

## NIHR Dissemination Centre THEMED REVIEW

## BETTER BEGINNINGS

Improving Health for Pregnancy



### **FOREWORD**

omen's health is a resource for life and the best start for children. Health for women before, during and after pregnancy sets the foundation for pregnancy and the lifelong health of their children. Paying attention to health before pregnancy helps women start pregnancy well. Supporting healthy behaviours brings benefits now and sets a path for long-term health. Managing long-term conditions for physical and mental health and addressing complex social needs reduces risks to health and improves pregnancy outcomes. Ensuring health after pregnancy invests in women and their families, and prepares for any future pregnancies.

This review brings together research from the National Institute for Health Research for factors that can be modified before, during and after pregnancy. The research covers smoking, healthy diet and weight, alcohol and drugs, mental health, violence against women, and supporting families using multifaceted approaches. This broad view of health links care around pregnancy with wider services in partnership with women and families.

The Maternity Transformation Programme in England provides an opportunity to shape services for the future. Improving women's health requires a collaborative approach between all stakeholders including commissioners, primary care, maternity services, public health and local authorities to meet the needs of women for pregnancy prevention, planning and preparation as well as preparation for parenthood. Putting research evidence into guidance and practice can help deliver better health for women and their children.

#### **Dr Matthew Jolly**

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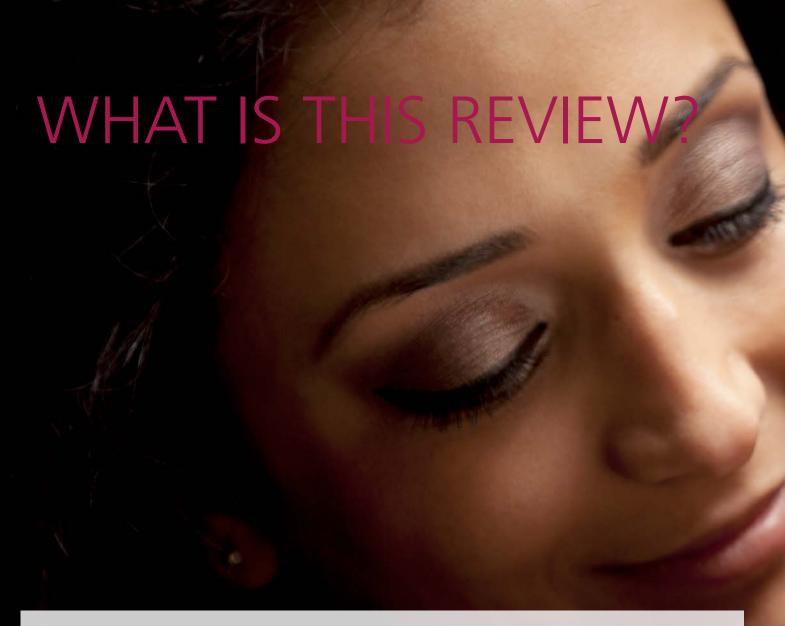


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#### Disclaimer

This independent report by the NIHR Dissemination Centre presents a synthesis of NIHR and other research. The views and opinions expressed by the authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR or the Department of Health. Where verbatim quotes are included in this publication, the view and opinions expressed are those of the named individuals and do not necessarily reflect those of the authors, the NHS, the NIHR or the Department of Health.



his review brings together recent evidence on improving health and wellbeing before, during, and after pregnancy from studies funded by the National Institute for Health Research (NIHR). The NIHR was set up in 2006 as the research arm of the NHS to provide a health research system focused on the needs of patients and the public.

Better Beginnings is not a comprehensive review of all evidence on improving health for pregnancy which is a broad area of knowledge and practice. It focuses on building health for women to support pregnancy and the future health of their children. Further relevant research from the NIHR is available, relating to the management of pregnancy, long term health conditions in pregnancy and the provision of maternity services, including workforce and models of care.

This review complements other initiatives, drawing on best evidence, including guidance and quality standards from the National Institute for Health and Care Excellence (NICE). Further sources of information and resources for each topic are signposted in this report.

Unless stated otherwise, all research mentioned in this report is funded entirely or substantively by NIHR. The appendices feature summaries of the research, and you can download full reports and protocols in most cases from the NIHR Journals Library website https://www.journalslibrary.nihr.ac.uk

This review provides research evidence for healthcare professionals working with women around the time of pregnancy, particularly midwives, general practitioners, obstetricians, and health visitors. It is also relevant to colleagues with a wider interest in women's and children's health including public health, children's services and social care. Evidence can help commissioners to plan and shape future services. We hope that the review will also be useful to women interested in research findings about health for pregnancy.

The Royal College of Midwives is delighted that the NIHR has published its themed review 'Better Beginnings'. The report supports midwives to fully understand the evidence that underlies our public health messages to women who are pregnant or planning a pregnancy. It is also important for midwives to understand the quality of research findings and where evidence needs strengthening.



#### **EVIDENCE HIGHLIGHTS**

#### **IMPROVING HEALTH BEFORE PREGNANCY**

- » Good health, from before pregnancy, is the best start for future health of women and their children
- » When women access services before and between pregnancies, opportunities should be taken to improve health behaviours and manage long-term health conditions

#### STOPPING SMOKING

- » Stopping smoking removes the greatest modifiable risk for poorer pregnancy outcomes
- » Identifying smokers and referring them to NHS Stop Smoking Services helps achieve smoking cessation in pregnancy
- » Psychosocial interventions and support help women stop smoking in pregnancy
- » Evidence for effectiveness of nicotine replacement therapy in pregnancy is mixed
- » Financial incentives to stop smoking in pregnancy may be helpful but more research is needed

#### **HEALTHY DIET AND NUTRITION SUPPLEMENTS**

- » A healthy balanced diet, with recommended supplements of folic acid and vitamin D, supports pregnancy outcomes and future health for the woman and baby
- » Research is ongoing for other vitamin and mineral supplements. Advice should be based on the latest national guidance as further evidence emerges

#### **HEALTHY WEIGHT**

- » Achieving a healthy weight before pregnancy reduces the risk of complications for the woman and baby
- » Interventions in pregnancy for women with obesity, particularly changing diet, can reduce weight gain and may reduce risk of some complications
- » Using metformin in pregnancy for women with obesity is currently not recommended to improve pregnancy outcomes unless they have type 2 diabetes
- » Achieving a healthy weight after pregnancy reduces health risks for the woman and for future pregnancies

#### **BREASTFEEDING**

- » Offering any form of support to women, especially if tailored to their needs, helps them start breastfeeding and breastfeed for longer
- » Skilled professional support is beneficial
- » For babies in neonatal units, professional and peer support, as well as approaches such as skinto-skin contact and offering advice on breastmilk pumping, improve duration of breastfeeding
- » Sidecar cots in hospitals improve breastfeeding initiation but not duration
- » The role of financial and other incentives to promote breastfeeding is unclear

#### **ALCOHOL AND DRUG USE**

- » Alcohol and non-medical drug use should be avoided in pregnancy or when trying to conceive as they can harm the health of women and babies
- » More research is needed on effective interventions to reduce alcohol and drug use in pregnancy, and care for women around the time of pregnancy with established substance misuse

#### ADDRESSING MENTAL HEALTH PROBLEMS AND PSYCHOSOCIAL STRESS

- » Early detection and management of mental health problems around the time of pregnancy is effective in reducing symptoms
- » Screening and referral pathways can improve identification and access to care
- » Psychological treatments can help women with anxiety and depression, including community approaches using trained health visitors
- » The use of psychotropic medication before and during pregnancy requires specialist review

#### **VIOLENCE AGAINST WOMEN**

- » Screening tools help to identify pregnant women who have experienced domestic violence but do not improve referral rates or outcomes
- » Brief advocacy interventions by health professionals to empower women can improve mental health and may reduce abuse in pregnancy
- » New research is evaluating different approaches to support and care for women which could reduce partner violence

#### SUPPORTING FAMILIES USING MULTIFACETED APPROACHES

- » Tailoring maternity services to meet the needs of local populations can improve engagement
- » Providing one-to-one support for disadvantaged woman during pregnancy and after birth, using a doula, led to a positive care experience and increased breastfeeding
- » Alternative models of maternity care are being studied to improve access to services, particularly for women from disadvantaged communities or with complex social factors
- » Research is evaluating the impact of vouchers, incentives and grants in pregnancy in supporting engagement and reducing inequalities

#### WHAT DOES THIS MEAN FOR ME?

his evidence raises questions that you and your organisation may want to consider in order to improve the care of women before, during and after pregnancy, and their children. These questions do not cover all aspects of care (as given in NICE guidance) but are prompted by the particular research studies featured in this review.

Our questions are aimed at everyone concerned with the care of women before, during and after pregnancy: women themselves, midwives, commissioners, managers, GPs, health visitors, public health professionals and others. Some particular questions for women are shown in blue.

#### **IMPROVING HEALTH BEFORE PREGNANCY**

- » What changes can I make to be as healthy as possible before pregnancy?
- » How could local services improve the health of women before pregnancy by offering effective interventions to promote health and manage long term conditions?

#### **STOPPING SMOKING**

- » How can I quit smoking, and reduce my exposure to other people smoking?
- » Is there a clear pathway for identifying pregnant women who are smoking, and for providing support and referral to specialist stop smoking services?
- » Are local services taking account of current knowledge and emerging research to support women to stop smoking around the time of pregnancy?

#### **HEALTHY DIET AND NUTRITION SUPPLEMENTS**

- » What changes could I make to ensure I eat a healthy balanced diet before, during and after pregnancy?
- » What information and resources are available to support women in eating a healthy balanced diet with recommended nutrition supplements?

#### **HEALTHY WEIGHT**

» What changes could I make to achieve a healthy weight before and after pregnancy?

- » How do local weight management pathways ensure that women can access services to meet their needs before and after pregnancy?
- » How do local interventions reflect current knowledge and research on pregnancy weight gain and reducing risks for women with obesity?

#### **BREASTFEEDING**

- » What support is available locally to help me breastfeed?
- » Are our staff trained and skilled to offer breastfeeding support?
- » What support is available to women in populations with lower breastfeeding rates, such as professional, peer, and group-based support?

#### **ALCOHOL AND DRUG USE**

- » What support can I get to help me avoid alcohol and non-medical drug use?
- » What advice and support do we provide to women to help them avoid the use of alcohol and drugs, and to respond to a range of needs?

#### ADDRESSING MENTAL HEALTH PROBLEMS AND PSYCHOSOCIAL STRESS

- » What resources and services can support my mental health before and around the time of pregnancy?
- » Are there clear processes in our service for the identification and referral of women with current or previous mental health problems?

#### **VIOLENCE AGAINST WOMEN**

- » Am I aware of how to recognise and find help for domestic violence?
- » Are there clear processes in our service to identify and refer women experiencing domestic violence to specialist multi-agency support?
- » What local interventions and support are available for women who experience domestic abuse or violence?

#### SUPPORTING FAMILIES USING MULTIFACETED APPROACHES

- » What local services can help me around the time of my pregnancy?
- » What can be done to assist women from disadvantaged communities or with complex social factors, before, during and after pregnancy?
- » How do local services promote access and engagement to reduce health inequalities for pregnancy and child health, taking account of current research?



THE AVERAGE AGE OF FIRST-TIME MOTHERS IN 2015

28.6

# WHY DOES IMPROVING HEALTH FOR PREGNANCY MATTER?

eing healthy is the best start to pregnancy for a woman and child. Preparing for pregnancy can focus attention on health, such as eating a healthy balanced diet, losing excess weight, as well as avoiding risks from smoking, alcohol and drug use. Ensuring the best care for long-term physical and mental health conditions is important for a healthy pregnancy, as well as addressing complex social needs. Women's health, particularly around conception and in early pregnancy, contributes to lifelong health for them and their children. Health underpins children's learning, development and future life opportunities. Better health and wellbeing from before birth, and in the early years, can reduce future health and social inequalities. Opportunities to improve women's health and wellbeing before, during and after pregnancy are shown in Box 1. This provides the framework and structure for this report.

#### Box 1: Opportunities to improve health before, during and after pregnancy

Modifiable risk factors for pregnancy and future child health are:

- » Improving health before pregnancy
- » Stopping smoking
- » Eating a healthy diet including folic acid supplements
- » Being a healthy weight and physically active
- » Breastfeeding
- » Avoiding alcohol and illict drug use
- » Addressing mental health problems and psychosocial stress
- » Supporting families with multifaceted approaches

Women rarely die in and around childbirth in the UK, with fewer than one death in 10,000 births, but more progress is needed to reduce maternal mortality related to modifiable risk factors and long-term health conditions. Reducing smoking in pregnancy is part of the NHS England Saving Babies Lives Initiative to reduce stillbirth, which affects 1 in 200 UK births.

Sources: Davies (2013); Davies (2015); Knight et al. (2015).

Getting the best start in life for children is a UK policy priority, focused on preventing problems and early intervention to improve outcomes. Research evidence is growing for modifiable factors to influence health before, during and after pregnancy. Across the UK, there are national and local initiatives to review services and models of maternity care and improve quality and safety. These provide a framework for change and opportunities to improve health towards better outcomes for women and children.



NHS Start 4 Life https://www.nhs.uk/start4life

Health matters: giving every child the best start in life (Public Health England) https://www.gov.uk/government/publications/health-matters-giving-every-child-the-best-start-in-life/health-matters-giving-every-child-the-best-start-in-life

**Pregnancy guidance (NICE)** https://www.nice.org.uk/guidance/conditions-and-diseases/fertility--pregnancy-and-childbirth/pregnancy

Pregnancy and Childbirth (Cochrane Library) http://www.cochranelibrary.com/topic/Pregnancy%20%26%20 childbirth/

National Maternity Review. Better Births: improving outcomes for maternity services in England (NHS England, 2016) https://www.england.nhs.uk/wp-content/uploads/2016/02/national-maternity-review-report.pdf

A strategic vision for maternity services in Wales (Welsh Government, 2011) http://www.wales.nhs.uk/documents/A%20Strategic%20Vision%20for%20Maternity%20Services%20in%20Wales%20-%20September%202011.pdf

A strategy for maternity care in Northern Ireland 2012 – 2018 (Department of Health, Social Services and Public Safety, Northern Ireland, 2012) https://www.health-ni.gov.uk/publications/strategy-maternity-care-northern-ireland-2012-2018

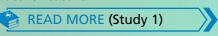
A refreshed framework for maternity care in Scotland (Scottish Government, 2011) http://www.gov.scot/resource/doc/337644/0110854.pdf





mproving health before pregnancy is often a missed opportunity. Health for women before and around conception builds on the health status of girls and women across different life stages (RCOG, 2011). Pre-pregnancy care includes improving health behaviours, folic acid supplements, managing long-term health conditions, immunisation, and genetic counselling where relevant (Seshadri et al. 2012). The needs of women with complex social problems can also be identified and addressed. Although most women in UK maternity services report planning their pregnancies, low awareness of pre-pregnancy health

among women and professionals, and fragmented care, limits potential health gains (Stephenson et al. 2014). Taking a wider approach to integrate services for pregnancy prevention, planning, preparation, and preparing for parenthood could improve preconception health and pregnancy outcomes (Davies, 2015). A review published in 2009 found little research on pre-pregnancy health promotion, and improving health at this time is an important area for future research.



There is potential to improve health before and between pregnancies with relevant and timely advice and support from healthcare professionals. In a survey of women attending maternity care in London, 73% reported planning their pregnancy, and women who received advice from health professionals were more likely to adopt healthier behaviours before pregnancy (Stephenson et al. 2014).

The Southampton Women's Survey found that few women met recommended advice for diet and lifestyle in the three months before pregnancy (Inskip et al. 2009). Fewer women smoked once pregnant, and intake of alcohol and caffeinated drinks was reduced, though the proportion of women eating fewer than five portions of fruit and vegetables a day did not change (Crozier et al. 2009). Women with lower educational qualifications and young women were less likely to switch to healthier behaviours. NICE guidance PH6 and PH49 describe effective approaches to changing behaviour for better health.

Preconception review of women with longterm physical and mental health conditions, with specialist referral where appropriate, allows optimal management and planning to improve outcomes for pregnancy (Seshadri et al. 2012). Pregnancy may worsen pre-existing health conditions or alter their control, while the underlying health condition can increase risk for pregnancy complications and poorer outcomes. Common health conditions of concern in pregnancy include diabetes, epilepsy, hypertension, cardiac disease and asthma. Care for women with mental health conditions, including communication, rapid assessment, and specialist care, was highlighted in a confidential enquiry into maternal deaths (Knight et al. 2015). Guidance is available for specific health conditions before, during and after pregnancy, with recommendations for treatment, medication, and monitoring. Further research is available for the management of long-term health conditions during pregnancy from the NIHR Journals Library.

#### **CONTRIBUTION OF RESEARCH**

Research has shown the importance of good health for women across life stages, starting before pregnancy, to the lifelong health of their children. Raising awareness of pre-pregnancy health among women and professionals, and implementing and sustaining effective interventions, requires further research to inform commissioning and policy.



**Planning your pregnancy (NHS Choices)** ) http://www.nhs.uk/conditions/pregnancy-and-baby/pages/planning-pregnancy.aspx

Pre-conception advice and management, Clinical Knowledge Summaries (NICE, 2012) https://cks.nice.org.uk/pre-conception-advice-and-management

Diabetes in pregnancy: management from preconception to the postnatal period, NG3 (NICE, 2015) https://www.nice.org.uk/guidance/ng3

Behaviour change: general approaches, PH6 (NICE, 2007) https://www.nice.org.uk/guidance/ph6

Behaviour change: individual approaches, PH49 (NICE, 2014) https://www.nice.org.uk/guidance/ph49

A lifecourse approach to sexual and reproductive health <a href="http://www.euro.who.int/en/health-topics/Life-stages/sexual-and-reproductive-health/publications/entre-nous/entre-nous/a-lifecourse-approach-to-sexual-and-reproductive-health.entre-nous-no.82,-2015</a>

HR Themed Review: Bester Besterings



PERCENTAGE OF WOMEN WHO SMOKE

17%

BABIES BORN TO WOMEN WHO SMOKE ARE ON AVERAGE LIGHTER THAN BABIES BORN TO NON-SMOKERS BY

200g

Midwives understand the importance of early referral in pregnancy to specialist Stop Smoking Services. Women who receive this expert support and advice, alongside their midwifery care, are more likely to quit and remain smoke-free. This is an example of great team working, resulting in healthier mothers and babies.

Cathy Warwick CBE, Chief Executive of the Royal College of Midwives (RCM)



moking is the greatest risk that can be changed to improve birth outcomes, and reduce health inequalities for women and children. Smoking in pregnancy increases the risk of complications including low birthweight, premature birth and pregnancy loss. Household smoking is linked to more illness in babies, particularly respiratory problems, and sudden infant death. Stopping smoking reduces health risks for the woman and family, reduces the likelihood of her children taking up smoking, and saves money.

Around 17% of adult women in the UK smoke. Rates have fallen in recent years, but some areas report up to a third of women smoking in pregnancy. Understanding local smoking profiles can focus action. Women from routine and manual occupations and teenagers are more likely to smoke throughout their pregnancy.

