

Drug and Alcohol Educational Interventions for Pregnant Women in a Rural Setting: A Randomized Trial

Author:

Jean Clulow
Clinical Nurse Consultant
Drug and Alcohol Service, Orange & Region
Mental Health and Drug & Alcohol Service
Western NSW Local Health District
Bathurst, NSW 2795

Jean.Clulow@qwahs.health.nsw.gov.au

Table of contents

Section	Page number
Acknowledgements	2
List of abbreviations	3
Abstract	4
Executive Summary	5
Introduction	8
Background	10
Methods	14
Results	16
Discussion	20
Conclusion	24
References	26
Appendices	28

Acknowledgements

Thank you to the women who gave freely of their time and knowledge during this important milestone in life.

Thank you to the Health Education and Training Institute -Rural and Remote Portfolio for providing the initiative and funding that enables this program to exist.

I would also like to acknowledge and express my gratitude to the following people for their support during the course of this project:

- Sandra O'Neill, Sue Mooney and Paul Stanfield, all wonderful librarians at Charles Sturt and Newcastle universities.
- Emma Webster, RRCBP, HETI Research Officer, who gave me encouragement to continue on to completion.
- David Schmidt – RRCBP, HETI Research Officer, whose steadfast patience has been awesome.
- Dr Margie Lesjak -Senior Lecturer, Broken Hill University Department of Rural Health, School of Public Health who supervised my stumbling steps in research.
- Tina Navin- Trainee Biostatistician for conducting the statistical analyses.
- Management and colleagues from Mental Health and Drug & Alcohol services. Orange and Region.
- Management and colleagues from the maternity unit and the drug and alcohol service at Bathurst Base Hospital.

List of abbreviations

CNC	Clinical Nurse Consultant
CUPS	Chemical Use in Pregnancy Services
DIPS	Drug Use in Pregnancy Service
D&A	Drug and Alcohol
FASD	Foetal Alcohol Spectrum Disorder
GWHS	Greater Western Area Health Service (now Western NSW Local Health District)
NHMRC	National Health & Medical Research Council
PI	Principal Investigator
SUA	Substance Use Assessment

Abstract

Context: A concerning number of neo-natal deaths occurred over a four month period at Bathurst Base Hospital in 2007. A series of case reviews revealed smoking as the only common risk factor amongst the mothers in this group. Further investigation identified that comprehensive antenatal drug and alcohol (D&A) assessments were not being conducted and subsequently problems associated with drugs and alcohol were not being identified. This in turn limited the ability to provide expectant mothers with appropriate information or referral to treatment that would assist improved health outcomes in the perinatal period.

Aim: This study sought to answer the research question:

Does educational material alone or educational material given in a face to face setting improve knowledge and reduce risk behavior in rural women who use psychoactive substances during pregnancy?

Method: All women accessing the antenatal booking-in clinic at Bathurst Base Hospital from October 2010 – April 2011 were assessed for substance use prior to confirmation of the current pregnancy. Participating women were randomised and allocated to either the control or intervention group. All participants completed a 13-question D&A questionnaire at enrolment and after the birth of the baby. The Intervention group was scheduled for a specific face to face educational package relating to the questionnaire with a D&A worker and a literature package. The control group received the literature package only.

Results: A total of 70 women were enrolled into the study: 38 were allocated to the control group and 32 to the Intervention group. Pre-intervention measures for the two groups were not significantly different. Knowledge scores post intervention had increased significantly for both control and intervention. Changes in behaviour showed no significant differences between the two groups.

Discussion: The use of a comprehensive D&A assessment in the antenatal clinic along with provision of literature to pregnant women improved their knowledge of issues associated with substance use in pregnancy. Further face to face education did not provide additional benefit, although the small sample size did not allow sufficient statistical power for this issue to be comprehensively examined.

Conclusion and recommendations: This study showed that when provided with comprehensive educational material pregnant women avail themselves of the content and make changes to their behaviour in this important time of life. The use of a comprehensive D&A assessment is in itself an invaluable tool and may reveal issues otherwise unknown to both midwife and expectant mother. Larger studies could explore the value of additional face-to-face education.

Keywords

Pregnancy, substance use, drugs, antenatal education.

Executive Summary

The problem

Alcohol and tobacco consumption in Australia have been considered, until recently, very socially acceptable and have been universally consumed at many social and community occasions in the western world. “In many countries, including Australia, alcohol is responsible for a considerable burden of death, disease and injury. Alcohol-related harm to health is not limited to drinkers but also affects families, bystanders and the broader community” (NHMRC, 2009). In the past decades research has influenced a reduction in consumption of alcohol and tobacco and continues to reflect the need for communities to continue reviewing current behaviours to ensure improved health outcomes. This is particularly important when women are pregnant or planning to become pregnant, as their consumption of alcohol and tobacco during this period can have serious consequences for their baby’s future life.

From the Midwives Data Collection 2004-2008 it was identified that 20% of pregnant women continued to smoke through their pregnancy and the data for those women who continued to drink alcohol was underestimated or not known. Known risks associated with consumption of tobacco are increased ectopic pregnancy, spontaneous abortion, prematurity, placental abruption, low birth weight and still birth (Burns L. et al, 2007). Other studies suggest that women who drink alcohol prior to becoming pregnant continue to consume alcohol at levels that may cause significant and permanent harm to their babies (Powers et al, 2010; Zammit et al, 2007). These harms are described as a wide array of effects (Krulewitch, 2005) under the term Fetal Alcohol Spectrum Disorder (FASD). This term is used to include some of the conditions that can occur from exposure of the fetus to alcohol including Fetal Alcohol Syndrome (FAS), alcohol related brain damage (ARBD), and alcohol related Neurodevelopmental disorder (ARND). These conditions are all preventable but have lifelong implications (Peadon, 2007). In a national survey conducted in 2010 (Peadon et al), of the women surveyed “92.7% agreed that alcohol can effect the unborn child. 16.2% did not agree that the difficulties could be life-long”. With this in mind providing educational and health promotional activities to reduce fetal exposure and damage were the key components of this study.

The response

Midwives are trusted health professionals and are in a strategic position to engage effectively with women. They are required to complete a thorough obstetric assessment and are skilled in this process. It has long been known that midwives are key providers of education and information to pregnant women, therefore it is within their scope of practice to provide relevant information and education relating to the effects of alcohol, tobacco and other drug use during pregnancy. To better determine substance usage of pregnant women midwives were provided with education around the completion of a drug and alcohol assessment to be completed at the antenatal booking in clinic appointment.

The study also wanted to ascertain what pregnant women currently knew about drugs and alcohol and their effects on the developing fetus considering the changes to the national guidelines for alcohol consumption, from 2001 to 2009. Women were recruited from the antenatal booking-in clinic at a rural maternity unit in NSW. On consent they were randomly allocated to one of two groups. Group one (control group) involved assessment and self directed drug and alcohol educational material. Group two (intervention group) involved assessment, self directed drug and alcohol educational material plus a face to face brief intervention. Their knowledge of drug and alcohol issues and substance use throughout the pregnancy was again measured postnatally.

Recommendations

There are several recommendations from this study:

1. Midwives in rural maternity hospitals will complete a comprehensive drug and alcohol assessment when pregnant women present for antenatal care.
2. Drug and alcohol education and information should be regularly provided by drug and alcohol service providers to build capacity of midwives in the completion of a comprehensive drug and alcohol assessment.
3. Women, who are identified through this process as being at risk of consuming alcohol and drugs through their pregnancy, to be provided with a package of drug and alcohol educational material and opportunistic interventions and D&A referrals as required.
4. A larger study to be completed to determine if face to face drug and alcohol educational interventions facilitate pregnant women to make lifestyle changes that improve fetal and maternal health outcomes.

The project

These recommendations are based on the results of a two year quantitative research project funded by the Health Education and Training Institute, Rural Directorate.

This project addressed the following question:

“Does educational material alone or educational material given in a face to face setting improve knowledge and reduce risk behavior in rural women who use psychoactive substances during pregnancy?”

The project targeted alcohol, tobacco and cannabis and aimed to measure increases in knowledge of drugs and alcohol and then measure any reductions in consumption during the perinatal period.

Findings

Several trends were identified from the analysis of prenatal and postnatal substance use assessments and from prenatal and postnatal drug and alcohol knowledge questionnaires.

1. Knowledge about the effects of drugs and alcohol on pregnancy was increased from prenatal to postnatal questionnaires in both groups.
2. There was a trend towards reductions in substance use from prenatal to postnatal periods.
3. There was no obvious difference between the two groups as numbers were too small.
4. The high level of caffeine consumption and the lack of awareness of the risks associated with pregnancy was in contrast with the recommended levels of consumption for reduced impact on the pregnancy and fetus.

Conclusion:

Although the numbers within the study were small women's knowledge about the effects of drugs and alcohol increased for both groups. It was also noted that women did reduce their alcohol, tobacco and caffeine consumption for the duration of their pregnancies following the provision of education. Pregnancy is a time when women are open and willing to gain knowledge and make changes in their behavior to improve the outcome for their babies.

Introduction

Substance use in pregnancy is an issue across Australia as a whole. The National Clinical Guidelines for the Management of Drug use during Pregnancy, Birth and the Early Development years of the Newborn (2006) states "The adverse effects on fetal development of alcohol and other drugs such as tobacco, psycho stimulants and opioids are well known" (pg ix). Much of the research around drugs in pregnancy has demonstrated a link between psychoactive substance use and adverse neonatal conditions such as miscarriage, lower birth weight, pre-term and still birth (Ministerial Council on Drug Strategy, 2006). Psychoactive substances include depressant substances such as marijuana, opiates, alcohol and stimulants such as speed, ecstasy, and caffeine. Anecdotal evidence has shown that these substances continue to be used throughout pregnancy in Australia significantly alcohol, tobacco and to a lesser degree cannabis.

