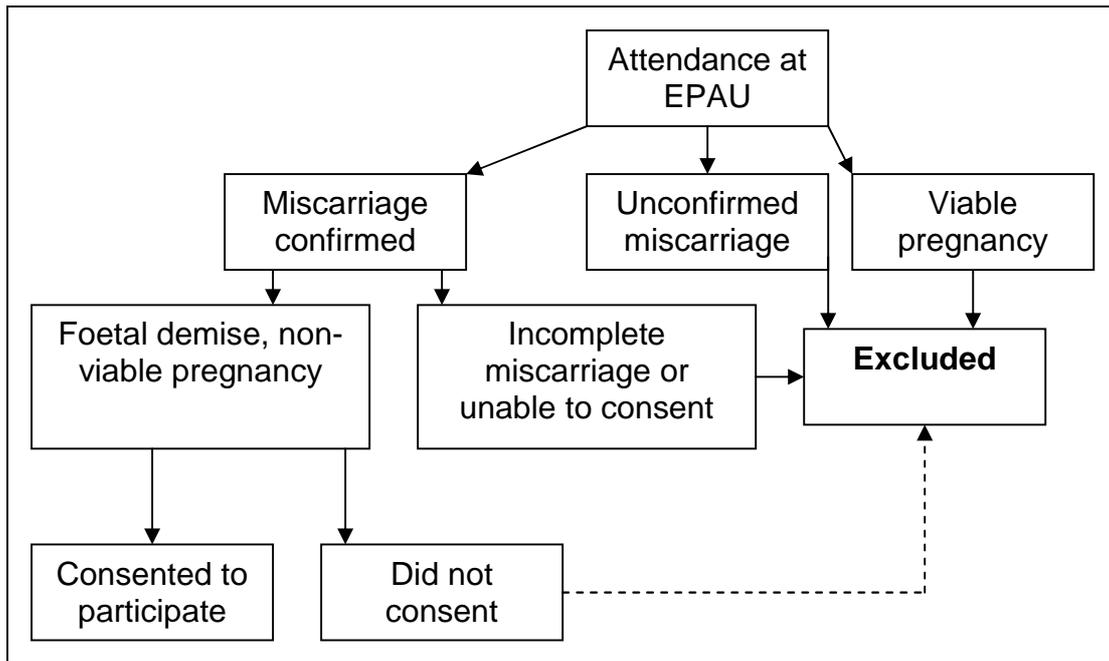


Figure 1.1: The study recruitment process

Diagnosis of miscarriage: definitions:

Foetal demise / non-viable pregnancy: Foetus identified (greater than 6mm) but no heartbeat detected. Additionally, when pregnancy is anembryonic (empty sac detected greater than 2cm, but with no or minimal structures).

Incomplete miscarriage: Non-viable pregnancy been diagnosed, expectant treatment given but there are retained products of conception at next scan (i.e. sac, thickened endometrium). At this point women are offered additional treatment (i.e. medical, surgical) and can be invited to participate in the study.

(The Royal College of Obstetricians and Gynaecologists Green top guideline, 2006).

As a consequence of outpatient medical treatment being a recent introduction to the hospital, it was unclear prior to the start of the study how many women attending the EPAU would opt for this, compared to other options. Based on historical treatment preferences and anecdotal evidence, it was expected that the majority of women would opt for either surgical or in-patient medical treatment. According to hospital statistics, approximately 20 women attending the EPAU are diagnosed with having had a miscarriage each week. Based on an anticipated 50% of these women being willing to initially participate in the study ($n = 10$), and a further 50% of this smaller population completing the full assessment ($n = 5$) it was anticipated that it would be possible to recruit approximately 260 women over a one-year period. The figure of 50% recruitment success rate is drawn from previous experience of the consultant gynaecologist and research team recruiting such a population.

Power analysis

No existing data was available on which to calculate accurate effect sizes and power analysis prior to the beginning of the study. Consequently, determining the appropriate sample size for the project was done on the basis of wishing to obtain medium – large effect sizes and achieving a power of 80% (Clark-Carter, 2001). Using the analysis anticipated for the primary outcome measure of GHQ-12 scores (repeated measures ANOVA), it was calculated that to achieve a medium effect size of 0.059 (Cohen, 1988) it would be necessary to recruit just over 50 individuals ($df = 2$). To yield a large effect size of 0.138, a sample of between 20 and 25 individuals would be required to produce an equivalent 80% power. If it turns out to be necessary to conduct

non-parametric analyses on the data due to not conforming to the conditions of parametric analysis, it is likely that the non-parametric equivalent (Friedman's test) will be more powerful (Clark-Carter, 2001). Power of the Friedman's test was considered relative to that of its parametric equivalent but depends on the number of levels of the independent variable. In this case, the independent variable had four levels (number of treatment options) and so the suggested sample size of 50 (for a medium effect size) can be multiplied by 1.31 (see Clark-Carter, 2001 pp. 480) to produce a desirable sample size of 65.5 (66) for 80% power. For a large effect size, this would be reduced to between 26.2 - 32.8 (26-33). Consequently, the objective of the study was to recruit between 100 and 150 women (and partner's if applicable) collectively based on achieving large effect sizes.

Actual numbers:

Analysis of the appointment books maintained by the EPAU over the course of the study (03.10.2006 to 23.09.2008) indicated that 3,237 women attended the unit. According to hospital records, these women would have been attending the unit for a number of reasons in addition to suspected miscarriage, including viable pregnancy and monitoring. In order to obtain the number of women who would have been eligible to participate in the study, two samples were selected at two independent time points over the course of the total study duration to obtain proportion data. From these figures, an estimate was then obtained to indicate the number of eligible women. It was not possible to obtain accurate numbers due to the nature of the unit's records and restricted resources being available to gather the necessary information

for all 3, 237 women who attended the unit over the course of the study. In this instance, eligible women were those with a diagnosis of non-viable pregnancy (i.e. foetal demise) or incomplete miscarriage (see above definitions). Non-eligible women at this stage were those whose scan revealed a viable pregnancy (live foetus). These sample populations produced the following proportion data:

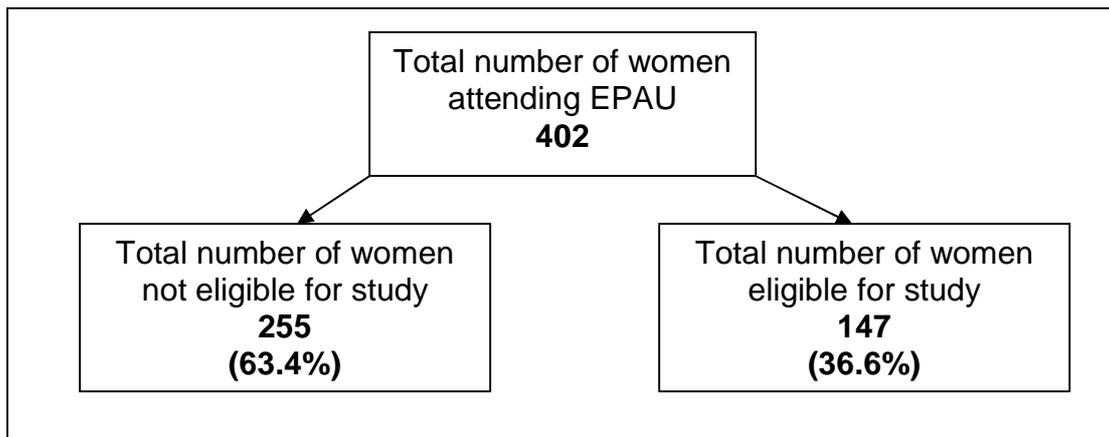
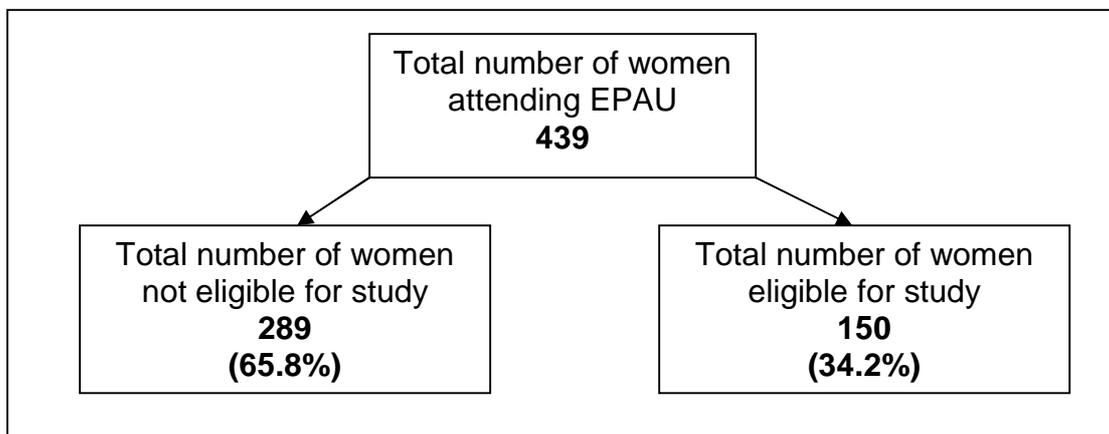


Figure 1.2: Proportion data (03.10.2006-18.12.2006)



1. 3: Proportion data (03.10.2007-18.12.2007)

In order to establish an estimate of the overall number of women eligible for participation in the study, an average was obtained from the percentages from each of the two samples for both eligible and non-eligible women. This produced percentages of 35.4% and 64.6% respectively.

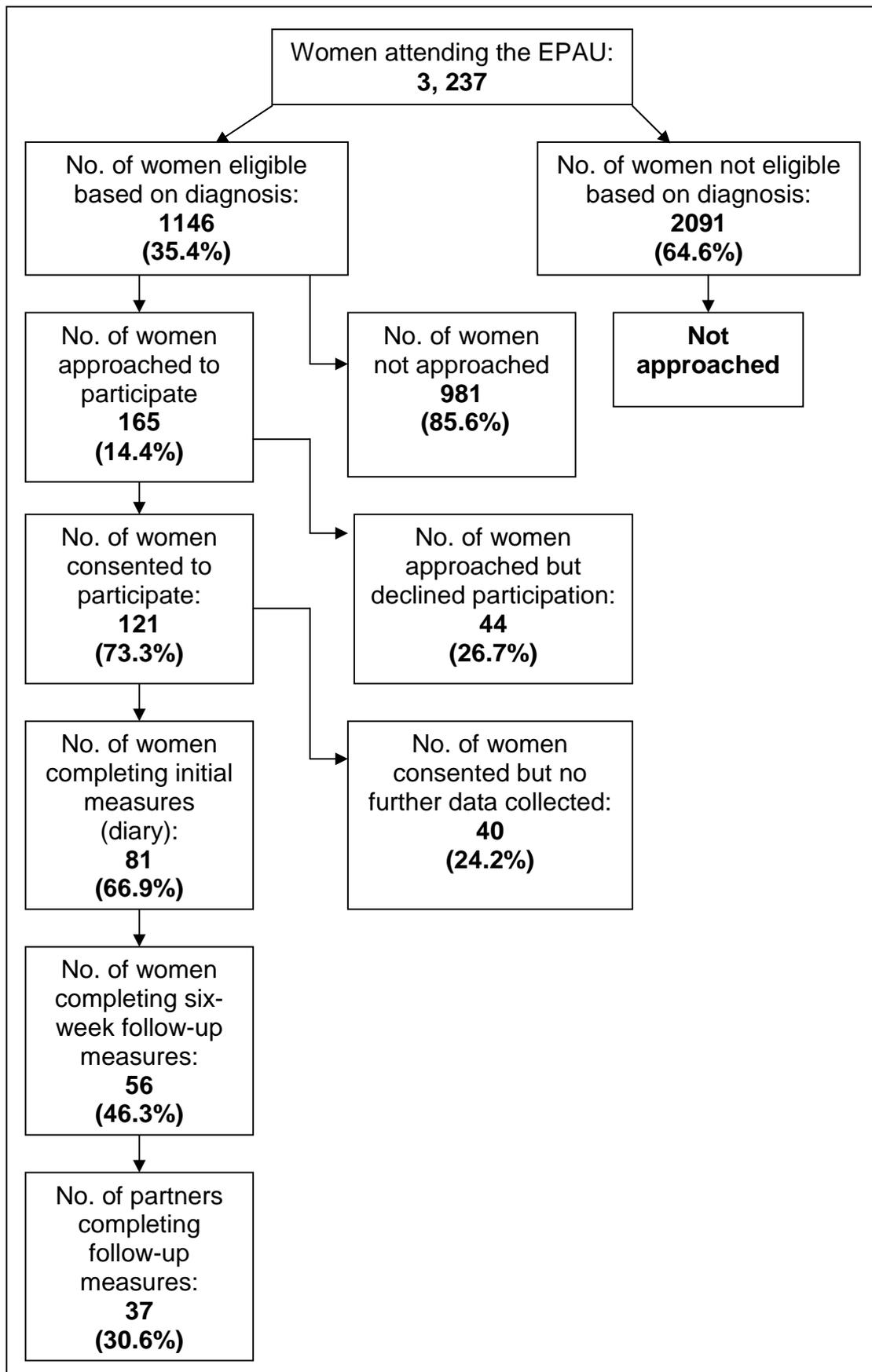


Figure 1.4: Recruitment numbers (percentages of participants in study are calculated based on number of women consented to participate)

Information sheets and consents forms were distributed by EPAU nursing staff to all women approached about the study (see below).



PATIENT INFORMATION SHEET

Women's experiences of the treatment of miscarriage.

'You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.'

Thank you for reading this.

What is the purpose of the study?

When an ultrasound scan shows that you have a miscarriage, you will be asked to choose how you would prefer the miscarriage to be treated. Women have been offered surgical treatment (a "scrape" or D&C) for many years. More recently, admission to hospital for medical treatment (where tablets are used to bring about the miscarriage) and expectant treatment (where you go home and wait for the miscarriage to occur naturally) have also been offered. We have recently introduced another choice - medical treatment without admission to hospital with the miscarriage taking place at home.

We do not want to influence your choice of treatment, but we would like to find out the reasons why women make that choice, and how well the treatment goes for them.

If you would like to take part the study lasts six weeks. First, you will be asked to fill out an "experience diary" for the first two weeks. This should take no more than five minutes each day. These diaries should be returned in the freepost envelope provided or to the Early Pregnancy Unit. As part of our usual follow-up after a miscarriage, we will ask you if you have been able to complete and return the questionnaires.

You will also be asked to fill out a second questionnaire that we will send to you by post at six weeks. This will ask about how you are feeling and what has happened to you. At this time we will also send a questionnaire for your partner (if this applies). It is entirely up to you whether or not you pass this on. These questionnaires will take about fifteen minutes to complete, depending on how many comments you wish to make. Please return all questionnaires as soon as possible after completing them in the freepost envelope provided. When we contact you as part of your follow-up, we might remind you to send the questionnaires back.

Why have I been chosen?

You have been chosen because a diagnosis of miscarriage has been made and you have decided what treatment you want.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to

withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What will happen to me if I take part?

If you choose to take part you will have the treatment and follow-up in the normal way. You will not have to make any extra visits to hospital, just fill out the questionnaires and return them using the freepost envelopes provided.

What are the possible benefits of taking part?

It is unlikely that taking part will be of direct benefit to you at this time, but we hope that the information we get from this study will help us look after women with miscarriage even better in the future.

Will my taking part in this study be kept confidential?

All information that is collected about you during the course of the research will be kept strictly confidential. If you consent to take part your medical records may be inspected by the Early Pregnancy Unit Staff, or the team analysing the questionnaires.

Your GP will be told that you are taking part in this study

What will happen to the results of the research study?

We hope that the results of this study will be published in a medical journal. You will not be identified in any report or publication.

What if there is a problem?

If you are unhappy with any aspect of your involvement in this study or encounter problems with the study please contact:

The Corporate Affairs Office,
Nottingham City Hospital
NG5 1PB tel. 0115 962 7749

Contact for further information

If you require help or more information, please contact:

Mrs Nicky Lindley, Mrs Linda Ahmed or Dr Judith Moore in the Early Pregnancy Unit
Tel. 0115 9691169 ex 57769

Thank you for reading this whether or not you wish to take part.



CONSENT FORM

Project Title: Women's experiences of the treatment of miscarriage.

Site: Nottingham City Hospital

Study Number

Investigators: Dr Judith Moore in the Early Pregnancy Unit. Professor Cris Glazebrook, Mrs Charlotte Sheard, Dr Sara Cox, and Dr Zoë Kyte in University of Nottingham

The patient should complete the whole of this sheet herself.

Please tick the boxes if you agree

- I have read & understood the patient information sheet (version 4, March 2007)
I have had the opportunity to ask questions & discuss the study
All my questions have been answered satisfactorily
I have received enough information about the study
I have spoken to Dr/Mrs/Ms
I understand that I am free to withdraw from the study
at any time
without having to give a reason
without affecting my future medical care
I agree to take part in the study

Signature (Patient)

Date

Name (In block capitals)

I have explained the study to the above patient and she has indicated her willingness to take part.

Signature (Investigator)

Date

Name (In block capitals)

2.4 Measures

In addition to the details provided in the research paper, further details on measures included in the study are as follows:

Demographics: At the outset, women were asked to complete a demographic form, which contained information on marital status, level of education, employment status, ethnicity, number of children, and previous experience of miscarriage. This information was used to characterise the diversity of population recruited.

Miscarriage diary: Included along with the possible contributing factors in treatment choice, this section also included the opportunity for collecting qualitative data on additional factors not included in the pre-existing list that may have contributed to their decision.

STAI: Marteau & Bekker (1992) described how the most highly correlated anxiety-present and anxiety-absent items were combined and correlated with scores derived from the 20-item version of the measure. Reliability and validity of the 6-item version have been shown to be similar to those obtained for the original version (Marteau & Bekker, 1992). In addition to presented psychometric properties, the six-item version has also been shown to be sensitive to fluctuations in state anxiety (Marteau & Bekker, 1992).

Qualitative comments: At the end of the diary and at the six-week follow-up, women were invited to make any additional comments pertinent to their experience of the miscarriage. This came in the form of a free text box. Partners were invited to do the same in their six-week follow-up.

Six-week follow-up – women: Specific questions were also included on: duration of bleeding following the miscarriage, complications experienced

following the miscarriage, duration off work (if applicable), and what support services they would have found valuable following the miscarriage.

Six-week follow-up – women and partners: Participants were invited to make any additional comments at the end of the follow-up relevant to their experience of miscarriage and/or treatment.

An originally constructed diary was necessary for this project as a result of no existing measure being available that measured the specific interests of the current study. This provided the opportunity to tailor the diary precisely to the specific research questions set out at the beginning of the study. The diary used in this phase of the existing study had been used in the previous phase of data collection, which provided the opportunity to pilot the measure and make any necessary adjustments. Through this opportunity, it has been possible to demonstrate the capacity of the diary to be an accurate and useful tool for measuring the desired variables, both on a qualitative and quantitative basis. Consequently, no modifications were made to the diary across phases of the study.