NICE guidance PH26 in 2010 recommended identifying pregnant smokers by sensitive exploration confirmed by a carbon monoxide test as social pressure not to smoke may reduce disclosure. Partners and others in the household who smoke are encouraged to stop to support women and to reduce their exposure to second-hand smoke. NICE guidance PH48 in 2013 for service approaches in maternity healthcare settings includes smoking cessation, temporary abstinence, and smoke-free policies to support service users, visitors and staff.

Smoking in pregnancy adversely affects many different aspects of the health of the woman and baby. One aspect was assessed in a study published in 2009, associating smoking while pregnant with changes in thyroid function - important for pregnancy outcomes for both the woman and baby. Thyroid function returned to normal when women stopped smoking during the first 12 weeks of pregnancy.



Research with women to understand what helps or prevents them stop smoking during and after pregnancy will explore their views and review evidence. Facilitators include psychological wellbeing, close relationships (particularly with partners), the connection between the woman and baby, and perceived smoking risk.



Better understanding is needed as a review of pregnancy smoking cessation studies found high rates of relapse with only 13% of women studied not smoking at delivery and 43% of these smoking again six months after birth, although women enrolling in smoking cessation studies may not be similar to those who quit without support.



#### **STOP SMOKING SERVICES**

Referral to NHS Stop Smoking Services is recommended in NICE guidance for all identified pregnant smokers. Research has been used to inform effectiveness of services and increase smoking cessation in pregnancy.

The BabyClear initiative reconfigured services for pregnant women to provide greater support to stop smoking in North East England. A new referral pathway starts with universal carbon monoxide tests at the first midwife appointment, a three-minute intervention, and agreed referral thresholds. This extensive study will assess the effect of BabyClear on birth outcomes.



A study will look at ways to increase the estimated 7% of pregnant women who use NHS Stop Smoking Services. Surveying all NHS Stop Smoking Services across England will inform service provision, and monitor national trends for the use of nicotine replacement therapy.



#### PHARMACOLOGICAL INTERVENTIONS

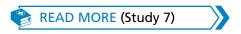
Nicotine replacement therapy (NRT) shows mixed evidence in helping pregnant smokers to stop, but may be offered after discussion of risks and benefits to women who have not been successful without it. Some medications for smoking cessation (varenicline or bupropion) are not recommended in pregnancy or during breastfeeding. Research has been investigating the effectiveness of NRT and the barriers to its use by some pregnant women.

A study published in 2014 found that using NRT patches led to significantly better smoking cessation rates in pregnancy after one month but no difference compared with placebo by the time of delivery, although adherence was low. In follow-up, two- year-olds born to women who used NRT were less likely to have a developmental impairment, though more research is needed to see if this is due to temporary smoking cessation early in pregnancy.



A review published in 2015 found that NRT combined with behavioural support increased successful quitting by late pregnancy by approximately 40%. However, this effect was not

seen when only the results of the most robust studies were considered. Where studies monitored adherence with NRT, this was poor. There was no evidence that NRT during pregnancy had either positive or negative impact on birth outcomes. Reported side effects included headaches and nausea.



Reasons for early stopping or poor adherence with NRT were explored in a series of interviews with pregnant women, showing they did not like side effects of using patches or felt that NRT could increase exposure to nicotine for their baby. Many women were smoking alongside using NRT and very few had tried e-cigarettes, which have uncertain effects in pregnancy.



A new study has recently been funded to examine whether e-cigarettes will help pregnant women quit smoking compared to usual care.



#### **PSYCHOSOCIAL AND OTHER INTERVENTIONS**

A review published in 2013 found that psychosocial interventions enabled women to quit during pregnancy and reduced low birthweight and preterm births. Treatments included counselling, feedback and social support. Some studies showed improved psychological wellbeing overall. Providing incentives to stop were also successful in studies in the USA. This review will be updated shortly.



A study published in 2015 explored views on providing financial incentives for reducing smoking in pregnancy. Pregnant women and partners, service providers, the general public and health professionals were studied. Incentives such as shopping vouchers were favoured, but only when offered to all pregnant smokers rather than targeted at low-income women. Non-judgemental social support was also needed, and further research is underway. Other research, offering shopping vouchers for engaging with stop smoking services and quitting in pregnancy, found significantly greater quit rates when incentives were added to routine care, which could be tested in larger studies.



In a study published in 2015 physical activity did not improve smoking cessation in pregnancy. Adding 14 supervised sessions on a treadmill combined with consultations with physical activity and behaviour change expert did not improve smoking cessation rates, compared to just having behavioural support. However, physical activity increased with the intervention, so promoting general health and wellbeing.



#### **CONTRIBUTION OF RESEARCH**

Reducing smoking in pregnancy is a priority for maternal and child health. Research is building evidence about the best ways to support smoking cessation and use of NRT in pregnancy to inform guidance and practice. Ongoing research could lead to new approaches for women who do not currently manage to stop smoking.

There remains a lack of evidence on smoking cessation interventions before or after pregnancy, and on preventing relapse after quitting during pregnancy.



Stopping smoking in pregnancy (Smokefree) https://www.nhs.uk/smokefree/why-quit/smoking-in-pregnancy

Smoking cessation: a briefing for midwifery staff (National Centre for Smoking Cessation and Training, 2016) http://www.ncsct.co.uk/publication\_briefing\_for\_midwifery\_staff.php

Smoking: stopping in pregnancy and after childbirth, PH26 (NICE, 2010) https://www.nice.org.uk/guidance/ph26

Smoking: acute, maternity and mental health services, PH48 (NICE, 2013) https://www.nice.org.uk/guidance/ph48

Smoking cessation in pregnancy: a call to action (Action on Smoking and Health, 2015) http://ash.org.uk/files/documents/ASH\_893.pdf

# HEALTHY DIET AND NUTRITION SUPPLEMENTS



omen's nutrition before conception and during pregnancy and breastfeeding is a foundation for a child's future health. The Eatwell Guide shows how to achieve a healthy diet by balancing intake of different food groups. NICE guidance PH11 in 2008 noted a lack of evidence specifically relating to nutrition for pregnancy and recommended

research on effective ways of improving the nutritional status of pre-conceptual, pregnant and breastfeeding women. For example, a recent review found there were no relevant trials on dietary advice in multiple pregnancies.



NIHR research has focused on vitamin and mineral supplements for pregnancy.

**VITAMINS** 

A review published in 2016 found that taking vitamin supplements before 20 weeks of pregnancy did not reduce the number of miscarriages, although the combination of various vitamin supplements may positively influence pregnancy outcomes.



**READ MORE (Study 14)** 



#### **FOLIC ACID**

Folic acid supplements taken before and during early pregnancy reduce the risk of neural tube defects in the baby.



**READ MORE (Study 15)** 



Foods such as peas, beans, green leafy vegetables, lentils and orange juice contain folate, as do fortified breakfast cereals. However, women are also advised to take daily folic acid supplements of 400 micrograms before conception and throughout the first 12 weeks of pregnancy, even if they are already eating a folate-rich diet. Some women, who are at particularly high risk, are advised to take higher dose folic acid supplements of five milligrams daily; this includes those at risk of a neural tube defect affecting women or their partners, a previous pregnancy or family history, or women with diabetes or taking some anti-epileptic medication. Women from disadvantaged groups are less likely to take folic acid or other supplements and improving uptake needs more research.

#### **VITAMIN D**

Vitamin D is essential for healthy bones in the woman and baby and calcium absorption. The primary source of vitamin D is sunlight, with limited amounts coming from foods such as oily fish, fortified foods such as breakfast cereals, fat spreads and eggs. New guidance in 2016 recommends that everyone over one year of age should have an intake of 10 micrograms of vitamin D every day (400 International Units) and should consider taking supplements, especially between October and the end of March when there is less sunlight. This guidance also applies to women who are pregnant or breastfeeding.

Research to inform future recommendations on vitamin D supplementation for pregnancy is underway. A review published in 2016 concluded it is unclear whether or not vitamin D should be given to all pregnant women as part of routine care.



A review published in 2014 found limited evidence for vitamin D supplementation in pregnancy. There is some evidence for a positive relationship between maternal vitamin D status and birthweight, as well as calcium concentrations and bone mass in newborn babies, but this requires further research.



A study published in 2016 of vitamin D supplementation in pregnancy found that higher dose supplements (1000 International Units daily) led to higher vitamin D levels compared to placebo, but maternal and environmental characteristics may influence supplement advice.



The higher dose vitamin D supplements in pregnancy improved neonatal bone mass for deliveries in winter months but not throughout the year. Taking these supplements did correct vitamin D insufficiency in over 80% of the women.



#### **VITAMIN A**

Vitamin A is important for vision, the immune system and skin. It is found in cheese, eggs, oily fish, milk and yoghurt. Beta-carotene in the diet can be converted in the body to vitamin A and is found in yellow, red and leafy green vegetables and yellow fruits. The recommended daily intake of vitamin A is 600 micrograms for women, but pregnant women should not take supplements as an excessive amount of vitamin A can harm the developing baby. A recent review that focused on women from countries with low vitamin A intake (such as India, Gambia, and Brazil), also found that giving daily supplements of vitamin A for six weeks after birth did not significantly benefit morbidity or mortality for the woman or infant, but there was a slight increase in retinol in breastmilk which could have general health benefits. Further research is needed concerning the potential interaction between vitamin A and other micronutrients.



#### **MINERALS**

#### CALCIUM

Calcium, an essential mineral, is necessary to support the healthy development of bones, and functioning of the heart, nerves, muscles and blood-clotting. Dairy foods, green leafy vegetables and some nuts and seeds contain calcium. During pregnancy, there is high demand for maternal calcium which can come from food.

A review published in 2014 found, looking across studies, a high dose calcium supplement during pregnancy, of at least one gram or more per day, reduced the risk of pre-eclampsia, particularly for women with low calcium diets, and their babies were less likely to be born early. Some studies also showed similar results at lower doses of calcium supplements. No adverse side effects were found, but more research is needed to define the recommended dose.



#### **IRON**

Iron is required for red blood cells. The recommended daily dose of iron for women is 14.8 milligrammes a day. This can be obtained from a variety of animal- and plant-based sources such as pulses, nuts, dried fruit, wholegrains and leafy green vegetables. Routine iron supplementation for all women in pregnancy is not recommended in the UK, although iron deficiency anaemia should be treated with oral iron tablets alongside nutritional advice. A review published in 2015 found that daily oral iron supplements during pregnancy, as well as iron with folic acid supplements, was associated with a reduced

risk of anaemia and iron deficiency. Taking iron supplements during pregnancy was also linked to a slightly reduced risk of low birthweight and pre-term birth. The studies were diverse across 27 countries with differing levels of anaemia in women. More high-quality research is needed to investigate the use of iron supplements before and during pregnancy.



#### **IODINE**

lodine is important for thyroid function, and sufficient iodine is needed during pregnancy and breastfeeding to support brain development in the baby. The recommended daily intake of iodine for adults is 140 micrograms, which can be obtained from food such as seaweed, white fish and milk. The UK does not have a specific recommendation for iodine intake during pregnancy. A review is looking at all the studies on iodine supplementation before, during and after pregnancy, and will focus on health outcomes for both women and their children to inform policy guidelines and clinical recommendations.



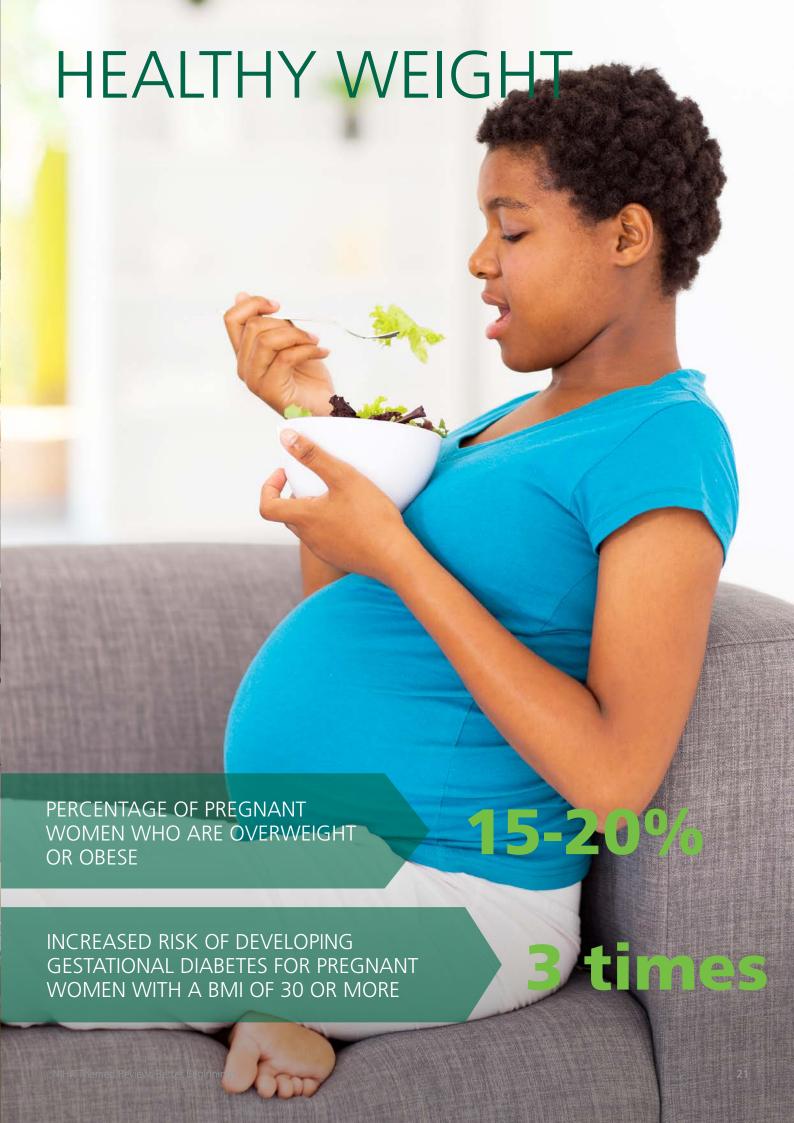
#### **CONTRIBUTION OF RESEARCH**

Good nutrition for women before and during pregnancy and when breastfeeding is important for women's and children's health. NIHR research is responding to evidence gaps about optimal nutrition supplements during pregnancy to support guideline development and provide clear messages for women and professionals.



Have a healthy diet in pregnancy and Eatwell Guide (NHS Choices) http://www.nhs.uk/conditions/pregnancy-and-baby/pages/healthy-pregnancy-diet.aspx

Maternal and child nutrition PH11 (NICE, 2008) https://www.nice.org.uk/guidance/ph11



chieving a healthy weight before pregnancy is advised, as excess weight increases the risk of pregnancy complications, and weight loss is not advised during pregnancy. Maternal obesity adversely affects pregnancy health and outcomes, and longer-term health of the woman and child (Box 2). NICE guidance PH27 from 2010 recommends women eat a healthy balanced diet to achieve a healthy weight, consisting of wholegrains and fibre-rich foods with a variety of fruit and vegetables daily and avoiding fried foods and those high in sugar. There are no UK guidelines on recommended pregnancy weight gain. Building physical activity into daily life, taking 30 minutes moderate intensity activity daily, and avoiding sedentary activities, contribute to having a healthy weight.

#### Box 2: Excess weight and Pregnancy

Excess weight increases health risks for the woman and child during pregnancy. It also increases longer-term risks for health conditions for the woman such as type 2 diabetes, cardiovascular disease and cancers.

The effects of maternal obesity identified in the Chief Medical Officer's Report on Women's Health are:

- » for the woman, lower fertility and higher risk of miscarriage, gestational diabetes, and birth complications
- » for the baby, greater risk of stillbirth and metabolic and developmental abnormalities
- » later in childhood, higher risk of overweight and obesity, type 2 diabetes and high blood pressure.

Healthy weight is a having a Body Mass Index (BMI) of 18.5 to 24.9 kg/m2, overweight is 25 to 29.9 kg/m2, and obesity is 30 kg/m2 or more. Obesity may be identified before pregnancy or at the booking appointment. In England in 2013, over a third of women aged 16–24 and half of women aged 25–34 were overweight or obese. Being underweight can also reduce fertility and increase some pregnancy risks, such as premature birth and low birthweight. Specialist monitoring and support is needed in pregnancy for women affected by eating disorders.

Source: Davies (2015).

#### **HEALTHY WEIGHT BEFORE PREGNANCY**

Research evidence is limited for specific interventions to address the needs of women before pregnancy. A 2015 review of interventions before pregnancy to improve outcomes for women who were overweight or obese found no suitable studies to assess. However these women are likely to benefit from accessing general weight management services.

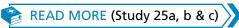


#### **MANAGING WEIGHT DURING PREGNANCY**

Weighing pregnant women at booking is recommended, but repeated weighing is not unless this would change clinical care. A study is looking at whether repeated weighing during pregnancy for all women could prevent excess weight gain. Weighing by community midwives, using guidelines for weight gain at each antenatal appointment, and women self-weighing at home, will show the effect on weight gain at 38 weeks of pregnancy compared to usual care. In initial research, women found it useful, and the intervention could be used within routine antenatal care. The results could inform guidelines for weight monitoring during pregnancy.



A study is using text messaging to manage weight gain for women with obesity in pregnancy. Messages were developed by exploring issues around weight in pregnancy with focus groups of women and midwives. Initial research found women receiving two daily motivational text messages, supported by four appointments with a healthy lifestyle midwife, diet and activity goal setting, and self-monitoring diaries had lower weight gain in pregnancy than women receiving usual care.



A review, published in 2012, found dietary and lifestyle interventions in pregnancy reduced maternal weight gain and reduced some risks for the woman and baby. Overall, dietary and lifestyle interventions modestly reduced weight gain, and complications of pre-eclampsia and shoulder dystocia. Dietary interventions appear most effective, decreasing risk of pre-eclampsia, gestational hypertension and preterm birth. With all interventions combined,

there were no significant differences in birthweight or babies that were large or small for gestational age. However, physical activity was associated with reduced birthweight. The quality of evidence for adverse outcomes was very low and is being evaluated in further research.



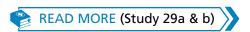
Another review published in 2015 also found excess weight gain in pregnancy could be prevented by diet or exercise or both, but more research was needed to inform guidelines on physical activity in pregnancy.



A further review will use individual results from weight management intervention research to understand the effects on health outcomes for women and babies, and to inform weight gain recommendations in pregnancy to minimise complications.



Improving diet and physical activity during pregnancy for women with obesity did not prevent gestational diabetes or result in fewer large babies. The intervention encouraged intake of foods with a lower glycaemic index and increased physical activity, aiming to reduce risk of gestational diabetes and preeclampsia, and to prevent excessive foetal growth. Maternal physical activity improved, and weight gain was restricted, but rates of gestational diabetes and babies born large for gestational age were not better than usual care. Instead, research should focus on identifying and treating gestational diabetes and reducing obesity in women of childbearing age.