Much research has demonstrated a link between substance misuse and other conditions such as lower birth weight, pre-term birth and still born birth (National Treatment Agency, 2002). In the USA in the middle of the 1990s it was reported that as many as one in three pregnancies were exposed to both alcohol and other drugs with adverse results; notably impaired foetal development, low birth weight, premature labour, and stillbirth (Siney, 1999).

Some drugs, in particular those that contain caffeine, are not considered by the general public to have serious effects on the developing fetus. However, it has been noted by Bracken et al (2003) that there is a strong association between smoking and the consumption of caffeine and this potentially may confound the outcome for the developing fetus and the impact on the outcome of the pregnancy. Bracken et al (2003, pg 465) and the CARE Study Group, a large prospective observational study in 2008 stated "large quantities of caffeine should be avoided". Certainly, when adverse events for the fetus are reported, the dosages need to be at high levels and with the increasing consumption of caffeine energy drinks this becomes a greater risk. In addition, Bracken et al (2003) state that since 1980, the US Food and Drug Administration have recommended that pregnant women avoid caffeine. They also state that "subsequent epidemiological studies have linked relatively high levels of caffeine (typically >300mg per day or greater than 2 cups per day) to low birth weight, spontaneous abortion and fetal growth retardation (pg 456).

In the Bracken et al study (2003), caffeine, in combination with tobacco smoking, particularly in the first and third trimesters of pregnancy, increased the risk for adverse outcomes in pregnancy, namely Inter Uterine Growth Retardation (IUGR) and low birth weight (pg 458). The National Clinical Guidelines state that the evidence for tobacco posing a considerable risk for both mothers and babies is substantial (Ministerial Council on Drug Strategy, 2006, pg 28).

From the NSW Midwives Data Collection (2004-2008) it has been estimated that 20% of women smoke tobacco during pregnancy (NSW Health, 2004-2008). Nicotine is transported across the blood/placenta barrier resulting in 15% higher blood concentration levels in the fetus' blood supply compared to that of the mother (Lambers & Clark, 1996). Lambers and Clark's study states that nicotine effects are seen throughout pregnancy, from increased spontaneous abortions in the first trimester, to increased premature delivery rates and decreased birth weights (Lambers & Clark, 1996). It was also noted in this study, that the birth weight of a baby is dependent on two factors: the gestational age of the fetus at the time of delivery and the rate of fetal growth (Lambers & Clark, 1996). Additional factors with the consumption of tobacco that Lambers and Clark (1996) identified were that carbon monoxide, also found in tobacco, forming carboxyhemoglobin prevented the release of oxygen into fetal tissues and that nicotine concentrates were also identified in blood, amniotic fluid, and breast milk. Nicotine has been found through other animal study research to increase maternal heart rate and blood pressure with an associated reduction in uterine blood flow (1996). Lambers and Clark conclude that "the physiological effect of tobacco on fetal growth seems to be a culmination of both the vasoconstrictive effects of nicotine on the uterine and potentially the umbilical artery and the effects on oxygenation by carboxyhemoglobin" (1996).

Alcohol consumption has shown distinct age-related patterns of drinking with a high prevalence of drinking among women who are pregnant. Colvin et al (cited in NHMRC, 2009) found in 2007, that 59% of Australian women were drinking alcohol at some time during their pregnancy. Of these women, 14% reported drinking above recommended levels for low risk drinking, reporting consumption of five or more drinks at one episode in the three months prior to pregnancy. Peadon et al, 2007 (as cited in NHMRC, 2009) also report that "34% of women had drunk alcohol during their last pregnancy and 24% indicated they would drink in future pregnancy, despite knowledge of the adverse effects of alcohol".

Research shows alcohol is a human teratogen and is a risk factor for poorer perinatal outcomes (Peadon.E et al, 2007). As a teratogen, alcohol damages the embryo and potentially fetal development may be affected, this is referred to collectively as fetal alcohol spectrum disorder (FASD), (NHMRC, 2009, pg 70). Fetal alcohol spectrum disorder (FASD) is an issue for any individual or group that consumes alcohol at harmful levels and with up to 51% of live births in Australia resulting from unplanned pregnancies many pregnancies may be exposed to alcohol before being confirmed (WebSurvey, 2008). In Australia alcohol consumption in pregnancy is being given greater recognition with new research being funded to identify improved diagnostic tools, preventative measures and early interventions to support children identified with FASD (FASD: The Hidden Harm - Inquiry into the prevention, diagnosis and management of Fetal Alcohol Spectrum Disorders, 2012). In Western Australia priority is being given for the development and use of preventative strategies to reduce the prevalence of FASD, as it is recognised that there is no cure for this avoidable condition (WA Department of Health. 2010, pg5).

In Australia it is estimated that approximately 59% of pregnant women consume alcohol at various levels during pregnancy (NHMRC, 2009). Within the revised National Health and Medical Research Council, Australian Guidelines to Reduce Health Risks from Drinking Alcohol it has been recommended that there is “no safe level of alcohol consumption in pregnancy or whilst breastfeeding” (NHMRC, 2009, p 67).

The NSW Health, Clinical Guidelines for Nursing and Midwifery Practice in NSW: identifying and responding to drug and alcohol issues (NSW Health, 2007) is regularly revised to reflect changes in clinical management, assessment and interventions that provide best practice for the care of patients identified with drug and alcohol issues relating to various clinical presentations within a health facility.

The process of implementation of the reviewed clinical practice guidelines and the updated assessment tools prompted a review of the local management of assessment and education around drugs in pregnancy in Bathurst. In earlier research (Chasnoff, 2005) it had been found that “identifying women early in pregnancy, treatment, and brief intervention and prevention services for this special population can be made available, reducing risk for the pregnancy and the child”. Drug and alcohol assessment for all pregnant women would enable midwives to identify those women who would benefit from educational material and referral to specialist perinatal services. This research project provided the opportunity to educate midwives about the effects of drugs in pregnancy and how to complete a comprehensive, D&A assessment using this particular assessment tool. This project details a research project conducted at Bathurst maternity service from October 2010 to April 2011 which provided an opportunity to measure alcohol and other drug consumption within this population of pregnant women. In addition the research project would combine a pre and post questionnaire, which when analyzed would provide information about what changes in knowledge and behaviors had occurred when educational messages and resources are incorporated into routine antenatal care.

Background

Substance use as an issue in pregnancy in Bathurst was observed directly with several neonatal deaths reported in 2007. Following an informal review of the medical files it was noted that the only factor linking these neonatal deaths was that each of the mothers smoked nicotine. The question then arose within the local drug and alcohol service as to what might be a useful way of educating pregnant women around the harms to their growing babies associated with consumption of nicotine and other psychoactive drugs as well as promoting harm reduction behaviors during pregnancy.

In light of the above research data and the changes to the Australian Alcohol Guidelines (NHMRC, 2009) the Bathurst drug and alcohol clinicians wondered if providing educational resources or educational sessions would be effective strategies, to assist in increasing women's awareness and provide motivation for women to choose improved lifestyles throughout their pregnancies in relation to consumption of alcohol and other drugs, and not only during their pregnancy but whilst breastfeeding. The information provided would include relevant material around standard alcohol drinks, energy drinks, cannabis, and nicotine. All these drugs provide a level of risk associated with their consumption in pregnancy, for both mother and baby (Ministerial Council on Drug Strategy, 2006).

Zammit et al (2007) recommended the need for accurate assessment and measurement of alcohol consumption across the pregnancy period and to provide ongoing education and support for women to assist them to reduce their consumption of alcohol and other drugs. In rural NSW there is limited access to services that specifically target pregnant women who consume psychoactive substances. Drug Use in Pregnancy service (DIPS) or Chemical Use in Pregnancy Services (CUPS) are not specifically funded as a statewide service delivery model and are generally located in larger metropolitan clinics. A comprehensive D&A assessment will assist midwives to be able to identify those women who require a brief intervention and more intensive support. In Bathurst it is the local midwife who is best placed to undertake this assessment and provide the relevant education and referral for expectant mothers.

Bathurst, with a population of 43,544 comprising of 11, 047 families lies 200kms west of Sydney in rural New South Wales between Lithgow and Orange (ABS, 2011). However this centre is not funded for either a DIPS or a CUPS within its drug and alcohol or maternity services. The investigation into the neonatal deaths in 2007 also showed up gaps in both the referral pathways and also the linkages to other service providers with limited educational material being offered at the maternity service's Booking-In Clinic.

Bathurst Base Hospital has a maternity unit that delivers approximately 600 babies per year. Women attend the hospital for a "one off" antenatal Booking-In appointment following confirmation of their pregnancy, generally following a visit to their local doctor. Pregnant women in Bathurst have several options for antenatal care, however the maternity unit does not currently have a model of care that incorporates a midwife controlled antenatal clinic. Therefore, the primary contact point for all pregnant women wishing to deliver their baby in Bathurst is through this Booking-In clinic process managed by the maternity unit. Prior to the project commencing it was noted that no comprehensive drug and alcohol assessment was completed at any time throughout this appointment and therefore the scale of any drug and alcohol problem that might be present was unknown. The brief assessment taken was as a "Yes/No" response to questions of "do you smoke?" or "do you drink alcohol?" Further D&A antenatal

assessment and subsequent intervention throughout the period of gestation was neither available nor performed by the midwives, unless a specific incident occurred that was referred to the maternity service. For example if a pregnant woman presented to the emergency or maternity units intoxicated or was currently on an Opiate Treatment Program in Bathurst referrals would be made to drug and alcohol for follow up or a postnatal referral would be made to the In-Patient D&A Consultation Liaison service following birthing.