Standardised measures were chosen over and above alternative measures of the same construct based on the existing evidence-base for their psychometric properties and use in populations experiencing symptoms comparable to those being explored in the current study. Shorter versions of the STAI and GHQ were specifically selected due to the lengthy nature of the overall commitment for women and their partners participating, particularly

given the difficult and emotional time being experienced by individuals at the time of involvement.

Complete copies of measures are included as follows:

- i) Demographics form
- ii) Miscarriage diary
- iii) Six-week follow up - women
- iv) Six-week follow up - partners

Early Pregnancy Assessment Unit

Nottingham City Hospital

WOMEN'S EXPERIENCES OF THE TREATMENT OF MISCARRIAGE

Study Number:

Thank you very much for agreeing to take part in this study. We would like to start by asking you a little bit about yourself.

The date you first attended the Early Pregnancy Assessment Unit:

Your Date of Birth:

Now we would like to ask you some questions about your previous medical history.

Have you ever had a miscarriage before (please tick as appropriate)?

- Yes
 No

If you have had a miscarriage before, what treatment did you receive (please tick as appropriate)?

- No treatment
 Medical treatment (tablets/medicine but no surgery)
 Surgical treatment

Now a question about this miscarriage.

What treatment are you hoping to have for this miscarriage (please tick as appropriate)?

- No treatment
 Medical treatment at home (tablets/medicine but no surgery)
 Medical treatment in hospital (tablets/medicine but no surgery)
 Surgical treatment

Now we would like to ask you some questions about yourself

What is your marital status (please tick as appropriate)?

- Married / living with partner
 Single
 Divorced / separated

What is your ethnic background (please tick as appropriate)?

- White European
 Asian / Asian British
 Black / Black British
 Chinese / Chinese British
 Other

Do you have any children (please tick as appropriate)?

<input type="checkbox"/>	Yes
<input type="checkbox"/>	If yes, how many?
<input type="checkbox"/>	No

What is your current occupation?

Do you work (please tick as appropriate):

<input type="checkbox"/>	Full time
<input type="checkbox"/>	Part time

If you are not currently working outside the home, what was your most recent occupation?

What is your highest educational level (please tick as appropriate)?

<input type="checkbox"/>	GCSE / O-Level
<input type="checkbox"/>	A-Level/ GCE / Scottish higher / International Baccalaureate
<input type="checkbox"/>	GNVQ
<input type="checkbox"/>	NVQ
<input type="checkbox"/>	Diploma
<input type="checkbox"/>	HND
<input type="checkbox"/>	Degree
<input type="checkbox"/>	Postgraduate qualification
<input type="checkbox"/>	Other (please specify):

Thank you for answering these questions at this difficult time. Now we would like you to look at the diary you have been given. Please could you return this questionnaire in the freepost envelope provided, along with your completed diary.

Diary

Women's experience of the treatment
of miscarriage

Study number _____



The University of
Nottingham

Nottingham City Hospital **NHS**
NHS Trust

Version 2 October 2007

Introduction to your diary

We appreciate that this is a difficult time and we are very grateful to you for agreeing to fill in this diary. Your answers will help us to improve the service of the early pregnancy unit in the future.

First of all we would like to ask you about what factors were important to you when you made your decision about which treatment to have. Please circle the appropriate number next to each factor to indicate how important it was to you, as shown in the example over the page. We have also left space for you to tell us about any other factors which influenced your decision.

You should fill in your diary every evening for 14 days. For each day we would like you to complete the short questionnaire by circling the appropriate number as shown in the example over the page. Then we would like you to put a mark on the line which represents how much pain you have experienced that day and the same for how much bleeding. Again examples are shown over the page.

We have left a space at the bottom for you to record your experience of miscarriage in your own words, if you would like to. We would be particularly interested in your views on the treatment you have received, for example any information that you feel you would have found useful.

Best wishes

**Judith Moore (Consultant)
Nicky Lindley (Nurse Practitioner)
Linda Ahmed (Staff Nurse)**

Example

Below are a number of statements which may have been important in your decision about which treatment to have for your miscarriage. Read each statement and then circle the most appropriate number to the right of the statement.

	Major factor	Strong factor	Minor factor	Not a factor
I wanted to get back to work as quickly as possible	1	2	3	4
I have no one to help look after my other children	1	2	3	4



Please rate the importance of the following factors in your decision about which treatment to choose

	Major factor	Strong factor	Minor factor	Not a factor
I wanted to get back to work as quickly as possible	1	2	3	4
I have no one to help look after my other children	1	2	3	4
I wanted to avoid staying in hospital	1	2	3	4
I wanted to avoid an operation	1	2	3	4
I wanted to avoid having an anaesthetic	1	2	3	4
Advice from my family	1	2	3	4
Advice from staff at the Early Pregnancy Assessment Unit	1	2	3	4
I was scared of miscarrying on my own	1	2	3	4
I was scared I would bleed heavily	1	2	3	4
I was frightened of seeing the miscarriage	1	2	3	4
I chose what seemed the most natural treatment	1	2	3	4
I thought this would be the least painful treatment	1	2	3	4

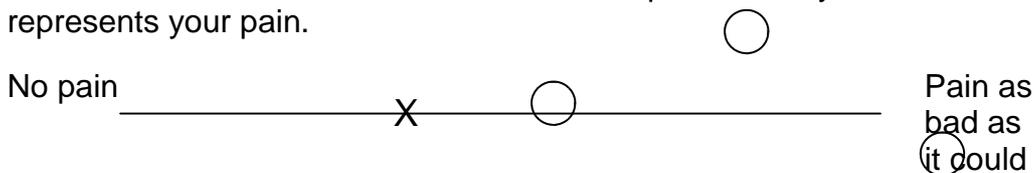
Example Page

Some questions about how you feel at the moment

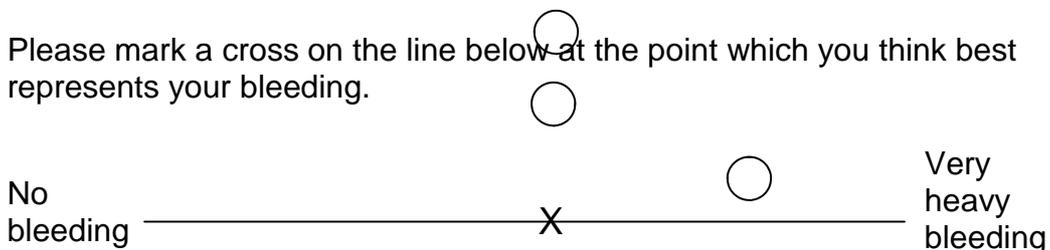
A number of questions which people use to describe themselves are given below. Read each statement and then circle the most appropriate number to the right of the statement to indicate how you feel right now, at this moment. Do not spend too much time on any one statement but give the answer which seems to describe your present feeling best.

	Not at all	Somewhat	Moderately	Very much
I feel calm	1	2	3	4
I am tense	1	2	3	4
I feel upset	1	2	3	4
I feel relaxed	1	2	3	4
I feel content	1	2	3	4
I am worried	1	2	3	4

Please mark a cross on the line below at the point which you think best represents your pain.



Please mark a cross on the line below at the point which you think best represents your bleeding.



Any comments:

The same pages were completed on each of the 14 days of the diary.

Day 7

Have you recently...				
1. Been able to concentrate on whatever you're doing?	Better than usual	Same as usual	Less than usual	Much less than usual
2. Lost much sleep over worry?	Not at all	No more than usual	Rather more than usual	Much more than usual
3. Felt that you are playing a useful part in things?	More so than usual	Same as usual	Less useful than usual	Much less useful
4. Felt capable of making decisions about things?	More so than usual	Same as usual	Less so than usual	Much less than usual
5. Felt constantly under strain?	Not at all	No more than usual	Rather more than usual	Much more than usual
6. Felt you couldn't overcome your difficulties?	Not at all	No more than usual	Rather more than usual	Much more than usual
7. Been able to enjoy your normal day-to-day activities	More so than usual	Same as usual	Less so than usual	Much less than usual
8. Been able to face up to your problems?	More so than usual	Same as usual	Less so than usual	Much less than usual
9. Been feeling unhappy and depressed?	Not at all	No more than usual	Rather more than usual	Much more than usual
10. Been losing confidence in yourself?	Not at all	No more than usual	Rather more than usual	Much more than usual
11. Been thinking of yourself as a worthless person?	Not at all	No more than usual	Rather more than usual	Much more than usual
12. Been feeling reasonably happy, all things considered?	More so than usual	About the same as usual	Less so than usual	Much less than usual

Thank you for completing this diary.
You should now return it in the freepost envelope provided. Please return your diary even if you have been unable to complete it all, any information will be useful for our research.
Alternatively you can post it to

Behavioural Sciences Section
A Floor, South Block
Queens Medical Centre
Nottingham
NG7 2UH

If you have questions regarding your diary you can ring Nicky or Linda on 0115 9691169 Extension 57769



Women's experiences of the treatment of miscarriage
Six-week follow-up

Study number _____ Date form completed _____

1. Some questions about how you have been feeling recently:

Please read this carefully.

We should like to know if you have had any medical complaints and how your health has been in general, over the last few weeks. Please answer ALL the questions simply by underlining the answer which you think most nearly applies to you. Remember that we want to know about present and recent complaints, not those that you had in the past.

It is important that you try to answer ALL the questions.

Thank you very much for your co-operation

Table with 5 columns: Question, Better than usual, Same as usual, Less than usual, Much less than usual. Contains 12 rows of questions related to concentration, sleep, usefulness, decision-making, strain, difficulties, enjoyment, facing problems, happiness, confidence, self-worth, and overall happiness.

2. Questions about how you are now and your experiences of the treatment of your miscarriage.

Please mark a cross on the line below at the point which you think best represents your pain now

No pain _____ **Pain as bad as it could be**

Please mark a cross on the line below at the point which you think best represents your bleeding now

No Bleeding _____ **Very heavy bleeding**

How long after your miscarriage did you bleed for?

Please tick the appropriate box

Less than 2 weeks	<input type="checkbox"/>
2 to 4 weeks	<input type="checkbox"/>
4 to 6 weeks	<input type="checkbox"/>
Still bleeding	<input type="checkbox"/>

Please indicate to what extent you agree with the following statements

	Strongly agree	Agree	Unsure	Disagree	Strongly disagree
If a friend had a miscarriage I would advise them to have surgery	4	3	2	1	0
If a friend had a miscarriage I would advise them to have medical management in hospital	4	3	2	1	0
If a friend had a miscarriage I would advise them to have medical management at home	4	3	2	1	0
If a friend had a miscarriage I would advise them to miscarry naturally	4	3	2	1	0
I found it easy to decide which treatment to have	4	3	2	1	0
I had all the information I needed about the treatment options available	4	3	2	1	0
I got all the support I needed from the Early Pregnancy Unit or Gynaecology wards	4	3	2	1	0
I made the right choice about treatment for my miscarriage	4	3	2	1	0

**3. Some questions about how you have felt about the miscarriage
(The Impact of Events Scale, Horowitz et al., 1979).**

Below is a list of comments made by people after stressful and upsetting life events. Please read through each item and underline the corresponding statement depending on how frequently these comments were true for you during the past seven days. If they did not occur during that time, please underline the “not at all” statement.

1. I thought about it when I didn't mean to	Not at all	Rarely	Sometimes	Often
2. I avoided letting myself get upset when I thought about it or was reminded of it	Not at all	Rarely	Sometimes	Often
3. I tried to remove it from memory	Not at all	Rarely	Sometimes	Often
4. I had trouble falling asleep or staying asleep because of the pictures or thoughts about it that came into my mind	Not at all	Rarely	Sometimes	Often
5. I had waves of strong feelings about it	Not at all	Rarely	Sometimes	Often
6. I had dreams about it	Not at all	Rarely	Sometimes	Often
7. I stayed away from reminders of it	Not at all	Rarely	Sometimes	Often
8. I felt as if it hadn't happened or it wasn't real	Not at all	Rarely	Sometimes	Often
9. I tried not to think about it	Not at all	Rarely	Sometimes	Often
10. Pictures about it popped into my mind	Not at all	Rarely	Sometimes	Often
11. Other things kept making me think about it	Not at all	Rarely	Sometimes	Often
12. I was aware that I still had a lot of feelings about it, but I didn't deal with them	Not at all	Rarely	Sometimes	Often
13. I tried not to think about it	Not at all	Rarely	Sometimes	Often
14. Any reminder brought back feelings about it	Not at all	Rarely	Sometimes	Often
15. My feelings about it were kind of numb	Not at all	Rarely	Sometimes	Often

4. Some questions about possible complications / medical complaints since your miscarriage

Did you need to be readmitted to hospital following treatment? Yes / No

If yes, where were you admitted to? _____

Have you needed to see your GP? Yes / No

If yes, why did you see your GP?

If yes, how many times have you visited your GP? _____

Have you been given antibiotics since your miscarriage? Yes / No

Have you had a period yet? Yes / No

If you work outside the home how long were you off work for? _____

5. Some questions about contact with services following a miscarriage

We would like to know if you would have found any of the following helpful after your miscarriage.

An out-patient appointment at the EPAU Yes/No

A routine appointment with your GP Yes/No

A visit at home from your area midwife Yes/No

A telephone call from staff at the EPAU Yes/No

Please use the space below for any comments you would like to make about your treatment. This may include things that went well or not so well, how you have been feeling, or additional ideas about how your care could have been improved. Please continue overleaf or attach an extra sheet if you need more space.

Thank you for filling out this questionnaire. We hope that we can use your answers to improve our treatment of other women in future. If you find that completing this questionnaire has made you realise you have unanswered questions or problems please contact us at the Early Pregnancy Assessment Unit on 0115 9691169 Extension 47769.

Please return your questionnaire in the freepost envelope provided (you do not need a stamp) or you can post it to

Behavioural Sciences Section

A Floor, South Block

Queen's Medical Centre

Nottingham

NG7 2UH

Even if you have been unable to complete the entire questionnaire please return it to us as any information will be useful for our research.

Thank you

Judith Moore, Nicky Lindley, Linda Ahmed



**Women's experiences of the treatment of miscarriage
Six-week follow-up - Partners**

Study number _____ **Date form completed** _____

4. Some questions about how you have been feeling recently:

Please read this carefully.

We should like to know if you have had any medical complaints and how your health has been in general, over the last few weeks. Please answer **ALL** the questions simply by underlining the answer which you think most nearly applies to you. Remember that we want to know about present and recent complaints, not those that you had in the past.

It is important that you try to answer **ALL** the questions.
Thank you very much for your co-operation

Have you recently.....				
1. Been able to concentrate on whatever you're doing?	Better than usual	Same as usual	Less than usual	Much less than usual
2. Lost much sleep over worry?	Not at all	No more than usual	Rather more than usual	Much more than usual
3. Felt that you are playing a useful part in things?	More so than usual	Same as usual	Less useful than usual	Much less useful
4. Felt capable of making decisions about things?	More so than usual	Same as usual	Less so than usual	Much less than usual
5. Felt constantly under strain?	Not at all	No more than usual	Rather more than usual	Much more than usual
6. Felt you couldn't overcome your difficulties?	Not at all	No more than usual	Rather more than usual	Much more than usual
7. Been able to enjoy your normal day-to-day activities?	More so than usual	Same as usual	Less so than usual	Much less than usual
8. Been able to face up to your problems?	More so than usual	Same as usual	Less so than usual	Much less than usual
9. Been feeling unhappy and depressed?	Not at all	No more than usual	Rather more than usual	Much more than usual
10. Been losing confidence in yourself?	Not at all	No more than usual	Rather more than usual	Much more than usual
11. Been thinking of yourself as a worthless person?	Not at all	No more than usual	Rather more than usual	Much more than usual
12. Been feeling reasonably happy, all things considered?	More so than usual	About same as usual	Less so than usual	Much less than usual

2. Some questions about your experiences of your partner's treatment.

Please indicate to what extent you agree with the following statements

	Strongly agree	Agree	Unsure	Disagree	Strongly disagree
If a friend had a miscarriage I would advise them to have surgery	4	3	2	1	0
If a friend had a miscarriage I would advise them to have medical management in hospital	4	3	2	1	0
If a friend had a miscarriage I would advise them to have medical management at home	4	3	2	1	0
If a friend had a miscarriage I would advise them to miscarry naturally	4	3	2	1	0
My partner found it easy to decide which treatment to have	4	3	2	1	0
We had all the information I needed about the treatment options available	4	3	2	1	0
I got all the support I needed from the Early Pregnancy Unit or Gynaecology wards	4	3	2	1	0
My partner made the right choice about treatment for her miscarriage	4	3	2	1	0
I feel I was involved in making decisions about my partner's treatment	4	3	2	1	0

**3. Some questions about how you have felt about the miscarriage
(The Impact of Events Scale, Horowitz et al., 1979).**

Below is a list of comments made by people after stressful and upsetting life events. Please read through each item and underline the corresponding statement depending on how frequently these comments were true for you during the past seven days. If they did not occur during that time, please underline the “not at all” statement.

1. I thought about it when I didn't mean to	Not at all	Rarely	Sometimes	Often
2. I avoided letting myself get upset when I thought about it or was reminded of it	Not at all	Rarely	Sometimes	Often
3. I tried to remove it from memory	Not at all	Rarely	Sometimes	Often
4. I had trouble falling asleep or staying asleep because of the pictures or thoughts about it that came into my mind	Not at all	Rarely	Sometimes	Often
5. I had waves of strong feelings about it	Not at all	Rarely	Sometimes	Often
6. I had dreams about it	Not at all	Rarely	Sometimes	Often
7. I stayed away from reminders of it	Not at all	Rarely	Sometimes	Often
8. I felt as if it hadn't happened or it wasn't real	Not at all	Rarely	Sometimes	Often
9. I tried not to think about it	Not at all	Rarely	Sometimes	Often
10. Pictures about it popped into my mind	Not at all	Rarely	Sometimes	Often
11. Other things kept making me think about it	Not at all	Rarely	Sometimes	Often
12. I was aware that I still had a lot of feelings about it, but I didn't deal with them	Not at all	Rarely	Sometimes	Often
13. I tried not to think about it	Not at all	Rarely	Sometimes	Often
14. Any reminder brought back feelings about it	Not at all	Rarely	Sometimes	Often
15. My feelings about it were kind of numb	Not at all	Rarely	Sometimes	Often

Please use the space below for any comments you would like to make about your treatment. This may include things that went well or not so well, how you have been feeling, or additional ideas about how your and your partner's care could have been improved. Please attach an extra sheet if you need more space.

Thank you for filling out this questionnaire. We hope that we can use your answers to improve our treatment of other women in future. If you find that completing this questionnaire has made you realise you have unanswered questions or problems please contact us at the Early Pregnancy Assessment Unit on 0115 9691169 Extension 47769.

Please return your questionnaire in the freepost envelope provided (you do not need a stamp) or you can post it to

Behavioural Sciences Section

A Floor, South Block

Queen's Medical Centre

Nottingham

NG7 2UH

Even if you have been unable to complete the entire questionnaire please return it to us as any information will be useful for our research.