Treating unselected women with obesity in pregnancy with metformin did not reduce birthweight so should not be used to improve pregnancy outcomes in obese women without diabetes. Metformin is widely used to treat type 2 diabetes during pregnancy. Using metformin in pregnancy to regulate blood glucose levels was tested in women with obesity, but without diabetes, to see if it reduced risk of obesity in their babies. Metformin had no significant effect on birthweight, compared

to placebo. Further understanding of the longer-term outcomes of using metformin in pregnancy will result from follow-up of babies born to women in the study.



#### **HEALTHY WEIGHT AFTER PREGNANCY**

Excess weight can affect future pregnancies, and increase risk of long-term health conditions. NICE guidance PH27 in 2010 recommended the 6–8 week postnatal check should be used as an opportunity to discuss weight management, providing tailored advice about weight loss after childbirth, especially if women are overweight or obese.

New studies will research approaches to weight management after pregnancy. Positive lifestyle information and 12 weeks' free access to Slimming World groups will be compared to standard care for women in an ethnically diverse population who are overweight or with excessive pregnancy weight gain. This study will explore willingness to join and complete group weight management after giving birth, and the best time to start.

Another study will compare tailored weight management SMS messages to general text messages about child health and development for women who are overweight or obese after pregnancy. Women can choose frequency and timing of messages, which will be tailored to weight management progress, social circumstances, eating triggers, and other health-related behaviours such as smoking, alcohol, or breastfeeding.



#### **CONTRIBUTION OF RESEARCH**

With rising obesity levels in women of childbearing age, better understanding is needed of how to help women achieve a healthy weight before, during and after pregnancy. There is ongoing research about the effect of interventions during pregnancy. Research is underway for weight management approaches after pregnancy with implications for women's long-term health and future pregnancies.





Overweight and pregnant (NHS Choices) http://www.nhs.uk/conditions/pregnancy-and-baby/pages/overweight-pregnant.aspx

Weight management before, during and after pregnancy PH27 (NICE, 2010) https://www.nice.org.uk/guidance/ph27

NICE guidance on diet, nutrition and obesity https://www.nice.org.uk/guidance/lifestyle-and-wellbeing/diet-nutrition-and-obesity

Maternal obesity series (Lancet Endocrinology and Diabetes, 2016) http://www.thelancet.com/series/maternal-obesity



hile NICE guidance considers the wider aspects of maternal and child nutrition, NIHR research has focused on breastfeeding. Breastfeeding has short and long-term health benefits for the woman and baby. For babies, it can reduce the risk of infections, diarrhoea, vomiting, sudden infant death syndrome, and future risks of obesity and cardiovascular disease in adulthood. NICE guidance PH11 in 2008 recommended health professionals encourage breastfeeding by providing information, practical advice and ongoing support, tailored to the needs of the woman. Exclusive breastfeeding for six months is recommended, when infants should progress to nutritious food in addition to milk. Breastfeeding can help bonding of the mother and baby, and aid maternal weight loss after pregnancy, with some evidence of lower future risks of breast and ovarian cancer, osteoporosis, cardiovascular disease and obesity.

In the UK, many women start but do not continue breastfeeding, and breastfeeding rates are relatively low compared to other countries. Babies of women from low income groups are least likely to be breastfed. Applying research findings within the UK, taking account of different contexts and populations, could help increase breastfeeding rates.

#### **SUPPORTING BREASTFEEDING**

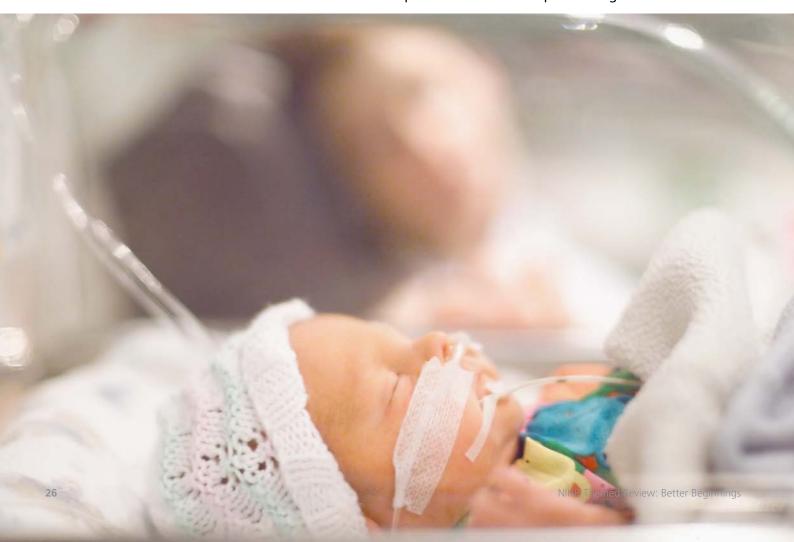
An extensive review published in 2000 compared the effectiveness of various methods of support for breastfeeding. While there were many different types of intervention, informal small group sessions were effective in helping women from a range of backgrounds to initiate breastfeeding. For women on low incomes, both one-to-one and peer support programmes were also useful.



In a 2012 review looking at studies from different contexts and over 20 countries, all forms of extra support, in addition to the usual standard care provided, increased the duration of breastfeeding (partial or exclusive). Support was helpful, either from peers or professionals, particularly when tailored to individual needs. Face-to-face support, especially on a planned rather than reactive basis, was more likely to succeed.



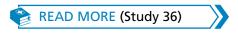
Effective approaches have been identified to support breastfeeding in hospitals. A sidecar crib (or co-sleeper) is a three-sided cot used to allow easy access to a baby from the mother's bed. A study, published in 2011 compared using sidecar cribs to



standalone cots in hospital after birth. Although previously shown to improve initiation, there was no difference in breastfeeding duration.



A review for promoting breastfeeding in neonatal units, published in 2009, found women benefited from skilled professional support in the hospital setting. A range of effective interventions supported breastfeeding in neonatal units and after discharge, including kangaroo skin-to-skin contact, peer support, pumping breast milk, staff training and maternity hospital Baby Friendly accreditation.



The effect of using pacifiers on breastfeeding has been debated. A review, published in 2016, found the use of pacifiers had little effect on the number of babies exclusively or partially breastfed at 3-4 months. However, none of the studies were based in the UK, and further studies are needed to assess breastfeeding and long-term effects of using pacifiers on infant health.

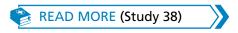


The effect of incentives to promote breastfeeding is unclear, with too few studies in a recent review

to recommend their use. They may be effective at increasing breastfeeding up to six weeks, when part of a combined approach of gifts, vouchers, a breast pump, and additional support, which could be assessed in further research.



A study is looking at supporting women in areas with low breastfeeding rates, comparing peer feeding helpers before and after pregnancy with usual care. Feeding helpers will contact women from 28 weeks of pregnancy, up to five months after birth, to signpost information and support and to meet or be in contact by phone or text.



#### **CONTRIBUTION OF RESEARCH**

The benefits of breastfeeding are clear for women and babies. Research is continuing to identify what types of support for women in the hospital or community improve breastfeeding uptake and duration of exclusive breastfeeding. Providing support for groups who are less likely to breastfeed, such as socially disadvantaged women, and addressing barriers and incentives needs further research.



Support for Parents (UNICEF UK, Baby Friendly Initiative) https://www.unicef.org.uk/babyfriendly/baby-friendly-resources/support-for-parents/

Maternal and child nutrition PH11 (NICE, 2008) https://www.nice.org.uk/guidance/ph11

Breastfeeding series (Lancet 2016) http://www.thelancet.com/series/breastfeeding

**Breastfeeding special collection (Cochrane Library, 2011)** http://www.cochranelibrary.com/app/content/special-collections/article/?doi=10.1002/(ISSN)14651858(CAT)na(VI)SC000020

# ALCOHOL AND DRUGUSE

Icohol and non-medical drug use in pregnancy can harm the health of women and babies. Information on the use of alcohol and drugs in pregnancy in the UK is limited. Alcohol and non-medical drug use can adversely affect mental health, and may also be a response to mental health problems. A supportive approach towards women who may be using alcohol or drugs can help identify their needs and link them to appropriate services.

The UK Chief Medical Officers advised avoiding drinking alcohol in pregnancy in guidelines in 2016 (CMO Alcohol Guidelines Review, 2016). Alcohol crosses the placenta and can damage brain cells in the developing foetus by restricting oxygen and nutrient intake. Heavy drinking during pregnancy can lead to the development of foetal alcohol syndrome in the baby. This is a serious condition, characterised by restricted growth, facial abnormalities, and learning and behavioural disorders, which may be lifelong. Foetal alcohol spectrum disorder is a less severe but more common disorder, which includes a range of neurodevelopmental defects.

There is uncertainty regarding a safe level of alcohol consumption in pregnancy. A review of published prospective studies on the safety of consuming up to two alcohol units twice a week in pregnancy compared to abstaining found a lack of high-quality evidence and further research is underway.



More research is needed about effects of lower levels of drinking in pregnancy and of drinking before pregnancy recognition.

There is limited evidence for psychological or educational interventions to reduce alcohol use in pregnancy.



A study will compare structured brief advice and referral to a 20-minute motivational interviewing session with an alcohol health worker to usual care to see if women would find this acceptable in practice before further research.



Drug use can damage the health of the woman and baby and cause complications during pregnancy. The effect of cannabis, and many other drugs, in pregnancy is uncertain and use should be avoided to reduce possible harm.

Some women will be identified as having wider difficulties with misuse of drugs, which may coexist with other health risks such as alcohol misuse and smoking, requiring specialist support and care during pregnancy. There were no NIHR studies identified relating to use of non-medical drugs during pregnancy.

#### **CONTRIBUTION OF RESEARCH**

Building research evidence on alcohol and non-medical drug use in pregnancy adds to a clearer message for women and professionals to reduce harm for women and their families. More research is needed for interventions to reduce alcohol use around the time of pregnancy. The use of drugs and their impact in pregnancy could be further researched, including harm reduction. Further research could support the specialist care around the time of pregnancy for women with established misuse of alcohol or drugs.



**Alcohol in pregnancy (NHS Choices)** http://www.nhs.uk/conditions/pregnancy-and-baby/pages/alcohol-medicines-drugs-pregnant.aspx

Illegal drugs in pregnancy (NHS Choices) http://www.nhs.uk/Conditions/pregnancy-and-baby/Pages/Illegal-drugs-in-pregnancy.aspx

UK Chief Medical Officers' Alcohol Guidelines Review 2016. (Department of Health, 2015) https://www.gov.uk/government/uploads/system/uploads/attachment\_data/file/489795/summary.pdf

Pregnancy and complex social factors CG110 (NICE, 2010) https://www.nice.org.uk/guidance/cg110



# ADDRESSING MENTAL HEALTH PROBLEMS AND PSYCHOSOCIAL STRESS

bout one in five women experience mental health problems during pregnancy or in the year after birth (Davies, 2015). Perinatal mental health problems are a risk to the woman and baby with possible long-term consequences for child development and wellbeing.

Deaths related to pregnancy and childbirth are rare, but a confidential enquiry into maternal mortality indicates that nearly a quarter of women who died between six weeks and one year after pregnancy died from mental-health related causes (Knight et al. 2015). The most common mental health conditions, which also occur in pregnancy, are depression and anxiety. Other disorders include obsessive-compulsive disorder, post-traumatic stress disorder, and an extreme fear of giving birth (tokophobia). Severe mental illness can emerge or relapse around the time of pregnancy. Barriers

to treatment before, during and after pregnancy include stigma, limited awareness of options and lack of access to specialist services.

NICE guidance CG192 in 2014 recommended a stepped care approach in the treatment of perinatal mental illnesses, promoting early detection and good management of mental health problems. Women should be adequately supported and treated in the community by GPs, midwives and health visitors, with access to psychological therapy services. Women with more severe illnesses should be treated in specialist services. Mental health screening by healthcare professionals is recommended. A brief screening questionnaire to detect depression during and after pregnancy is being evaluated for validity and acceptability to health workers and women.



PERCENTAGE OF WOMEN WHO EXPERIENCE POSTNATAL DEPRESSION

**10-15%** 

WOMEN WHO EXPERIENCE MENTAL HEALTH PROBLEMS IN PREGNANCY OR IN THE YEAR AFTER BIRTH

1 in 5

A research programme is looking at the most effective way to support women with mental health issues during and after pregnancy, including a review of NHS services and screening tools.



#### **MENTAL HEALTH IN PREGNANCY**

A cohort study of the effects of depression in pregnancy and after birth found an influence on infant growth at six months. Overall, maternal distress was much improved six months after birth compared to during pregnancy. Looking across the population, Pakistani women experienced more somatic and depressive symptoms than white women, with complex influences of ethnicity and deprivation on maternal mental health.



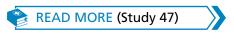
Some approaches to reduce antenatal depression and anxiety have been investigated. A guided self-help psychological intervention to help women prepare for parenthood and manage their emotional responses is being evaluated for effectiveness, and to assess possible delivery in routine care. Pregnant women identified with high anxiety will be invited to attend three midwife-led group sessions.



An early study showed potential for using cognitive behavioural therapy for antenatal depression, with women given 12 home-based sessions having fewer symptoms after birth than those receiving routine care.



A review of novel approaches for antenatal depression, such as omega 3 fatty acid supplements, depression-specific acupuncture, maternal massage and bright light therapy, did not have enough evidence to be recommended but could be researched further.



The use of psychotropic medication in the treatment of mental illness during pregnancy should be fully discussed, including the risks and benefits for both the woman and baby. A review published in 2016 looked at the use of psychotropic medication in pregnancy to treat pre-existing severe

mental illness including schizophrenia and bipolar disorder. Overall, psychotropic medication was often discontinued in pregnancy but resumed after delivery. Antipsychotic medication was not linked to congenital malformations, though there were poorer birth outcomes compared to women not taking medication, which may have been explained by other health and lifestyle factors. Babies born to women taking valproate showed twice the risk of major congenital malformations, and poorer neurodevelopmental and behavioural outcomes, compared to other mood-stabilising anticonvulsants.



NICE have identified further research needs for management of women with severe mental health problems around the time of pregnancy.

#### PREVENTING AND TREATING POSTNATAL DEPRESSION

Approximately 10-15% of women experience postnatal depression (PND), and about 30% of women diagnosed still have depression one year after giving birth. The effectiveness of antenatal and postnatal interventions to prevent the development of PND was published in a review in 2016. Women valued consistent and ongoing support from healthcare professionals and the involvement of partners. Midwifery-redesigned postnatal care, psychological therapies, and psychosocial, parenting or peer support had beneficial effects. More research was needed on clinical and cost-effectiveness.



Improving the psychological and physical health of new mothers, using expressive writing for 15 minutes per day for three consecutive days, is being explored in a new study.



A review of methods to identify PND in primary care published in 2009 found that the most widely used measure was the Edinburgh Postnatal Depression Scale. This measurement was a valid tool and acceptable to women when used by a trained and empathic health visitor.



A small study assessed an intervention designed to enable GPs to overcome barriers to referring women with postnatal depression to psychological treatment. The intervention included an educational session and an electronic referral template leading to a significant increase in referrals.



A number of studies have researched interventions by health visitors for PND. Health visitors were trained to identify women at risk of PND, and delivered eight sessions based on either a person-centred approach or a cognitive-behavioural approach. At six months follow-up, both groups had reduced symptoms of depression compared to women receiving routine care, indicating a preventative effect of health visitor intervention. The interventions were assessed as cost-effective when published in 2009.



Another study published in 2010 compared antidepressants with non-directive counselling by health visitors to treat women with PND. For the first four weeks after birth, women received antidepressants or general supportive care, then could continue with antidepressants or access the counselling intervention. Results suggested that early treatment with antidepressants had clinical benefits for reducing PND.



Psychological treatments for PND are recommended, but access to resources may be limited; group therapy may offer an alternative model of care. A review, published in 2010, assessed the effectiveness of group cognitive behavioural therapy (CBT) for women with PND. Only a small number of studies were identified, some of which indicated a beneficial effect of group CBT in reducing depression symptoms. However, the study also found mixed views about the acceptability of group therapy to women.



The feasibility of a web-based intervention to treat PND has been assessed. Women completed an average of 5 out of 12 sessions, which included interactive exercises, access to moderated chat rooms and other resources. Depression severity was reduced in women using the web-based intervention compared to routine care. Positive outcomes were still evident at six months follow-up, though a larger study is needed.



A new study that has just started will compare a culturally adapted group-based psychological intervention for PND to routine care. The study will recruit British South Asian women identified as having PND for 12 intervention sessions, looking at intervention delivery, women's views and acceptability, and outcomes over a year.



#### **CONTRIBUTION OF RESEARCH**

Research is building evidence for the prevention, identification and treatment of mental health problems around the time of pregnancy. The health burden upon, and risk to, women and babies could be reduced if awareness of mental health was raised among women, their families and communities, and professionals. Improving access to effective treatments and services based on research is important.

Further research for mental health problems around the time of pregnancy could address approaches to management to improve health.



Mental health problems and pregnancy (NHS Choices) http://www.nhs.uk/conditions/pregnancy-and-baby/pages/mental-health-problems-pregnant.aspx

Antenatal and postnatal mental health CG192 (NICE,2014) https://www.nice.org.uk/guidance/cg192



omen are more likely than men to suffer domestic or sexual abuse. Domestic violence includes physical or non-physical abuse, threats, sexual assault or stalking perpetrated by a partner, expartner or family member. Domestic violence during pregnancy can affect pregnancy outcomes and affects the physical and mental health of the woman. NICE guidance PH50 in 2010 recommended identifying domestic violence and responding using multi-agency protocols and pathways to offer support and safety for women to reduce harm.

Different methods to effectively screen for partne violence in healthcare were reviewed in 2015.

Screening increased identification of individuals at risk of partner violence in healthcare settings but did not appear to improve referrals or outcomes.

Pregnant women may be more likely to disclose intimate partner violence if screened in antenatal care. More research is needed to determine if universal screening or case finding would be beneficial in identifying individuals at risk.



A review of interventions to reduce domestic violence against pregnant women published in 2014 showed a range of approaches, from individual consultations with a social worker or nurse, to multiple therapy sessions and home visits.



One study that used a psycho-behavioural intervention approach led to a reduction in partner violence. However, it was difficult to compare such varied interventions with more high-quality research needed.

A review published in 2015 found that brief advocacy interventions, based on empowering women, may benefit short-term mental health and reduce abuse in pregnancy.



Research is looking at support and care for women following domestic violence. Understanding the support needs of women who have experienced domestic violence, and ways in which they sought help will be used to inform the development of a free web-based resource of the type already developed for people experiencing physical and mental health conditions.



A study is evaluating the effectiveness of a psychological intervention, delivered by domestic

abuse support workers to women seeking help from specialist services, for reducing psychological distress and depression.



Another research programme is examining the response of health care professionals when dealing with family members who experience domestic violence by developing and evaluating specialist training for GPs and other frontline staff.

A group-based intervention programme for men with abusive behaviours will also be evaluated, and the study will explore the complexities of abuse, including the needs of minority groups.



New research is starting about the healthcare experience of women and girls who have experienced female genital mutilation (FGM), and the views and experience of professionals providing care to them.