The Booking-In Clinic appointments are scheduled within the maternity unit for only one day per week and the woman makes her appointment via a phone call to the maternity unit with supporting documentation and referral from the woman's local doctor. This limited service delivery means that this appointment is not always held with the midwife until the pregnancy is greater than 20 weeks gestation. The recommended time for this initial appointment is 14-20 weeks (NSW Department of Health, 2009). The antenatal booking-in appointment is a long process (approximately one and half hours) to ensure all obstetrical aspects of the woman's history are completed and documented via the electronic database for maternity services, Obstetrix. The current appointment schedule does not afford the midwife an opportunity to provide any further screening or ensure the woman receives other comprehensive health education during this appointment. As a result, an estimate of substance use prevalence amongst pregnant women in Bathurst was unknown.

The review of the national alcohol guidelines in 2009 was seen as an additional motivator to measure the local drug and alcohol consumption within the population of pregnant women in Bathurst. It was also planned to measure any changes in knowledge and behavior when women are provided with educational messages and resource leaflets around safe and low risk consumption of drugs and alcohol in pregnancy. This project aimed to both; identify the women who were continuing to consume psychoactive substances in their current pregnancy, and, to measure the changes in behavior and knowledge that a specific educational intervention would bring about within the participants.

NSW Health have continued to review and update The Clinical Guidelines for Nursing and Midwifery Practice (2007) which provides for all nurses and midwives a "benchmark for quality drug and alcohol assessment and care in daily practice" (p 4). The guidelines state that "a drug and alcohol use assessment is important in order to; establish a correct diagnosis, ...plan appropriate intervention, ensure duty of care and to gain an understanding of the patient as a whole person, not merely in terms of their symptoms (pregnancy)" (p 16). A recommended assessment process is outlined in detail to cover the following criteria of "indicators of risk, past medical history, psychosocial issues, physical signs and symptoms, mental health status and pathology results" (p 16). Prior to the commencement of the study a comprehensive drug and alcohol assessment process for all general hospital in-patients was being implemented across

GWAHS. This was in line with best practice, as outlined in the Clinical Guidelines (NSW Health, 2007). In 2008, NSW Health provided significant training and additional resources to support the Clinical Guidelines. This training was rolled out across the state to support all nurses and midwives to implement these mandatory interventions as documented in the Policy Directive.

Along with the comprehensive assessment, the guidelines note that “all episodes of care provide an important opportunity or a critical moment for a person to be offered appropriate and easy-to-understand health information and education” (NSW Health, 2007, p 7). The “critical moment” for these women is also compounded by the importance of the health of their baby during this time. This study sought to bring together the revised guidelines, a comprehensive assessment and a combination of educational material and targeted D&A education in expectant mothers with identified substance use in the Bathurst region.

The study was designed to measure what current knowledge local women had of the effects of drugs and of the changes within the current Australian Guidelines and how this was impacting on their decision making in relation to psychoactive substance consumption in this current pregnancy.

Research question:

This study sought to answer the following research question:

“Does educational material alone or educational material given in a face to face setting improve knowledge and reduce risk behavior in rural women who use psychoactive substances during pregnancy?”

Study Goals and Objectives

The study aimed to measure:

- a) Changes to levels of self reported consumption of psychoactive substances
- b) Changes in knowledge about the effects of psychoactive substances on the baby during pregnancy.

Other objectives of the study were to:

- Ensure the GWAHS substance use assessment tool was applied for all pregnant women attending the Booking-In clinic.
- Engage with all identified substance using pregnant women to interact with qualified health professionals via participation in the study.
- Provide educational material and educational group interventions to all identified substance using pregnant women
- Evaluate the effectiveness of the educational intervention against that of the control group for both
 - Increase in knowledge

- Reduction of substance use in pregnancy.

Materials and Methods

Women were assessed using the newly introduced GWAHS Substance Use Assessment Form (SUA) during the routine antenatal Booking-In appointment within the Bathurst Base Hospital antenatal clinic. The assessment form had been revised and endorsed through the Greater Western Area Health Service (GWAHS) Forms Committee. This was the standardized assessment tool for all in-patient drug and alcohol assessments throughout the health service. All nurses and midwives for all admissions of in-patient facilities within GWAHS were to utilize this tool, commencing April 2010. This assessment tool was utilized at the Booking-In Clinic for the duration of the study.

The NSW Midwives Data Collection (MDC) records for 2004-2008 for Bathurst indicated that between 18-23% of women giving birth at Bathurst Base Hospital reported smoking tobacco during their pregnancy. Of these women an average of 2.2% reported not smoking in the second half of pregnancy. To determine whether the number of women smoking in the second half of their pregnancy could be significantly ($p < 0.05$) reduced by up to 20% through the intervention with education material, a sample size of $n=58$ women would be required in each group. A 20% reduction was deemed clinically achievable given what is known about smoker's readiness to quit smoking spontaneously in pregnancy (Ma Y et al, 2005).

Recruitment processes and data collection

A randomised control trial design was used for this study. The control group and intervention group were randomised from informed, consenting women at the Bathurst Health Service antenatal booking-in clinic.

General Practitioners (GP) direct all pregnant women, who are choosing to deliver their baby at Bathurst Base Hospital, to the Booking-In Clinic. Local GPs were informed by letter of the study and asked to publicize the project to pregnant women who presented to their surgeries (Appendix 3).

Presentation to the Booking-In clinic is recommended to "occur at the first presentation for antenatal care or as early as possible in the antenatal period, before 20 weeks of pregnancy (NSW Health, 2009). The antenatal Booking-In clinic at Bathurst Base Hospital is held weekly with 5 appointments scheduled during the day. All women were given a Participants Information Sheet (Appendix 4) to read as they arrived at the clinic. The attending midwife provided the primary antenatal care required during the appointment. At this appointment the drug and alcohol assessment was introduced and completed either by the midwife or the principal investigator (PI), at the midwife's invitation and with

the woman's consent. Women, who met the inclusion criteria (Table 1), were invited to take part in the study.

Table 1: Inclusion and exclusion criteria for selection of candidates into the present study

Inclusion	Exclusion
>17 years old and <37 weeks gestation	<17 years old and >37 weeks gestation
Provide informed consent	Women unable to provide informed consent due to mental impairment or non English speaking background
No diagnosed obstetrical risk	Previously diagnosed obstetrical risk
Consumed alcohol or other drugs prior to or during this pregnancy	Previous still birth or birth abnormality

The PI was notified of any consenting participants and attended the clinic to answer any further questions that the participant might have about the study. At this time the pre intervention questionnaire (Appendix 2) was completed and the consent form (Appendix 5) was explained to the women who either signed immediately (signed forms were stored confidentially) or provided with a stamped, addressed envelope to assist the return of the consent form. Follow up phone contact was made to these participants within 7-10 days and it was during these telephone contacts when early withdrawals from the project, were requested by participants.

When the signed consent form and the pre-questionnaire were returned, the participant's medical record was "flagged" and their unique patient identifier number was randomized into either the control or intervention group. This was a simple matter of "flipping a coin" performed by a colleague not linked to the project. Withdrawal from the project also occurred when women were informed that they had been randomized for the face to face education session as outlined in the participation information sheet.

Flagging of files for those women who continued on with the study, enabled the midwives to notify the PI when each woman returned to the hospital for the purpose of birthing. Following this notification the PI then visited the maternity unit and when convenient met with the participant to complete the post SUA and questionnaire. Questionnaires could be taken home to be completed and returned in a stamped addressed envelope. With each post questionnaire given out, an Acceptance Card (Appendix 6) was completed by the woman and returned with the questionnaire, indicating her agreement for her name to be entered into a post study "thank you" raffle, If discharge occurred prior to the PI collecting the post birth SUA data, a follow up phone consultation occurred for both the post SUA data collection and questionnaire.

Design and Statistical Analysis

Consenting women were randomly allocated into parallel arms in the study, Group 1 (control) or Group 2 (intervention group).

- **Group 1** – The control group was provided with a self-help drug and alcohol educational package which included specific information about the effects of drugs in pregnancy (NSW Health, 2007, p20).
- **Group 2** – The intervention group participants, in addition to the drug and alcohol educational package, were contacted by phone, and a time, date, and location for the face to face, brief intervention, education session was arranged. This session was planned to provide brief interventions for an improved understanding of issues relating to drug use and pregnancy as outlined in the NSW Health, Drug and Alcohol Psychosocial Interventions (NSW Health, 2008, p26). This would be in the form of open discussion around effects of substance use in pregnancy and to explore cessation strategies, if requested, and additional referral if needed. These education sessions were scheduled as early as possible following the antenatal booking-in appointment once written consent was confirmed. An outline of the education session can be found in Appendix 7.

Student's paired *t tests* were used to compare pre intervention and birth follow up questionnaire scores for women in the intervention and control groups. SAS Enterprise Guide 4.3 was used for linear regression analysis.

Ethics

Ethics approval for the Research Project was received from the Greater Western Area Health Service Human Research Ethics Committee (HREC)

Results

1. Patient demographics and substance use profile – prenatal enrolment

Women were recruited from October 2010 to April 2011 with 120 approached and total of 70 women recruited over this period, 33 to the intervention group and 37 to the control group. Nine women indicated an initial interest in the study but withdrew prior to signed consent. The enrolment flowchart diagram demonstrates the numbers of participants through allocation, follow up and analysis. The demographic information and substance use profile of the women from the initial recruitment are given in Table 2.