Thank you

Judith Moore, Nicky Lindley, Linda Ahmed

2.5 Procedure

At both time points of the study, participants were provided with freepost, addressed envelopes in which they could return completed measures to the research team. These measures were then stored in accordance with the Data Protection Act (1998) in a locked filing cabinet within the office of the research team. Signed consent forms were retained by the EPAU staff and stored in a locked filing cabinet within the unit. The data was stored in this manner in accordance with ethical considerations and requirements.

Women who provided their consent at the outset but failed to return their diaries were sent reminder letters (including another copy of the diary and pre-paid addressed envelope) as soon as possible to ensure that if they still wished to complete the diary, it would be done so as soon as possible after initiation of treatment. However, if diaries were still not returned, it was assumed women had decided to withdraw from the study. According to ethical considerations, it was not necessary for women to make contact to indicate their withdrawal from the study. Nor were they obliged to provide a reason for their withdrawal. Women who withdrew from the study were not affected in terms of the medical treatment they were receiving from the EPAU. Similarly, women who failed to return their six-week follow-up questionnaires were sent a reminder letter (along with further copies of the questionnaires and a pre-paid envelope). If these were still not returned, it was assumed that women did not wish to participate in the follow-up phase of the study. If follow-up questionnaires were not returned from the partners of these women, it was assumed that this was either due to women not having passed them on, there

not being a partner present or involved at the time of the miscarriage, or due to partners not wishing to get involved in the study.

2.6 Ethics

Ethical approval for the study was obtained from the North Nottinghamshire Local Research Ethics Committee. Given the previous phase of this study, ethical approval had already been obtained for the majority of the methodologies and procedures at the time of joining the study (obtained on 31/08/2006). However, an application was submitted to the committee prior to the start of the second phase of the study for a minor amendment to include a telephone interview with women (and their partners if appropriate) at the six-week follow up. This application (submitted on the 12th July 2007) was considered by the sub-committee on the 23rd July 2007 and again by the full committee on the 6th August 2007. A response was received on the 21st August 2007. Members of the Committee decided that they could not give a favourable ethical opinion to the amendment for a number of reasons, including breaching patient's confidentiality and concerns over how any distress caused by the interview would be addressed (over and above the provision of the consultant obstetrician and gynaecologist who was available as part of the existing protocol). Although the committee invited the research team to resubmit the application with amendments, it was felt this would delay the study to such an extent as to outweigh the benefits of collecting the additional information from participants. It was therefore decided by the research team to submit an amendment to the study including only an extension to the end date of the study, inclusion of a new research team

member and inclusion of an additional measure within the six-week follow-up (the IES). This amendment was submitted to the committee on 28th September 2007. Approval was obtained from the Committee on the 12th December 2007. In addition, ethical approval was obtained from the University of Lincoln, in line with course requirements. This approval was obtained on the 18th September 2007. Research & Development (R&D) approval was obtained from Nottingham University Hospitals NHS Trust Research and Development Department on the 12th September 2006, with amendments including additional researcher and extended end date being approved on the 10th December 2007.

In accordance with the ethical approval obtained, all participants were made aware at the time of providing their consent for the study, that their involvement was on a voluntary basis and that they would be free to withdraw at any point during their participation, without explanation, and without their medical care being compromised in any way. On consenting to take part in the study, all participants were also made aware that they were providing their approval for members of the research team to access previous and current medical files in order to gather information pertinent to their current treatment for miscarriage. Likewise, they were informed that data collected as part of the study would be handled in accordance with the Data Protection Act (1998) and as such would be stored as detailed previously, and would be destroyed within 15 years of the end of the study, or immediately upon withdrawal from the study prior to its end.

All participants were aware that the consultant gynaecologist was available should they experience any additional distress as a result of taking part in the study.

Word count: 7, 398

Appendix 3

Results

3.1 Missing data

All data that was missing from measures was defined as missing with the use of “999” within the SPSS datafile. All analyses were then conducted on existing data.

3.2 Normality testing

a) STAI

Table 3.1: Normality test results for Spielberger State Trait Anxiety Measure

Measure	Skewness		Kurtosis		Kolmogorov-Smirnov		
	Statistic	Std. Error	Statistic	Std. Error	Statistic	df	Sig.
STAI day 1	-0.525	0.299	0.060	0.590	0.100	64	0.177
STAI day 7	0.201	0.299	-0.505	0.590	0.099	64	0.191
STAI day 14	0.613	0.299	-0.096	0.590	0.141	64	0.003

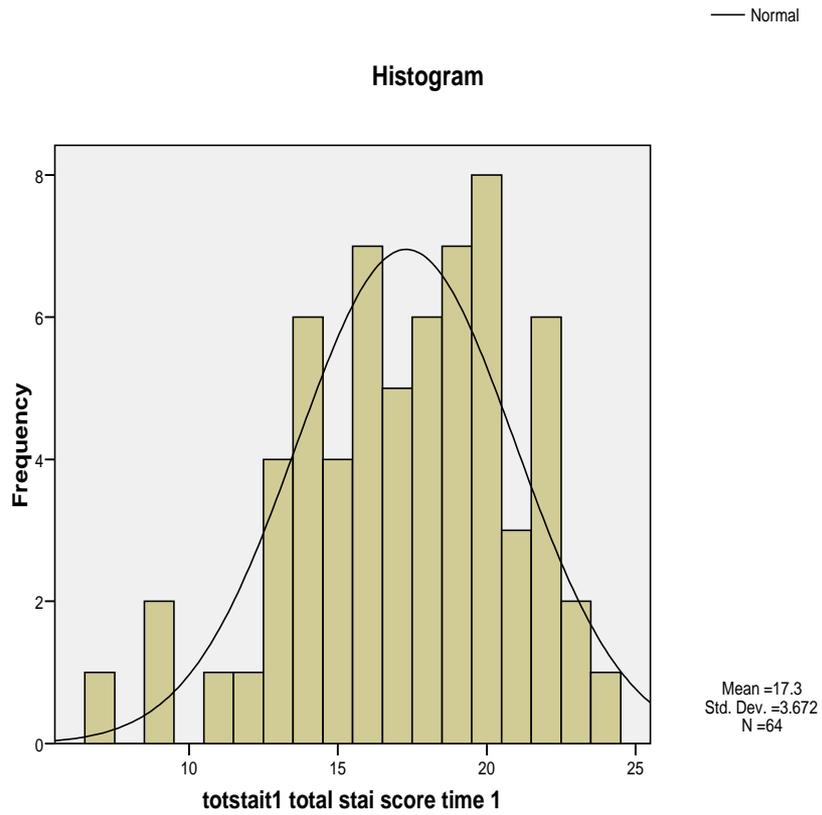


Figure 3.1: Normality histogram for day 1 of STAI

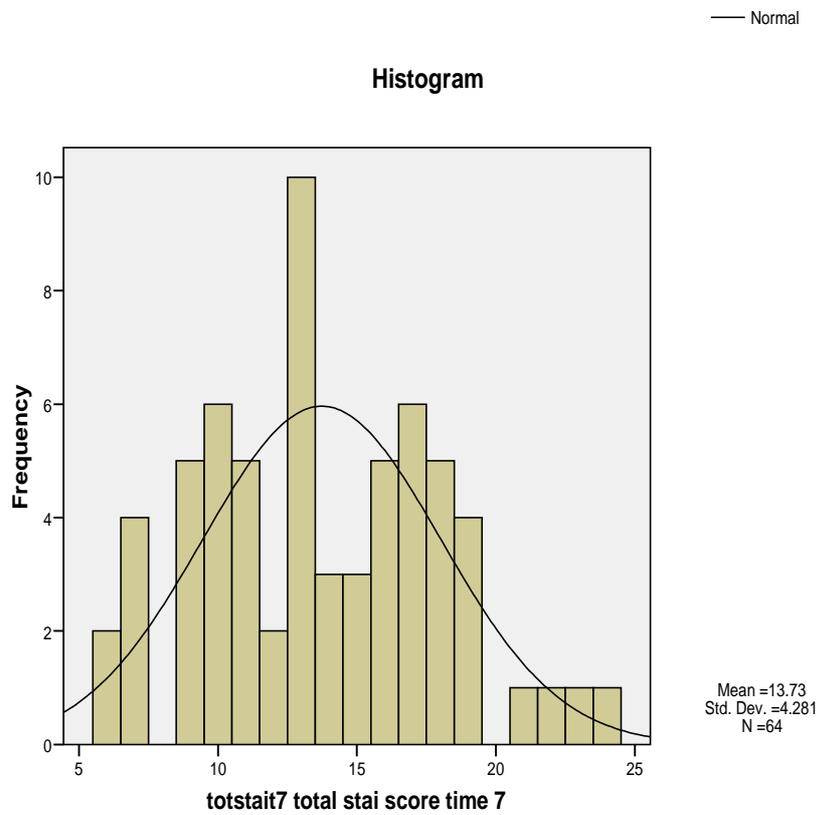


Figure 3.2: Normality histogram for day 7 of STAI

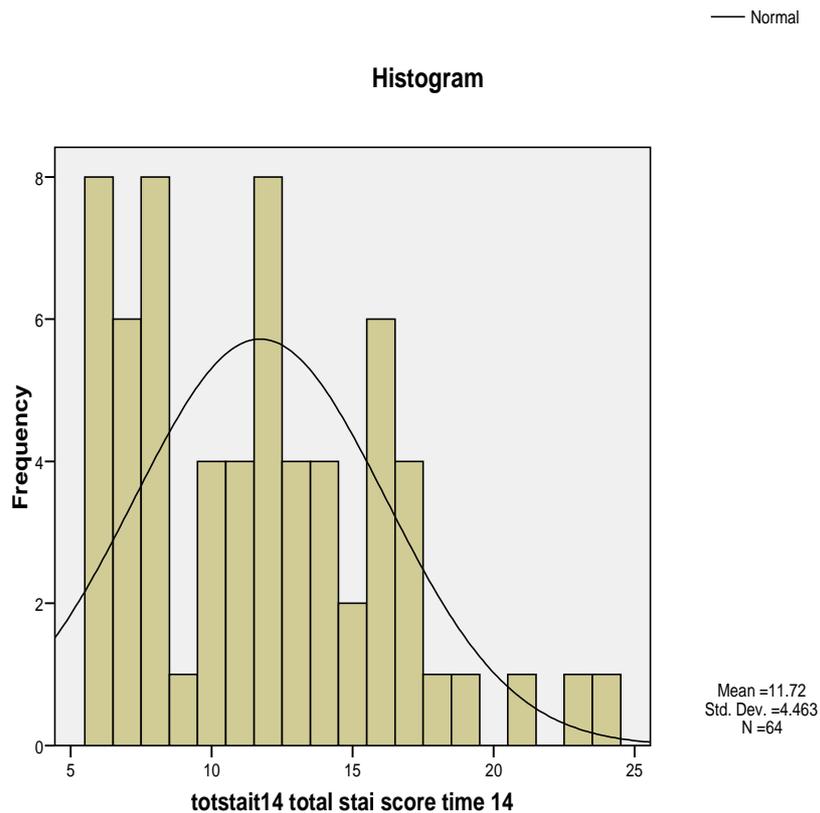


Figure 3.3: Normality histogram for day 14 of STAI

Significantly deviant from normal distribution on day 14 of measurement

b) GHQ-12

Table 3.2: Normality test results for the General Health Questionnaire

Measure	Skewness		Kurtosis		Shapiro-Wilk		
	Statistic	Std. Error	Statistic	Std. Error	Statistic	df	Sig.
GHQ total day 7	-0.040	0.403	-0.835	0.788	0.974	34	0.578
GHQ total 6wks	0.656	0.403	0.176	0.788	0.961	34	0.267
GHQ total partners	0.845	0.403	1.637	0.788	0.954	34	0.162

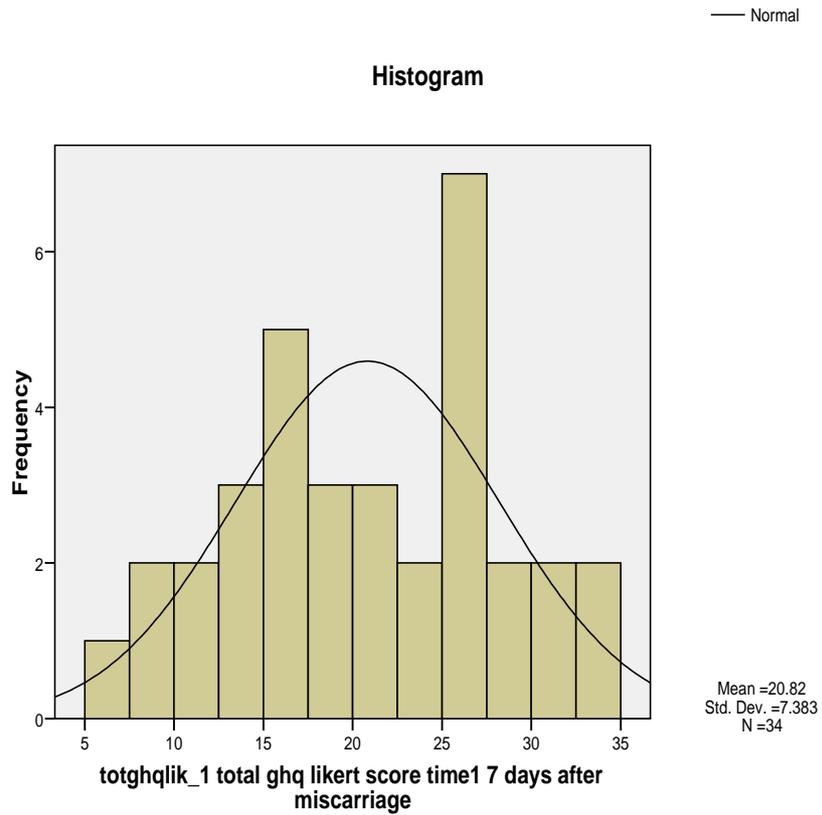


Figure 3.4: Normality histogram for day 7 GHQ-12

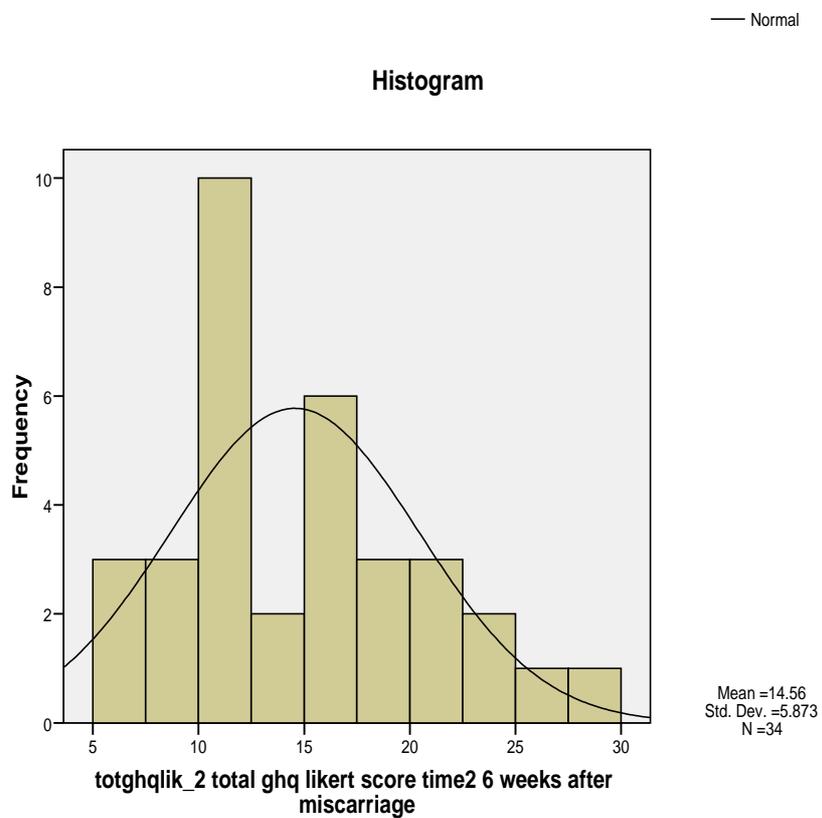


Figure 3.5: Normality histogram for 6 weeks GHQ-12

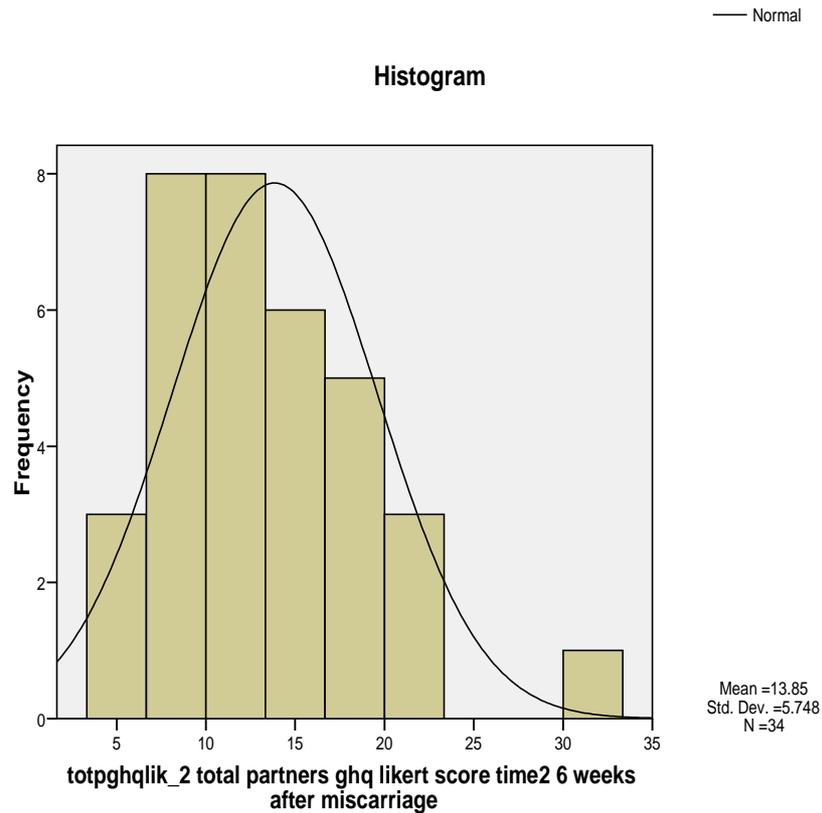


Figure 3.6: Normality histogram for partners at 6 weeks GHQ-12

c) Impact of Events Scale

Table 3.3: Normality test results for the Impact of Events Scale

Measure	Skewness		Kurtosis		Shapiro-Wilk		
	Statistic	Std. Error	Statistic	Std. Error	Statistic	Df	Sig.
IES total women	-0.398	0.524	-0.530	1.014	0.964	19	0.663
IES total partners	0.064	0.524	-0.501	1.014	0.942	19	0.287