#### **CONTRIBUTION OF RESEARCH**

Research is assessing how to identify domestic violence in pregnancy, and what support and care to offer to reduce harm and violence and promote recovery. Research is starting on healthcare response to women affected by FGM. Insights from research can inform the healthcare and multi-agency response.



**Domestic abuse (NHS Choices)** http://www.nhs.uk/conditions/pregnancy-and-baby/pages/domestic-abuse-pregnant. aspx

Domestic violence and abuse - professional guidance (Department of Health, 2013) https://www.gov.uk/government/publications/guidance-for-health-professionals-on-domestic-violence

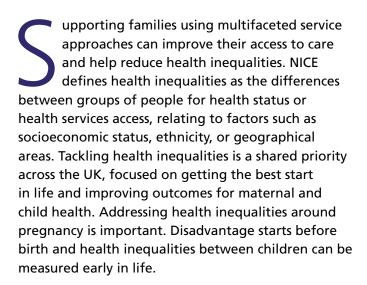
Domestic violence and abuse: multi-agency working PH50 (NICE, 2014) https://www.nice.org.uk/Guidance/PH50

Pregnancy and complex social factors CG110 (NICE, 2010) https://www.nice.org.uk/guidance/cg110

# SUPPORTING FAMILIES USING MULTIFACETED APPROACHES

In many areas midwives provide targeted extra infant feeding support for socially disadvantaged pregnant women. This can transform breastfeeding rates, with the health benefits for new mothers and their babies widely known. Midwives work hard to be innovative in their approach to supporting women to breastfeed as long as they wish to.

Cathy Warwick CBE, Chief Executive of the Royal College of Midwives (RCM)

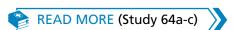


#### **PREGNANCY CARE**

Woman-focused care is a priority for ensuring access and engagement in high-quality maternity services to reduce health inequalities. Research has been used to understand the impact of adapting services to meet the needs of different population groups.

A study has explored the effect of maternity care provided at a free-standing midwifery-led birth centre, in a multi-ethnic inner city area of London. It found that women who attended the centre were more likely to be cared for by the same midwife

during pregnancy and labour. Beneficial outcomes included less use of pharmacological pain relief during labour, and more skin-to-skin contact with their baby in the first hours after birth, compared to women attending standard hospital care.



Another study is aiming to improve access to antenatal care for socially disadvantaged and ethnically diverse women in London. This project will include a community-based intervention for pregnant women, with the goal of improving the health of women and babies.



A collaborative project in the North West England is investigating whether providing a care package will increase access to health and community resources amongst socially deprived women and their families. The care package will include peer support, a short intervention for pregnant women and comprehensive information about local services. A major focus will be on psychological health and wellbeing.



Offering a doula, a woman who provides one-to-one support during pregnancy and for a short while after birth, has improved care experience and breastfeeding rates for disadvantaged women. The largest evaluation of volunteer doula services for disadvantaged women was published in 2015. Gathering data from the doulas, pregnant women and various healthcare professionals, showed that doulas were highly regarded and their support had a positive impact. For example, for those women who had a doula, breastfeeding was initiated and maintained at 6 weeks at a higher rate compared to usual care. Doulas were seen to be non-judgemental and knowledgeable.



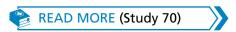
A new review will be looking at what interventions exist to improve maternity care for immigrant women living in the UK. Evaluating information from a wide range of sources, the researchers hope to provide information to guide service provision.



Research is evaluating how to support women to improve outcomes for their children and reduce harm and maltreatment, by looking at the effectiveness of the Group Family Nurse Partnership (gFNP) programme, compared to routine antenatal care. The study will recruit pregnant women with low or no educational qualifications, and those aged under 20 with one or more previous births. The gFNP programme will address a range of factors such as personal and environmental health, maternal confidence, and mother-infant attachment.



A further study will follow up teenage mothers who received Family Nurse Partnership care to assess family wellness and child maltreatment until children are six years old.



Other antenatal parenting interventions will be evaluated in a study of women identified as having additional health or social care needs in pregnancy. Use of Mellow Bumps or Enhanced Triple P for Babies will be compared to usual care for maternal health and wellbeing and child outcomes to 18 months.



#### **GRANTS, VOUCHERS AND INCENTIVES**

A study is evaluating the effect of the Health in Pregnancy Grants, which were provided to pregnant women on the condition they attended antenatal sessions. Data from across Scotland on health outcomes of babies were compared with five years before the grant was available, and with a period after it was withdrawn. A specific analysis will look at whether the subsidy reduced inequalities for subgroups of women, such as teenage mothers and those living in the most deprived areas.



A review published in 2015 examined whether providing incentives, such as gift cards, cash and baby items, would improve attendance at antenatal care. While attendance did improve, the studies did not give enough evidence to assess pregnancy outcomes. Furthermore, as most of the studies were based in Central America, the implications for the UK are unclear.



Another study is looking at the potential benefits of the Healthy Start Voucher in the UK. Provided to low-income pregnant women and pregnant women under 18, the voucher aims to improve nutrition by helping women get milk, fruit, vegetables and vitamin supplements. Maternal and child health outcomes will be evaluated, alongside cost effectiveness of the scheme and reasons for not claiming the vouchers.



#### **CONTRIBUTION OF RESEARCH**

Health inequalities are seen early in life, and improving health and wellbeing for women before, during and after pregnancy has the potential to modify the impact of disadvantage on children. Multi-faceted service approaches can be used to reduce health inequalities. Research on improving access and engagement in antenatal care, and support for parenting, will inform service provision to improve outcomes for different groups of women and children. Evaluation of grants, vouchers and incentives will inform future policy for supporting women in pregnancy.



About health inequalities (Best Beginnings) https://www.bestbeginnings.org.uk/health-inequalities

Pregnancy and complex social factors CG110 (NICE, 2010) https://www.nice.org.uk/guidance/cg110

Fair Society, Healthy Lives: the Marmot Review: strategic review of health inequalities in England post-2010 (The Marmot Review 2010) http://www.instituteofhealthequity.org/projects/fair-society-healthy-lives-the-marmot-review

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# **APPENDICES**

#### **SUMMARIES OF FEATURED NIHR STUDIES**

These studies received substantive funding by the NIHR through a wide range of programmes, research centres, collaborations and work streams. They include a variety of studies, from large, long-term primary research projects to smaller grants and reviews of published research. To find out more about these programmes and other funded work, visit www.nihr.ac.uk.

#### Abbreviations used

CI – confidence interval

OR – odds ratio

RCT - randomised controlled trial

RR – relative risk

SD - standard deviation

# STUDY 1 PUBLISHED

Routine pre-pregnancy health promotion for improving pregnancy outcomes

Published 2009, Whitworth

The aim of this review was to assess the effectiveness of routine pre-pregnancy health promotion for improving pregnancy outcomes when compared with no pre-pregnancy care or usual care. Four trials, totalling 2300 women, were included. The interventions ranged from brief advice on a single topic to multiple sessions of education on health and lifestyle. Comparisons between studies was limited. Only one study followed up through pregnancy and there was no strong evidence of a difference between groups for preterm birth, congenital anomalies or weight for gestational age. There was some evidence that health promotion interventions were associated with positive maternal behavioural change including lower rates of binge drinking. However, the authors cautioned that there is a lack of evidence on the effects of pre-pregnancy health promotion on pregnancy outcomes and more research is needed.

Cochrane Database of Systematic Reviews 2009 DOI: 10.1002/14651858.CD007536.pub2.

#### STUDY 2 PUBLISHED

CLARHC Pen: Cigarette Smoking during Pregnancy Is Associated with Alterations in Maternal and Foetal Thyroid Function.

Published 2009, Shields.

The aim of this study was to examine whether smoking is associated with changes in thyroid function of pregnant women and their foetus. Analyses were conducted in the first-trimester cohort (median gestation 9 weeks, n = 1428) and third-trimester

cohort (gestation 28 weeks, n = 927). The relationship between maternal smoking and thyroid hormone levels in cord serum of 618 full-term babies born to the women in the third-trimester cohort was also analysed. In smokers compared with non-smokers, median serum Thyroid-Stimulating Hormone (TSH) was lower (firsttrimester cohort: 1.02 vs. 1.17 mIU/litre, P= 0.001; third-trimester cohort: 1.72 vs. 1.90 mIU/litre, P = 0.037), and median serum Free T3 was higher (first-trimester cohort: 5.1 vs. 4.9 pmol/litre, P< 0.0001; third trimester cohort: 4.4 vs. 4.1 pmol/litre, P = 0.0001). In both cohorts, serum Free T4 in smokers and non-smokers were similar. The prevalence of anti-thyroperoxidase antibodies was also similar in smokers and non-smokers in both cohorts. Cord serum TSH of babies born to smokers was lower than of those born to nonsmokers (6.7 vs. 8.1 mIU/litre, P 0.009). The authors concluded that cigarette smoking is associated with changes in maternal thyroid function throughout the pregnancy and in foetal thyroid function.

Journal of Clinical Endocrinology & Metabolism 2009. doi: 10.1210/jc.2008-0380

#### STUDY 3 ONGOING

Barriers and facilitators to smoking cessation in pregnancy and following childbirth: literature review and qualitative study

Due to publish 2017

This study will enhance understanding of barriers and facilitators to smoking cessation in pregnancy and post-partum and explore the feasibility and acceptability of interventions to reach and support pregnant women to stop smoking and remain abstinent. Firstly, a description of existing interventions for smoking cessation in pregnancy will be presented. Secondly, a qualitative study design will combine three systematic reviews and three exploratory studies conducted over a two-year period. The set of reviews of qualitative evidence of barriers and facilitators will focus on pregnant women, partners/significant others (SOs) and health professionals respectively. The exploratory studies (involving semistructured interviews and focus groups) will be conducted in one study site in Scotland and one in England. The sample will comprise pregnant women who are continuing to smoke during pregnancy and those who have recently stopped smoking, partners/SOs, and professionals including midwives and midwifery managers, consultant obstetricians, health visitors and smoking cessation advisers. A subsample of 10 women originally interviewed will also be followed up post-partum to identify longer-term experiences. Findings from the interviews will identify barriers and facilitators to smoking cessation in pregnancy from the perspective of each group of interviewees. These findings will be brought together with the evidence from the systematic reviews to produce a narrative synthesis of key themes and issues. Lastly, the findings will be utilised to make recommendations for practice and for proposals for interventions to address smoking in pregnancy that can be tested in future research.

https://www.journalslibrary.nihr.ac.uk/programmes/hta/119301/#/

# STUDY 4 PUBLISHED, INTERIM RESULTS

Improving the effectiveness and reach of NHS support for smoking cessation in pregnancy

Published 2011, Coleman.

This study aims to develop i) ways of increasing pregnant women's uptake of effective NHS stop smoking support and ii) effective methods of NHS support to help the majority of pregnant smokers who currently try stopping alone. Four different approaches will be taken. The cost and use of services will be assessed by relating the costs of providing NHS stop smoking help in England with the numbers of women who use this service. Pregnant women will be asked when they want NHS help with stopping and will test out two different methods of offering NHS stop smoking help in pregnancy. The study will analyse women's and infants' medical records to see if using nicotine replacement therapy in pregnancy is more or less safe than smoking for the baby. Finally it will aim to refine and test new, effective 'self-help' methods for pregnant women to use on their own to help them to stop smoking. An initial systematic review of RCTs concluded that there is insufficient evidence to determine whether or not nicotine replacement therapy is effective or safe when used in pregnancy for smoking cessation.

Addiction 2011 doi: 10.1111/j.1360-0443.2010.03179.x

#### STUDY 5 ONGOING

Babyclear - the North East's regional approach to reducing maternal smoking rates

The BabyClear initiative is a co-ordinated approach to reducing maternal smoking levels across the North East, which has been developed by the Tobacco Control Collaborating Centre and rolled out into routine service in 2013. This initiative aimed to reconfigure services for pregnant women and provide greater support to stop smoking. It comprised a new referral pathway based on universal carbon monoxide monitoring by midwives at the booking appointment, which included a 3 minute intervention, with agreed referral thresholds. A range of materials were developed to support this initiative, and full training was provided to midwives and stop smoking advisors in how to give effective advice to support pregnant women to quit smoking. An indepth evaluation of BabyClear, led by Newcastle University and funded by the NIHR School for Public Health Research, will follow approximately 30,000 pregnancies, and assess the impact of this new approach on birth outcomes.

http://sphr.nihr.ac.uk/wp-content/uploads/2014/02/Summary-SPHR-FUS-PES-BBC.pdf

# STUDY 6 PUBLISHED

The SNAP trial: a randomised placebo-controlled trial of nicotine replacement therapy in pregnancy - clinical effectiveness and safety until 2 years after delivery, with economic evaluation

Published 2014, Cooper

The aim of this study was to compare at delivery, the clinical effectiveness and cost-effectiveness for achieving biochemically validated smoking cessation of NRT (nicotine replacement therapy) patches with placebo patches in pregnancy, and behaviour, development and disability in infants at 2 years of age. Participants included women between 12 and 24 weeks' gestation who smoked ≥ 10 cigarettes a day before and ≥ 5 during pregnancy, with an exhaled carbon monoxide reading of ≥8 parts per million). The intervention was NRT patches (15 mg per 16 hours) or matched placebo as an 8-week course issued in two equal batches. A second batch was dispensed at 4 weeks to those abstinent from smoking. One thousand and fifty women enrolled (521 NRT, 529 placebo). At one month after randomisation, the validated cessation rate was higher in the NRT group (21.3% vs. 11.7%, (OR [95% CI] for cessation with NRT, 2.05 [1.46 to 2.88]). At delivery, there was no difference between groups' smoking cessation rates: 9.4% in the NRT and 7.6% in the placebo group [OR (95% CI), 1.26 (0.82

to 1.96)]. For infants at 2 years, in the NRT group, 72.6% had no impairment compared with 65.5% in placebo (OR 1.40, 95% CI 1.05 to 1.86). Adherence to both the NRT patches and placebo patches was low. The authors concluded that NRT had no enduring, significant effect on smoking in pregnancy; however, 2-year-olds born to women who used NRT were more likely to have survived without any developmental impairment.

Health Technology Assessment 2014. doi: 10.3310/hta18540.

#### STUDY 7 PUBLISHED

Pharmacological interventions for promoting smoking cessation during pregnancy

Published 2015, Coleman

The aim of this review was to determine the efficacy and safety of smoking cessation pharmacotherapies (including NRT, varenicline and bupropion), other medications, or Electronic Nicotine Delivery Systems (ENDS) when used for smoking cessation in pregnancy. Nine trials were included. There was borderline evidence to suggest that NRT combined with behavioural support might help women to stop smoking in later pregnancy. However, when just the higher-quality, placebo-controlled trials were analysed, NRT was found to be no more effective than a placebo. There was insufficient evidence to conclude whether or not NRT had either positive or negative impacts on rates of miscarriage, stillbirth, preterm birth (less than 37 weeks), low birthweight, admissions of babies to neonatal intensive care or neonatal deaths, or whether this affected mean birthweights amongst infants. Side effects included headache, nausea and local reactions (e.g. skin irritation from patches). The authors concluded that NRT used in pregnancy for smoking cessation increases smoking cessation rates measured in late pregnancy by approximately 40%. There is no evidence that NRT used for smoking cessation in pregnancy has either positive or negative impacts on birth outcomes.

Cochrane Database of Systematic Reviews 2015 DOI: 10.1002/14651858.CD010078.pub2

### STUDY 8 PUBLISHED

Understanding Pregnant Smokers' Adherence to Nicotine Replacement Therapy during a Quit Attempt: A Qualitative Study.

Published 2016, Bowker

The aim of this study was to understand the experience of pregnant women who use nicotine replacement therapy (NRT) but discontinue this early. Semi-structured telephone interviews were conducted with 14 pregnant smokers who had recently been prescribed NRT, but self-reported poor NRT adherence or discontinuing treatment prematurely. Four main themes were identified; expectations of NRT, experience of using NRT, safety concerns and experience of using e-cigarettes. Some women intentionally used NRT to substitute a proportion of their cigarette intake and smoked alongside. Most women smoked while using NRT. Women who underutilized NRT did so as they experienced side effects, or were concerned that using NRT instead of smoking could actually increase their nicotine exposure and potential for increased nicotine dependence or foetal harm. Most women spoke about the use of e-cigarettes as a smoking cessation method but only a few had actually experienced using them during pregnancy. The authors concluded that challenging negative perceptions about NRT and educating women further about the risks of smoking may encourage them to use NRT products as

Nicotine & Tobacco Research 2016 doi: 10.1093/ntr/ntv205

# STUDY 9 ONGOING

Helping pregnant smokers quit: Multi-centre RCT of electronic cigarettes vs usual care (15/57/85).

Due to publish 2020

This is a recently funded RCT evaluating the use of electronic cigarettes compared to usual care in pregnancy. Results are expected in 2021.

#### STUDY 10 PUBLISHED

Psychosocial interventions for supporting women to stop smoking in pregnancy

Published 2013, Chamberlain.

The aim of this review was to assess the effects of smoking cessation interventions during pregnancy on smoking behaviour and perinatal health outcomes. Seventy-seven trials (involving 29,000 women) provided data on smoking abstinence in late pregnancy. The intervention that supported the most women to stop smoking in pregnancy appeared to be providing incentives. However, these results are based on only four trials with a small number of women (all in the US), and they only seemed to help women stop smoking when provided intensively (three trials). Counselling also appeared to be effective in supporting women to quit, but only when combined with other strategies. The effectiveness of counselling was less clear when women in the control group received a less intensive smoking intervention. It was unclear whether health education alone helped women quit. The authors concluded that psychosocial interventions to support women to stop smoking in pregnancy can increase the proportion of women who stop smoking in late pregnancy, and reduce low birthweight and preterm births.

This Cochrane review will be updated soon, and publication is expected for 2017.

Cochrane Database of Systematic Reviews 2013. DOI: 10.1002/14651858.CD001055.pub4

#### STUDY 11 PUBLISHED

Benefits of Incentives for Breastfeeding and Smoking cessation in pregnancy (BIBS): a mixed-methods study to inform trial design

Published 2015, Morgan

The aim of this mixed-methods study was to understand incentive mechanisms of action for smoking cessation in pregnancy and breastfeeding, develop a taxonomy and identify interventions to inform trial design. The qualitative study included 88 pregnant women/recent mothers/partners, 53 service providers, 24 experts and 63 conference attendees. The surveys included 1144 members of the general public and 497 health professionals. The discrete choice experiment study included 320 women with a history of smoking. Furthermore, 23 smoking cessation and 19 breastfeeding studies were included in the review of effectiveness. Vouchers contingent on biochemically proven smoking cessation in pregnancy were effective compared with non-contingent incentives for participation. Effects continued until 3 months post-partum. Inconclusive effects were found for breastfeeding incentives compared with no/smaller incentives but provider commitment contracts for breastfeeding show promise. Agreement over the type of incentives was greatest for a free breast pump and least for vouchers for breastfeeding. Universal incentives were preferred to those targeting low-income women. Initial daily text/telephone support, a quitting pal, vouchers for >£20.00 per month and values up to £80.00 increase the likelihood of smoking cessation. Doctors disagreed with provider incentives. Incentive interventions provide opportunity 'rungs' to help women. The authors concluded that incentives provided with other tailored components show promise but reach is a concern. They recommend formal evaluation and the

involvement of services users.