Enrolment Flow Diagram

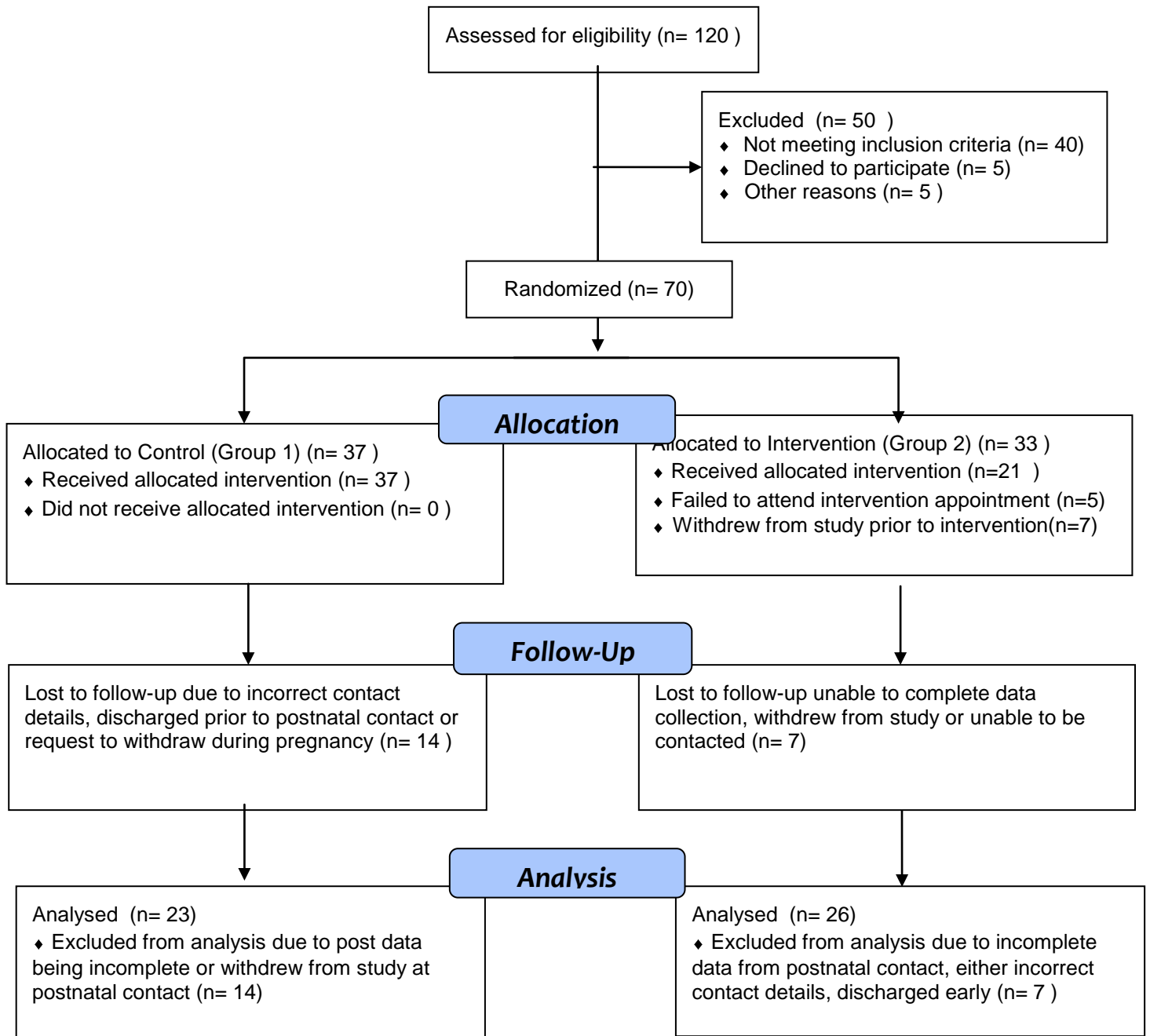


Table 2: Demographic and substance use profile of women at enrolment – prenatal

Variable	Control (n= 37)	Intervention (n= 33)	Total (%) (n= 70)
Mean age (min - max)	28 (17-38)	30 (18-40)	17-40
Smoking prior to pregnancy	8 (22%)	4 (12%)	12 (17%)
Ceased smoking at confirmation of pregnancy	2 (25%)	0 (0%)	2 (17%)
Fagerstrom Dependence Score (mean)	2	1.75	1.9
Drink alcohol prior to pregnancy	21 (57%)	13 (39%)	34 (48%)
Std drinks/wk (mean)	5.07	3.41	4.35
Ceased drinking alcohol at confirmation of pregnancy	10 (48%)	11 (85%)	21(61%)
Caffeine (including chocolate)	31 (84%)	28 (67%)	59 (84%)

The two groups were similar in age and substance consumption at enrolment. The only illicit drug use disclosed was one user of cannabis who stated she had ceased when her pregnancy was confirmed. One participant disclosed drinking around 46 standard drinks of alcohol per week and another reported drinking 1.25 l of caffeine (cola) on a daily basis at the time of their antenatal assessment. Both these women declined referral to D&A services.

2. Substance use profile postnatal intervention

Of the original 70 participants, 21 (30%) were lost to follow up either due to withdrawal by the participant at various contact points during the study or incomplete data from the pre or postnatal questionnaire or SUA. Table 3 below covers the intervention and post-delivery assessments. Five women from the Intervention group did not attend the face to face education session, however their data has been included in the intervention group and analysis has been conducted based on intention-to-treat.

Caffeine remained the most commonly consumed drug amongst the women however 5 women changed to a decaffeinated product during their pregnancy. Total numbers for the dependence ratings for nicotine were too few to be included in any analysis. Five women (1 in the intervention group and 4 in the control group) ceased smoking during the pregnancy while 4 women continued to drink alcohol, albeit at < 2 standard drinks/week, during their pregnancy.

Table 3: Substance use profile of women - postnatal survey

Variable	Control (n= 23)	Intervention (n= 26)	Total (n= 49)
Attended education	N/A	21 (80.7%)	21 (42.8%)
Did not attend education	N/A	5 (19.2%)	5 (10.2%)
Ceased smoking during pregnancy	4 (17.3%)	1 (3.8%)	5 (10.2%)
Drinking alcohol after pregnancy	12 (52%)	6 (23%)	18 (36.7%)
Decreased amount of alcohol from pre survey	11 (47.8%)	3 (11.5%)	14 (28.5%)
Number of standard drinks per week	1.8	1	1.75
Caffeine	23 (100%)	18 (69.2%)	41 (83.6%)
Decaffeinated drink	2 (8.6%)	3 (11.5%)	5 (10.2%)

3. Knowledge of effects of substance use in pregnancy

Knowledge scores at the pre testing stage were not significantly different between the Intervention and control groups, with a mean knowledge score for the control group being 24.6 and Intervention group 24.2 (see Table 4), with a lower score indicating more correct answers.

Table 4: Pre and post knowledge questionnaire scores, both groups

	Pre	Post	Difference (post-pre)	
	Mean (sd)	Mean (sd)	Mean (95% CI)	t-statistic (p-value)
Control Group (n=23)	24.6 (4.9)	20.7 (3.1)	-4.0 (-6.4,-1.6)	-3.42 (0.0025)
Intervention Group (n=22)	24.2 (5.5)	19.1 (3.7)	-5.0 (-7.1,-3.0)	-5.08 (<0.0001)
Overall	24.4 (5.2)	19.9 (3.4)	-4.5 (-6.0,-3.0)	

There was a significant improvement in the knowledge scores within both groups using Students paired t tests, with significance set at $p < 0.05$. The control group improved on average by 4 points (95% CI -6.4,-1.6), and the intervention group improved by 5 points (95% CI -7.1,-3.0).

When examining post-intervention changes in knowledge of the intervention group compared to the control group, a linear regression analysis was conducted, the results of which are found in Table 5. After controlling for the 'pre' questionnaire score, the intervention group appeared to have a 1.4-point lower score on average at their 'post' questionnaire (i.e. had more correct answers), however this was not statistically significant ($t = -1.48$, $p = 0.1466$).

Table 5: Linear regression analysis- post intervention knowledge scores control vs intervention

	Parameter Estimate	Standard Error	t-statistic	p-value
Intercept	16.5	2.79	5.91	<0.0001
Score 'Pre'	0.2	0.09	2.41	0.0207
Group	-1.4	0.96	-1.48	0.1466

4. Changes to alcohol consumption

Further analysis assessed whether the percentage of alcohol drinkers had decreased from pre to post survey, and whether any change was significantly different for the intervention and control groups. The numbers were too small to reach statistical significance at $p < 0.05$, as can be seen in Table 6.

Table 6: Changes in standard drinks consumption from pre-intervention levels, both groups

	Pre	Post	Difference (post-pre)	t-statistic (p-value)
	Mean (sd)	Mean(sd)	Mean (95% CI)	
Control group (n= 12)	2.2 (1.4)	1.8 (2.1)	-0.4 (-1.8,1.1)	-0.57 (0.5831)
Intervention Group (n= 5)	3.2 (2.6)	1.0 (0.6)	-2.2 (-5.6,1.2)	-1.77 (0.1509)

Both groups showed a trend toward reduced alcohol consumption using Student's paired t test. The analysis was based on very small numbers and therefore no significant decrease in alcohol consumption for either group was found. Small numbers also meant between-group comparison was not able to be provided.

Discussion

This study found that incorporating a comprehensive D&A assessment tool enabled midwives to identify women who might benefit from D&A education and information and could be incorporated into standard practice. This comprehensive D&A assessment, along with providing pregnant women with information on substance use during pregnancy increased their

knowledge of the effects of such use. While the additional effect of further, individual education is not proven in this study there is a reasonable expectation that for some women this additional education could increase the proportion of women who stop or reduce the consumption of substances.