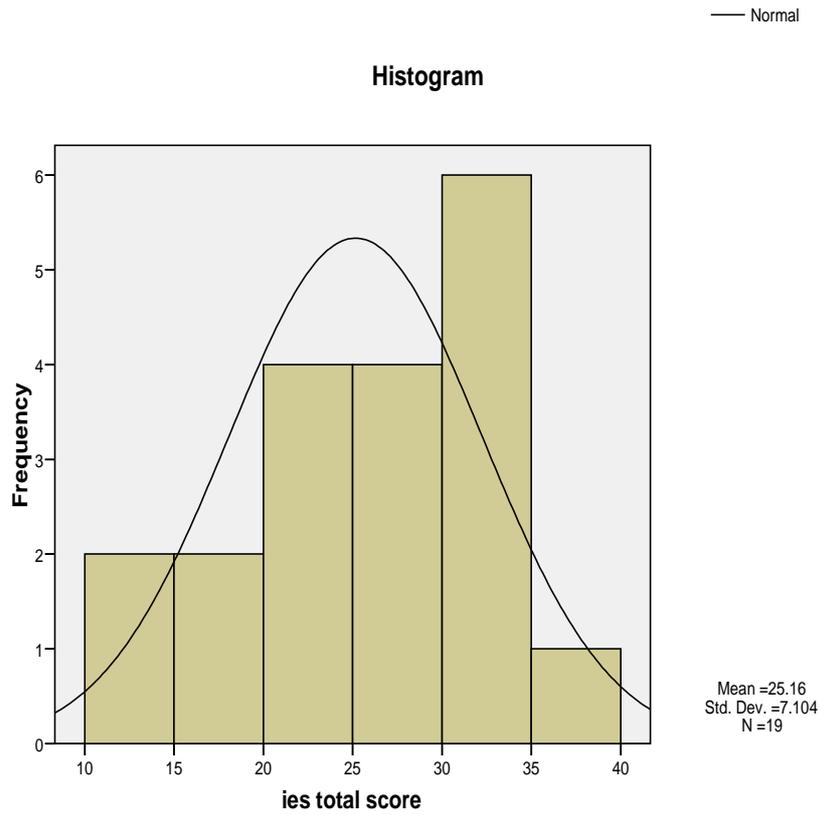


Figure 3.7: Normality histogram for IES at 6 weeks

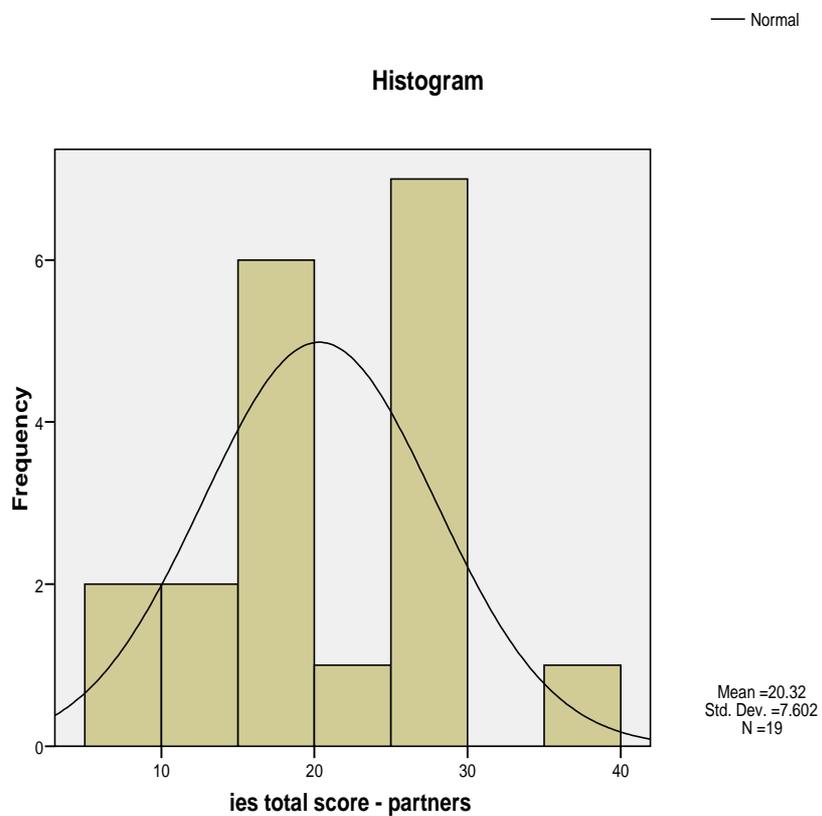


Figure 3.8: Normality histogram for IES at 6 weeks - partners

d) Pain VAS

Table 3.4: Normality test results for the VAS pain ratings

Measure	Skewness		Kurtosis		Kolmogorov-Smirnov		
	Statistic	Std. Error	Statistic	Std. Error	Statistic	Df	Sig.
Pain day 1	1.348	0.337	1.067	0.662	0.262	50	0.000
Pain day 7	2.056*	0.337	3.770**	0.662	0.257	50	0.000
Pain day 14	2.881**	0.337	7.708**	0.662	0.341	50	0.000
Pain 6 wks	4.769**	0.337	25.690**	0.662	0.373	50	0.000

* = significant at $p < 0.05$

** = significant at $p < 0.01$

Significantly deviant from normal distribution across all days of measurement

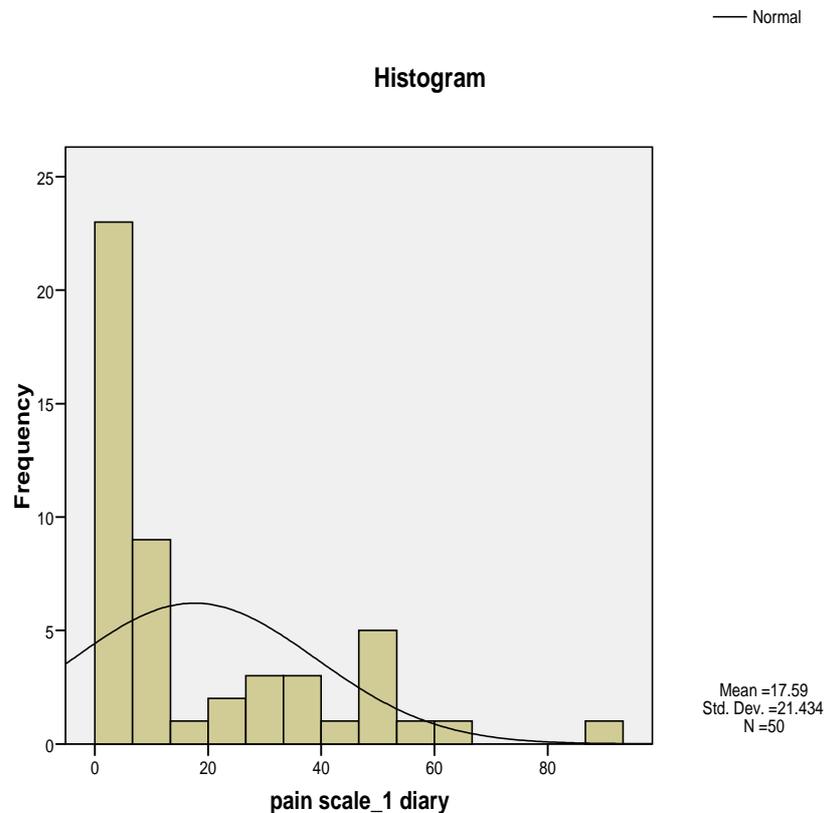


Figure 3.9: Normality histogram for pain ratings – day 1

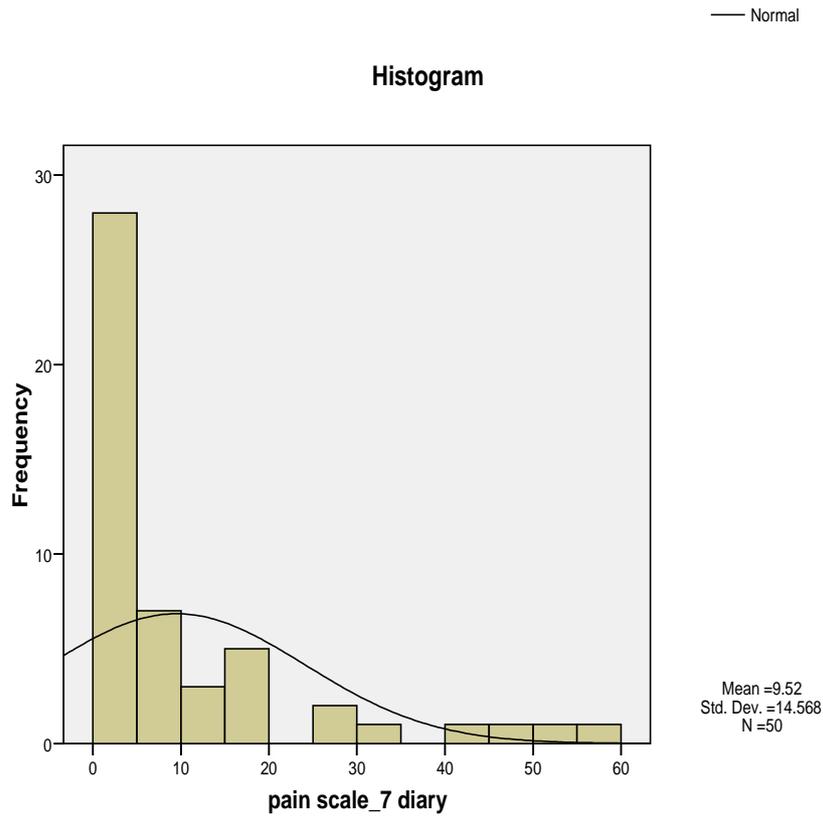


Figure 3.10: Normality histogram for pain ratings – day 7

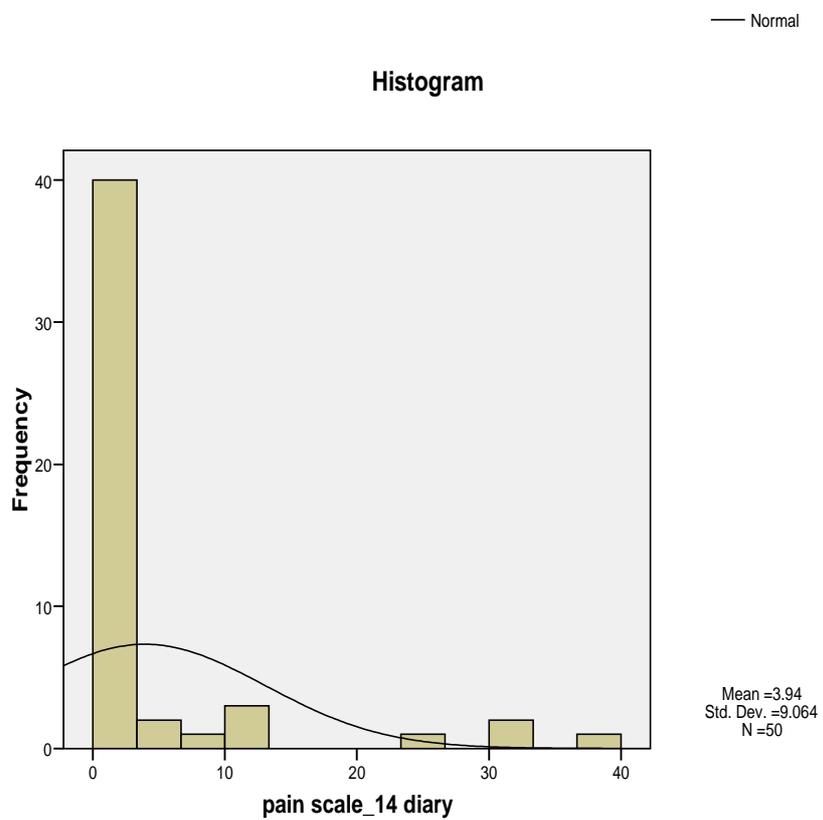


Figure 3.11: Normality histogram for pain ratings – day 14

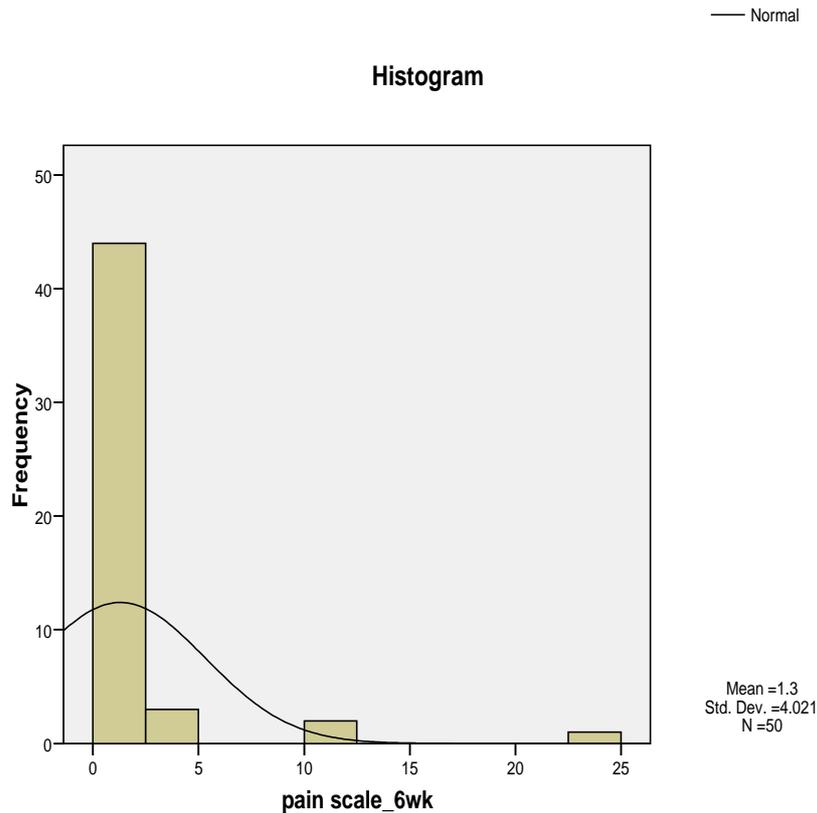


Figure 3.12: Normality histogram for pain ratings – 6 weeks

e) Bleeding VAS

Table 3.5: Normality test results for the VAS bleeding ratings

Measure	Skewness		Kurtosis		Kolmogorov-Smirnov		
	Statistic	Std. Error	Statistic	Std. Error	Statistic	df	Sig.
Bleeding day 1	0.928	0.333	0.012	0.656	0.186	51	0.000
Bleeding day 7	1.894	0.333	3.694**	0.656	0.212	51	0.000
Bleeding day 14	2.406*	0.333	6.324**	0.656	0.259	51	0.000
Bleeding 6 wks	4.477**	0.333	21.535**	0.656	0.372	51	0.000