Health Technology Assessment 2015 doi: 10.3310/hta19300. BMJ 2015 doi: http://dx.doi.org/10.1136/bmj.h134

#### STUDY 12 PUBLISHED

The London Exercise And Pregnant smokers (LEAP) trial: a randomised controlled trial of physical activity for smoking cessation in pregnancy with an economic evaluation

Published 2015, Ussher

The aim of this study was to examine the effectiveness and costeffectiveness of a physical activity (PA) intervention plus standard behavioural support for smoking cessation relative to behavioural support alone for achieving smoking cessation at the end of pregnancy. The setting was 13 hospitals in the UK, and recruited women between 10 and 24 weeks' gestation smoking five or more cigarettes a day before pregnancy and one or more during pregnancy. Participants were randomised to behavioural support for smoking cessation (control) or behavioural support plus a PA intervention consisting of supervised treadmill exercise plus PA consultations. There was no significant difference in the rate of abstinence at the end of pregnancy between the PA group (7.7%) and the control group (6.4%) For the PA group compared with the control group, there was a 33%, 28% and 36% significantly greater increase in self-reported minutes of moderate- and vigorous-intensity PA from baseline to 1 week, 4 weeks and 6 weeks respectively. There were no significant differences between the groups for change in maternal weight, depression, withdrawal symptoms or urges to smoke. The authors concluded that during pregnancy, offering an intervention combining supervised exercise and PA counselling does not add to the effectiveness of behavioural support for smoking cessation.

Health Technology Assessment 2015 doi: 10.3310/hta19840

#### STUDY 13 PUBLISHED

Nutritional advice for improving outcomes in multiple pregnancies Published 2015, Bricker

This review assessed the effects of specialised diets or nutritional advice for women with multiple pregnancies (two or more foetuses). No trials were identified to be included in the review. The authors concluded that there is no robust evidence from randomised trials to indicate whether specialised diets or nutritional advice for women with multiple pregnancies do more good than harm. There is a clear need to undertake a randomised controlled trial.

Cochrane Database of Systematic Reviews 2015 DOI: 10.1002/14651858.CD008867.pub3 13)

# STUDY 14 PUBLISHED

Vitamin supplementation for preventing miscarriage

Published 2016, Balogun

The objectives of this review were to determine the effectiveness and safety of any vitamin supplementation on the risk of spontaneous miscarriage. A total of 40 trials (involving 276,820 women and 278,413 pregnancies assessing supplementation with any vitamin(s) starting prior to 20 weeks' gestation were eligible for the review. Eight trials were cluster-randomised and contributed data for 217,726 women and 219,267 pregnancies in total. Supplementing women with any vitamins does not reduce the number of women who have miscarriages. However, the risk for stillbirth was reduced among women receiving multivitamins plus iron and folic acid compared with iron and folate only groups in studies in several low and middle income countries. Although

total foetal loss was lower in women who were given multivitamins without folic acid and multivitamins with or without vitamin A, these findings included one trial each with small numbers of women involved. Also, they include studies where the comparison groups included women receiving either vitamin A or placebo, and thus require caution in interpretation. The authors concluded that taking any vitamin supplements prior to pregnancy or in early pregnancy does not prevent women experiencing miscarriage. However, evidence showed that women receiving multivitamins plus iron and folic acid had reduced risk for stillbirth.

Cochrane Database of Systematic Reviews 2016 DOI: 10.1002/14651858.CD004073.pub4

# STUDY 15 PUBLISHED

Effects and safety of periconceptional oral folate supplementation for preventing birth defects

Published 2015, De-Regil

This review examined whether periconceptional folate supplementation reduces the risk of neural tube defects (NTDs) and other congenital anomalies (including cleft palate) without causing adverse outcomes in mothers or babies. Five trials involving 7391 women (2033 with a history of a pregnancy affected by a NTD and 5358 with no history) were included. From 6708 births with information on NTDs and other infant outcomes, a protective effect of daily folic acid supplementation (alone or in combination with other vitamins and minerals) in preventing NTDs compared with no interventions/placebo or vitamins and minerals without folic acid was found. There is no evidence of any preventive or negative effects on cleft palate, cleft lip, congenital cardiovascular defects, miscarriages or any other birth defects. There were no included trials assessing the effects of this intervention on neonatal death, maternal blood folate or anaemia at term. The authors concluded that folic acid, alone or in combination with vitamins and minerals, prevents NTDs, but does not have a clear effect on other birth defects.

Cochrane Database of Systematic Reviews 2015, DOI: 10.1002/14651858.CD007950.pub3.

# STUDY 16 PUBLISHED

Vitamin D supplementation for women during pregnancy.

Published 2016, De-Regil

This review examined whether oral supplements with vitamin D alone or in combination with calcium or other vitamins and minerals given to women during pregnancy can safely improve maternal and neonatal outcomes. This is an updated review that included 15 trials assessing a total of 2833 women, excluded 27 trials, and 23 trials are still ongoing or unpublished. Risk of bias in the majority of trials was unclear and many studies were at high risk of bias for blinding and attrition rates. Data from seven trials involving 868 women consistently show that women who received vitamin D supplements alone, particularly on a daily basis, had higher 25-hydroxyvitamin D than those receiving no intervention or placebo, but this response was highly heterogeneous. Also, data from two trials involving 219 women suggest that women who received vitamin D supplements may have a lower risk of pre-eclampsia than those receiving no intervention or placebo. Overall, the authors concluded that supplementing pregnant women with vitamin D in a single or continued dose increases serum 25-hydroxyvitamin D at term and may reduce the risk of pre-eclampsia, low birthweight and preterm birth. However, when vitamin D and calcium are combined, the risk of preterm birth is

Cochrane Database of Systematic Reviews 2016 DOI: 10.1002/14651858.CD008873.pub3.

#### STUDY 17 PUBLISHED

Vitamin D supplementation in pregnancy: A systematic review Published 2014. Harvey

This review aimed to answer the following questions: (1) What are the clinical criteria for vitamin D deficiency in pregnant women? (2) What adverse maternal and neonatal health outcomes are associated with low maternal circulating 25(OH)D? (3) Does maternal supplementation with vitamin D in pregnancy lead to an improvement in these outcomes)? (4) What is the optimal type (D2 or D3), dose, regimen and route for vitamin D supplementation in pregnancy? (5) Is supplementation with vitamin D in pregnancy likely to be cost-effective? Seventy-six studies were included. The evidence base was insufficient to answer question 1. For questions 2 and 3, modest positive relationships were identified between maternal 25(OH)D and (1) offspring birthweight in meta-analysis of three observational studies using log-transformed 25(OH) D concentrations after adjustment for potential confounding factors but not in those four studies using natural units, or across intervention studies; (2) offspring cord blood or postnatal calcium concentrations in a meta-analysis of six intervention studies (all found to be at high risk of bias; mean difference 0.05 mmol/l, 95% CI 0.02 to 0.05 mmol/l); and (3) offspring bone mass in observational studies judged to be of good quality, but which did not permit meta-analysis. The evidence base was insufficient to reliably answer questions 4 and 5. Study methodology varied widely. The authors concluded that the evidence base is currently insufficient to support definite clinical recommendations regarding vitamin D supplementation in pregnancy. High-quality randomised trials are required.

Health Technology Assessment 2014 doi: 10.3310/hta18450.

# STUDY 18 PUBLISHED

#### **MAVIDOS Studies**

The Maternal Vitamin D Osteoporosis Study (MAVIDOS) is a large, multi-centre trial examining the role of Vitamin D in pregnancy. It began in September 2008 and has recruited more than 1,000 women from three centres (Southampton, Sheffield and Oxford). Women who participated in the study, and had Vitamin D levels in the low-normal range, were randomised at 14 weeks gestation to either 1,000 units of Vitamin D daily or to a matched placebo tablet for the duration of pregnancy. A range of maternal measures were taken at various time points, as well as bone mass of the offspring, using a DXA scanner. MAVIDOS has received funding from NIHR, MRC, Arthritis Research UK and the Bupa Foundation.

#### STUDY 18A

Determinants of the maternal 25-hydroxyvitamin D response to vitamin D supplementation during pregnancy. Moon, 2016.

This study assessed which maternal and environmental characteristics were associated with 25(OH)D after supplementation with cholecalciferol, set in hospital antenatal clinics. 829 pregnant women were randomised (422 placebo, 407 cholecalciferol). At 14 and 34 weeks of gestation, maternal anthropometry, health, and lifestyle were assessed and 25(OH)D measured. Compliance was determined using pill counts at 19 and 34 weeks. The intervention consisted of 1000 IU/d of cholecalciferol or matched placebo from 14 weeks of gestation until delivery. It was found that 25(OH)D at 34 weeks of gestation was higher in the women randomized to vitamin D (mean [SD], 67.7 [21.3] nmol/L) compared with placebo (43.1 [22.5] nmol/L; P < .001). In women randomized to cholecalciferol, higher pregnancy weight gain from 14 to 34 weeks of gestation (kg) ( = -0.81 [95% CI -1.39, -0.22]), lower compliance with study medication (%) ( = -0.28 [-0.072,

-0.48]), lower early pregnancy 25(OH)D (nmol/L) ( = 0.28 [0.16, 0.40]), and delivery in the winter vs the summer ( = -10.5 [-6.4, -14.6]) were independently associated with lower 25(OH)D at 34 weeks of gestation. The authors concluded that women who gained more weight during pregnancy had lower 25(OH)D in early pregnancy and delivered in winter achieved a lower 25(OH)D in late pregnancy when supplemented with 1000 IU/d cholecalciferol.

Journal of Clinical Endocrinology & Metabolism 2016 doi: 10.1210/jc.2016-2869

#### STUDY 18B

Tracking of 25-hydroxyvitamin D status during pregnancy: the importance of vitamin D supplementation. Moon, 2015.

This study tracked serum 25(OH)D from early to late pregnancy. Lifestyle, diet, and 25(OH)D status were assessed at 11 and 34 week of gestation. Seasonal variation was also taken account of in the model. It was found that there was a moderate correlation between season-corrected 25(OH)D measurements at 11 and 34 weeks of gestation (r = 0.53, P = 0.0001; n = 1753). Vitamin D supplementation was the strongest predictor of tracking. The authors concluded that there was a moderate tracking of 25(OH) D status from early to late pregnancy. Status may also be influence by Vitamin D supplementation, weight gain, physical activity and dietary sources of Vitamin D.

American Journal of Clinical Nutrition 2015 doi: 10.3945/ajcn.115.115295

#### STUDY 18C

Maternal gestational vitamin D supplementation and offspring bone health (MAVIDOS): a multicentre randomised, double-blind, placebo-controlled trial. Cooper, 2016.

This multicentre, double-blind, randomised placebo-controlled trial (MAVIDOS) recruited pregnant women from three study sites in the UK (Southampton, Oxford and Sheffield). Eligible participants were older than 18 years with a singleton pregnancy, gestation of less than 17 weeks, and had a serum 25-hydroxyvitamin D concentration of 25-100nmol per litre in early pregnancy. They were randomly assigned to a supplement of cholecalciferol 1000 units daily or matched placebo, taken until delivery. The primary outcome measure was neonatal bone mass assessed using DXA. Although no difference was observed in this measure overall, the study confirmed that supplementation at this dose corrected vitamin D insufficiency in over 80% of pregnant women, and there was a statistically significant benefit on neonatal bone mass, from treatment of women with deliveries during winter months.

Lancet 2016 DOI: http://dx.doi.org/10.1016/S2213-8587(16)00044-9

#### STUDY 19 PUBLISHED

Vitamin A supplementation for postpartum women

Published 2016, Oliveira

This review evaluated the effects of vitamin A supplementation for postpartum women on maternal and infant health. Fourteen trials enrolling 25,758 women and infant pairs were included. The supplementation schemes included high, single or double doses of vitamin A (200,000 to 400,000 internation units (IU)), or 7.8 mg daily beta-carotene compared with placebo, no treatment, other (iron); or higher (400,000 IU) versus lower dose (200,000 IU). In all trials, a considerable proportion of infants were at least partially breastfed until six months. The evidence from 14 included trials was found was to be of low quality. These studies involved the mothers being given vitamin A or not, within the first six weeks after giving birth, or compared a high dose of

vitamin A with a low dose. The mothers and their babies did not experience adverse effects and there was evidence of improved amounts of retinol in breast milk. The authors concluded that there was no evidence of benefit from different doses of vitamin A supplementation for postpartum women on maternal and infant mortality and morbidity, compared with other doses or placebo. Although maternal breastmilk retinol concentrations improved with supplementation, this did not translate to health benefits for either women or infants.

Cochrane Database of Systematic Reviews 2016 DOI: 10.1002/14651858.CD005944.pub3

#### STUDY 20 PUBLISHED

Calcium supplementation during pregnancy for preventing hypertensive disorders and related problems

Published 2014, Hofmeyr

This review assessed the effects of calcium supplementation during pregnancy on hypertensive disorders of pregnancy and related maternal and child outcomes. The review of 24 trials found good quality evidence that calcium supplementation with high doses (at least 1 g daily) during pregnancy (13 studies involving 15,730 women) is a safe and cost effective way of reducing the risk of pre-eclampsia, especially in women from communities with low dietary calcium and those at increased risk of pre-eclampsia. Women receiving calcium supplements were also less likely to die or have serious problems related to pre-eclampsia. Babies were less likely to be born preterm. No adverse effects have been found but further research is needed into the ideal dosage of supplementation. Limited evidence from 10 trials (2234 women) suggested that a relatively low dose may be effective although co-interventions such as vitamin D, linoleic acid or antioxidants were given in six of the included trials. The authors concluded that calcium supplementation (≥ 1 g/day) is associated with a significant reduction in the risk of pre-eclampsia, particularly for women with low calcium diets.

Cochrane Database of Systematic Reviews 2014 DOI: 10.1002/14651858.CD001059.pub4.

# STUDY 21 PUBLISHED

Daily oral iron supplementation during pregnancy

Published 2015, Pena-Rosas

This review assessed the effects of daily oral iron supplements for pregnant women, either alone or in conjunction with folic acid, or with other vitamins and minerals as a public health intervention in antenatal care. 61 trials were included from 27 countries. Forty-four trials, involving 43,274 women, contributed data and compared the effects of daily oral supplements containing iron versus no iron or placebo. The use of iron or iron and folic acid supplements was associated with a reduced risk of anaemia and iron deficiency during pregnancy. There was some indication that maternal iron supplements during pregnancy could improve outcomes for babies (birthweight and preterm birth) but the evidence for this was not of high quality. The authors concluded that supplementation reduces the risk of maternal anaemia and iron deficiency in pregnancy but the positive effect on other maternal and infant outcomes is less clear. Implementation of iron supplementation recommendations may produce heterogeneous results depending on the population's background risk for low birthweight and anaemia, as well as the level of adherence to the

Cochrane Database of Systematic Reviews 2015 DOI: 10.1002/14651858.CD004736.pub5

#### STUDY 22 PUBLISHED

lodine supplementation for women during the preconception, pregnancy and postpartum period.

Published 2015, De-Regil

This review will assess the benefits and harms of supplementation with iodine, alone or in combination with other vitamins and minerals, for women in the preconceptional, pregnancy or postpartum period on their and their children's outcomes.

Cochrane Database of Systematic Reviews 2015. DOI: 10.1002/14651858.CD011761

#### STUDY 23 PUBLISHED

Directed preconception health programs and interventions for improving pregnancy outcomes for women who are overweight or obese

Published 2015, Opray

The aim of the study was to evaluate the effectiveness of preconception health programs and interventions for improving pregnancy outcomes in overweight and obese women. The review searched for RCTs (including those using a cluster-randomised design), comparing health programs and interventions with routine care in women of reproductive age and a BMI greater than or equal to 25 kg/m2. No studies met the inclusion criteria. The authors stated that until the effectiveness of preconception health programs and interventions can be established, no practice recommendations could be made. Further research is therefore required in this area.

Cochrane Database of Systematic Reviews 2015 DOI: 10.1002/14651858.CD010932.pub2

#### STUDY 24 PUBLISHED, INTERIM FINDINGS

CLARHC WMids: Effectiveness of regular weighing and feedback by community midwives in preventing excessive gestational weight gain: randomised controlled trial (POPS 2)

#### STUDY 24A

The POPS2 trial is looking at whether regular weighing and feedback by community midwives can prevent excessive weight gain during pregnancy.

The intervention included 1) self-monitoring: actively engaging women by recording weekly weight and 2) weighing. Community midwives weigh women at each antenatal appointment and plot their weight on a weight gain chart, appropriate to their BMI, set a maximum weight gain limit for each subsequent appointment, and give brief feedback on their progress emphasising the importance of healthy weight gain. The follow up length is 7 months.

http://www.clahrcprojects.co.uk/impact/projects/effectiveness-regular-weighing-and-feedback-community-midwives-preventing-excessive

#### STUDY 24B

Effectiveness of regular weighing, weight target setting and feedback by community midwives within routine antenatal care in preventing excessive gestational weight gain: randomised controlled trial.

Daley, 2016.

This study aimed to recruit six hundred and ten pregnant women (between 10-14 weeks gestation), aged ≥18 years with a body mass index (BMI) ≥18.5 kg/m2, from four maternity centres in England. Community midwives completed a short training module before delivering the intervention. In the intervention, midwives weighed women, set maximum weight limits for weight gain at each antenatal appointment and asked women to monitor their weight

at home. The intervention was compared to usual antenatal care. The primary outcome was the proportion of women per group who exceed the Institute of Medicine guidelines for gestational weight gain at 38 weeks of pregnancy according to their early pregnancy BMI category. Early results indicate that there were no specific benefits of weighing in terms of preventing excess weight gain or mean weight increase. Nonetheless, the proportion of women gaining excess weight was much lower than assumed in the power calculation. It was also noted that women had no negative experiences of being weighed. The full results of this study are expected in early 2017.

Obesity 2016 doi: 10.1186/s40608-016-0086-4

#### STUDY 25 PUBLISHED

CLARHC Yorks: Using Mobile Technology in Tackling Maternal Obesity (MOMTech)

This project links with existing care pathways and will include the development of an e-health platform, delivered through a portable device. It aims to optimise access and promote effectiveness by overcoming challenges associated with the stigma of obesity in pregnancy. It includes an initial review of types of behavioural interventions.

#### STUDY 25A

An Analysis of Behaviour Change Techniques Used in a Sample of Gestational Weight Management Trials.

Soltani, 2016.

Journal of Pregnancy 2016 doi:10.1155/2016/1085916

#### STUDY 25B

Talking about weight in pregnancy: An exploration of practitioners' and women's perceptions.

Furness, 2014.