There have been few Australian studies that have estimated the substance use in pregnant women and why or who ceases drinking and smoking during pregnancy. Giglia et al (2006) in WA found that of those who reported smoking before pregnancy 34% quit during pregnancy. Quitters were more likely to be first time mothers, women who smoked less than 10 cigarettes a day and those who also drank alcohol. The comprehensive assessments completed during this project found that smoking had reduced from 22% in 2008 (NSW Health, 2004-2008) to 17%, in line with national figures. In the Bathurst study, of the 10 women who were continuing to smoke at the pre-intervention assessment, five of these had quit smoking at the post-intervention assessment. This reduction of 50% is admittedly based on very small numbers, but hints toward the additional effect of education over the known smoking cessation rate shown in the study by Giglia et al (2006).

Impacts of education on smoking rates varied for participants within the study. Some women were able to cease smoking tobacco, without replacement therapy or other strategies, for the duration of their pregnancy but resumed smoking as soon as their baby was born. As the project did not provide for a longer period of follow up, it was not able to assess if the women who maintained smoking cessation in the postnatal period were permanent or temporary.

Rates of drinking within the population of pregnant women in Bathurst were not known as a comprehensive assessment was not routinely completed for pregnant women. The substance use assessments in this study indicated that women were drinking alcohol at higher levels than had been anticipated. This underestimation of the level of drinking in this population is an important finding and underlines the value in the use of a comprehensive screening tool as routine practice.

For the general community low risk levels of alcohol consumption are recommended at a consumption of two (2) standard drinks (10gms alcohol) per day (National Alcohol Guidelines. 2009). However the recommendation for alcohol consumption in pregnancy and breastfeeding is that there is “no safe level of alcohol consumption” (National Alcohol Guidelines. 2009). This knowledge was recorded on pre and post surveys by 86% of the participants but the remaining 14% of respondents were uncertain and provided a range of options for consumption of alcohol during pregnancy and whilst breast feeding. There were also four respondents who indicated that there was “no safe level of drinking alcohol in pregnancy” from the questionnaire however

disclosed through the post SUA that they continued to consumed alcohol during their pregnancy, although at very low levels.

Knowledge about alcohol use in pregnancy and the effects of alcohol on the unborn child were not clearly understood by participants in this study. This observation was seen most keenly when, during the D&A assessment, women disclosed episodes of low to moderate drinking levels within the weeks prior to confirmation of the pregnancy. Even women who were trying to fall pregnant did not know the health message to cease alcohol consumption prior to conception and the associated risks “highest in the earlier stages of pregnancy, including the time from conception to the first missed period” (Ministerial Council on Drug Strategy, 2006, p 26).

Similarly there were women who although they had chosen to breastfeed had recommenced consumption of alcohol following the birth, however at a lower level than pre-pregnancy. It was noted by some of the breastfeeding women that one well known breastfeeding support organization and the Alcohol Guidelines (NHMRC, 2009) suggest strategies for breast feeding women to enable them to continue consuming alcohol whilst breast feeding, with the intention of reducing the effect of the alcohol on the baby. However, these compromise solutions continue to add confusion for both clinicians and the general public about best practice. Discussion and consultation remains to be had by authorities and clinicians around how best to present these points of view when the national clinical guidelines are recommending that no consumption of alcohol during the perinatal period is the recommended approach for best outcomes.

Some of the women when prompted with educational material, particularly those involved in the face to face educational session were unaware or not overtly conscious that caffeine was considered a risk substance in relation to pregnancy. There was a consistent view that two cups of coffee or tea per day would not contribute to any harmful consequences for their baby. Additionally they were also not aware that a reduction of their current consumption would provide them with general health benefits. For example some women who consumed caffeinated products (>300mgs/day) were willing to change to de-caffeinated products when shown the difference in levels of caffeine and the impact that moderate-high levels of caffeine might have on their pregnancy. Caffeine was consumed readily by 84% of the participants from hot chocolate, coffee, tea, cola and other energy drinks throughout their pregnancies. From the resource literature utilised, consuming less than 200mg (2 - 4 cups of coffee or tea a day, depending on the strength of caffeine) when pregnant, is recommended. Caffeine comes in a variety of strengths from 60-350mgs per cup dependent on various forms of coffee (espresso, percolated, filter or instant) and tea, through to 75mgs per 375mls for energy drinks (Red Bull, Mother). However caffeine consumed at greater than 200mgs /day during pregnancy, has been known to increase the risk of miscarriage, prematurity, or still-birth (NSW Health, 2007).

This combination of alcohol and caffeine consumption and smoking rates indicates that there is an ongoing need for routine screening and intervention in this group. Midwives are in a key position to assess women comprehensively for substance use and to provide brief interventions and D&A educational resources. These screening and opportunistic educational activities have long been identified as being “the hallmarks of nursing care” (Pender, 1996, cited in Hymen, 2006). The adverse effects of substances, particularly alcohol, tobacco and cannabis on fetal development are well known as it is documented in the National Clinical Guidelines for the management of drug use during pregnancy, birth and the early development years of the newborn, (Ministerial Council on Drug Strategy, 2006). However, within the Introduction to the guidelines it states, “there has been limited information to guide clinicians in the care of these women and infants” (page ix). The routine use of a comprehensive D&A assessment as demonstrated in this study provides a structure that will help midwives identify and intervene with women using substances during their pregnancy. An additional benefit of routine assessments is gathering prospective data providing evidence about the extent of drug and alcohol consumption of pregnant women in rural NSW. This additional evidence will assist policy makers and public health educators to develop consistent public health messages and policy initiatives to assist women to make informed and healthy choices for improved pregnancy outcomes (Bowen & Zwi, 2005).

Limitations and Strengths of the study

Limitations

1. Recruitment

The sample size originally calculated for this study was 116 per group. A number of factors contributed to low recruitment including ongoing health system reforms within the maternity unit, regular changes in staffing for the clinic providing an inconsistent approach to the new D&A assessment process and understanding of the research project. The PI was also redirected by management to provide clinical relief relating to vacancies of other D&A positions during the course of the recruitment phase. This prevented the PI from being able to consistently attend the clinic and support the midwife through the D&A assessment phase and identify eligibility for the study. As a result recruitment was not prioritised and the sample size required for statistical power was not reached. This was evident where the reductions in drinking in the intervention group were encouraging, they did not reach significance.

2. Timing and Training

Some other limitations were noted at the completion of the project. These included the time restraints of the scheduled booking-in appointment, the amount of obstetric data to be collected, other assessment questions to be covered by the midwife and limited opportunity to educate the midwives in the implementation of the D&A assessment tool. Due to the pressures of service delivery within the maternity unit, the opportunities for education of the midwives

around completing a drug and alcohol assessment were brief; ideally 3 x 30min sessions would have provided a clearer understanding for improved delivery of the assessment. There was also some confusion around the question relating to current alcohol consumption. The wording on the form states “do you drink alcohol?” and the study was asking “did you drink alcohol prior to confirmation of this pregnancy?”

3. Loss to follow up

The maternity unit’s model of care provides for early discharge which became problematic for capturing the post-delivery data, particularly after hours and at weekends. Contact information for the women was not routinely checked for accuracy prior to discharge by the maternity staff. This became problematic when gathering the postnatal data and reduced the paired information (pre and post) for analysis by 35%.

Strengths

This study had several strengths:

- Midwives showed a good understanding of a non-judgemental attitude in completing the D&A assessment. This engaged positively with the women and encouraged women to disclose their substance use. Midwives are viewed as trustworthy health professionals and women can disclose this information with confidence when prompted.
- Data was gathered and measured for the first time amongst this cohort in Bathurst.
- Pregnant women responded positively to the D&A educational material and demonstrated an increase in knowledge about the effects of drugs and alcohol and made appropriate changes for improved outcomes for their babies.
- Midwives were provided with training in accordance with the NSW Health Policy Directive that guides all nurses and midwives to provide clinical guidance around substance use issues.
- In completing the assessment it was noted that a review of the template questions, specifically for the booking-in clinic, would be helpful to guide the assessment process and to support new midwifery staff working in the clinic.

Conclusion

This study demonstrated that providing information to pregnant women increases knowledge of substance use in pregnancy. This increase in knowledge was accompanied by encouraging changes in alcohol consumption and smoking in both the control and intervention groups. This study showed high levels of alcohol and caffeine use, an issue which had not been previously identified in this community.

Midwives are strategically positioned to identify and provide interventions for pregnant women who are using substances at confirmation of pregnancy. The use of a comprehensive D&A

assessment provides a critical tool for midwives and will provide data to assist service planners and policy makers in addition to the key focus of midwives; the expectant mother and baby.

Recommendations

This study has produced the following recommendations:

- Routine use of a comprehensive D&A assessment for all pregnant women attending the Bathurst Base Hospital booking-in clinic
- Training to be provided for all midwives in the use of the comprehensive assessment as part of orientation to the maternity unit.
- Routine provision of D&A information to all pregnant women attending the Bathurst Base Hospital booking-in clinic in consultation with the D&A service.
- A larger study to be conducted to investigate any additional benefit of targeted one-to-one education over the provision of information alone.