* = significant at $p < 0.05$

** = significant at $p < 0.01$

Significantly deviant from normal distribution across all days of measurement

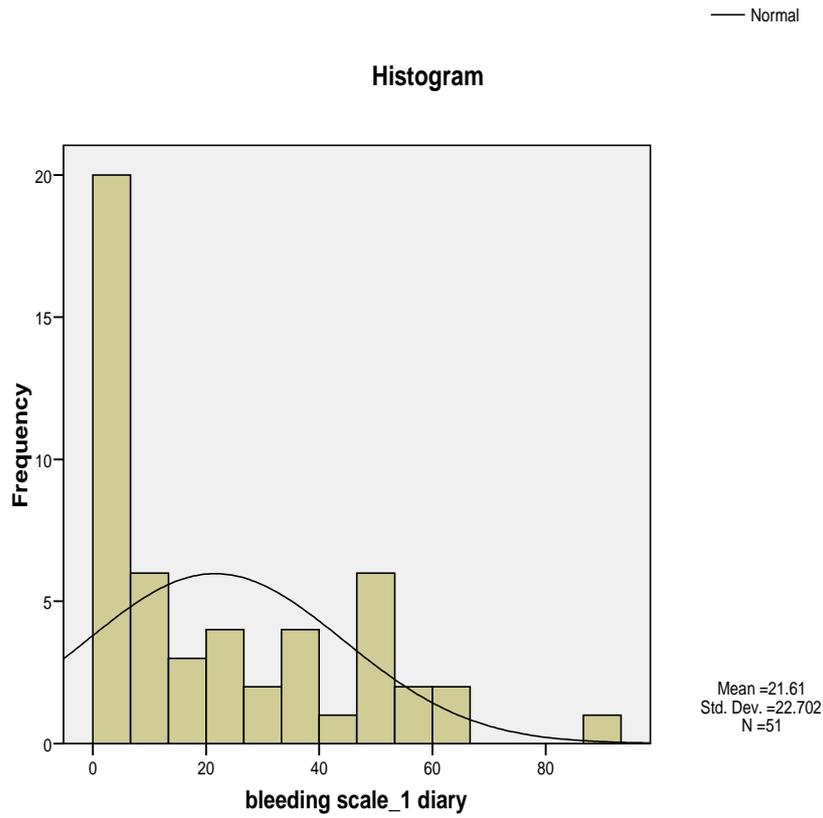


Figure 3.13: Normality histogram for bleeding ratings – day 1

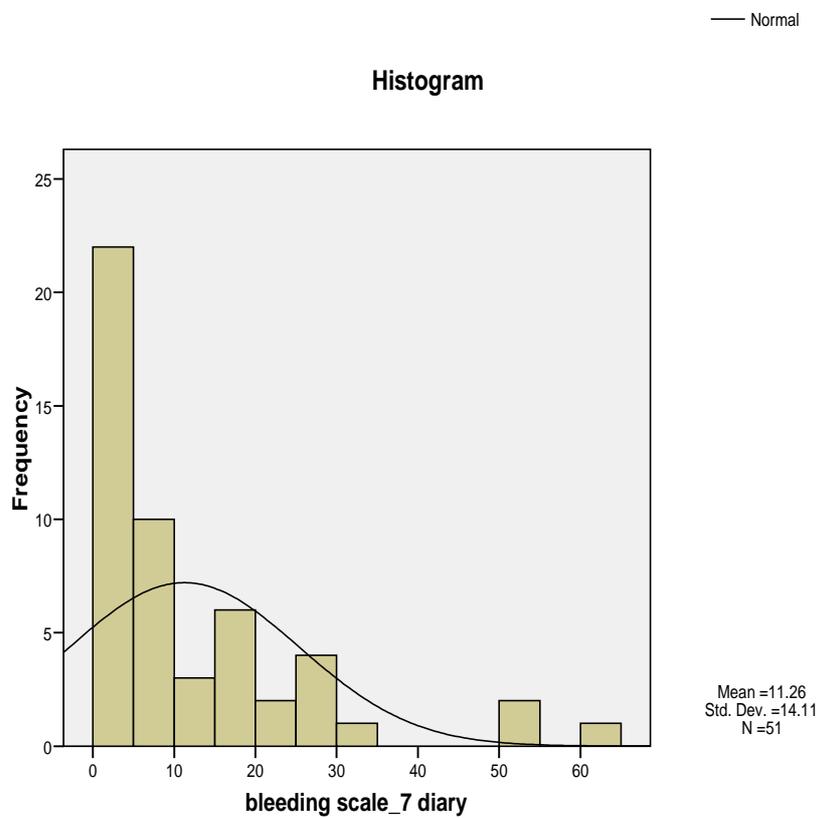


Figure 3.14: Normality histogram for bleeding ratings – day 7

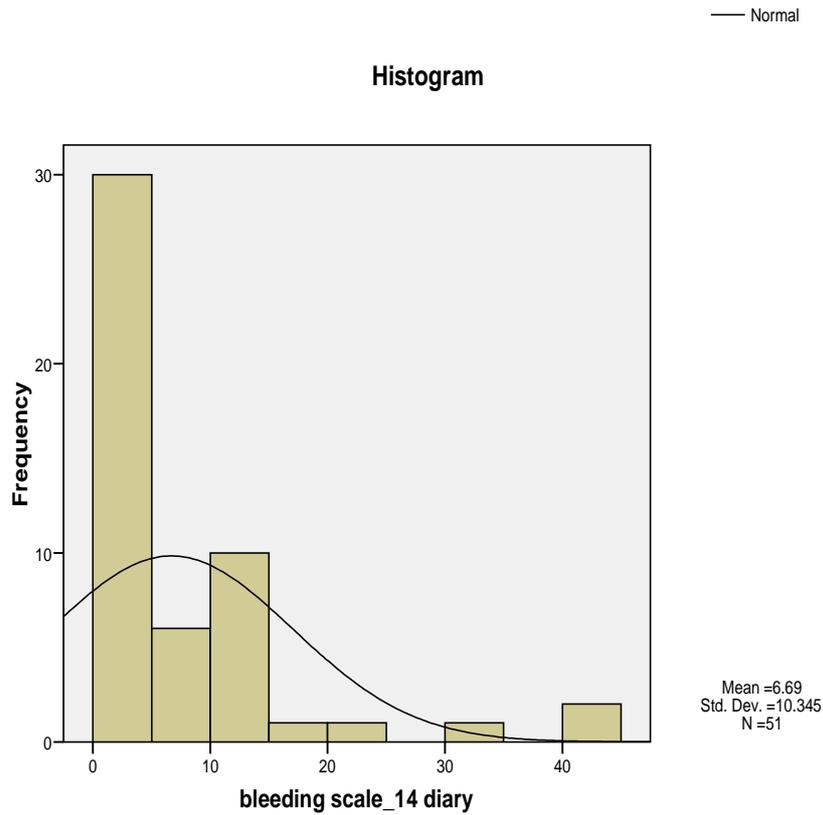


Figure 3.15: Normality histogram for bleeding ratings – day 14

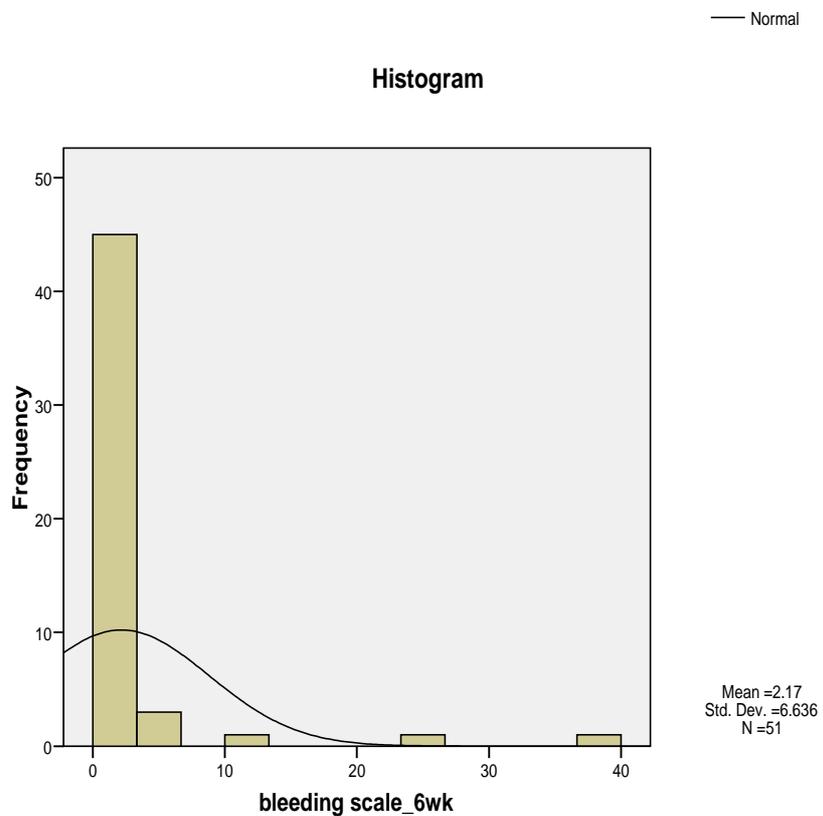


Figure 3.16: Normality histogram for bleeding ratings – 6 weeks

Although measures are mixed in relation to distribution, it was decided that subsequent analyses should be non-parametric due to the unequal sample sizes in each of the four treatment groups.

3.3 Population characteristics

a) Diagnoses

Table 3.6 details the diagnoses received by all women participating in the study, according to treatment choice.

Table 3.6: Women's diagnoses

Population	Diagnosis		
	Non-viable pregnancy (i.e. foetal demise)	Incomplete miscarriage	Other
Expectant (18)	17 (94.4%)	1 (5.6%)	0 (0%)
Medical inpatient (13)	12 (92.3%)	1 (7.7%)	0 (0%)
Medical outpatient (15)	15 (100.0%)	0 (0%)	0 (0%)
Surgical* (35)	31 (88.6%)	2 (5.7%)	1 (2.9)

* data missing for one woman

b) Outcomes

A successful outcome was defined by the EPAU as women having received an ultrasound scan confirming no remaining products of conception = a complete miscarriage (see table 3.7).

Table 3.7: Treatment choices and outcomes

Treatment (n / %)	Outcome				
	Complete miscarriage – no treatment	Complete miscarriage after treatment	Changed to medical inpatient	Changed to medical outpatient	Changed to surgical
Expectant (18/22.2%)	4 (22.2%)	0 (0%)	6 (33.3%)	1 (5.6%)	7 (38.9%)
Medical inpatient (13/16.0%)	0 (0%)	11 (84.6%)	-	0 (0%)	2 (15.4%)
Medical outpatient (15/18.5%)	0 (0%)	13 (86.7%)	0 (0%)	-	2 (13.3%)
Surgical* (35/43.2%)	0 (0%)	34 (97.1%)	0 (0%)	0 (0%)	-

* data missing for one woman.

In women who changed to an additional treatment (i.e. medical inpatient/ medical outpatient / surgical), outcomes were successful following completion of the additional treatment in all cases.

3.4 Factors underpinning treatment choices made by women

In addition to the data presented in the research paper, table 3.8 details additional data on ratings as minor factors. This data corresponds to the original research question set out in the aims of the study to determine which psychological factors affect women's choice of treatment for miscarriage.

Table 3.8: Frequency of endorsed factors influencing treatment choice by women

Factor influencing treatment choice	Frequency (% of treatment group)							
	Expectant (18)		Medical inpatient (13)		Medical outpatient (15)		Surgical (35)	
	Minor factor	Major factor	Minor factor	Major factor	Minor factor	Major factor	Minor Factor	Major factor
1. Wanted to get back to work as quickly as possible	13 (72.2)	5 (27.8)	10 (76.9)	3 (23.1)	13 (86.7)	2 (13.3)	27 (77.1)	7 (20.0)
2. Have non-one to help look after my other children	16 (88.9)	1 (5.6)	11 (84.6)	2 (15.4)	15 (100)	0 (0)	31 (88.6)	2 (5.7)
3. Wanted to avoid staying in hospital	5 (27.8)	13 (72.2)	7 (53.8)	6 (46.2)	3 (20.0)	11 (73.3)	28 (80.0)	6 (17.1)
4. Wanted to avoid an operation	9 (50)	9 (50)	2 (15.4)	11 (84.6)	1 (6.7)	14 (93.3)	32 (91.4)	2 (5.7)
5. Wanted to avoid having an anaesthetic	10 (55.6)	8 (44.4)	2 (15.4)	11 (84.6)	3 (20.0)	12 (80.0)	31 (88.6)	3 (8.6)
6. Advice from family	16 (88.9)	2 (11.1)	10 (76.9)	3 (23.1)	13 (86.7)	2 (13.3)	24 (68.6)	8 (22.9)
7. Advice from EPAU staff	12 (66.7)	6 (33.3)	9 (69.2)	4 (30.8)	11 (73.3)	4 (26.7)	20 (57.1)	14 (40.0)
8. Was scared of miscarrying on my own	15 (83.3)	3 (16.7)	8 (61.5)	5 (38.5)	11 (73.3)	4 (26.7)	17 (48.6)	18 (51.4)
9. Was scared of bleeding heavily	14 (77.8)	4 (22.2)	7 (53.8)	6 (46.2)	12 (80.0)	2 (13.3)	16 (45.7)	19 (54.3)
10. Was frightened of seeing the miscarriage	15 (83.3)	3 (16.7)	8 (61.5)	5 (38.5)	13 (86.7)	1 (6.7)	13 (37.1)	21 (60.0)
11. Chose what seemed the most natural treatment	6 (33.3)	12 (66.7)	5 (38.5)	8 (61.5)	5 (33.3)	10 (66.7)	24 (68.6)	10 (28.6)
12. Thought this would be the least painful treatment	11 (61.1)	7 (38.9)	11 (84.6)	2 (15.4)	12 (80.0)	3 (20.0)	12 (34.3)	23 (65.7)

N.B. Data is missing for some women.

Qualitative data

In addition to the above, women were invited to comment on any additional factors that contributed to their decision regarding miscarriage treatment. This qualitative data was gathered in response to an open text question contained in the miscarriage diary. It was felt obtaining qualitative information in addition

to the quantitative analysis discussed in the research paper provided an opportunity for women to highlight factors not previously identified in the literature or anecdotally. Furthermore, it was felt the information obtained would be richer and more in depth as a result of combining quantitative and qualitative data. It was recognised that the opportunity to gather additional qualitative information would have been beneficial to the study through the inclusion of a telephone interview. However, as explained in appendix 2.6, this did not receive ethical approval and therefore had to be removed from the original research protocol. Had this been possible, additional data would have been collected on women's experiences of the process of being involved in their treatment choice, their beliefs and cognitions with regard to the miscarriage, their attachment to the foetus, and thoughts and feelings around their future reproductive health.

All women who completed the miscarriage diary were invited to provide qualitative information. Therefore, analysis on qualitative data is conducted on the 81 women involved in the overall study. Data was subjected to theme analysis (Boyatzis, 1998), which involved examination of all women's responses in the free text section of the miscarriage diary, followed by the identification of possible themes within the women's responses. These were then used to construct a code book, which could be used to code all the responses made by two independent raters. Thematic analysis was selected as the favoured approach to analysing the qualitative data collected in the study, over and above alternative qualitative analytical approaches such as grounded theory and interpretative phenomenological analysis (IPA) for the

reasons that thematic analysis is accessible and flexible in application both in theoretical and methodological terms (Braun & Clarke, 1996). The amount and content of data was not complex enough to warrant lengthier, more rigid analytical approaches.

Thematic analysis is a method for identifying, analysing and reporting patterns or themes within a data set. Boyatzis (1998) defines a theme as “a pattern found in the information that at the minimum describes and organises the possible observations or at the maximum interprets aspects of the phenomenon.” (pp.161).

Possible themes within the data collected in this study were discussed with another member of the research team before construction of a formal coding book (see table 3.9) which was supplied along with a sample of quotes to be examined and verified by another member of the research team who had not previously been involved in the data collection or analysis of themes.

Table 3.9: Thematic analysis code book

Theme	Boyatzis' 5 elements	Example
1	Label	Speedy return to normality
	Definition	Woman refers to the need to return to normal life as quickly as possible.
	How to know when theme occurs	Evidence of women explicitly stating or implying that they wish to have a treatment that can be started soon and will be completed quickly so they can return to normal, both emotionally and physically, and get on with life.

	Qualifications or exclusions to the identification of the theme	Does include statements relating to closure and getting their body back to normal. Does not include statements relating to risks or complications of the miscarriage.
	Example of positive coding	"Surgery felt like the best option as it would be over and done with and quick and allow me to move on quickly."
	Example of negative coding	"I would have been very frightened imagining being in a lot of pain and not knowing when it would be over."
2	Label	Impact on family
	Definition	Woman refers to the impact the miscarriage and her treatment will have on other family members.
	How to know when theme occurs	Evidence of woman stating explicitly or referring to the impact of the miscarriage and treatment on family members both emotionally and practically. Includes impact on partners and other children.
	Qualifications or exclusions to the identification of the theme	Includes statements relating to woman's role in family and people being reliant on her. Does not include statements relating to support from family members
	Example of positive coding	"It's not nice for my husband to watch me in so much pain and can't do anything and he just feels so helpless."
	Example of negative coding	"I wanted to be at home with my family and in particular my son."
3	Label	Control
	Definition	Woman refers to or implies the need to have some control over the miscarriage and her treatment.
	How to know when theme occurs	Evidence of direct statements or implications that the woman wishes to feel in control of her miscarriage and the treatment she receives.
	Qualifications or exclusions to the identification of the theme	Does not include statements relating to how the treatment may control the outcome
	Example of positive coding	"As an inpatient I feel I'm in a controlled environment should anything unexpected happen."
	Example of negative coding	"I agreed it would be best to have medical as it would be quicker and hopefully straight-forward."
4	Label	Support from family and environment

	Definition	Woman refers to the need for support from the family, both emotional and practical, and the desire to be in a safe and familiar environment.
	How to know when theme occurs	Evidence of woman directly expressing or alluding to the need for support from family and friends to assist them in their treatment and recovery from miscarriage.
	Qualifications or exclusions to the identification of the theme	Includes statements relating to emotional and physical support as well as supportive environment. Does not include statements relating to the impact on family and friends.
	Example of positive coding	"Needing family around me when the time came...needed to feel relaxed with my husband right at hand. I wanted to feel as comfortable and relaxed as I possibly could be, with familiar people and surroundings."
	Example of negative coding	"My husband works away during the week and I have two other children to consider."
5	Label	Wanting to avoid hospital
	Definition	Woman refers to the desire to avoid hospital and hospital-based procedures.
	How to know when theme occurs	Evidence of statements explicitly or implying woman's desire to avoid having to go into hospital for treatment.
	Qualifications or exclusions to the identification of the theme	Includes statements relating to being in hospital as well as procedures such as operations and anaesthetics. Does not include statements relating to risks, invasive nature of procedure or medical / reproductive complications.
	Example of positive coding	"Best to avoid surgery and anaesthetic if possible."
	Example of negative coding	"I didn't want to have surgery with all the risks involved if it could be avoided. I felt the risks (operation going wrong, infection, anaesthetic) were 'worse' than the pain, bleeding and seeing the miscarriage."
6	Label	Fear of pain, bleeding and complications
	Definition	Woman refers to the fear of pain, bleeding or possible medical and/or reproductive complications associated with the treatment
	How to know when theme occurs	Evidence of woman explicitly stating or referring to her fears of the degree of pain, extent of bleeding or experience of complications or risk associated with the treatment.

	Qualifications or exclusions to the identification of the theme	Includes statements relating to fear of seeing the miscarriage, initial treatments failing, and implications on future chances of pregnancy. Does not include statements relating going to hospital or undergoing hospital procedures such as anaesthetics.
	Example of positive coding	"I felt that the operation would be the least traumatic and....I didn't know how long I'd bleed for and how painful it would be. Lastly, sometimes natural miscarriages don't completely empty the womb and you have to have an op anyway."
	Example of negative coding	"It was too traumatising returning to EPAU and sitting in a waiting room with others celebrating positive news."
7	Label	Past experience
	Definition	Woman refers to past experience of miscarriage
	How to know when theme occurs	Any mention of past treatments or past miscarriages. These may be either positive or negative experiences, either stating explicitly or implying why the woman is choosing the same or different treatment as before.
	Qualifications or exclusions to the identification of the theme	Does not include woman's beliefs about what the treatment, miscarriage experience and outcome will be like
	Example of positive coding	"This was my second miscarriage. The first one was 9 months ago. I miscarried at home and the experience was dreadful and even more upsetting."
	Example of negative coding	"At least with the operation it seemed the cleanest and best option for me, I would imagine it being much quicker and everything would be cleared out."
8	Label	Seeking an explanation
	Definition	Woman refers to wanting to get an explanation for the miscarriage from medical staff.
	How to know when theme occurs	Evidence of explicit statements or references to the woman wanting to understand the reasons for her miscarriage.
	Qualifications or exclusions to the identification of the theme	Includes statements relating to increased chances of finding an explanation for the miscarriage. Does not include statements referring to speed or outcome of treatment.
	Example of positive coding	"The baby was taken away to test to see if they could tell us why this has happened."

	Example of negative coding	"I thought it may help and have this one removed so my womb would be cleaned and get better quicker.... it was upsetting to think it was dead still inside me."
9	Label	Staff advice
	Definition	Woman refers to receiving advice from hospital staff.
	How to know when theme occurs	Evidence of explicit statements or referring to obtaining advice from hospital staff.
	Qualifications or exclusions to the identification of the theme	Includes statements referring to advice from nurses and doctors. Does not include statements relating to advice from others (i.e. partner/husband) or previous experience of treatments.
	Example of positive coding	"The nurse and doctor both strongly recommended this."
	Example of negative coding	"Me and my partner discussed the miscarriage and both decided on the treatment I would receive which was for the baby to try and come out on its own."
10	Label	Desire for the most natural option
	Definition	Woman refers to wishing to choose the most natural treatment.
	How to know when theme occurs	Evidence of explicit statements or references to preferring the most natural option. Can be positive or negative in relation to the expectations of the treatment process.
	Qualifications or exclusions to the identification of the theme	Includes statements relating to different treatments. Does not include statements relating to associated risks or complications.
	Example of positive coding	"I thought the natural way would be the best way for me. No risks at all."
	Example of negative coding	"I felt that the operation would be the least traumatic and....I didn't know how long I'd bleed for and how painful it would be. Lastly, sometimes natural miscarriages don't completely empty the womb and you have to have an op anyway."

i) Reliability

To examine the reliability of themes identified, 20% of quotes (minimum of 2) were selected from each theme and given to an additional researcher to

categorise into themes. Out of a total of 42 quotes, 40 were correctly allocated to a theme, which equates to an overall agreement rate of 95.2%.

Boyatzis (1998) argues that a percentage agreement on presence can be calculated which takes into account that “the absence of the coded theme does not imply the opposite of presence, or there is not an equal likelihood of observing presence and absence.” (p.155).