This study aimed to explore women's, midwives' and health visitors' perceptions of current practice in helping women manage their weight and supporting healthy behaviour change during pregnancy, and their perceived training needs. A modified grounded theory methodology was adopted, based upon critical realist assumptions. Following consultation events with 56 practitioners to inform data collection tools, 20 (different) practitioners and nine women participated in focus groups. Comparative analysis generated four themes: A core theme, "Discouraging discourses", described health professionals' negative beliefs and reactive approach to communicating about weight. "Staff resources" identified limitations in and requirements for practitioner knowledge, skills and tools for effective communication. "Contextual influences" were social factors, which hindered practitioners' efforts to achieve healthy behaviour change. "Communicating as a Team" identified the importance of and challenges to a team approach.

Journal of Nursing Education and Practice 2014 DOI: 10.5430/jnep. v5n2p89

## STUDY 25C

Maternal Obesity Management Using Mobile Technology: A Feasibility Study to Evaluate a Text Messaging Based Complex Intervention during Pregnancy.

Soltani, 2015.

The maternal obesity management using mobile technology (MOMTech) study aimed at evaluating the feasibility of text messaging based complex intervention designed to support obese women (BMI ≥ 30) with healthier lifestyles and limit gestational weight gain (GWG). Participants received two daily text messages, supported by four appointments with a healthy lifestyle midwife, diet and activity goal setting, and self-monitoring diaries.

The comparison group were obese mothers who declined to participate but consented for their routinely collected data to be used for comparison. Postnatal interviews and focus groups with participants and the comparison group explored the intervention's acceptability and suggested improvements. Fourteen women completed the study. Participants had lower mean GWG than the comparison group (6.65 kg versus 9.74 kg) and few (28% versus 50%) exceeded the Institute of Medicine's upper limit of 9 kg GWG for obese women. The authors concluded that MOMTech was feasible within clinical setting and acceptable intervention to support women to limit GWG.

Journal of Obesity 2015 http://dx.doi.org/10.1155/2015/814830

#### STUDY 26 PUBLISHED

Interventions to reduce or prevent obesity in pregnant women: A systematic review of evidence synthesis

#### STUDY 26A

Interventions to reduce or prevent obesity in pregnant women: a systematic review.

Thangaratinam, 2012.

This study evaluated the effectiveness of dietary interventions in reducing or preventing obesity in pregnancy. Eight-eight studies involving 182,139 women evaluated the effect of weight management interventions in pregnancy on maternal and foetal outcomes. Meta-analysis of 30 RCTs (4503 women) showed a reduction in weight gain in the intervention group of 0.97 kg compared with the control group (95% CI -1.60 kg to -0.34 kg; p = 0.003). Weight management interventions overall in pregnancy resulted in a significant reduction in the incidence of pre-eclampsia (RR 0.74, 95% CI 0.59 to 0.92; p = 0.008). Dietary interventions in pregnancy resulted in a significant decrease in the risk of preeclampsia (RR 0.67, 95% CI 0.53 to 0.85; p = 0.0009), gestational hypertension (RR 0.30, 95% CI 0.10 to 0.88; p = 0.03) and preterm birth (RR 0.68, 95% CI 0.48 to 0.96; p = 0.03). There were no differences in the incidence of small-for-gestational-age infants between the groups (RR 0.99, 95% CI 0.76 to 1.29). There were no significant maternal or foetal adverse effects observed for the interventions in the included trials. The quality of evidence was moderate for interventions, moderate to low for pregnancy outcomes, and very low for adverse outcomes. The authors concluded that Interventions in pregnancy to manage weight result in a significant reduction in weight gain in pregnancy.

Health Technology Assessment 2012 DOI: http://dx.doi.org/10.3310/ hta16310

# STUDY 26B

Effects of interventions in pregnancy on maternal weight and obstetric outcomes: meta-analysis of randomised evidence.

Thangaratinam, 2012.

This review evaluated the effects of dietary and lifestyle interventions in pregnancy on maternal and foetal weight. Fortyfour RCTs involving 7278 women were included. Overall, there was 1.42 kg reduction in gestational weight gain with any intervention compared with control. With all interventions combined, there were no significant differences in birth weight (mean difference –50 g, –100 to 0 g) and the incidence of large for gestational age (RR 0.85, 0.66 to 1.09) or small for gestational age (1.00, 0.78 to 1.28) babies between the groups, though by itself physical activity was associated with reduced birth weight (mean difference –60 g, –120 to –10 g). Dietary intervention resulted in the largest reduction in maternal gestational weight gain (3.84 kg, 2.45 to 5.22 kg), with improved pregnancy outcomes compared with other

interventions. The authors concluded that dietary and lifestyle interventions in pregnancy can reduce maternal gestational weight gain and improve outcomes for both mother and baby. Among the interventions, those based on diet are the most effective and are associated with reductions in maternal gestational weight gain and improved obstetric outcomes.

BMJ 2012. doi: http://dx.doi.org/10.1136/bmj.e2088

# STUDY 27 PUBLISHED

Diet or exercise, or both, for preventing excessive weight gain in pregnancy

Published 2015, Muktabhant

This review evaluated the effectiveness of diet or exercise, or both, interventions for preventing excessive weight gain during pregnancy and associated pregnancy complications. 65 RCTs were included, out of which 49 RCTs involving 11,444 women contributed data to quantitative meta-analysis. Study interventions involved mainly diet only, exercise only, and combined diet and exercise interventions, usually compared with standard care. Overall, diet, exercise, or combined interventions reduced the risk of excessive gestational weight gain (GWG) on average by 20% overall (average RR 0.80, 95% CI 0.73 to 0.87; participants = 7096; studies = 24;  $I^2$  = 52%). The authors concluded that high-quality evidence indicates that diet or exercise, or both, during pregnancy can reduce the risk of excessive GWG. Other benefits included a lower risk of caesarean delivery, macrosomia, and neonatal respiratory morbidity, particularly for high-risk women receiving combined diet and exercise interventions

Cochrane Database of Systematic Reviews 2015 DOI: 10.1002/14651858.CD007145.pub3.

#### STUDY 28 ONGOING

Effects of weight management interventions on maternal and foetal outcomes in pregnancy: Individual patient data (IPD) meta-analysis of randomised trials and model based economic evaluation

Due to publish 2017

This is an individual patient data meta-analysis of RCTs. To date, 22 study investigators will be able to provide access to individual patient data for over 4000 pregnant women. This will enable intervention effects to be quantified for clinically relevant groups. It will also allow the magnitude of benefit due to weight change in pregnancy to be quantified for both the mother and baby. The economic evaluation will determine the characteristics of the weight management intervention that are most cost-effective. The study will also generate recommendations on optimal weight gain in pregnancy to minimise maternal and foetal complications and the cost effectiveness of these interventions.

https://www.journalslibrary.nihr.ac.uk/projects/120150/#/

# STUDY 29 PUBLISHED

Improving pregnancy outcome in obese women

# STUDY 29A

Effect of a behavioural intervention in obese pregnant women (the UPBEAT study): a multicentre, randomised controlled trial. *Poston, 2015.* 

UPBEAT is an RCT at antenatal clinics in multi-ethnic, inner-city locations in the UK. Pregnant women (15–18 weeks plus 6 days of gestation) older than 16 years who were obese were recruited and randomly assigned to either a behavioural intervention or standard antenatal care. The intervention was delivered once a week through eight health trainer-led sessions. 1555 women

were recruited, with a mean BMI of 36·3 kg/m2 (SD 4·8) and 772 were randomly assigned to standard antenatal care and 783 were allocated the behavioural intervention. Gestational diabetes was reported in 172 (26%) women in the standard care group compared with 160 (25%) in the intervention group (risk ratio 0·96, 95% CI 0·79–1·16; p=0·68). 61 (8%) of 751 babies in the standard care group were large for gestational age compared with 71 (9%) of 761 in the intervention group (1·15, 0·83–1·59; p=0·40). The authors concluded that a behavioural intervention addressing diet and physical activity in women with obesity during pregnancy is not adequate to prevent gestational diabetes, or to reduce the incidence of large-for-gestational-age infants.

The Lancet Diabetes and Endocrinology 2015 DOI: http://dx.doi.org/10.1016/S2213-8587(15)00227-2

#### STUDY 29B ONGOING STUDY

#### The UPBEAT trial

One in five UK women of childbearing age is clinically obese. Obese women are more likely to suffer from nearly every complication of pregnancy, including diabetes, and pre-eclampsia. This study is developing an individually tailored 'life style' programme for obese pregnant women, working with them to change their diet and physical activity. The advice is targeted at lowering the amount of glucose in the mother's blood, thereby preventing excessive foetal growth and reducing her risk of developing diabetes and pre-eclampsia. Reducing fatness in the baby will also lower the risk of her child becoming obese. Once the health style package has been developed the research team will carry out a study in 1550 women in four geographically diverse populations in the UK to determine whether it improves the health of the mother and child. Acceptability, feasibility and cost effectiveness of the intervention in the clinical setting will be assessed. If successful, we will then be able to rapidly implement these health measures within routine antenatal care in the NHS.

http://www.medscinet.net/upbeat/about.aspx

# STUDY 30 PUBLISHED

Does metformin reduce excess birthweight in offspring of obese pregnant women? A randomised controlled trial of efficacy, exploration of mechanisms and evaluation of other pregnancy complications

#### STUDY 30A

Metformin and maternal and foetal outcomes in obese pregnant women (EMPOWaR): a randomised double blind placebo controlled trial

Pregnant women between 12 and 16 weeks' gestation who had a BMI of 30 kg/m2 or more and normal glucose tolerance were randomly assigned to receive oral metformin 500 mg (increasing to a maximum of 2500 mg) or matched placebo daily from between 12 and 16 weeks' gestation until delivery of the baby. Four hundred and forty-nine women were randomly assigned to either placebo (n=223) or metformin (n=226), of whom 434 (97%) were included in the final modified intention-to-treat analysis. Mean birthweight at delivery was 3463g (SD 660) in the placebo group and 3462g (548) in the metformin group. The estimated effect size of metformin on the primary outcome was non-significant (adjusted mean difference -0.029, 95% CI -0.217 to 0.158; p=0.7597). The authors concluded that metformin has no significant effect on birthweight percentile in obese pregnant women; metformin should not be used to improve pregnancy outcomes in obese women without diabetes.

Lancet Diabetes and Endocrinology 2015 DOI: http://dx.doi. org/10.1016/S2213-8587(15)00219-3

#### STUDY 30B

Does metformin reduce excess birthweight in offspring of obese pregnant women? A randomised controlled trial of efficacy, exploration of mechanisms and evaluation of other pregnancy complications

This is the first study to test the efficacy of metformin in reducing high birth weight in the children of obese pregnant women. Results are similar to above, with the trial and conclusions discussed in greater detail.

Efficacy and Mechanism Evaluation 2016. https://dx.doi.org/10.3310/eme03070

#### STUDY 31 ONGOING

A two-arm feasibility trial of lifestyle information and Slimming World groups to promote weight management and positive lifestyle behaviour in postnatal women from an ethnically diverse inner city population

Due to publish 2018

This study will determine whether it is feasible to conduct a definitive RCT of lifestyle information and access to Slimming World groups designed to achieve and maintain healthy weight and positive lifestyle behaviour in postnatal women most at risk of weight retention in an inner city population. The study aims to recruit 190 women. Obese (Body Mass Index (BMI) >30 kg/m²) or overweigh t(BMI 25 29.9 kg/m²) women at antenatal booking and women with normal booking BMI but excessive gestational weight gain (GWG) will be recruited and randomised at 36 weeks gestation to intervention or standard care only. The intervention will consist of standard care, positive lifestyle information and postnatal access to Slimming World groups. The primary assessment is difference between trial arms in weight 12 months postnatally, expressed as percentage change from weight recorded at the woman's first antenatal appointment.

https://www.journalslibrary.nihr.ac.uk/projects/146714/#/

## STUDY 32 ONGOING

A woman-centred, tailored SMS-delivered multi-component intervention for weight loss and maintenance of weight loss in the postpartum period: intervention adaptation and pilot RCT

Due to publish 2019

The overall aim is to adapt and pilot test an evidence and theorybased tailored SMS-delivered intervention supporting overweight or obese women's behaviour change for weight loss and weight loss maintenance in the postpartum period. Women who are overweight or obese after pregnancy will be invited to take part and randomised to either receive weight management messages or to receive general messages about child health and development for one year. The SMS-delivered intervention will allow message tailoring according to women s weight management progress; their social circumstances and eating triggers (gathered from women at baseline); other health-related behaviours (smoking, alcohol, breastfeeding); and individual preferences for time and frequency of messages. Measurements like weight and waist circumference will be recorded at 0, 3, 6, 9 and 12 months. If successful, this work could result in a weight management intervention that is made widely available to postpartum women.

https://www.journalslibrary.nihr.ac.uk/projects/146720/#/

#### STUDY 33 PUBLISHED

Systematic review to evaluate the effectiveness of interventions to promote the initiation of breastfeeding

Published 2000, Fairbank.

This systematic review evaluated the effectiveness of breastfeeding promotion programmes. 59 studies met the selection criteria, comprising 14 RCTs, 16 non-RCTs and 29 before-after studies. There were many intervention types, for example health education, health sector initiatives, peer support, media campaigns and multifaceted package interventions. Outcomes varied across studies. The results indicated that informal, small group health education, delivered during the antenatal period, was effective at increasing breastfeeding initiation rates among women from different income groups and from some minority ethnic groups. One-to-one health education was effective at increasing breastfeeding initiation rates among women on low incomes. In addition, peer support programmes were effective among women on low incomes. Effective packages that increased initiation and duration of breastfeeding included a peer support programme and/or a media campaign combined with structural changes to the health sector and/or health education activities.

Health Technology Assessment 2000 DOI: http://dx.doi.org/10.3310/ hta4250

#### STUDY 34 PUBLISHED

Support for healthy breastfeeding mothers with healthy term babies

Published 2012, Renfrew

This review assessed the effectiveness of support for breastfeeding mothers. 52 studies, from 21 countries, contributed outcome data to the review (56,451 mother-infant pairs). All forms of extra support showed an increase in duration of 'any breastfeeding' (includes partial and exclusive breastfeeding) (RR for stopping any breastfeeding before six months 0.91, 95% CI 0.88 to 0.96). All forms of extra support together also had a positive effect on duration of exclusive breastfeeding (RR at six months 0.86, 95% CI 0.82 to 0.91; RR at four to six weeks 0.74, 95% CI 0.61 to 0.89). The authors concluded that all women should be offered support to breastfeed their babies to increase the duration and exclusivity of breastfeeding. This support can be in the form of professionals or peers, or a combination of both. Strategies that rely mainly on face-to-face support are more likely to succeed. Reactive support is less effective, whilst ongoing support should be offered and tailored to the population group.

Cochrane Database of Systematic Reviews 2012 DOI: 10.1002/14651858.CD001141.pub4

#### STUDY 35 PUBLISHED

Randomised trial of sidecar crib use on breastfeeding duration (NECOT)

Published 2011, Ball

A previous study by the researchers found that facilitating close proximity between mothers and babies via sidecar cribs for the duration of the postnatal ward stay was effective in increasing feed frequency and facilitating the initiation of breastfeeding. This present study assessed whether sidecar cribs also facilitated increased breastfeeding duration. Breastfeeding outcomes using sidecar cribs in postnatal wards were compared to normal postnatal ward care of stand-alone cots. 870 mothers were included in the study (433 intervention; 437 controls). The primary outcome measures were time to cessation of exclusive breastfeeding, and any breastfeeding. Data was recorded for the 6 months after birth. No significant difference was found between the two groups for duration of any breastfeeding (sidecar crib vs cot, hazard ratio (HR) 0.96, 95% CI 0.79 to 1.18), or exclusive breastfeeding (HR 0.99, 95% CI 0.85 to 1.16) adjusting for maternal age, education, previous breastfeeding and delivery type. At 6 months, about 50% of mothers were still breastfeeding. Furthermore, sidecar crib provision had no effect on mother–infant bed sharing at home. The authors concluded sidecar cribs help with breastfeeding initiation, but duration of breastfeeding was not improved.

Arch Dis Child 2011 doi:10.1136/adc.2010.205344

#### STUDY 36 PUBLISHED

Breastfeeding promotion for infants in neonatal units: a systematic review and economic analysis

Published 2009, Renfrew

This review evaluated the effectiveness and cost-effectiveness of interventions that promoted or inhibited breastfeeding for infants admitted to neonatal units. Forty-eight studies were included, of which 17% were conducted in the UK. Short periods of skin-to-skin contact increased the duration of any breastfeeding for 1 month after discharge [risk ratio (RR) 4.76, 95% confidence interval (CI) 1.19 to 19.10] and for more than 6 weeks (RR 1.95, 95% CI 1.03 to 3.70) among clinically stable infants in industrialised settings. There is strong evidence for the effectiveness of peer support at home (in Manila) for mothers of term, low birthweight infants on any breastfeeding up to 24 weeks (RR 2.18, 95% CI 1.45 to 3.29) and exclusive breastfeeding from birth to 6 months (RR 65.94, 95%) CI 4.12 to 1055.70), and for the effectiveness of peer support in hospital and at home for mothers of infants in Special Care Baby Units on providing any breastmilk at 12 weeks [odds ratio (OR) 2.81, 95% CI 1.11 to 7.14; p = 0.01]. Additional skilled professional support in hospital was more effective and less costly than normal staff contact. The authors argued for a unified approach for a national surveillance of feeding for infants and mothers in neonatal units.

Health Technology Assessment 2009, DOI: http://dx.doi.org/10.3310/ hta13400

#### STUDY 37 PUBLISHED

Effect of restricted pacifier use in breastfeeding term infants for increasing duration of breastfeeding

Published 2016, Jaafar

The aim of this review was to assess the effect of restricted versus unrestricted pacifier use in healthy full-term new-borns on the duration of breastfeeding and infant health. Meta-analysis of two studies (involving 1302 healthy full-term breastfeeding infants) showed that pacifier use had no significant effect on the proportion of infants exclusively breastfed at three months (risk ratio (RR) 1.01; 95% confidence interval (Cl) 0.96 to 1.07, two studies, 1228 infants), and at four months of age (RR 1.01; 95% Cl 0.94 to 1.09). There was no effect on the proportion of infants partially breastfed at three months (RR 1.00; 95% Cl 0.98 to 1.02) and at four months of age (RR 0.99; 95% Cl 0.97 to 1.02). None of the studies were conducted in the UK. The authors concluded that well-designed trials are needed to assess difficulties associated with breastfeeding and pacifier use, and the long-term effect of pacifier use on mother and infant health.

Cochrane Database of Systematic Reviews 2016 DOI: 10.1002/14651858.CD001059.pub4.