References

- Bowen, S., Zwi, A.B. (2005) Pathways to "Evidence Informed" Policy and Practice: A Framework for action. *PlosMED*. 2(7).
- Bracken. M.B., Triche. E.W., Belanger, K., Hellenbrand, K., Leaderer, B.P. (2003) The Association of Maternal Caffeine Consumption with Decrements in Fetal Growth. *American Journal of Epidemiology*. Vol 157. 5. 456-466.
- Burns, L., Mattick, R.P., Wallace, C. (2007) Smoking Patterns and Outcomes in a Population of Pregnant Women with other Substance Use Disorders. *Nicotine and Tobacco Research*. Vol 10:6, 969-974. Informa Health Care.
- CARE Study Group. 2008, 'Maternal Caffeine intake during pregnancy and risk of fetal growth restriction: a large prospective observational study'. *British Medical Journal* 2008;337:a2332
- Chasnoff, I.J., McGourty, R.F., Bailey, G.W., Hutchins, E., Lightfoot, S.O., Pawson, L.L., Fahey, C., May, B., Brodie, P., McCulley, L., Campbell, J. (2005). The 4P's Plus© Screen for Substance Use in Pregnancy: Clinical application and outcomes. *Journal of Perinatology*, 25:368-374.
- Colvin, L., Payne, J., Parsons. D., Kurinczuk, J.J., Bower. C. (2007) Alcohol Consumption During Pregnancy in Nonindigenous West Australian Women. *Alcoholism: Clinical and Experimental Research*. Volume 31, Issue 2, 276–284.
- Department of Health, Western Australia. 2010. Fetal Alcohol Spectrum Disorder Model of Care. Perth: Health Networks Branch, Department of Health, Western Australia.
- Giglia, R.C., Binns, C.W., Alfonso, H.S. Which Women Stop Smoking during Pregnancy and the Effect on Breast Feeding Duration. (2006). *BioMed Central Public Health*. 6:195.
- Hymen, Z. (2006). Brief Interventions for High Risk Drinkers. *Journal of Clinical Nursing*. Vol 15:11. 1383-1396.
- Krulewitch, C.J. (2005). Alcohol consumption during pregnancy. *Annual Review of Nursing Research*. Vol 23. 101-134.
- Lambers DS, Clark KE. 1996 The maternal and fetal physiologic effects of nicotine. *Seminars in Perinatology*. April. 20(2):115-26 *Department of Obstetrics and Gynaecology*, University of Cincinnati College of Medicine. USA.
- Ma Y, Goins KV, Pbert L, Ockene JK. 2005. Predictors of smoking cessation in pregnancy and maintenance postpartum in low-income women. *Maternal Child Health Journal*. Dec;9(4):393-402. Division of Preventive and Behavioral Medicine, University of Massachusetts Medical School, Worcester, MA. USA.
- Ministerial Council on Drug Strategy, 2006, National clinical guidelines for the management of drug use during pregnancy, birth, and the early development years of the newborn, Canberra, Australian Government.
- National Health and Medical Research Council. 2009. Australian Guidelines to reduce health risks from drinking Alcohol. Canberra, Australian Government.
- NSW Department of Health, NSW Midwives Data Collection 2004-2008.
- NSW Department of Health. 2007. Clinical Guidelines for Nursing and Midwifery Practice in NSW: identifying and responding to drug and alcohol issues. North Sydney. NSW Health
- NSW Department of Health. 2007. Caffeine Factsheet NSW Department of Health, North Sydney.

NSW Department of Health, 2008, NSW Health Drug and Alcohol Psychosocial Interventions Professional Practice Guidelines. NSW Department of Health

NSW Department of Health, 2009, NSW Health/Families NSW Supporting Families Early Package – maternal and child health primary health care policy, NSW Department of Health

Parliament of Australia, House of Representatives, Social Policy and Legal Affairs Committee Report (2012). FASD: The Hidden Harm - Inquiry into the prevention, diagnosis and management of Fetal Alcohol Spectrum Disorders. Canberra

Peadon, E., O'Leary, C., Bower, C., Elliott, E. (2007) Impacts of Alcohol Use in Pregnancy, *Australian Family Physician*, Vol 36, No 11, 935 – 939.

Peadon, E., Payne, J., Henley, N., D'Antoine, H., Bartu, A., O'Leary, C., Bower, C., Elliott, E.J. (2010). Women's knowledge and attitudes regarding alcohol consumption in pregnancy: a national survey. *BioMed Central Public Health*, 10, 510. Published online 2010 August 23.

Powers, J., McDermott, L.J., Loxton, D.J., Chojenta, C.L.,. (2012). A prospective study of prevalence and predictors of concurrent alcohol and tobacco use during pregnancy. *Maternal Child Health Journal*. Springer Netherlands. 1-9.

Siney.C. (1999) *An Overview. In Pregnancy and Drug Misuse*. Books for Midwives Press: 9.

WebSurvey. 2008. Real Choices. Women, contraception and unplanned pregnancy, commissioned by *Marie Stopes International*. Accessed on 20 February 2009;
<http://www.mariestopes.org.au/research/australia/australia-real-choices-key-findings>

Zammit, S. L., Skouteris, H., Wertheim, E. H., Paxton, S. J., & Milgrom, J. (2008). Pregnant women's alcohol consumption: The predictive utility of intention to drink and pre-pregnancy drinking behavior. *Journal of Women's Health*, 17(9), 1513-1522



Drug and Alcohol educational interventions for pregnant women in a rural setting: a randomized trial.

Aim

This study will provide an education intervention within a randomized control trial, to identify if educational material alone or educational material given in a face to face setting improves knowledge and reduces risk behavior in women who use psychoactive substances during pregnancy. For this project a ‘psychoactive substance’ is defined as: a substance that, when ingested, affects mental processes, emotions and behavior. The study will target alcohol and tobacco as legal substances and cannabis as an illegal substance. The study aims to assess the reduction in psychoactive substance use during the period of the pregnancy and the increase in knowledge about effects of psychoactive substances on the fetus. The outcomes of the study can then be used to inform maternity and drug and alcohol services of the effect of the educational reference material vs educational reference material AND face-to-face education methods applied in the study

Introduction

Research has demonstrated a link between psychoactive substance use and adverse neonatal conditions such as lower birth weight, pre-term birth and still birth. It is estimated that 20% of women smoke cigarettes in pregnancy (NSW Midwives Data Collection 2004-2008.) This is of great concern as nicotine crosses the placental barrier and the fetus has 15% higher blood concentration levels than the mother. Drug use is common place in Australian society and thus the need for assessment and monitoring for improved health outcomes for pregnant women is important. Maternal alcohol consumption can also cause a spectrum of harm to the developing fetus. In Australia it is estimated that approximately 50% of pregnant women consume alcohol at various levels during pregnancy (NHMRC, 2009). Within the revised Australian, National Health and Medical Research Council, Alcohol Guidelines it is recommended that there is no safe level of alcohol consumption in pregnancy or whilst breastfeeding. At the same time the NSW Health Clinical Guidelines for Nursing and Midwifery Practice in NSW: identifying and responding to drug and alcohol issues was revised to update recent changes in clinical management. In the light of these new recommendations and changes it was seen as an opportune time to apply the revised comprehensive assessment tool within the population of pregnant women in a local rural setting and to measure changes in knowledge and behavior when educational messages are provided.

Study Goals and Objectives

- Evaluate the effectiveness of the educational intervention vs usual practice
- Evaluate increase in knowledge
- Evaluate reduction of substance use in pregnancy for nicotine, alcohol and other drugs

Study design

Control group and intervention group will be randomised from informed, consenting women at the Bathurst Health Service antenatal booking-in clinic (see Appendix 1). Women to be included are:

- those who are identified, from the GWAHS Substance Use Assessment, to have consumed alcohol and/or other drugs on a regular basis during this pregnancy,
- >17yrs of age
- < 37 weeks gestation
- Able to provide informed consent
- No previously diagnosed obstetric risk factors as per the exclusion criteria

The exclusion criteria for the study will be determined by the following criteria:

- Women <17years of age
- Women > 37 weeks gestation
- Women unable to provide informed consent for reasons of mental impairment or non English speaking background.
- Women with previously diagnosed obstetric risk factors:
 - Previous still birth
 - Previous birth abnormalities

Method

1. Recruitment

Bathurst Health Service currently registers approximately 600 women for birthing within the maternity department each year. All women are assessed for substance use during routine clinical practice using the Greater Western AHS (GWAHS), Substance Use Assessment Form (SUA - Attachment 2). The assessment form has recently been revised and endorsed through the Greater Western AHS, Forms Committee as the nursing and midwifery assessment tool for all drug and alcohol assessments throughout the area. All nurses and midwives for all admissions of in-patient facilities within Greater Western AHS will utilize this tool. This process commenced in April 2010.

The assessment process occurs when women present to the booking-in clinic, usually at 20 weeks gestation. Women, who disclose through this usual assessment process of consuming any substances, both prior to the confirmation of this current pregnancy and currently, will be invited to take part in the study.

a) SAMPLING: From the NHMRC Australian data it is estimated that nationally 50% of pregnant women consume alcohol during pregnancy. The NSW Midwives Data Collection (MDC) records for 2004-2008 for Bathurst indicated that between 18-23% of women giving birth at Bathurst Base Hospital reported smoking tobacco during pregnancy. Of these women an average of 2.2% reported not smoking in the second half of pregnancy. This study hopes that 20% of women in the intervention group report not smoking in the second half of pregnancy. To detect this difference with a significance level of 5% and a power of 80%, the sample size required would be 58 women in each group.

b) ACCESSING POTENTIAL PARTICIPANTS

Initially a letter will be distributed to local General Practitioners (GPs) and Obstetricians informing them of the study and asking for their support in publicizing the project to pregnant women who present to their surgeries (Appendix 3).

Due to the fact that all babies are delivered at Bathurst Base Hospital, all pregnant women are given information about arranging an appointment at the Bathurst Base Hospital Booking –in clinic by their Medical Officer.

Presentation to the Booking-In clinic is usually at 20 weeks gestation via an appointment system. The booking-In clinic at Bathurst Base Hospital occurs weekly with 5 appointments scheduled per day. All women will be given the Participants Information Sheet to read as they arrive at the clinic. The midwife will complete the consultation including the Substance Use Assessment Form (SUA) (Copy attached), which is completed as a usual component of the overall antenatal consultation. Women who disclose substance use via the SUA will be asked if they would be interested to participate in the study. If the women are interested then the PI will be asked to come and meet with the woman before leaving the clinic.