He suggests using the following equation:

Percentage agreement on presence =

$$2 \times (\text{no. of times both coder A and B saw it})$$

$$(\text{no. of times coder A saw it present} + \text{no. of times coder B saw it present})$$

Table 3.10 displays the percentage agreement on presence for each of the themes identified:

Table 3.10: Percentage agreement on presence results

Theme	No. of quotes containing theme	Percentage agreement on presence
Speedy return to normal	8	100
Past experience	4	100
Desire for natural option	4	100
Support from family and home environment	4	100
Impact on family	4	100
Staff advice	2	100
Fear of pain, bleeding, complications	4	75
Wanting to avoid hospital	4	100
Control	4	75
Seeking an explanation	4	100

Percentage agreement on presence rates ranged from 75% to 100%. Typically, scores of 70% are considered necessary in this type of research (Boyatzis, 1998, pp 156). However, it is acknowledged that frequency of occurrence or observation will affect reliability. Thus, the fewer the number of occurrences, the lower the denominator in percentage agreement in presence formula so that a small change in agreement can change the percentage dramatically. Consequently, low reliability can be associated with a lower number of quotes per theme.

Following reliability testing, any disagreements were resolved on discussion. Therefore, data was coded without modification of the coding scheme.

ii) Themes

Accordingly, the following themes were identified from the information women provided on additional factors that contributed to their treatment choice:

1. Speedy return to normality
2. Past experience
3. Desire for natural option
4. Support from family and home environment
5. Impact on family
6. Staff advice
7. Fear of pain, bleeding, complications
8. Wanting to avoid hospital
9. Control
10. Seeking an explanation

1. Speedy return to normality (number of total quotes: 42)

Women expressed a desire to receive a treatment that would be quick. This did not always correspond to women choosing to have surgical treatment, which may have been the expectation.

“I chose to have the operation as I wanted the experience over and done with and I felt this was the quickest option.” [surgical]

“I chose the medical treatment, which I was able to start straight away and this made me feel that at least things were on the way and in a strange way was at least starting to move forwards.” [medical outpatient]

“It seemed the quickest way of miscarrying without surgery.” [medical inpatient]

“By opting for surgical treatment, I could ensure the baby was removed quickly.” [surgical]

“Time was a factor – didn’t want to prolong it.” [medical outpatient]

“I believe a faster way to recovery (physically).” [medical outpatient]

“I also wanted it over with quickly and D&C would be done almost immediately.” [surgical]

“I didn’t want to wait – wanted to get it over with.” [medical outpatient]

“At least with the operation it seemed the cleanest and best option for me, I would imagine it being much quicker and everything would be cleared out.” [surgical]

“Quicker method. Don’t have to stay the night and wait for things to happen.” [surgical]

“Once I had found out about the miscarriage it was important to me that any treatment was quick.” [surgical]

“I chose the surgical method because I felt I’ll get the whole issue over and done with.” [surgical]

“Surgery felt like the best option as it would be over and done with and quick and allow me to move on quickly.” [surgical]

“I didn’t want to drag it out any longer than necessary.” [surgical]

“I agreed it would be best to have medical as it would be quicker and hopefully straight-forward.” [medical inpatient]

“I wanted a treatment that would be quick.” [surgical]

“Easier to manage. Also just wanted it to be over in a matter of hours.” [surgical]

“It is half term so I am not at work and really want it sorted now. Time to move on.” [surgical]

“I am hoping to go on holiday in less than 3 weeks (abroad). This has made me want to start the process as quickly as possible.” [medical inpatient]

Combined with wanting to start treatment quickly, women also expressed a preference for a treatment that would allow them to return to their normal life as soon as possible.

"I need to get back to normal as soon as possible rather than waiting to miscarry naturally." [surgical]

"I wanted to try and get to normal as soon as possible." [surgical]

"I really just wanted to get it over with. So my treatment I thought would be the quicker and most effective. I wanted to get on with life." [surgical]

"I felt in limbo and did not like the unpredictability..... can get on with life."
[medical outpatient]

"I want to get on – move on. Didn't like the idea of waiting to see what/when (not functional)." [surgical]

"I just feel that I want to return to normal as soon as possible and not drag it out any longer and surgical treatment seems the quickest way." [surgical]

"My body would recover better and we would conceive again quicker. But I couldn't bear to keep waiting. Desperately wanted to move on and try again." [medical inpatient]

“Once the surgery was completed I felt I could then start to move forward as leading up to the surgery I felt in some kind of limbo.” [surgical]

“I just wanted to have the operation and move on as soon as I could.”
[surgical]

“Getting things back to normal as soon as possible.” [medical inpatient]

“D&C – personally I felt the treatment I chose would be quicker / more effective and involve less emotional stress. I felt this process would help me return back to normal quicker.” [surgical]

This seemed to be driven by a need to put the miscarriage behind them and move on both physically and emotionally. This incorporates ideas around experiencing distressing feelings associated with carrying around a dead foetus and ability to achieve closure following treatment.

“For my health and emotional well-being I felt it was best to have a D&C.”
[surgical]

“I chose to go into hospital as I felt it was the best thing to do for myself both physically and mentally.” [surgical]

“I thought the surgery would bring a definitive end to things.” [surgical]

“Experiencing the bleeding is almost like closure of the miscarriage.”

[surgical]

“I do not wish to carry on everyday knowing there was once a living thing inside me that has died, for any longer than I have to. Therefore, that is why I have chosen the D-C.” [surgical]

“Did not wish to prolong the experience – surgery seemed a quicker way to resolve the situation so I could focus upon mentally recovering.”

[surgical]

“Carrying a dead baby in my womb indefinitely felt very disturbing and somehow wrong.” [surgical]

“I thought it may help and have this one removed so my womb would be cleaned and get better quicker.... it was upsetting to think it was dead still inside me.” [surgical]

“We felt that to allow us to move on emotionally, some medical intervention would be a good idea.” [medical inpatient]

“Too scared already of losing next one.” [medical inpatient]

“Decided to have surgery as did not like the thought of taking pills to make me contract to get rid of all the sac. I found it was dragging it out and

prolonging which made me feel worse. Until it is done you cannot even begin to try to get over it and sort out your life. So just wanted it to stop so I could come to terms with it so that is why I chose surgery as this was instant.” [surgical]

“Emotionally, I was not ready to jump in and have the medical / surgical interventions. I needed to get stronger emotionally before I thought about the physical side of things.” [medical inpatient]

2. Past experience (23)

Women described past experience of miscarriage and treatment as having both positive and negative influences on their choice on this occasion. Those who experienced positive experiences in the past often ended up choosing the same treatment again, either out of knowing what to expect or broadly being satisfied with the treatment they received previously.

Positive experiences (8)

“I have had two previous miscarriages. The last one was also managed medically, therefore I chose to use the same procedure again.” [medical outpatient]

“My previous experience has been that it is not a painful procedure and that subsequent bleeding is minimal.” [surgical]

“Having already experienced an evac I believed that it was the best option for me as I knew what to expect.” [surgical]

“I had the same surgical treatment last time and was satisfied with it.”
[surgical]

“For me personally I chose to have a D&C on both occasions.” [surgical]

“I have previously had a problem with my first baby who had a heart condition and therefore was terminated at 23 weeks so I knew what to expect from this treatment.” [medical outpatient]

“This was my second miscarriage in 7 months and even though the first was worse than I thought it would be, I still chose the same way for the second.” [medical inpatient]

“Having miscarried before I knew what to expect.” [expectant]

In contrast, women who had previously negative experiences tended to choose different treatment on this occasion due to expectation that the same treatment would be equally negative this time. Although in the majority of cases, women who had unpleasant and negative experiences in the past tended to opt for surgical treatment this time, this was not always the case.

Negative experiences (12)

“As I have had many miscarriages in the past and each of them was very painful, I couldn’t go through that again.” [surgical]

“I was worried that the miscarriage would be as frightening for me as my first miscarriage.” [surgical]

“Had an incomplete miscarriage so had already experienced very heavy bleeding, strong contraction like pain and seen matter/lumps within the bleeding. Did not want to experience that again with medical treatment.” [surgical]

“I had an ectopic back in February this year, never been in hospital before and was very scared and had no choice but to have surgery. I did not want to go through that all again....I’ve gone through enough this year losing two babies in one year.” [medical outpatient]

“I have never bled after a miscarriage so I didn’t want to wait as I knew it could go on for a long time.” [surgical]

“As I have already had a miscarriage in the past 14 mths, I am aware of the heavy bleeding and last time I started to miscarry it took 6 days before completion of the miscarriage.” [surgical]

“Previous miscarriage where had been bleeding but no loss of tissue – advised to have D&C at time..... Lack of consideration and after care on

ward, following and before procedure, despite some staff known to me previously, for this reason wished to avoid hospitalisation.” [expectant]

“This was my second miscarriage. The first one was 9 months ago. I miscarried at home and the experience was dreadful and even more upsetting.” [surgical]

“I’ve had miscarriages on my own before at home, it’s very upsetting and sometimes there has been a lot of blood.” [surgical]

“Eight months previous to this miscarriage I experienced a very long and drawn out miscarriage that went on for approximately 7 weeks.” [surgical]

“I’ve had medical treatment for a previous miscarriage and it didn’t work. After being in hospital for 3 days I ended up having surgical treatment after all and wanted it sooner as I’d already had to wait 2 weeks.” [surgical]

“Having had 2 previous experiences; surgery and medical management as an outpatient (for this I did end up in hospital), I knew there were no easy and pain free options.” [medical outpatient]

Neutral (3)

“A previous miscarriage in June’07.” [expectant]

“Had previous ERPOC procedure 6 months ago. Wanted to try alternative treatment.” [medical outpatient]

“I have had a previous miscarriage before I wanted the quickest, least painful option.” [surgical]

3. Desire for natural option (16)

A number of women referred to the desire to receive what they believed to be the most natural treatment option. Although previous literature (i.e. Ogden & Maker, 2004) might lead one to expect this would result in women choosing expectant treatment, women in the current study also appeared to view medical outpatient as “natural”. This suggests that it may be something to do with being at home / not in hospital that makes women feel this way about their treatment.

Positive (11)

“Originally I opted to go home and let nature take its course.” [expectant]

“Tempted to wait for nature.” [medical outpatient]

“...and natural.” [expectant]

“Medical management is closer to being ‘natural’ it ‘helps’ nature.”
[medical outpatient]

“I thought this would be the best way to proceed (tablets) at first as thought this was a more natural approach.” [medical outpatient]

“I wanted a natural m/c because I felt my body ought to do it – to make up for missing it. Also, on no scientific basis, I felt natural = best.” [medical outpatient]

“I thought the natural way would be the best way for me. No risks at all.” [expectant]

“I think it is the last thing you can do for the baby as a mother to give birth to it and not to have it scraped or sucked away.” [medical inpatient]

“Natural option.” [medical outpatient]

“Tablets seem more natural.” [medical outpatient]

“Waiting would have been an ideal / most natural option.” [surgical]

Whilst some women clearly believed natural to be best, others expressed concerns and doubts over whether natural would produce the best outcome in terms of their treatment. This often linked in with women wanting a quick resolution to their miscarriage and resulted in them choosing either medical or surgical treatment.

Negative (5)

"I had no confidence in my body not taking weeks longer to do it naturally."

[medical outpatient]

"I couldn't bear the thought of waiting for things to occur naturally."

[surgical]

"I didn't want to wait any longer for a natural miscarriage to occur."

[medical outpatient]

"I definitely didn't want to leave the baby to miscarry naturally as it could have taken weeks." [surgical]

"I was worried that just waiting for a natural miscarriage might take too long." [surgical]

4. Support from family and home environment (10)

Women's family situation and home environment appeared to be an important influence on their treatment decision. In some cases, women opted for the treatment that would most quickly get them back home to their families. In others, women expressed a deep desire to be at home during the treatment in order to receive support from family and loved ones and to be in an environment which they felt to be safe, familiar, comfortable and private. Some women also commented on how their choice in treatment was based on a joint decision made with their partner.

"I wanted to be at home with my husband when it happened. We were in it together at the beginning and wanted to be together at the end... Being at home is less stressful and have the support and comfort of family members and my own surroundings. Less clinical environment. Being home feels safe." [expectant]

"I wanted to be at home with my family and in particular my son." [medical outpatient]

"It would allow me to stay at home." [medical outpatient]

"I wanted to get back home to my family." [surgical]

"I wanted to be in the comfort of my own home." [medical outpatient]

"I wanted to be at home for my miscarriage around people I love and love me." [medical outpatient]

"I was quite relieved to start bleeding and stay at home to have the miscarriage instead." [surgical]

"Me and my partner discussed the miscarriage and both decided on the treatment I would receive which was for the baby to try and come out on its own." [expectant]

“The option to have the treatment and go home was also appealing.”

[expectant]

“Needing family around me when the time came...needed to feel relaxed with my husband right at hand. I wanted to feel as comfortable and relaxed as I possibly could be, with familiar people and surroundings.” [medical outpatient]

5. Impact on family (8)

Women also expressed consideration of the impact of their treatment on other family members, including partners, other children and the wider circle of family and friends. This included not only their perception of the emotional impact on others but also the effect it would have on their role within the family and expectations on them to continue with their usual responsibilities. Consequently, the majority of women who commented on this as a factor chose surgical treatment, presumably out of a belief that this would have less impact on their families.

“My husband works away during the week and I have two other children to consider.” [surgical]

“I do have people available to help care for my daughter but wanted to have as little impact on her as possible.” [surgical]

“It’s not nice for my husband to watch me in so much pain and can’t do anything and he just feels so helpless.” [surgical]

“With Christmas looming and a five-year-old to look after, the D&C appeared to be the most sensible option for me.” [surgical]

“The main reason for choosing surgical treatment was that I have to go to Aberdeen for 2 days in the 20th Dec to collect my mother who has Alzheimer’s – she is staying with us for 3 weeks. I was worried that just waiting for a natural miscarriage might take too long or have complications, which may mean I would be unable to care for her. Plus for husband and children it seemed easier to manage this way.” [surgical]

“Impact this has on family and childcare arrangements, felt it would be more appropriate to be at home.” [expectant]

“I already have a little boy and I don’t want him to see mummy in any distress at home.” [surgical]

“My partner was scared about helping me through the tablet treatment at home.” [surgical]

6. Staff advice (2)

Although only commented on by two women, receiving staff advice was considered important in influencing their decision. This is interesting in the

context of looking at choice, as it suggests that although women have strong preferences and ideas around their miscarriage treatment, in some cases, women still look to professional advice to help guide them. This is informative for the provision of services, particularly when thinking about women / couples who are potentially experiencing significant distress and feel unable, in such circumstances, to make such important decisions without professional advice. Thus, whilst there is clearly a role for choice in treatment, this opportunity should not be provided to the exclusion of involving staff in decisions, should this be the wish of the individual woman / couple.

“The nurse and doctor both strongly recommended this.” [surgical]

“Advice from the nurse after my scan.” [surgical]

7. Fear of pain, bleeding, complications (29)

Women expressed anxieties over the physical experience of the treatment, particularly the pain they expected to feel and amount of bleeding. It is not clear, however, from women’s comments whether this derived from the belief that pain and bleeding indicated that something was wrong, or whether it reflected what they expected and associated with the miscarriage, either through past experience or having been informed of such. In circumstances where women expressed concerns over a treatment option not working, they tended to then opt for surgical treatment, which may reflect the expectation that women view this option as the most definitive / successful treatment option when other, preferred options have been tried but failed. Those women

who did not choose surgical appeared to do so having considered some of the documented risks associated with the procedure, including the potential impact on future conception.

Positive (1)

"I didn't feel anything and I hardly had any bleeding when I was home."

[surgical]

Negative (28)

"I quickly ruled out surgery due to the risk of physical damage (Asherman's)." [medical outpatient]

"I would have been very frightened imagining being in a lot of pain and not knowing when it would be over." [surgical]

"I didn't want to have it medically managed and later need surgery if it wasn't all removed." [surgical]

"I was really frightened of passing something that looked like a baby." [medical inpatient]

"Big factor was avoiding risk." [medical inpatient]

"Every possibility that I would have to have surgery anyway." [surgical]

"I couldn't bear the thought of not happening properly with the tablet."

[surgical]

"I didn't want to be in a lot of pain." [surgical]

"I was also scared that if I didn't start bleeding I may get an infection."

[surgical]

"If possible I want to avoid medical intervention and therefore anything causing damage which might affect my chance of having a successful pregnancy in the future." [expectant]

"Least invasive procedure was chosen as I was very concerned that an operation could affect my chances of conceiving again if anything should go wrong." [medical outpatient]

"I was concerned that if I had medical management that if all did not come away I would need a D&C anyway." [surgical]

"Bleeding not as heavy as medical management...less pain afterwards."

[surgical]

"I felt I couldn't risk having a D & C and it would have a small possibility of problems with uterus resulting in no further pregnancy." [expectant]

“I felt that the operation would be the least traumatic and....I didn’t know how long I’d bleed for and how painful it would be. Lastly, sometimes natural miscarriages don’t completely empty the womb and you have to have an op anyway.” [surgical]

“I was also worried if I waited for too long I might get an infection.”
[surgical]

“Thought surgical intervention would be less painful ... felt worried it may not work and would have to undergo surgery anyway.” [surgical]

“I don’t want to have to come back and forth if it doesn’t come away or the tablets didn’t work.” [surgical]

“If surgery increases the risk of any potential factors for a miscarriage I would want to avoid it as well as any other potential side affects.”
[expectant]

“Medical management seemed less intrusive than surgery although I did worry about side effects.” [expectant]

“Pain was not an issue – rather the fear that I would faint whilst vomiting.”
[surgical]

“My high blood pressure concerned me with the surgical option.” [medical inpatient]

“I did not want to have a D&C if possible, due to....the risk of infection.”
[medical outpatient]

“I am a “worrier” and am frightened of the potential pain – this has made me chose to have the medical management as an in-patient.” [medical inpatient]

“I didn’t want to have surgery with all the risks involved if it could be avoided. I felt the risks (operation going wrong, infection, anaesthetic) were ‘worse’ than the pain, bleeding and seeing the miscarriage.” [medical outpatient]

“Surgery felt invasive.” [medical outpatient]

“I was worried about surgery as I have never been put to sleep before.”
[expectant]

“I felt medical management would be less intrusive than the operation.”
[medical outpatient]

8. Wanting to avoid hospital (11)

In addition to worries relating to the experience of the miscarriage and potential medical risks and complications, a number of women also expressed a desire to avoid hospital and its associated procedures. This appeared to correspond to either wanting to avoid the hospital environment or anxieties relating to undergoing an anaesthetic.

"I wanted to avoid an anaesthetic." [medical outpatient]

"...anaesthetic unpleasant." [medical outpatient]

"I didn't want to expose myself to being in hospital." [medical outpatient]

"Best to avoid surgery and anaesthetic if possible." [medical inpatient]

"I did not want an operation." [medical outpatient]

"It was too traumatising returning to EPAU and sitting in a waiting room with others celebrating positive news." [surgical]

"Don't like hospitals. Scared of needles. Don't want to be in a hospital ward or around other people (who are in hospital also receiving treatment)." [expectant]

"Avoiding surgery." [medical inpatient]

“An operation in hospital seemed quite severe / scary.” [expectant]

“I did not want to have a D&C if possible, due to having to stay in hospital.”

[medical outpatient]

“At the time, I was unsure about an operation as I had never had one before.” [medical outpatient]

9. Control (6)

The perceived control women felt they would have over their treatment also appeared to be an important influence on their decision. In this case, women appeared to associate medical procedures with a greater degree of control.