#### STUDY 38 ONGOING

Assets-based feeding help Before and After birth (ABA): feasibility study for improving breastfeeding initiation and continuation

Due to publish May 2019

This feasibility study will be examining the rate of breastfeeding in areas of low uptake in a sample of 100 women. Pregnant mothers in their first pregnancy will be invited to receive routine

care and additional support from a feeding helper or only routine care from midwives and health visitors. Peer supporters will be trained as feeding helpers, who will provide non-judgemental support, information about support groups, websites and other resources, and be flexible and woman-centred in their approach. Feeding helpers will meet the pregnant woman, plus any other family members, from 28 weeks, and then send monthly texts with personalised messages. After birth, the feeding helper will meet with the mum and baby, and then make brief phone calls (or texts) daily for 2 weeks. Less frequent texts will be provided until the baby is 5 months old. At 3 days, 8 weeks and 6 months after birth, mothers will be sent a text to ask about their feeding methods. Women and feeding helpers will be interviewed about their experiences, acceptability and feasibility of the intervention. A cost effectiveness analysis will also be conducted.

https://www.journalslibrary.nihr.ac.uk/projects/155304/#/

#### STUDY 39 ONGOING

#### CLARHC West: Alcohol toxicity during (and before) pregnancy

This work aims to find out what is known about the effects of prenatal alcohol consumption on pregnancy, including complications, delivery outcomes and foetal alcohol syndrome. All available evidence will be reviewed in order to inform new guidance for pregnant women. This project also looks at the existing guidelines on alcohol consumption during pregnancy and the evidence they were based on. A focus for the project is identifying practical and meaningful outcomes of alcohol toxicity during pregnancy.

http://clahrc-west.nihr.ac.uk/research/projects/alcohol-toxicity-during-and-before-pregnancy/

#### STUDY 40 PUBLISHED

Psychological and/or educational interventions for reducing alcohol consumption in pregnant women and women planning pregnancy.

Published 2009, Stade

This study aimed to determine the effectiveness of psychological and educational interventions to reduce alcohol consumption during pregnancy in pregnant women or women planning pregnancy. Four studies met the inclusion criteria (715 pregnant women). Meta-analyses could not be performed as the interventions and outcomes measured in the studies were not sufficiently similar. For most outcomes there were no significant differences between groups; and results relating to abstaining or reducing alcohol consumption were mixed. Results from individual studies suggest that interventions may encourage women to abstain from alcohol in pregnancy. There was very little information provided on the effects of interventions on the health of mothers and babies. The authors concluded that psychological and educational interventions may result in increased abstinence from alcohol, and a reduction in alcohol consumption among pregnant women. However, results were not consistent, which limits the ability to determine the type of intervention that would be most effective in increasing abstinence from, or reducing the consumption of, alcohol among pregnant women.

Cochrane Database of Systematic Reviews 2009 DOI: 10.1002/14651858.CD004228.pub2.

# STUDY 41 PUBLISHED

Brief intervention to reduce risky drinking in pregnancy: study protocol for a randomized controlled trial

Published 2012, Wilson

This pilot study aims to investigate whether pregnant women can

be recruited and retained in a RCT of brief intervention aimed at reducing risky drinking in women receiving antenatal care. Over 8 months, women aged 18 years and over (target number 2,742) attending their booking appointment with a community midwife in north-east England will be screened for alcohol consumption using the consumption questions of the Alcohol Use Disorders Identification Test (AUDIT-C). Those screening positive, without a history of substance use or alcohol dependence, with no pregnancy complication, and able to give informed consent, will be invited to participate in the trial. Midwives will be randomized in a 1:1 ratio to deliver either treatment as usual (control) or structured brief advice and referral for a 20-minute motivational interviewing session with an alcohol health worker (intervention). Measures will be repeated in telephone follow-ups in the third trimester and at 6 months post-partum, when a questionnaire on use of NHS and social care resources will also be completed. Information on pregnancy outcomes and stillbirths will be accessed from central health service records before the follow-ups. Primary outcomes will be rates of eligibility, recruitment, intervention delivery, and retention in the study population, to inform power calculations for a definitive trial.

Trials 2012 DOI: 10.1186/1745-6215-13-174

#### STUDY 42 ONGOING

The detection and prognosis of perinatal depression: a prospective validation of the National Institute for Health and Clinical Excellence (NICE)-endorsed ultra-brief questions

Due to publish 2017

This study will evaluate the use of a NICE recommended brief questionnaire used to detect depression in pregnancy and motherhood. The questionnaire will be validated alongside the commonly used Edinburgh Postnatal Depression Scale (EPDS) at two time points (20 weeks pregnancy and 3-4 months postbirth). Qualitative interviews will also be used with mothers and healthcare professionals to discuss acceptability of screening, and any implications for the care pathway.

https://www.journalslibrary.nihr.ac.uk/projects/11200423/#/

# STUDY 43 ONGOING

The Effectiveness and cost-effectivenesS of perinatal Mental health services (ESMI)

Due to publish 2018

This five-year programme of research aims to investigate the best ways to support women who experience mental health problems during pregnancy and after childbirth within NHS services. The research will examine effective ways of identifying depression during routine midwife appointments. The effectiveness of a guided self-help intervention, adapted for pregnant women with antenatal depression, will be evaluated. Qualitative work will focus on seeking the views of women who have experienced mental health issues during and after pregnancy, as well as from healthcare professionals. Finally, services for intensive treatment such as specialist Mother and Baby psychiatric wards will be assessed.

https://europepmc.org/grantfinder/grantdetails?query=pi:%22Howard+L%22+gid:%22RP-PG-1210-12002%22

#### STUDY 44 PUBLISHED

Maternal Mental Health and Its Association with Infant Growth at 6 Months in Ethnic Groups: Results from the Born-in-Bradford Birth Cohort Study

Published 2012, Traviss

The aim of this programme of research was to look at the nature

of emotional and somatic distress in pregnant women across different cultures in the UK and develop working partnerships with relevant healthcare professionals and patient groups. The work utilises the Born in Bradford cohort study. The current study looked at factors associated with infant growth at 6 months in relation to maternal distress. Mental health was assessed using the General Health Questionnaire (GHQ) at 26-28 weeks gestation and 6 months after birth in a cohort of White and Pakistani women in the UK. Almost half of women in the study scored above cut-off on the GHQ in pregnancy. Results indicated that maternal distress improved from pregnancy to 6 months postpartum. At both time points, Pakistani women had more symptoms of antenatal depression than did White women. Depression in pregnancy was associated with lower infant growth at 6 months. Pakistani women lived in areas of higher social deprivation, reported less alcohol consumption and smoking postnatally, all of which were independent factors on growth at 6 months. Pakistani women had significantly smaller babies at both birth and six months. The authors concluded that their findings indicate a relationship between maternal depression and reduced infant growth, which is a complex relationship with ethnicity and deprivation.

PLoS One 2012 doi: 10.1371/journal.pone.0030707

### STUDY 45 ONGOING, INTERIM PUBLICATION

Adapting and testing a brief intervention to reduce maternal anxiety during pregnancy. Central and North West London NHS Foundation Trust

Published 2016, Wilkinson.

This programme of research, set to finish November 2016, is evaluating a brief guided self-help, psychological intervention (Towards Parenthood) that has been tested in Australia. It has been designed to help parents prepare for parenting, specifically managing their emotional responses to parenthood. Women will be recruited who are experiencing a high level of anxiety, as identified by their midwives during their routine appointments. The intervention will include a workbook within group-based midwife-led care and consist of three sessions. The intervention will be developed through a small pilot study before acceptability and feasibility will be evaluated in a larger RCT. It is hoped that such an intervention can be delivered routinely in NHS maternal care.

Trials 2016, DOI: 10.1186/s13063-016-1274-8

#### STUDY 46 PUBLISHED

A pilot randomised controlled trial of cognitive behavioural therapy for antenatal depression

Published 2013, Burns

This is a pilot RCT of individualised cognitive behaviour therapy (CBT) to treat antenatal depression before the end of pregnancy. The pilot study will be used to develop a larger trial. The study was set in an urban area (North Bristol) with some high areas of high deprivation. Women between 8-18 weeks pregnancy were recruited during routine care, and were randomised if they screened positive for depression. 18 women received the intervention and 18 received usual care. The intervention consisted of 12 sessions of individual CBT at the woman's home. Followup was completed at 15 weeks (the end of pregnancy) and 33 weeks post-randomisation. At 15 weeks post-randomisation, more women in the intervention group (68.7%) recovered from depression compared to women receiving usual care (38.5%). The authors argued that this study demonstrated the feasibility of implementing a larger RCT to determine the intervention's effectiveness.

BMC Psychiatry DOI: 10.1186/1471-244X-13-33

#### **STUDY 47 PUBLISHED**

Interventions (other than pharmacological, psychosocial or psychological) for treating antenatal depression

Published 2013, Dennis

This review assessed the effect of interventions other than pharmacological, psychosocial, or psychological, compared with usual antepartum care in the treatment of antenatal depression. The review included six randomised controlled trials, involving 402 women, from USA, Switzerland and Taiwan. The interventions consisted of depression-specific acupuncture, maternal massage, bright light therapy, and the use of omega-3 fatty acids. Given that the trials were small and used a variety of interventions, no conclusions or recommendations could be reached. The authors argued that further research is needed.

Cochrane Database of Systematic Reviews 2013, doi: 10.1002/14651858.CD006795.pub3.

#### STUDY 48 PUBLISHED

Risks and benefits of psychotropic medication in pregnancy: cohort studies based on UK electronic primary care health records

Published 2016, Peterson

Using retrospective cohorts, this study aimed to provide a descriptive account of psychotropic medicine before, during and after pregnancy in the UK, and identify risk factors for discontinuation and restarting of lithium and antipsychotic medication. The study also examined relative risks of adverse maternal and child outcomes of psychotic treatment in pregnancy. Data from The Health Improvement Network (THIN) and General Practice Research Database (GPRD) showed that prescribing of psychotropic medication was relatively constant before pregnancy, decreased sharply in early pregnancy and peaked after delivery. Pregnancy often led to the discontinuation of psychotropic medication. However, between 40% and 76% of women who discontinued psychotropic medication before or in early pregnancy restarted treatment by 15 months after delivery. The risks of adverse maternal and child outcomes in women who continued antipsychotic use in pregnancy were not greater than in those who discontinued treatment before pregnancy. The results support previous associations between valproate and adverse child outcomes but there was no evidence of such an association for antipsychotics.

Health Technology Assessment 2016. DOI: http://dx.doi.org/10.3310/ hta20230

#### STUDY 49 PUBLISHED

A systematic review, evidence synthesis and meta-analysis of quantitative and qualitative studies evaluating the clinical effectiveness, the cost-effectiveness, safety and acceptability of interventions to prevent postnatal depression

Published 2016, Morrell

This review evaluated the clinical and cost-effectiveness of antenatal and postnatal interventions for pregnant and postnatal women to prevent postnatal depression. 86 trials were included in the quantitative review and 44 studies were included in the qualitative review. The most effective interventions were midwifery redesigned postnatal care, person-centred approach and cognitive-behavioural therapy approaches. Qualitative analysis showed that women valued having consistent care, multiple visits from health professionals and the involvement of partners. Although some interventions appeared to be more cost-effective than usual care, results were not clear. The authors called for more RCTs to establish both clinical and cost-effectiveness.

Health Technology Assessment 2016 http://dx.doi.org/10.3310/ hta20370

#### STUDY 50 ONGOING

# Using expressive writing interventions to promote health in women after birth

This study is investigating the effectiveness of an expressive writing intervention in improving psychological and physical health for new mothers. The women will be recruited 6 weeks after birth and randomised to one of three groups: an expressive writing group (writing thoughts and feelings about stressful or difficult issues during or after birth), a control intervention group (writing about how they use their time), or routine care. The writing groups will be instructed to write for 15 minutes a day on three consecutive days. Psychological and physical health and quality of life will be measured before, 1-month and 6-months after the intervention. The effect of socio-demographic factors and ethnicity on uptake of the intervention will also be examined. The researchers argued that this could be a cost-effective intervention that can be easily accessed via the internet.

http://www.isrctn.com/ISRCTN58399513?q=expressive%20writing&filters=&sort=&offset=5&totalResults=15&page=1&pageSize=10&searchType=basic-search

#### STUDY 51 PUBLISHED

Methods to identify postnatal depression in primary care: an integrated evidence synthesis and value of information analysis

Published 2009. Hewitt

This review aimed to identify the methods of screening for postnatal depression in primary care and to assess their validity. The most frequently used measure was the Edinburgh Postnatal Depression Scale (EPDS). Women found this an acceptable measure, especially when implemented by a trained, empathic health visitor. Regarding validity measures, postnatally the EPDS performed well: sensitivity ranged from 0.60 (specificity 0.97) to 0.96 (specificity 0.45) for major depression only; from 0.31 (specificity 0.99) to 0.91 (specificity 0.67) for major or minor depression; and from 0.38 (specificity 0.99) to 0.86 (specificity 0.87) for any psychiatric disorder. Suggestive evidence from the clinical effectiveness review indicated that use of the EPDS, compared with usual care, might lead to reductions in the number of women with depression scores above a threshold. However, cost effectiveness analysis was not clear.

Health Technology Assessment 2009, DOI: http://dx.doi.org/10.3310/ hta13360

#### STUDY 52 PUBLISHED

CLAHRC Yorkshire and Humber: Theory-based multi-faceted interventions increase health professionals' referrals of women with mild to moderate postnatal depression (PND) for psychological treatment by 25%

Published 2012, CLAHRC

This small study (from 2012) looked at the barriers faced by health professionals in one Primary Care Trust around referring women with mild to moderate postnatal depression to psychological treatment. This led to the development of a multifaceted intervention comprising an educational session and an electronic GP referral template. Assessment of routinely collected audit data on referral decisions indicated that the tailored intervention was associated with a significant increase in referrals after the intervention compared with before. The researchers argued that the intervention successfully addressed the GPs' main barriers to referral.

http://www.clahrcprojects.co.uk/sites/default/files/fields/download/ Theory-based.pdf

#### STUDY 53 PUBLISHED

Psychological interventions for postnatal depression: cluster randomised trial and economic evaluation. The PoNDER trial

Published 2009, Morrell

The aim of the PoNDER Trial was to assess the clinical and cost effectiveness of two psychological interventions delivered by health visitors (HV) for postnatal depression (PND). Women were recruited by HVs who received training in the identification of symptoms of postnatal depression. The women received either a person-centred approach or a cognitive-behavioural approach intervention, or usual care. The intervention consisted of 8 weekly one-hour intervention visits from a specially trained HV. Outcomes were assessed by self-report questionnaire at four time points. The primary outcome was the proportion of at-risk women with a 6-month Edinburgh Postnatal Depression Scale (EPDS) score > or = 12. 4084 women consented to take part: 17.3% (595/3449) of women who returned a 6-week questionnaire had a 6-week EPDS score > or = 12 and were at-risk women. Overall, 45.6% (67/147) of control group at-risk women had a 6-month EPDS score > or = 12 versus 33.9% (93/271) of intervention group women (p = 0.036). The control group mean 6-month EPDS score for at-risk women was 11.3 (SD 5.8) versus 9.2 (SD 5.4) for the intervention group (p =0.002) and this remained statistically significant after adjusting for 6-week variables (p = 0.001). At 6 months, for women who were followed up at all time points, the EPDS scores were lower in the whole cohort in the intervention arms not just in the at-risk women in the intervention arms, indicating a preventive effect. Reduction in symptoms was maintained at 12 months postnatally in the atrisk women in the intervention arm. Furthermore, the reduction in symptoms was maintained at 12 months postnatally in the whole cohort. The economic evaluation indicated that the training intervention was cost-effective at 6 months postnatally and 12 months postnatally for the at-risk women in the intervention arm and the whole cohort of women in the intervention arm, at 6 and 12 months postnatally.

Health Technology Assessment 2009 DOI: http://dx.doi.org/10.3310/ hta13300

#### STUDY 54 PUBLISHED

A pragmatic randomised controlled trial to compare antidepressants with a community-based psychosocial intervention for the treatment of women with postnatal depression: the RESPOND trial

Published 2010, Sharp

This RCT compared the effectiveness of antidepressants and non-directive counselling delivered by trained health visitors for women with postnatal depression. Women were recruited 6 weeks after birth, and followed up until their child reached 1 year. The counselling utilised a community-based psychosocial approach and the antidepressant was a selective serotonin reuptake inhibitor. Two hundred and fifty-four women who had major depression were recruited and randomised. The trial was designed to compare antidepressants with general supportive care for the first 4 weeks, after which women allocated to counselling started their sessions. It allowed women to receive the alternative intervention if they had not responded to their allocated intervention or wished to change to, or add in, the alternative intervention at any time after 4 weeks. At 4 weeks, women were more than twice as likely to have improved if they had been randomised to antidepressants compared with counselling, which started after the 4-week follow-up, i.e. after 4 weeks of general supportive care. At 18 weeks, intention to treat analysis revealed that the proportion of women improving was 11% greater in the antidepressant group, but logistic regression analysis showed no clear benefit for one

group over the other. After the initial 4 weeks, many women were prescribed antidepressants, so received both interventions by 18 weeks, thus power was reduced. The authors concluded that early treatment with antidepressants has clinical benefits for PND.

Health Technology Assessment 2010 DOI: http://dx.doi.org/10.3310/ hta14430

#### STUDY 55 PUBLISHED

Group cognitive behavioural therapy for postnatal depression: a systematic review of clinical effectiveness, cost effectiveness and value of information analyses

Published 2010, Stevenson

The review assessed the clinical and cost effectiveness of group cognitive behavioural therapy (GCBT) for postnatal depression. Six studies met the inclusion criteria (3 of which were RCTs). A metaanalysis was not possible. One study showed that the reduction in the depression score (EPDS) through GCBT compared with routine primary care was 3.48 [95% CI 0.23 to 6.73] at the end of the treatment period. At 6-month follow-up the relative reduction in EPDS score was 4.48 (95% CI 1.01 to 7.95). Three studies showed the treatment to be effective in reducing depression when compared to RPC, usual care or waiting list groups. The qualitative review of 2 studies found that whilst some women found GCBT acceptable, others had negative feelings about such treatment. Uncertainly remained around the cost-effectiveness analysis because of the limited evidence base. The authors argued that the lack of high quality evidence prevents service provision recommendations from being made.

Health Technology Assessment 2010 DOI: http://dx.doi.org/10.3310/ hta14440

#### STUDY 56 PUBLISHED

CLAHRC South West Peninsula: Netmums: a phase II randomized controlled trial of a guided Internet behavioural activation treatment for postpartum depression

Published 2013, O'Mahen

This study assessed the feasibility of a guided internet-based behaviour activation intervention for postnatal depression. 249 women were recruited via Netmums.com (a UK parenting site). 83 women meeting DSM-IV criteria for major depressive disorder were randomised to the intervention (n= 41) or treatment as usual (n= 42). The intervention consisted of 12 modular internet sessions, and 12 telephone support sessions. Women completed an average of 8 telephone and 5 internet sessions. There was a large effect size favouring women who received the intervention on depression (measured with Edinburg Postnatal Depression Scale), as well as work and social impairment, and anxiety scores at post-treatment compared with women in the control group. The benefits for depression persisted at 6 months post-treatment.

Psychological Medicine 2013 DOI: 10.1017/S0033291713002092

#### STUDY 57 ONGOING

Multi Centre RCT of a group psychOlogical intervention for poStnatal depression in britisH mothers of south asiaN origIn - ROSHNI-2 (The word Roshni means 'light' in Urdu/Hindi).