The PI will provide further explanation and information about the study at this time. The PI will assure the women that involvement in the study is voluntary. And that all conversations and paperwork directly related to the study are anonymous. They will be offered all usual support, referral and assistance with accessing counseling or other obstetric services or other assistance as required through the stages of the study. They will be informed that they can withdraw from the study at any time without loss of benefit or health care for themselves and their baby of which they are entitled to and that they may also choose not to answer some or all of the questions. When the women indicate that all their questions have been answered the PI will ask the women if they would be willing to consent to the study. Following this the Consent Form (Attachment 5) is given to be taken home and to be returned signed, if she wishes to participate, using the stamped addressed envelope provided.

2. Stages following Consent

STAGE 1 When the PI receives the signed consent form, the first stage of the study, the pre-questionnaire with a stamped addressed envelope will be forwarded to the woman for completion and return. The woman's medical record will be flagged to enable the PI to be notified by the midwives when each woman is admitted to hospital for birthing and completion of Stage 3 of the study

STAGE 2: Consenting women will be randomized into **Group1 (control)** or **Group 2 (intervention)**. The drug and alcohol team members who are cited, as co-investigators will perform this task weekly as consent forms arrive.

Group 1 – the control group, will be given to read the usual healthy pregnancy educational reference package with drugs in pregnancy information.

Group 2 –the intervention group, receives the usual healthy pregnancy educational package plus a specifically prepared educational training session provided as a face to face delivery model, with a trained drug and alcohol counselor. This group of women will be contacted by phone and a time, date, and location for their face-to-face education session will be arranged. This session will be provided in this manner to assist with tailoring the drug education and maximizing the educational interventions for the women and allowing for open discussion and substance use cessation opportunities. Group 2 sessions will be scheduled as soon after receiving the signed consent form and randomization. These sessions will occur prior to 37th week of gestation.

STAGE 3: The PI will visit the maternity unit when notified by the midwives of the woman's admission for birthing. The midwives will however inform the PI of any birthing issues that would exclude the mother from continuing in the study – birth complications, defects or still birth. The PI will ascertain from the midwives that it is convenient to meet with the participant to reapply the SUA and provide a copy of the post-questionnaire to be completed and returned in the stamped addressed envelope to the PI at her convenience. If discharge occurs prior to the PI collecting the post birth SUA data, a follow up phone consultation will occur and questionnaires posted out with stamped addressed envelopes. The PI will ensure that the timing for the visit or phone call is convenient for the woman prior to applying the SUA post birth. With each post questionnaire given out there will be an Acceptance Card to be completed by the woman and returned with the questionnaire, if she agrees to have her name entered into the post study "thank you" raffle, (Appendix 6).

3. Educational Material

The educational reference material is a standard publication from the Australian Drug Foundation. This material is given to all women presenting to the booking-in clinic at Bathurst Base Hospital.

(Copy attached)

Along with this educational reference material the educational sessions given to Group 2 participants will provide more detailed information of the effects of psychoactive substance use in pregnancy as outline in the Educational Lesson Plan (Copy attached). The sessions will cover both legal and illegal substances and provide specific education as per the relevant information from each woman's substance use assessment documentation. For example; if tobacco is the only substance that the woman consumes then the session will be weighted toward tobacco information in pregnancy with less emphasis on other drug information. Due to the small numbers of

The education session will be delivered by the co –investigators who are qualified drug and alcohol counselors employed by Mental Health Drug and Alcohol Services at Bathurst Hospital.

The duration of each session will be approximately 30-45 min.

4. Confidentiality

All information gathered by the principal investigator will be de-identified and a unique identifying code will be allocated for the purpose of matching the participant's information.

Storage of documents will be with the principal investigator in a purpose locked filing cabinet in their office. Storage and future destruction of all documentation will be according to the Greater

Western AHS, Standards of Practice, If it is determined, following assessment and thorough consultation with maternity services that the information given falls within the mandatory reporting requirements, this information will be referred to the Nurse Unit Manager of the Maternity Unit. This means that staff are required by law to report to the Department of Community Services when they have reasonable grounds to suspect that a child, or a class of children, is at risk of harm from abuse or neglect and information of this type is shared during the course of this project. This information is also included in the Participants Information Sheet and Consent Form.

Follow-Up

All participants of the program will be encouraged to access further drug and alcohol support as required through the GWAHS, Drug and Alcohol Help Line (DAHLine 1300 887 000 Mon- Fri, 8.30am -4.30pm) This information will be provided in the educational reference packages (Copy attached)

Data Management and Statistical Analysis

- Data analysis from both pre and post substance use assessment forms for all consenting participants using paired and unpaired t tests
- Data from both pre and post questionnaires will be analyzed on intention-to-treat basis for all participants.
- Descriptive statistics (age, number of previous pregnancies, resident of Bathurst or surrounds, income, aboriginality, housing,
- Attendance at the intervention session for those women in face-to-face intervention group.

.Expected Outcomes of the study

- Comprehensive drug and alcohol substance use data collected for all pregnant women in Bathurst.
- Reduction or cessation of legal and illegal substance use in pregnancy as per post questionnaire.
- Effect of reference material vs reference material plus face to face education on D&A knowledge and behavior.

Dissemination of Results and Publication Policy

- Relevant Journal Publication
- Relevant conference presentation
- IRCST quarterly reports

Duration of the Project

Data collection commence July 2010 until April 2011.

Financial Support

Principal Investigator supported by Mental Health Drug and Alcohol Service with external sponsorship provided by NSW Institute of Rural Clinical Services and Teaching and NSW Health.

Links to other projects

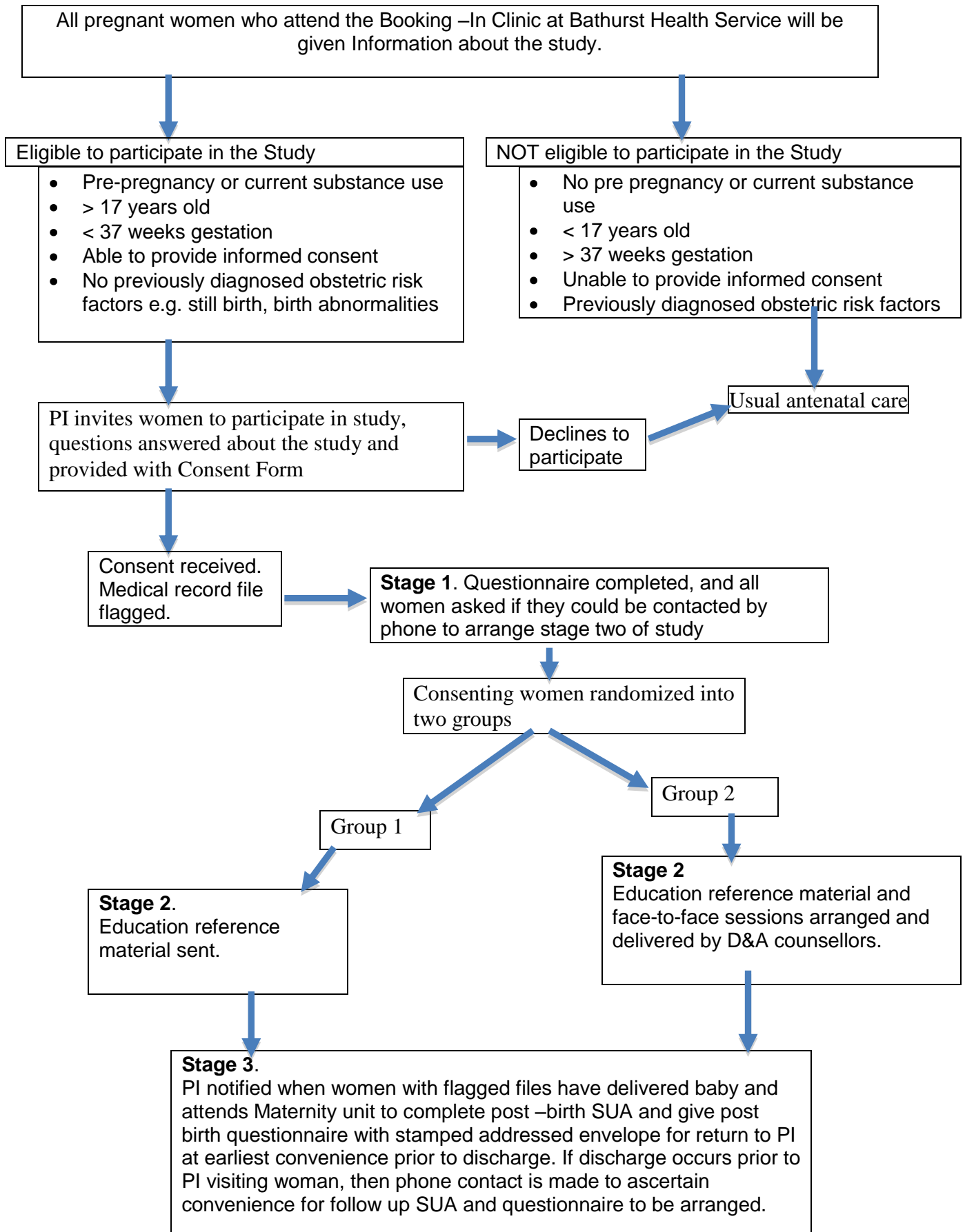
Currently there are no links to other projects.