“Having the D&C at hospital was controlled.” [surgical]

“Chose medical management because it is controlled.” [medical outpatient]

“Feel more in control.” [surgical]

“With some treatment there is some control.” [medical outpatient]

“As an inpatient I feel I’m in a controlled environment should anything unexpected happen.” [medical inpatient]

“That I would have some control over what was happening.” [surgical]

10. Seeking an explanation (4)

Women who were concerned about finding an explanation for their miscarriage appeared to show a preference for surgical treatment as they felt this would provide them with the best opportunity for doing so.

“The baby was taken away to test to see if they could tell us why this has happened.” [surgical]

“I also felt the quicker it was dealt with the quicker we could get on with looking into why this keeps happening as this is my third miscarriage.” [surgical]

“I also felt this treatment offered the best possibility of finding out why the pregnancy may have failed as I want to have the embryo tested.... we need answers before we can move forward.” [surgical]

“The EPAU could gain tissue sample which they could look at to hopefully provide clues as to why this keeps happening.” [surgical]

3.5 Psychological impact of miscarriage

The study aims with regard to psychological impact of miscarriage were as follows:

1. Does a relationship exist between choice of treatment and psychological outcome in women both immediately and six-weeks post-miscarriage?
2. Do the experiences of the women's partners differ depending on the choice of treatment?
3. Do the experiences of male partners differ significantly from those of women?

Accordingly, the following analyses were conducted (in support of those results presented within the research paper).

a) Anxiety (STAI)

To examine differences in state anxiety scores according to time since the miscarriage a Friedman's test (non-parametric repeated measures ANOVA) was carried out on the data for all participants. This revealed a significant reduction over time in STAI scores [$\chi^2 = 51.15$, $df = 2$, $p < 0.0001$]. This was followed up with post hoc Wilcoxon Signed Ranks Tests as reported in the research paper for each of the individual treatment groups (comparing day 1 and 14).

The results of the majority of these tests were significant and were included in the research paper. The exception to this was for the medical inpatient group.

This result was as follows:

$z = -2.17$, $p = 0.03$

[Bonferroni adjusted p-value = 0.0125]

Effect sizes of results from Wilcoxon tests: $r = \frac{z}{\sqrt{n}}$

Expectant group: $2.83 / 3.87 = 0.73$ (large)

Medical outpatient group: $3.07 / 3.61 = 0.85$ (large)

Surgical group: $3.97 / 5.39 = 0.74$ (large)

($r = 0.1$ small effect size; $r = 0.3$ medium effect size; $r = 0.5$ large effect size; Cohen, 1988)

Retrospective power (based on above effect sizes and sample sizes as noted in research paper):

Expectant group ($n = 15$): between 71% and 82 % power (av. 76.5%)*

Medical outpatient ($n = 13$): between 75% and 85% power (av. 80%)

Surgical group ($n = 29$): between 96% and 99% power (av. 97.5%)

*To obtain 80% power with the same effect size, a sample of 18 would have been required.

To examine whether a relationship existed between choice of treatment and psychological outcome in terms of anxiety, a series of Kruskal-Wallis tests were conducted according to individual time points throughout data collection (with STAI score as the test variable and treatment group as the grouping variable). Rather than examining group differences on each of the 14 days the STAI was completed, it was decided it would be sufficient enough to conduct analysis based on the first, middle and last days.

These produced the following non-significant group differences:

day 1: $H = 5.38$, $df = 3$, $p = 0.15$

day 7: $H = 2.30$, $df = 3$, $p = 0.51$

day 14: $H = 5.88$, $df = 3$, $p = 0.12$

There was no data from male partners to make comparisons

b) Non-psychotic psychiatric symptoms – women (GHQ-12)

To examine differences in GHQ-12 scores according to time since the miscarriage a Friedman's test (non-parametric repeated measures ANOVA) was carried out on the data for all participants. This revealed a significant reduction over time in GHQ-12 scores [$\chi^2 = 36.26$, $df = 1$, $p < 0.0001$]. This was followed up with post hoc Wilcoxon Signed Ranks Tests as reported in the research paper for each of the individual treatment groups (comparing day 7 and 6 weeks).

The results of the majority of these tests were significant and were included in the research paper. The exception to this was for the medical inpatient group.

This result was as follows:

$z = -2.08$, $p = 0.04$

[Bonferroni adjusted p-value = 0.0125]

Effect sizes of results from Wilcoxon tests: $r = \frac{z}{\sqrt{n}}$

Medical inpatient group: $2.55 / 3.16 = 0.81$ (large)

Medical outpatient group: $2.53 / 3.00 = 0.84$ (large)

Surgical group: $4.11 / 5.29 = 0.78$ (large)

($r = 0.1$ small effect size; $r = 0.3$ medium effect size; $r = 0.5$ large effect size; Cohen, 1988)

Reterospective power (based on above effect sizes and sample sizes as noted in research paper):

Medical inpatient group ($n = 10$): 60% power*

Medical outpatient ($n = 9$): between 54% and 65% power (av. 59.5%)*

Surgical group ($n = 28$): between 92% and 99% power (av. 95.5%)

*To obtain 80% power with the same effect size, a sample of 14/15 would have been required for the medical inpatient group and medical outpatient group.

To examine whether a relationship existed between choice of treatment and psychological outcome in terms of non-psychotic symptoms, a series of Kruskal-Wallis tests were conducted according to individual time points throughout data collection (with GHQ-12 score as the test variable and treatment group as the grouping variable).

These produced the following non-significant group differences:

day 7 women: $H = 1.92$, $df = 3$, $p = 0.59$

6 weeks women: $H = 3.43$, $df = 3$, $p = 0.33$.

6 weeks partners: $H = 6.41$, $df = 3$, $p = 0.09$

To examine whether the psychological impact (in terms of non-psychotic symptoms) was comparable between women and their partners at six-weeks, individual Wilcoxon Signed Ranks tests were conducted according to treatment group.

These produced the following non-significant differences:

Expectant group: $z = -1.26$, $p = 0.21$

Medical inpatient group: $z = -0.92$, $p = 0.36$

Medical outpatient group: $z = -0.27$, $p = 0.79$

Surgical group: $z = -0.15$, $p = 0.88$

To examine whether the number of women and partners reaching “caseness” differed according to treatment choice, Chi-Square analysis was conducted with the following non-significant results:

Day 7: $\chi^2 = 28.16$, $df = 36$, $p = 0.82$

6 weeks - women: $\chi^2 = 29.92$, $df = 33$, $p = 0.62$

6 weeks – partners: $\chi^2 = 35.90$, $df = 33$, $p = 0.33$

To examine whether there were differences in the number of women versus partner cases within each of the four treatment groups, Chi-Square analysis as conducted with the following non-significant results:

Expectant group: $\chi^2 = 6.13$, $df = 6$, $p = 0.41$

Medical inpatient group: $\chi^2 = 15.00$, $df = 12$, $p = 0.24$

Medical outpatient group: $\chi^2 = 6.25$, $df = 6$, $p = 0.40$

Surgical group: $\chi^2 = 101.20$, $df = 90$, $p = 0.20$

c) Post-traumatic stress response (IES)

To compare differences in IES scores, a series of Kruskal-Wallis tests were conducted for IES total, IES intrusion subscale and IES avoidance subscale. In each case, IES score was the test variable and treatment group was the grouping variable. The results of these analyses are reported in the research paper, along with their accompanying post-hoc Mann Whitney tests.

Effect sizes of results from Mann-Whitney tests: $r = \frac{z}{\sqrt{n}}$

Total scores:

Medical outpatient vs. expectant group: $2.68 / 2.24 = 1.20$ (large)

Medical outpatient vs. medical inpatient group: $2.74 / 2.24 = 1.22$ (large)

Medical outpatient vs. surgical group: $3.21 / 2.24 = 1.43$ (large)

Surgical vs. medical inpatient group: $2.81 / 2.45 = 1.15$ (large)

Intrusion scores:

Medical outpatient vs. medical inpatient group: $2.73 / 2.24 = 1.22$ (large)

Avoidance scores:

Medical outpatient vs. medical inpatient group: $2.75 / 2.24 = 1.23$ (large)

Surgical vs. medical inpatient group: $1.94 / 2.45 = 0.79$ (large)

($r = 0.1$ small effect size; $r = 0.3$ medium effect size; $r = 0.5$ large effect size; Cohen, 1988)

Retrospective power (based on above effect sizes and sample sizes as noted in research paper):

Medical outpatient vs. expectant group ($n = 5$): less than 60%*

Medical outpatient vs. medical inpatient group ($n = 5$): less than 60 – 67% (av. 63.5%)*

Medical outpatient vs. surgical group ($n = 5$): less than 74%*

Surgical vs. medical inpatient group ($n = 6$): less than between 52 – 60% (av. 56%)*

*To obtain 80% power with the same effect size, a sample of between 9 and 14 would have been required for the treatment groups.

Non-significant results from the series of post-hoc Mann Whitney tests were as seen in table 3.11.

Table 3.11: Group comparisons on IES scores

Group comparison	Total IES score	IES intrusions	IES avoidance
Expectant vs. surgical	z = -0.56 p = 0.55	z = -0.88 p = 0.38	z = -0.76 p = 0.45
Expectant vs. medical inpatient	z = -1.15 p = 0.25	z = -0.94 p = 0.37	z = -1.00 p = 0.32
Expectant vs. medical outpatient	z = -2.68 p = 0.007	z = -2.12 p = 0.03	z = -2.36 p = 0.02
Medical inpatient vs. medical outpatient	z = -2.74 p = 0.006	z = -2.56 p = 0.01	z = -2.75 p = 0.006
Medical inpatient vs. surgical	z = -2.81 p = 0.005	z = -2.13 p = 0.03	z = -1.94 p = 0.005
Medical outpatient vs. surgical	z = -3.21 p = 0.001	z = -2.73 p = 0.006	z = -2.22 p = 0.03

* Bonferroni adjustment: $0.05 / 6 = 0.008$

To examine differences in partner's IES scores according to treatment group three individual Kruskal-Wallis tests were conducted with IES score as the test variable and treatment group as the grouping variable.

These analyses produced the following non-significant results:

IES total score: $H = 3.60$, $df = 3$, $p = 0.31$

IES intrusion score: $H = 6.09$, $df = 3$, $p = 0.11$

IES avoidance score: $H = 2.46$, $df = 3$, $p = 0.48$

To examine whether the psychological impact (in terms of post-traumatic stress symptoms) was comparable between women and their partners at six-weeks, individual Wilcoxon Signed Ranks tests were conducted according to treatment group.

These analyses produced the following non-significant results:

Expectant group: $z = -1.10$, $p = 0.27$

Medical inpatient group: -0.73 , $p = 0.47$

Medical outpatient group: No results – n = 1 partners

Surgical group: $z = -2.10$, $p = 0.04$

Bonferroni adjustment: $0.05 / 4 = 0.0125$

To examine whether there was a significant difference across treatment groups in the number of women and partners obtaining scores within the moderate-severe range on the IES measure, individual Chi-Square analyses were conducted. The significant result for women is included in the research paper. The non-significant result for partners was as follows:

$\chi^2 = 4.63$, $df = 9$, $p = 0.87$

Effect size of the result from the Chi-square analysis for women: $\sqrt{[\chi^2 / n]}$

$\sqrt{[24.38 / 31]} = \sqrt{0.79} = 0.89$ (large)

($w = 0.1$ small effect size; $w = 0.3$ medium effect size; $w = 0.5$ large effect size; Cohen, 1988)

Retrospective power (based on above effect sizes and sample sizes as noted in research paper):

($n = 31$): between 96 and 98

3.6 Pain and bleeding

In order to examine whether intensity of pain or degree of bleeding changed over time according to each of the different treatment groups, a series of Wilcoxon Signed Ranks Tests were conducted. Significant results of these

analyses are included in the research paper. Additional non-significant findings (once the p value was adjusted according to multiple comparisons) are shown in table 3.12.

Table 3.12: Bleeding statistics over time

Treatment group	Wilcoxon Signed Rank Test (Average vs. 6 wks)	
	Z	P value
Medical inpatient	-2.40	p = 0.02
Medical outpatient	-2.43	p = 0.02

* Bonferroni adjustment: $0.05/4 = p < 0.0125$

Effect sizes of results from Wilcoxon tests: $r = \frac{z}{\sqrt{n}}$

\sqrt{n}

Pain:

Expectant group: $2.70 / 3.16 = 0.85$ (large)

Medical inpatient group: $2.70 / 3.16 = 0.85$ (large)

Medical outpatient group: $2.67 / 3.00 = 0.89$ (large)

Surgical group: $4.08 / 5.20 = 0.78$ (large)

Bleeding:

Expectant group: $2.83 / 3.16 = 0.90$ (large)

Surgical group: $4.46 / 5.20 = 0.86$ (large)

($r = 0.1$ small effect size; $r = 0.3$ medium effect size; $r = 0.5$ large effect size;

Cohen, 1988)

Reterospective power (based on above effect sizes and sample sizes as noted in research paper):

Pain:

Expectant group (n = 10): between 60% and 71% (av. 65.5%)*

Medical inpatient group (n = 10): between 60% and 71% (av. 65.5%)*

Medical outpatient (n = 9): between 54% and 65% (av.59.5%)*

Surgical group (n = 27): between 92% and 99% (av. 95.5%)

*To obtain 80% power with the same effect size, a sample of 14/15 would have been required for the expectant group, medical inpatient group, and medical outpatient group.

Bleeding:

Expectant group (n = 10): between 36% and 48% (av. 42%)*

Surgical group (n = 27): between 97% and 99% (av.98%)

*To obtain 80% power with the same effect size, a sample of between 20 and 25 would have been required for the expectant group.

In order to examine whether the intensity of pain or degree of bleeding varied significantly according to treatment option, a series of Kruskal-Wallis tests were conducted with pain / bleeding rating as the test variable and treatment group as the grouping variable.

The significant result for the average of days 1 to 4 is included in the research paper.

In addition, these analyses produced the following non-significant results for pain ratings:

Average days 1-4: $H = 5.54$, $df = 3$, $p = 0.14$

Average days 5-10: $H = 3.47$, $df = 3$, $p = 0.33$

Average days 11-14: $H = 2.54$, $df = 3$, $p = 0.47$

6 weeks: $H = 4.29$, $df = 3$, $p = 0.23$

And the following non-significant results for bleeding ratings:

Average days 5-10: $H = 7.00$, $df = 3$, $p = 0.07$

Average days 11-14: $H = 3.50$, $df = 3$, $p = 0.32$

6 weeks: $H = 2.88$, $df = 3$, $p = 0.41$

Effect size of result from Mann-Whitney test: $r = \frac{z}{\sqrt{n}}$

Expectant vs. surgical group: $2.88 / 4.00 = 0.72$ (large)

($r = 0.1$ small effect size; $r = 0.3$ medium effect size; $r = 0.5$ large effect size; Cohen, 1988)

Retrospective power (based on above effect size and sample sizes as noted in research paper):

Medical outpatient vs. expectant group ($n = 16$): between 48% and 59% (av. 53.5%) *

*To obtain 80% power with the same effect size, a sample of between 30 and 35 would have been required.

3.7 Evaluation of treatment

Results from participant's evaluations of their treatment can be seen in the research paper. However, additional data on percentages is included in tables 3.13 for women and 3.14 for partners.

Table 3.13: Women's evaluations of treatment

Treatment group (n)	Advise same treatment (%)		Easy decision (%)		Fully informed (%)		Fully supported (%)		Right decision (%)	
	1	2	1	2	1	2	1	2	1	2
Expectant (10)	10.0	70.0	60.0	40.0	90.0	0.0	90.0	0.0	70.0	20.0
Medical inpatient (10)	60.0	0.0	70.0	30.0	100	0.0	100	0.0	80.0	10.0
Medical outpatient (9)	89.0	11.0	78.0	22.0	100	0.0	100	0.0	89.0	0.0
Surgical (28)	78.6	17.9	78.6	14.3	100	0.0	92.6	3.7	92.6	0.0

1 = agree, 2 = disagree (missing % accounted for by "unsure" responses)

Table 3.14: Partner's evaluations of treatment

Treatment group (n)	Advise same treatment (%)		Easy decision (%)		Fully informed (%)		Fully supported (%)		Right decision (%)	
	1	2	1	2	1	2	1	2	1	2
Expectant (10)	14.3	28.6	42.9	57.1	100	0.0	85.7	0	100	0
Medical inpatient (10)	80.0	20.0	40.0	40.0	100	0.0	80.0	20.0	60.0	0.0
Medical outpatient (9)	40.0	20.0	40.0	40.0	80.0	0.0	80.0	0.0	80.0	0.0
Surgical (28)	47.6	9.5	70.0	10.0	85.7	4.8	76.2	14.3	95.0	0.0

1 = agree, 2 = disagree (missing % accounted for by "unsure" responses)

In order to examine whether agreement rates varied according to treatment group, a series of Chi-Square tests were conducted.

These analyses produced the following non-significant groups differences:

Women:

Would recommend the same treatment: $\chi^2 = 15.21$, $df = 3$, $p < 0.01$

(see research paper and table 3.15)

Easy to make the decision: $\chi^2 = 1.46$, $df = 3$, $p = 0.69$

Received all necessary information: $\chi^2 = 4.78$, $df = 3$, $p = 0.19$

Received all necessary support: $\chi^2 = 1.72$, $df = 3$, $p = 0.63$

Made the right decision: $\chi^2 = 3.40$, $df = 3$, $p = 0.33$

Partners:

Would recommend the same treatment: $\chi^2 = 5.26$, $df = 3$, $p = 0.15$

Easy to make the decision: $\chi^2 = 3.12$, $df = 3$, $p = 0.37$

Received all necessary information: $\chi^2 = 2.20$, $df = 3$, $p = 0.53$

Received all necessary support: $\chi^2 = 0.30$, $df = 3$, $p = 0.96$

Made the right decision: $\chi^2 = 6.41$, $df = 3$, $p = 0.09$

Effect size of the result from the Chi-square analysis for women: $\sqrt{[\chi^2 / n]}$

$\sqrt{[15.21 / 57]} = \sqrt{0.27} = 0.52$ (large)

($w = 0.1$ small effect size; $w = 0.3$ medium effect size; $w = 0.5$ large effect size; Cohen, 1988)

Reterospective power (based on above effect sizes and sample sizes as noted in research paper):

(n = 57): between 89% and 74%

Table 3.15: Endorsement of recommendations of same treatment

Treatment group	Number in agreement with recommending the same treatment		Number not in agreement with recommending the same treatment	
	Women	Partners	Women	Partners
Expectant	1	1	9	6
Medical inpatient	6	4	4	1
Medical outpatient	8	2	1	3
Surgical	20	10	8	11

Word count: 10, 221

Appendix 4

Discussion

4.1 Treatment choice

Although historically surgical has been the preferred option for miscarriage treatment, the greater proportion of women choosing this option in the current study may not be representative of the true demographics of treatments administered within the service. Due to the nature of miscarriage diagnosis and the clinic practice, women can only be diagnosed when certain criteria are met (i.e. length of foetal pole > 6mm, having two scans two weeks apart confirming no growth). This means that for a number of women, they are inadvertently required to experience two weeks of expectant treatment before a diagnosis can be confirmed. A large proportion of these women will miscarry over this two-week period resulting in no further treatment being necessary. These women would have been included in the 1146 women thought to be eligible for the study. However, they would not have been eligible on the basis of coming to the unit and making a choice with regard to treatment.