Due to publish 2021

The aim of this trial was to refine the culturally appropriate psychological intervention; the 'Positive Health Programme (PHP), that is based on the principles of Cognitive Behavioural Therapy (CBT), and to assess the feasibility and acceptability of the PHP intervention for British South Asian women with postnatal depression. Six hundred and fifteen mothers from Lancashire and Manchester were screened for participation in the trial, of

these 137 were assessed further to determine eligibility. Eighty three mothers were randomized to receive either PHP (n=42) or treatment as usual (n=41). The research team was successful in recruiting participants beyond target. The retention rate was high and the intervention was acceptable to the participating mothers. This demonstrates the team's ability to engage with this 'hard to reach' group and retain participants from screening to six months follow up stage. The views of health professionals and depressed mothers were explored. Three focus groups were held with health professionals including health visitors. The key finding was the need to address the cultural and language barriers, which made it difficult for health professionals to communicate effectively with the Asian community. Several other factors, which often lead to difficulties in engagement, were also identified including stigma of mental illness, different cultural beliefs, lack of trust in mental health services and a lack of awareness of services available. Furthermore, qualitative interviews were carried out with 17 women who received the intervention. The mothers found the PHP intervention to be acceptable and many reported benefits such as higher overall wellbeing. The participants expressed their satisfaction with the PHP intervention and felt an overall positive change in their attitudes, behaviour and confidence level.

https://www.journalslibrary.nihr.ac.uk/projects/146808/#/

# STUDY 58 ONGOING, INTERIM PUBLICATIONS

Improving the health care response to domestic violence.

This research programme aimed to improve the quality of health care for victims and perpetrators of domestic violence. This includes a training and support package for health professionals supporting male victims, and focus on supporting female victims with mental health problems.

#### STUDY 58A

Screening women for intimate partner violence in healthcare settings.

Published 2013, Taft

This review assessed the effectiveness of screening for intimate partner violence (IPV) conducted within healthcare settings for identification, referral to support agencies and health outcomes for women. 11 trials, which recruited 13,027 women, were included in the review. When data from six comparable studies were combined (n = 3564), screening increased identification of victims/survivors (RR 2.33; 95% CI 1.40 to 3.89), particularly in antenatal settings (RR 4.26; 95% CI 1.76 to 10.31). There was no evidence that screening increased such referrals. Only one study measured adverse effects and data from this study suggested that screening may not cause harm. The authors concluded that there is insufficient evidence to justify universal screening in healthcare settings. Further studies comparing screening versus case finding for women's long-term wellbeing are needed.

Cochrane Database of Systematic Reviews 2013 10.1002/14651858. CD007007.pub2

# STUDY 58B

Psychological advocacy toward healing (PATH): study protocol for a randomized controlled trial.

Published 2013, Brierley

This RCT will recruit women ages 16 years and older experiencing domestic violence and abuse (DVA). They will receive either usual DVA agency advocacy support (control) or usual DVA agency support plus a psychological intervention (intervention). Alongside the DVA agency support, the intervention group will receive eight specialist psychological advocacy sessions weekly or fortnightly, with two follow-up sessions, 1 month and then 3 months later. This

study will increase our understanding of the management of the psychological needs of women experiencing DVA.

Trials, 2013 DOI: 10.1186/1745-6215-14-221

#### STUDY 59 PUBLISHED

Interventions for preventing or reducing domestic violence against pregnant women

Published 2014, Jahanfar

This review examined the effectiveness and safety of interventions in preventing or reducing domestic violence against pregnant women. Seven trials, recruiting 2629 pregnant women who were at high risk of partner violence, contributed data to the review. The interventions ranged from brief individualised consultations to multiple therapy sessions. There was limited evidence for the primary outcomes of reduction of episodes of violence (physical, sexual, and/or psychological) and prevention of violence during and up to one year after pregnancy. One study found that the total number of women reporting partner violence during pregnancy and after birth was reduced for women receiving a psycho-behavioural intervention based on empowerment theory (RR 0.62, 95% CI 0.43 to 0.88, 306 women). None of the studies reported results for outcomes such as stillbirth, neonatal death, miscarriage, or maternal deaths. The authors concluded there is a need for high quality RCTs to assess effectiveness of intervention programmes in preventing or reducing domestic violence during pregnancy.

Cochrane Database of Systematic Reviews 2014 DOI: 10.1002/14651858.CD009414.pub3.

#### STUDY 60 PUBLISHED

Advocacy interventions to reduce or eliminate violence and promote the physical and psychosocial well-being of women who experience intimate partner abuse.

Published 2015, Rivas

This study assessed the effects of advocacy interventions within or outside healthcare settings in women who experienced intimate partner abuse. 13 trials involving 2141 participants were included. After one year, brief advocacy had no effect on physical abuse in two healthcare studies of moderate quality or in one community study at low risk of bias, but it reduced minor abuse in another antenatal care study. Two studies provided weak evidence that intensive advocacy reduces physical abuse up to two years after the intervention. Four studies failed to show benefits from advocacy for sexual abuse. One antenatal care study reported reduced emotional abuse at 12 months after advocacy. Brief advocacy prevented depression in abused women attending healthcare services and pregnant women immediately after advocacy (with one woman likely to benefit for every four to eight treated). Intensive advocacy did not reduce depression in shelter women followed up at 12 and 24 months. Intensive advocacy showed a weak benefit in two studies in domestic violence shelters/refuges. The authors concluded that intensive advocacy may improve everyday life for women in domestic violence shelters/refuges in the short term and reduce physical abuse one to two years after the intervention.

Cochrane Database of Systematic Reviews 2015 DOI: 10.1002/14651858.CD005043.pub3.

# STUDY 61 ONGOING

Learning from women's experiences: improving our understanding of the physical, psychological and emotional health impacts of domestic violence and abuse (DVA), help-seeking trajectories and outcomes

Due to publish 2017

This programme of research, to be completed by the end of 2016, will examine the lived experiences, health problems, information and support needs of women who have experienced domestic violence and abuse (DVA), as well as their experiences of help-seeking. The research aims to develop a web-based resource, as part of www.healthtalkonline.org, for women experiencing DVA.

http://www.bristol.ac.uk/primaryhealthcare/researchthemes/eoshome/

#### STUDY 62 ONGOING

REPROVIDE (Reaching Everyone Programme of Research On Violence in diverse Domestic Environments)

Due to publish 2022

This six year programme (2016-2022) will investigate ways of improving how healthcare professionals respond to all family members experiencing or perpetrating domestic violence and abuse (DVA). Research will include reviews of the evidence base and development and evaluation of interventions such as specialist training for general practice staff. REPROVIDE will also examine the effectiveness of a group programme for men who perpetrate DVA to help them stop being abusive. The needs of minority groups will also be explored.

http://www.bris.ac.uk/policybristol/news/2016/research-domestic-violence.html

#### STUDY 63 ONGOING

Improving care for women and girls who have undergone female genital mutilation: qualitative evidence synthesis

Due to publish 2018.

This study is a qualitative evidence synthesis that will assess the care available for women and girls who have undergone female genital mutilation. The barriers and facilitators to care, as well as the experiences and needs of women, girls and health professionals will be evaluated. Results are expected in 2018.

https://www.journalslibrary.nihr.ac.uk/programmes/hsdr/1513704/#/

#### STUDY 64 PUBLISHED

Assessing the impact of a new birth centre on choice and outcome of maternity care in an inner city area

This project assessed the impact of a new birth centre in Tower Hamlets by comparing the experiences of women who started their care at the birth centre with those of women who satisfied the criteria for using the birth centre but chose hospital care. The birth centre is based in a multi-ethnic inner city area. Women who attended the birth centre were significantly more likely to rate their care as good or very good overall than corresponding women who initially booked at the hospital. Women who started labour care in spontaneous labour at the birth centre were significantly more likely to be cared for by a midwife they had already met, have one to one care in labour and have the same midwife with them throughout their labour. The women were more likely to use non-pharmacological methods of pain relief, most notably water, and less likely to use pethidine than women who started care at the hospital. The majority of women who had a spontaneous onset of labour delivered vaginally. A higher proportion of women at the birth centre reported skin-to-skin contact with their baby in the first two hours after birth. The authors concluded that the women who attended the birth centre had a positive experience overall. The economic costs of intrapartum maternity care for women opting to give birth in the midwifery unit were compared with those for women who chose birth in hospital by using data extracted from clinical notes to micro-cost the health service

resources used in the intrapartum care of mothers and their babies during the period between admission and discharge. This showed that the total average cost per mother and baby for care where mothers started their intrapartum care at the birth centre was approximately £850 less than the average cost per mother and baby who received all their care at the Royal London Hospital.

64a Macfarlane, 2014. Survey of women s experiences of care in a new freestanding midwifery unit in an inner city area of London, England – 1: Methods and women s overall ratings of care. Midwifery, doi: 10.1016/j.midw.2014.03.013

64b Macfarlane, 2014. Survey of women s experiences of care in a new freestanding midwifery unit in an inner city area of London, England: 2. Specific aspects of care. Midwifery. doi: 10.1016/j. midw.2014.05.008

64c Schroeder, 2016.The economic costs of intrapartum care in Tower Hamlets: a comparison between the cost of birth in a freestanding midwifery unit and hospital for women at low risk of obstetric complications. Midwifery, http://dx.doi.org/10.1016/j.midw.2016.11.006

#### STUDY 65 ONGOING

The REACH Pregnancy Programme (Research for Equitable Antenatal Care and Health).

Due to publish 2019.

This ongoing study aims to improve access to, and enhance the value and experience of, antenatal care (ANC) for socially disadvantaged and ethnically diverse women. There are four areas of research. 1) The effectiveness and cost effectiveness of a community-based intervention for increasing early uptake of antenatal care and improving health outcomes will be assessed. 2) The optimum methods for testing the effectiveness of groupbased ANC in an NHS setting serving populations with high levels of social deprivation and cultural, linguistic and ethnic diversity. 3) The effectiveness and cost effectiveness of group-based ANC for improving health and safety outcomes for women and babies and satisfaction with ANC, and 4) investigating how user involvement in planning, monitoring and improving maternity services can be strengthened.

https://www.uel.ac.uk/IHHD/Our-work/Research-themes-and-projects/Health-and-the-Life-Course-temp/Reach-pregnancy-programme

# STUDY 66 ONGOING

CLARHC NW: Perinatal Access to Resources and Support (PEARS) Improving access to support for perinatal women through peer facilitation: a feasibility study with external pilot.

The NIHR CLAHRC NWC PEARS project aims to examine access to health and community resources amongst socially deprived women and families. It aims to reduce gaps in health inequalities by testing whether combining elements of care, which have improved access to services and psychological health and wellbeing in other settings, can be implemented locally. The three elements of this care intervention include support from a non-professional peer, provision of detailed information about existing local services and help with identification of what would be useful including "If Then" planning (a simple way to help people put their intentions into action). The intervention will incorporate these elements into a 20 minute session offered to women early in pregnancy. The intervention will be delivered by trained peer facilitators, whilst a comparison group will receive a leaflet about local resources. The women in the intervention arm will also receive a telephone follow-up and a face-to-face meeting in the early post-natal period. The feasibility and acceptability of the intervention will be assessed through interviews and focus groups with the women,

peer facilitators, children's centres and health services staff.

http://www.clahrc-nwc.nihr.ac.uk/our-work/improving-mental-health/PEARS.php

#### STUDY 67 PUBLISHED

Multisite implementation of trained volunteer doula support for disadvantaged childbearing women: a mixed-methods evaluation

Published 2015, Spiby

This study is the largest evaluation of volunteer doula support in the UK, which looked at five schemes in England that offered support to disadvantaged pregnant women. Doula support starts in pregnancy and lasts for 6 weeks after birth. The experiences of using doula services was evaluated using a range of methods including questionnaires, focus groups, existing data sets, and obtaining information from a range of stakeholders including mothers, doulas and midwives. The study found that volunteer doulas were highly regarded by women and doula support was accepted by NHS midwives. Doulas enjoyed the role and reported positive impacts for various areas of their lives. There were significant improvements in initiating and maintaining breastfeeding at 6 weeks compared to a comparison group. The majority of women who accepted doula support valued it highly, and appreciated the volunteer doulas for the knowledgeable companionship, relief of isolation, help with accessing services and non-judgemental approach. Reductions in rates of smoking at birth were not consistently statistically significantly different from available comparators. Whilst the doula scheme had positive impact, it was found that funding was a major issues for the services.

Health Services and Delivery Research, 2015 DOI: http://dx.doi.org/10.3310/hsdr03080

# STUDY 68 ONGOING

Interventions that improve maternity care and access for immigrant women in England: a narrative synthesis systematic review

Due to publish 2018

The main research question of this review is "What interventions exist that are specifically focused on improving maternity care for immigrant women in the UK?" The narrative synthesis of quantitative and qualitative research will include a literature search of all major databases as well as grey literature and non-empirical reports. The review aims to identify the most effective and appropriate means of service delivery for maternity care for immigrant women, looking at acceptability of services at individual, community and organisational levels. Birth and postnatal outcomes will be examined. The findings of the synthesis review are hoped to have direct relevance in guiding the provision of maternity services for immigrant groups. In a wider context, the synthesis may also identify themes that have broader application for service delivery (including healthcare, immigration and multiculturalism) and public health initiatives/programs in relation to immigrant groups.

https://www.journalslibrary.nihr.ac.uk/projects/155503/#/

#### STUDY 69 ONGOING

Randomised trial of the effectiveness of Group Family Nurse Partnership (gFNP) programme in improving outcomes for highrisk mothers and preventing abuse

Due to publish 2017

The aim of this study is to determine the effectiveness of the Group Family Nurse Partnership (gFNP) programme in improving parenting outcomes. It compares the partnership to routine

antenatal and postnatal services, with respect to risk factors for maltreatment in expectant mothers aged under 20 with one or more previous live births or expectant mothers aged 20-24 with low/no educational qualifications and no previous live births. The RCT has recruited families, randomised to either gFNP (consisting of 44 sessions over 76 weeks, delivered in Children's Centres) or standard care. The intervention sessions focused on personal health, maternal role, family and friends, life course, and environmental health, and promoted secure mother-infant attachment, healthy lifestyles and increase maternal confidence over her life choices. Data collection, which is now complete, included quantitative and qualitative methods, and cost-effectiveness.

https://www.journalslibrary.nihr.ac.uk/programmes/phr/11300202/#/

#### STUDY 70 ONGOING

Evaluating the long-term effectiveness, and the cost and consequences of the Family Nurse Partnership parenting support programme in reducing maltreatment in young children

This ongoing study is evaluating the Family Nurse Partnership in relation to teenage mothers from 18 English centres. The study will extend a previous follow-up of the babies, and will follow up the same group of women until their child is 6 years of age. The study will assess whether the FNP programme reduces child maltreatment by accessing medical and education records of participating women and their children. The study will also focus on aspects of programme delivery and patient experiences that may affect outcomes. Data linking will be conducted in an anonymous manner to maintain confidentiality and anonymity.

https://www.journalslibrary.nihr.ac.uk/programmes/phr/11300211/#/

#### STUDY 71 ONGOING

Trial of Healthy Relationship Initiatives for the Very Early-years (THRIVE): a Three-Arm Randomised Controlled Trial for Mothers Identified as Vulnerable in Pregnancy and their Babies who are at High Risk of Maltreatment

This ongoing study will compare two parenting interventions with routine care. The interventions are Enhanced Triple P for Baby (ETPB) and Mellow Bumps (MB). ETPB is informed by social learning theory, consisting of four antenatal group sessions. These will be supplemented with telephone support and individual sessions. ETPB has demonstrated efficacy and effectiveness. MB, based on attachment theory, involves seven antenatal group sessions, and content centres around encouraging positive and nurturing mother-baby interactions. The study will recruit mothers who have been identified as having additional health and social care needs in pregnancy, and are between 20-30 weeks pregnant at the start of the intervention. The researchers will determine if these interventions will improve mental health and wellbeing, and lead to positive mother-child relationships. Incidence of child maltreatment as well as language and emotional development of the child will also be assessed.

https://www.journalslibrary.nihr.ac.uk/programmes/phr/11300201/#/

## STUDY 72 ONGOING, INTERIM PUBLICATION

Evaluation of Health in Pregnancy Grants in Scotland: natural experiment using routine data

Published 2014, Dundas.

This study will evaluate the effect of the Health in Pregnancy Grants, a payment of £190 made to women following the 25th week of pregnancy on the condition that they had sought

antenatal advice from a doctor or midwife. Routinely collected data from across Scotland will be used to compare the period when the grant existed (2009 to 2011) to a period of 5 years prior to the existence of the grant and 22 months following its withdrawal. Measures such as birth weight, size at birth and stage of birth will be assessed. Sub-group analysis will be used for example focusing on women living in the most deprived areas, those in the lowest social classes, lone mothers, women having their first baby and teen mothers to address whether the grant reduced inequalities. Cost effectiveness will also be evaluated.

BMJ Open 2014, doi:10.1136/bmjopen-2014-006547 https://www.journalslibrary.nihr.ac.uk/projects/12307002/#/

#### STUDY 73 PUBLISHED

Incentives for increasing prenatal care use by women in order to improve maternal and neonatal outcomes

Published 2015, Till

This review examined whether offering incentives was an effective way to improve attendance at prenatal care early in pregnancy. Five trials were included and 1893 pregnancies contributed data towards the review. Incentives in these studies included cash, gift card, baby carrier, baby blanket and taxicab voucher. Overall, the trials were at a moderate risk of bias. There was no evidence to determine whether incentive programs can decrease the incidence of preterm birth, small-for-gestational-age babies, or perinatal mortality, as no studies reported on these review outcomes. There was limited evidence to suggest that incentives may improve the frequency and ensure adequate quality of prenatal care, but at the cost of increased caesarean rates. None of the studies were based in the UK, and two of the studies which accounted for the majority of women in the review were conducted in rural, low-income, Hispanic communities in Central America. The authors therefore concluded that the studies were not representative of ethnically diverse communities. They argued that there is a need for more, high-quality RCTs to evaluate the impact of offering incentives to pregnant women for attending prenatal care visits and the effects of this on preterm birth, low birthweight and perinatal outcomes.

Cochrane Database of Systematic Reviews 2015 DOI: 10.1002/14651858.CD009916.pub2

# STUDY 74 ONGOING

Evaluation of the Healthy Start Voucher Scheme in UK: a natural experiment using the Growing Up in Scotland record linkage study and the Infant Feeding Survey

Due to publish 2017

This is a mixed method, natural experiment to investigate the effectiveness of the Healthy Start Voucher scheme (HSV) in the UK. This means tested voucher scheme aimed to provide low-income pregnant women, new mothers and children under four years with access to appropriate nutrition. The aim of the study is to evaluate the HSV scheme in relation to the extent to which it improves the nutrition and health of pregnant women, including vitamin use, and initiation and duration of breastfeeding, and the health outcomes of their infants, including infant and child weight and body size. Cost effectiveness will also be assessed, as well as reasons why people do not claim the vouchers.

https://www.journalslibrary.nihr.ac.uk/projects/1316410/#/

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