References

- Australian Guidelines: to reduce health risks from drinking alcohol, 2009; NHMRC
- O'leary CM, Nassar N, Kuniczuk JJ, Bower C, *The effect of maternal alcohol consumption on fetal growth and preterm birth*. British Journal of Obstetrics and Gynaecology, 2009; 116 (8): 390-400

- Burns L, Mattick RP, Wallace C, *Smoking patterns and outcomes in a population of pregnant women with other substance use disorders*. *Nicotine and Tobacco Research*, Vol 10, No 6(June 2008), pp969-974
- Clinical Guidelines for nursing and midwifery practice in NSW: identifying and responding to drug and alcohol issues, 2007, NSW Health.
- Midwives Data Collection, 2004-2008, NSW Health.

Flow Chart for Project



Drug and Alcohol Questionnaire - Research Project 2010

Appendix 2

The purpose of this questionnaire is to assist with evaluating the Education Package that you have been given as a participant in the research study. **Please answer the questions according to your current knowledge.** This questionnaire is not a test.



The following questions are about alcohol.

1. How many drinks per day would be recommended to reduce the risk of alcohol related harms?

2. How would you describe a standard drink?

3. How long does it take for the liver to break down the alcohol in one (1) standard drink?

4. What age group or groups are at the highest risk of harm from drinking alcohol?

5. How many alcohol drinks would limit the risk of injury on a single occasion of drinking alcohol?

6. For women who are pregnant what is the recommended level of alcohol consumption?

7. For women who are breastfeeding what is the recommended level of alcohol consumption?

The following questions are about nicotine and cannabis.

8. How many chemicals are contained in one cigarette?

9. What are the long-term health effects from smoking cigarettes?

10. What are some of the immediate physical effects in our bodies from smoking a cigarette?

11. What are the long term health effects from smoking cannabis?

12. What are some of the immediate physical effects in our bodies from smoking cannabis?

13. What is the chemical that is active in cannabis?

Thank you for committing the time required in completing this questionnaire. Please return in the stamped addressed envelope

Information about a local, rural Antenatal Education Research Project relating to drug and alcohol in pregnancy - 2010.



October 18, 2010

Dear Doctor

I wish to inform you about a research study that is to be conducted at Bathurst Base Hospital and will be aimed at pregnant women who consume drugs and alcohol prior to and during pregnancy. My name is Jean Clulow, Clinical Nurse Consultant (CNC) for Drug and Alcohol Service in the Greater Western AHS (GWAHS).

This project will be introduced and commenced from the Antenatal Booking -In Clinic at Bathurst Base Hospital and will involve eligible pregnant women in educational interventions to measure changes to knowledge and behavior around drug and alcohol substance use in pregnancy. This project is sponsored, approved and supported by the NSW Institute of Rural Clinical Services and Teaching and NSW Health (also see below)

What I would ask you to do?

I would ask that the attached Participant Information Sheet be displayed strategically in your surgery waiting room so that the pregnant women within your practice are aware of this study and may consider participating.

What if you require further information?

If you wish to receive further information about this project please contact the Principal Investigator – Jean Clulow on 0428 965 958

Yours Sincerely

Jean Clulow
Clinical Nurse Consultant
Drug and Alcohol Services
Greater Western AHS
Bathurst Base Hospital
Howick St, Bathurst NSW 2795

The ethical aspects of this project have been approved by the Human Research Ethics Committee (HREC) of the Greater Western Area Health Service. If you have any concerns of complaints please contact: The Executive Officer, PO Box 143 Bathurst NSW 2795 or telephone (02) 6339 5601

Drug and Alcohol Antenatal Education Intervention Research Study



1) What is the study about?

The purpose of this study is to find out what drug and alcohol educational approaches are better to assist rural, pregnant women to make better choices and lifestyle changes around drugs and alcohol during this important period of time.

2) Who is carrying out the study?

I am Jean Clulow, a Clinical Nurse Consultant with the drug and alcohol service of the Greater Western Area Health Service based at Bathurst Base Hospital. The NSW Institute of Rural Clinical Services and Teaching and NSW Health are sponsoring me for this study.

3) What does the study involve?

Following being given information and completing a written consent

You will be involved in three stages:

1) Firstly completing a questionnaire that asks about your current knowledge of alcohol and other drugs.

2) Secondly participants will be randomly selected into one of two educational packages. One consists of educational material for reading at home during your pregnancy and the second package includes the reading material plus a personal, education session around drugs and alcohol that will take about 30-40 minutes. This will be held at the Bathurst, MHD&A Community Health Centre at a negotiated time that suits you.

3) Lastly, following the birth of your baby, either in the hospital or at home via phone, you will be asked questions about your current alcohol or drug usage and given or sent a further questionnaire for completion and a stamped addressed envelope will be supplied for you to return it to the principal investigator.

4) Will the study benefit me?

Drug and alcohol use is common place in Australian society and there is a need for assessment and monitoring for healthy outcomes for both pregnant women and their babies. The benefits you receive may be up to date information about the effects of alcohol and drug consumption in pregnancy and useful knowledge for healthy outcomes for yourself and your baby. Also the results of the project may help us to formulate better educational approaches for women around drug and alcohol to assist with choices around pregnancy. You will be offered all usual support, referral and assistance with accessing counseling or other obstetric services or other assistance as required through the stages of the study.

5) Can I withdraw from the study?

You are free to choose to participate in the study or not, or withdraw from the study without any loss of health care to which you are entitled. You and your baby will receive the same standard of care and treatment, irrespective of your participation in this project. You may also choose not to answer some or all of the questions.

6) Will anyone else know the results?

The information provided by you will remain anonymous. Your name and identity will not be disclosed at any time without your permission. All information that you give will be stored in a locked storage unit and only accessed by the principal investigator for the purposes of the project. However persons involved in reviewing the project, for clarification and analysis may see the data. The results may be published in a journal and elsewhere without disclosing your identity. For the purposes of the project and to facilitate timely collection of post birth information, your medical record will be flagged so that when your baby is born the midwives will notify the principal investigator of your admission. This will allow time to meet with you to collect the Stage 3 questions about your current alcohol or drug usage and provide you with the post –birth questionnaire.

7) Mandatory Reporting

All staff involved in the study are required by law to report to the Department of Community Services when they have reasonable grounds to suspect that a child, or a class of children, is at risk of harm from abuse or neglect and information of this type is shared during the course of this project.

8) What if I require further information?

If you have any further questions you may contact the Principle Investigator, Jean Clulow at Bathurst Base Hospital on 6330 5809 or 0428 965 958 or if you wish to make a complaint please contact the Executive Officer of the GWAHS Human Research Ethics Committee on 6339 5601.

The ethical aspects of this project have been approved by the Human Research Ethics Committee (HREC) of the Greater Western Area Health Service. If you have any concerns of complaints please contact: The Executive Officer, PO Box 143 Bathurst NSW 2795 or telephone (02) 6339 5601



Drug and Alcohol educational interventions for pregnant women
I,[name].....

In giving my consent I acknowledge that:

1. The stages required for the project and the time involved have been explained to me, and any questions I have about the project have been answered to my satisfaction.
2. I have read the Participant Information Sheet and have been given the opportunity to discuss the information and my involvement in the project with the researcher/s.
3. I understand that I can withdraw from the study at any time, without affecting my relationship with the researcher(s) or my treatment now or in the future, and without having to give a reason.
4. I understand that my involvement is strictly anonymous and no information about me will be used in any way that reveals my identity.
5. I agree to the flagging of my file so that the principal investigator can be notified of the birth of my baby to enable post birth Substance Use Assessment and questionnaire to be provided.
6. I understand that the principal investigator and other persons involved with this project are mandatory reporters. A mandatory reporter is an individual required by law to report to the Department of Community Services when they have reasonable grounds to suspect that a child, or a class of children, is at significant risk of harm from abuse or neglect and those grounds arise during the course of this project.
7. I have the option to enter into a "thank you" raffle to be drawn after completion of the study

8-3. I will be offered a copy of the study findings on request

Yes, I consent to:

- Completing and posting first questionnaire.
- Reading educational material **or** reading educational material plus attending face to face educational session
- Completing post birth Substance Use Assessment and completing and posting the second questionnaire.

The ethical aspects of this project have been approved by the Human Research Ethics Committee (HREC) of the Greater Western Area Health Service. If you have any concerns of complaints please contact: The Executive Officer, PO Box 143 Bathurst NSW 2795 or telephone (02) 6339 5601

Signature:

Date:

Name:.....



Acceptance Card



I....., would be very happy to have my
(Printed name)
name entered into the “thank you” raffle.

Signature:

I can be contacted by phone: Hm:.....Mob:.....

EDUCATION SESSION PLAN

Appendix 7

INTRODUCTION TO DRUGS AND THEIR EFFECTS IN PREGNANCY

FORMAT: 1:1
TIME FRAME: 30-40 mins dependant on specific substances
TARGET GROUP: Group 2, intervention



TIME FRAME	SESSION CONTENT	RESOURCES REQUIRED
5 mins	INTRO: What is a drug? Name some drugs? Classification into Depressants/Stimulants/Hallucinogens	Factsheets
5 mins	PHYSIOL: CNS Blood/Brain Barrier/Placental Barrier functions Basic Pharmacology – Neurotransmitters and the effect of drugs in synaptic gap	Power Point Presentaion
10 mins	CLOSER LOOK AT SPECIFIC DRUGS – Commonly used Alcohol – Its impact on foetus – spectrum of harms, amount consumed, frequency See Aust Guidelines pg 5, Include: Teratogens – a reproductive toxin – an agent that can cause a birth defect Nicotine: Use of intermittent NRT for quitting, further research Cannabis: THC, associated respiratory issues.	
10 mins	Aust Guidelines breastfeeding pp 81/79 - Harm minimization strategies in breast feeding	
5 mins	OTHER STIMULANTS – Caffeine, Ecstasy, Speed. OTHER MEDICATIONS (1 Slide) – Confirm safety with GP, Obstetrician	
5 mins	QUESTIONS	