From the data collected from those women who did participate in the study through exerting a choice in their treatment, it is important to acknowledge the need to develop services in a way that allows for the provision of accurate, clear and realistic descriptions of women's experiences so that women can feel fully informed with regard to their own treatment decisions. In addition to the quantitative data discussed in the research paper, qualitative data was collected with regard to additional factors that may have contributed to the treatment choices women made. These have been presented and described

in appendix 3.4. Whilst some of the factors raised in this analysis reflected those included in the original list (i.e. staff advice, wanting the most natural option, wanting to avoid hospital and concerns around impact on family life), others were supplementary and provided interesting insights into the processes women (and their partners) undergo when making such a decision. Although the analysis was not conducted according to the individual treatment groups, examination of women's comments indicate that different treatments may be associated with different factors, as was found with the quantitative analysis. For example, the majority (approx. 60%) of women who commented on wanting a speedy return to normality following their treatment opted for surgical treatment. This implies women felt this to be the quickest both in terms of initiating and finishing treatment. Similarly, almost 80% of women who mentioned the impact on their family chose surgical. This is particularly interesting given the result reported in the research paper that although it may be expected that surgical has less impact on the partner, it would seem this is not so as they are more likely to be cases according to the GHQ-12 than partners in the other treatment groups. This suggests that women's perceptions of impact are not reflective of the actual experiences of those around them and on whom they are perhaps basing their decision. Surgical treatments were also predominantly chosen by those women who commented on being influenced by seeking an explanation to their miscarriage (100%), past experience (both positively and negatively; 50%-75% respectively), staff advice (100%), wanting control (50%) and fearing pain, bleeding and complications (46%). In contrast, women who chose expectant treatment, were more likely, as seen in the quantitative analysis, to endorse the desire

for a natural treatment (27%) or the need for support from family and their home environment (30%) than any of the other factors identified. Similarly, medical outpatient treatment was selected by those women who considered support from the family and home as important (50%) as well as wanting to avoid hospital (55%), wanting the most natural treatment (55%), and wanting control (33%). There was not any one factor that was predominantly associated with medical inpatient treatment interestingly.

The factors of control and wanting the most natural option are interesting in particular with regard to the cognitive theories of depression and anxiety discussed in the research paper. In this sense, if making internal-stable-global attributions for their miscarriage makes women more vulnerable to psychological distress, attempts to gain some degree of control and predictability over their treatment may reflect attempts to defend against this prospect. Similarly, a number of women reported the natural option as being a more negative choice as they felt they were then not in control of what the outcome would be and did not appear to have the confidence in nature to be predictable and controllable.

What these results endorse is the notion that women have an understanding, perception and expectation of the different treatments available to them which influences on a number of levels, the option they chose. Whether this is developed out of the existing information that is provided to them by EPAU staff, or other experiences is not clear. However, it is useful in informing the kinds of areas of information women do consider and therefore need to be

fully and accurately informed about if they are to be involved in their treatment.

4.2 Psychological impact on women and partners

Much of the discussion around results on the psychological impact of miscarriage on women and their partners is included in the research paper. However, it is interesting to further consider the links with psychological theory and other areas of the existing literature with these results in mind. The most prominent psychological theories of relevance to this discussion are those discussed in the research paper and appendix 1.9.

With regard to attachment theory, there is unfortunately a limited amount of data included in the study that allows for a lengthy discussion on this topic. This opportunity would have been improved had more information been obtained about factors that may be associated with the development of attachment relationships in the prenatal period (which may have been gathered through the proposed telephone interview). It has been shown that, for example, greater family support, better psychological well-being and being given an ultrasound scan all contribute to the development of stronger maternal-fetal attachments. Conversely, depression, substance abuse and greater anxiety contribute to poorer attachments (Alhusen, 2008). Similarly, information on factors such as gestational age at the time of miscarriage, previous reproductive history, and desire for pregnancy would also have been informative and interesting areas on which to obtain more detail. Collectively, this may have afforded a greater opportunity for discussion with regard to

attachments between women and their babies, specifically around exploring the hypothesis that attachments are formed in the prenatal period (Rubin, 1975; Peppers & Knapp, 1980; Muller, 1992).

Although this information is not available in the current study, due to being mindful of the amount of data being asked of women participating, some interesting considerations can still be discussed. Through exploring the psychological impact of miscarriage, it has been possible to document the extent to which women (and their partners) are affected by miscarriage. As well as psychological outcomes being influenced by the attachment relationship developed prior to the miscarriage (of which there is little data to base a discussion on), there may also be important implications in relation to future pregnancies and attachment relationships. Bergner, Beyer, Klapp and Rauchfuss (2008) have reported that experience of early miscarriage can significantly increase the risk of disturbances in the psychological adaptation to subsequent pregnancies. This being so, there may be important implications on the attachments that women (and their partners) are able to develop with their unborn child. Furthermore, Bakermans-Kranenburg, Schuengel and Van Ijzendoorn (1999) have reported that unresolved parental loss following miscarriage is significantly associated with infant disorganised attachment in subsequent children. They additionally report that whilst this is unrelated to the time that has lapsed since the miscarriage, it is significantly related to the duration of the pregnancy before the miscarriage took place. What these studies suggest is that it may not only be the attachment to the foetus that miscarries that is important for psychological well-being, but that

the association between the two extends to have implications for future reproduction and attachment relationships.

The matter of attachments between partners and unborn babies is an interesting one when considering the existing literature. In light of the lack of differences in psychological impact between partners and women, it would seem appropriate to consider the likelihood that partners are in fact developing attachments with their unborn children, even in the early stages of pregnancy. This is inconsistent with a number of reports that argue in support of more intense emotional reactions in women (i.e. Furman, 1978), greater physical and psychological distance from the baby in men (Leon, 1992), and a lagging development of attachment in men particularly at the start of pregnancy (Goldbach, Dunn, Toedter & Lasker, 1991). Whilst further studies would be necessary to explore this issue further, the results from this study highlight the possibility that, just as potentially happens for women, partner's attachments may be one factor that influences the extent of psychological impact following miscarriage. Taking this a step further, this may also mean there are important implications to consider in relation to the future attachments that partners develop with subsequent pregnancies, as with the literature for women.

In contrast to attachment theory, the cognitive theories discussed previously focus more so on offering an explanation for vulnerability to increased psychological distress / symptomatology following miscarriage (although attachment relationships may also influence this). According to the Learned

Helplessness model (Seligman, 1975), women's beliefs about the future (i.e. outcomes of miscarriage treatment, outcomes of future pregnancies) may make them more or less vulnerable to depression. This may be more likely in those women (and partners) who perceive their circumstances as uncontrollable (see discussion on factors influencing treatment choice from qualitative analysis), and made attributions that explained their miscarriage in an internal-stable-global manner (i.e. that it was due to something they had done, that this will happen again, and will result in them not ever being able to have a family). Similarly, women (and their partners) may be more vulnerable to anxiety as a result of the beliefs they develop about why the miscarriage occurred (whether they feel responsible), how they behave as a consequence (whether they are able to accept it and move on, whether they feel in control) and how they feel about the future (whether they are anxious that the same thing will happen again or whether they feel more optimistic). The notion of having control and assumptions about the self and the world around us are also highlighted in the theories of PTSD raised in the research paper. In this context, challenging the assumptions of women that they are worthy and competent and are in a world that is predictable and competent may be a significant vulnerability factor to the development of PTSD symptoms. Furthermore, experience of particular treatment options (i.e. medical inpatient treatment – given this group reported the highest scores on the IES), may further exacerbate the challenge of these assumptions.

In addition to providing a useful framework for understanding some of the mechanisms underpinning the psychological impact of miscarriage, and

raising the important question of whether assessment of such vulnerabilities should be incorporated into existing services, it also raises the question of how symptoms may be maintained. With psychological theories in mind, there is the possibility that a vicious cycle develops that makes each experience of miscarriage potentially more psychologically distressing (i.e. reinforcement of maladaptive beliefs). Experience of miscarriage as a threat to future fertility and reproduction may also maintain symptoms over time. There exists a distinct yet complementary body of literature that explores multiple (recurrent) miscarriages that is outside of the realms of discussion for the current purposes. Needless to say, however, further knowledge and understanding of such processes may be valuable in indicating where interventions can be aimed in order to ensure women and their partners are provided with the best possible support and that the risks of psychological distress are minimised.

4.3. Implications for services and clinical practice

Inherent in many of the previous discussion points (as well as those included in the research paper itself), are ideas around implications of these results on the provision of services in early pregnancy units and the clinical practices that staff adhere to. Most notably, results clearly support a move towards a shared-model of decision-making with regard to treatment for miscarriage. This is discussed in length within the research paper. This would imply a significant shift from existing models of treatment for a majority of units. Whilst it is unclear how much support this shift would receive from professional staff members working on the unit, it is clear that evidence in its favour is

increasing and therefore needs to be considered as a real possibility in the future.

An additional implication as far as services are concerned would be potential changes to additional services that are offered either directly or indirectly through the early pregnancy unit. It has previously been mentioned that incorporation of screening measures to assess vulnerability to psychological distress may be useful in informing staff of those women who may be more likely to face difficulties and require additional support through their miscarriage. Obtaining such information may also have implications on the information women are provided with when making their treatment choice. Although this study did not report differences between the treatments in terms of psychological impact, they suggest women who receive medical outpatient (and to a lesser degree, surgical) may benefit if vulnerable to post-traumatic stress symptoms, for example. Services may also be developed further with regard to follow-ups of women. Current results suggest that women and their partners continue to experience significant levels of psychological distress six-weeks post-miscarriage. As it stands, women are only seen at this point in time if they are experiencing medical complications as a result of their miscarriage. However, it may be valuable to consider the possibility of offering women a follow-up phone call or appointment to ascertain medical as well as psychological adjustment to their experience. In the event that women (and partners) continue to experience significant distress, they may then be advised of additional services to contact (either in-house counselling or through other agencies such as clinical psychology or psychotherapy). In the

example of involvement from clinical psychology, this could be done so either through provision of direct therapeutic work with individuals, or through consultation work with existing nursing staff on the units. With existing literature and current results in mind, it is likely that therapeutic work would be focussed predominantly on working with individuals around their symptoms of depression, anxiety and possibly post-traumatic stress. Collaborative work in these areas would be supported by NICE guidelines, New Ways of Working for Psychologists and the Improving Access to Psychological therapies programme, and is in line with suggestions from Brier (1999) and Swanson (1999) with regard to developing more multi-disciplinary teams within early pregnancy units to offer a more comprehensive, integrated, and evidence-based service that meets the needs of women and couples across the range of experiences.

4.4 Strengths and limitations

Many of strengths and limitations of the study have been discussed directly in the research paper. Additional points that are noteworthy, however, include the following:

Strengths:

- i) Use of a range of psychological measures, which accurately reflect the current literature and theories around what may be important to consider in the content of miscarriage.

- ii) Use of both quantitative and qualitative data to provide a richness in detail that would be more difficult to achieve with either methodology alone.
- iii) Inclusion of partners in the study, which addresses a gap in the existing literature but has proven to be a valuable addition to the study.
- iv) Use of a specifically designed diary that allowed for flexibility in the information it collected, whilst offering the opportunity to incorporate more standardised and rigorously studied measures.

Limitations:

- i) Using nursing staff in the recruitment procedure introduced additional variables that contributed to a more biased population of women.
- ii) Not including additional information on known risk factors for psychological distress following miscarriage (i.e. gestational age etc.) which may have allowed for a greater understanding of how the relationship is mediated.
- iii) Relatively short follow-up and only at one point. Would have been useful to extend the follow up to perhaps six months to explore further the duration of psychological impact and whether this varies according to treatment
- iv) Use of questionnaires to measure psychological outcomes at the expense of obtaining richer and more flexible information from one-to-one interviews. This may have also influenced response rates (i.e. higher with telephone interviews).

4.5 Future research

The most notable direction for future research to take with respect to the current study is to attempt to replicate findings using a larger, more representative population. Although power calculations on the current data suggested the existing sample size would not need to be vastly increased in order to increase the strength of findings, a larger population would allow for more generalisable results and afford the opportunity to explore other interesting avenues such as cultural and/or spiritual influences, and variations according to units and NHS trusts / private services.

In addition to the discussion points made within the research paper on this matter, however, there are some additional prospects for future research, which are worth mentioning.

Firstly, although some qualitative data was obtained in the current study, this was done so through limited opportunities for women to note down additional comments pertinent to the study. One of the original aims of the study, that did not receive ethical approval and therefore did not get incorporated into the final methodology, was to invite women to engage in a telephone interview about their experiences, how they were coping and what expectations they had about the future. This did not receive ethical approval due to concerns over confidentiality, but would have provided a valuable opportunity to obtain more detailed information on the reasoning behind women's decisions and the psychological processes that corresponded to both their decisions and how they managed the experience of their miscarriage. This may have also

allowed for incorporation of questions relating to the psychological models discussed previously (i.e. attachment relationships developed with the unborn child from the perspective of both women and their partners and cognitive attributions, coping strategies). Within the framework of the current study, it is not possible to speculate on what factors mediated the psychological impact of the miscarriage. Whether this was related to factors such as social support, individual coping styles or other personality variables would be an interesting avenue to explore and could either be included in an interview or further questionnaires.

As discussed in the research paper, it would be beneficial for the study to include additional comparison groups in order to establish the specificity of the findings to women who are given a choice in the treatment they receive for their miscarriage. It would also be an interesting development for future research to explore the variation in scores depending on gestational age of the foetus (i.e. women who miscarried in the first, second and third trimester of pregnancy and perhaps even those who lost a child in the neonatal period / stillbirth). This idea links back to consideration of attachment theory discussed previously and the opportunity of evaluating how this relationship develops over the course of pregnancy. It would also be informative with regard to the nature and extent of support women and their partners may require, possibly differentially, across the different trimesters of pregnancy.

Finally, current results suggest that the concept of a relationship between PTSD and the experience of miscarriage is worthy of further examination.

Future research could be conducted that is focussed on developing a more comprehensive understanding of current findings in the context of establishing which of the existing psychological models of trauma and PTSD best fit the context of miscarriage.

4.6 Critical reflection

The process of conducting a piece of research raises a number of scientific, theoretical and ethical issues that are worthy of commentary, not least in relation to what constitutes science and how a given piece of research contributes to advancing scientific knowledge within a given domain of interest. Accordingly, whether science is viewed as something that is abstract in nature (i.e. Karl Popper) or develops out of the result of experience (i.e. empiricism) may have important implications for the way in which research is conducted, interpreted and absorbed into the existing pool of knowledge.

In thinking about such matters for the current study, it is useful to reflect on one's own philosophy of science in terms of its influence on how the research was designed, conducted and evaluated. This is particularly important if one is to fulfil the scientist-practitioner role that is assigned to clinical psychologists as a profession. In light of this role, my philosophy of science, as applied to my own research, has developed out of a number of origins. These include conventional teaching on psychological topics, prior experience of conducting research within a range of professional environments (i.e. psychology, psychiatry, health care services), and experience as a practitioner utilising

scientific methodology to inform and guide my clinical practice as well as my own development of scientific methodology.

From this, I approach my role as scientist-practitioner from very much an empirical perspective, whereby hypotheses and theories relating to aspects of experience have been tested through observation of a given phenomenon in an experimental fashion. It is thought that an empirical philosophy to research is best understood as a quantitative paradigm that may be influenced by additional philosophies (Gergen, 1985; Valle, King & Halling, 1989; Clark, 1998). Historically, the single most influential philosophy thought to contribute to the development of empiricism is that of positivism. Positivism is a position through which the goal of knowledge is to describe the phenomena that is experienced and discover the “truth” through verification and replication of observable findings (Wolfer, 1993; Poole & Jones, 1996). Thus, science consists of what we can observe and measure, based on the assumption that there exists an objective reality, which can be accurately perceived through human senses.

Criticisms of this approach on the basis of being over-reductionist, failing to account for subjective experience and the reality that true objectivity is impossible based on observer biases, have led to a more contemporary post-positivism movement within research philosophy (Phillips, 1990; Dzurec & Abraham, 1993). Within this school of thought, a more realist perspective of science has been advocated with the recognition that unobservable phenomena could exist and furthermore, could contribute to our

understanding of the function of observable phenomena (Schumacher & Gortner, 1992). Within this theoretical framework, it became possible to obtain evidence for a given phenomena from inferable forms such as self-report questionnaires (Bronowski, 1956).

With this in mind, it is my belief that quantitative analysis allows for the discovery of phenomena, which are likely to be a genuine reflection of reality rather than occurring as a consequence of chance. This compares to the use of qualitative approaches to research, which are more susceptible to uncertainties over generalisability. That being said, this current project has alerted me to the role of qualitative research alongside that of quantitative in providing a richness to the data that supports and emphasises quantitative findings whilst contributing a more “natural” sense of the reality of the findings. Based on current findings, this has also highlighted how frequency of phenomena does not necessarily reflect importance, as in the case with some of the themes identified in the analysis of factors contributing to women’s treatment choices. Whilst this flags up one of a number of disadvantages to applying quantitative analysis in “missing” some of the finer details, it highlights the role of using both approaches in a complementary fashion to address the research questions and advance the science.

Use of these different analytical approaches potentially has implications not only in terms of what data is collected and how it is interpreted, but also on ethical grounds, particularly in a study involving vulnerable individuals. One of the most significant ethical considerations of the current study was that of

approaching women at a time of considerable distress and requesting them to reflect on their physical and psychological experience for an extended period of time. Awareness of what women were being asked to do, in conjunction with the drive to produce a high quality and valuable piece of research (bearing in mind matters around my philosophy of science) had a significant bearing on the methodological approach adopted. As noted in the limitations of the study, there would have been significant advantages to being able to use a face-to-face interview as a technique to gather information from women and their partners about their experience. However, as beneficial as this may have been to the amount and type of information collected, it was felt, fundamentally, that presenting women with the opportunity to participate in a face-to-face interview in which they would be asked very personal and potentially distressing questions would be done so at the expense of ethical consideration of their emotional well-being and recovery from their experience physically. Offering the alternative of completing self-report measures felt less intrusive and less susceptible to creating additional distress for women. In hindsight and on reflection, this may not necessarily have been true, as a number of women stated they would have liked the opportunity to talk more about their experiences and would have felt they would have benefitted psychologically as a consequence. However, this was not something that could have been predicted at the outset and serves to provide important evidence in support of possibilities for future directions of this kind of research. It is also important in highlighting the importance of such opportunities via the provision of counselling and / or access to psychological therapies following miscarriage.

Word count: 4, 274

Total appendices word count: 26, 500

Total thesis word count: 35, 516

Appendix 5

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