NICE National Institute for Health and Care Excellence

Surveillance report 2017 – Antenatal and postnatal mental health: clinical management and service guidance (2014) NICE guideline CG192

Surveillance report

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Contents

Surveillance decision

We will not update the guideline on antenatal and postnatal mental health at this time.

During surveillance, editorial or factual corrections were identified. Details are included in appendix A: summary of evidence from surveillance.

Reason for the decision

Assessing the evidence

We found 29 studies through surveillance of this guideline.

This included evidence to support current recommendations on case identification and assessment, experience of care, and pharmacological and non-pharmacological interventions.

We also identified evidence that was not consistent with current recommendations on access to services and exercise interventions. This evidence was considered to be insufficient in volume and conclusive results to change recommendations in these areas at this time. Topic expert opinion was sought as to whether this evidence would affect current recommendations. Generally, the topic experts agreed that the new evidence would not impact recommendations in these areas.

We did not find any evidence related to the organisation of perinatal mental health services. We also did not find any new evidence on postnatal post-traumatic stress disorder, which was an area considered to be important during post-publication correspondence.

Additionally, we identified relevant ongoing research due to be published in the next 3 to 5 years. There are 4 ongoing trials investigating the effectiveness of pharmacological treatments for postpartum depression which are due to publish by the end of 2017. Three studies investigating psychological or psychosocial treatments have completed recruitment at this time. One study has investigated strategies for postnatal depression screening and is currently in press. A further 3 studies are investigating the effectiveness of perinatal mental health service delivery. The progress of the ongoing studies will be monitored and they will be considered at the next surveillance review when results publish.

Equalities

No equalities issues were identified during the surveillance process.

Overall decision

After considering all the evidence and views of topic experts and stakeholders, we decided that an update is not necessary for this guideline.

See how we made the decision for further information.

Commentary on selected evidence

With advice from topic experts we selected 2 studies for further commentary.

Providing interventions in pregnancy and the postnatal period – psychosocial interventions

We selected the randomised controlled trial by Kenyon et al. (2016) for a full commentary because it supports recommendations to offer psychosocial interventions during the antenatal period. The study also considered the mother–baby relationship as an outcome, which was deemed a critical outcome in NICE guideline CG192.

What the guideline recommends

NICE guideline CG192 (recommendations 1.7.1, 1.7.2 and 1.7.5) recommends the use of psychosocial interventions to prevent and treat mental health problems in pregnant women. These interventions should be delivered by competent practitioners and be based on the relevant treatment manuals. Healthcare professionals should also understand how treatment could be affected by the variations in presentation and course of mental health problems. The guideline also recommends that these treatments should be provided within a stepped-care model of service delivery.

Methods

The Kenyon et al. (2016) randomised controlled trial investigated the effects of providing additional lay support to pregnant women with social risk factors. Participants were recruited from 3 maternity units in the UK. Nulliparous pregnant women under 28 weeks' gestation were eligible for the study if social risk factors were identified during routine midwife antenatal appointments. Women who had previously given birth were excluded as were women aged under 16 years and teenagers who were already part of a separate trial. A prespecified subgroup of women with 2 or more social risk factors was also included in the analysis. The study considered the following as social risk factors:

- Housing problems
- Teen parent
- Smoking
- Difficulty with the English language

- UK resident for under 1 year
- Clinical diagnosis of past or present mental illness
- No support from either partner or family or friend
- BMI ≤18 or ≥35
- Booking after 18 weeks' gestation
- In receipt of social services support
- Drug or alcohol misuse
- Domestic abuse
- Did not attend 2 or more antenatal appointments.

Computer-generated block randomisation was used to assign participants to either standard maternity care or addition of lay support. Assignment to treatment group was stratified according to the 3 maternity units. The additional lay support was provided by a pregnancy outreach worker (POW) service trained in individual case management and home visits. During pregnancy, the POW service provided social, emotional and practical support with an aim to encourage antenatal appointment attendance. During the initial 6-week postnatal period, the POW service provided advice about breastfeeding and infant care. Standard maternity care included referrals and signposting to specialist services other than the POW service.

The trial investigated the effects of additional lay support on 2 primary outcomes. Firstly, the attendance rate for all antenatal appointments, other than routine dating and abnormality scans, was calculated. Secondly, postnatal depression at 8 to 12 weeks after birth was measured using the Edinburgh Postnatal Depression Scale (EPDS). Secondary outcomes included maternal and neonatal birth outcomes. Maternal self-efficacy was measured using the Pearlin and Schooler Mastery Scale and bonding was measured with the Mother-to-infant Bonding Scale. Further secondary outcomes included attendance at child development assessments, breastfeeding and immunisation uptake.

Results

A total of 1,324 participants were randomised with 662 allocated to each intervention arm. Analyses included participants with available follow-up data. This consisted of 613 women in the standard care and 600 women in the POW groups.

Primary outcomes

No significant differences were found for the mean number of antenatal attendance between POW (10.1) and standard care (10.1) groups (mean difference −0.00, 95% confidence interval [CI] −0.37 to 0.37, p=0.99).

No significant differences were found for the mean EPDS scores between POW (6.76) and standard care (7.35) groups (mean difference −0.59, 95% CI −1.24 to 0.06, p=0.08).

The subgroup comparison for women with 2 or more social risk factors found a significant reduction in mean EPDS scores for the POW group compared with standard care (mean difference −0.79, 95% CI −1.56 to −0.02, p=0.05).

No significant differences were found between groups for the subgroup comparison of antenatal attendance.

Secondary outcomes

A significant improvement in mother-to-infant bonding was found for the POW group compared with standard care (mean difference −0.30, 95% CI −0.61 to 0.00, p=0.05).

No significant differences were found for any other secondary outcomes across groups overall or in the subgroup.

Strengths and limitations

Strengths

The population in the study is directly relevant to NICE guideline CG192 with the inclusion of pregnant women at risk of mental health problems. Special consideration is given in the guideline for women with social risk factors as investigated in this study.

The study methodology has strengths with the use of randomisation, allocation concealment and blinding of outcome assessors. These methods reduce the risk of potential bias in the study.

The outcomes considered in the study are highly relevant to NICE guideline CG192. All the primary and secondary outcomes are noted as critical outcomes within the guideline.

Limitations

Although EPDS scores were compared between groups at follow-up, scores were not collected at baseline. It is possible that differences in depression symptoms and/or diagnosis were present between groups at baseline. This has the potential to influence the results.

A further limitation is that sensitivity analyses were not conducted to account for the differences in missing data between groups. Dropout rates varied between the groups at different stages of the trial. The authors also note how 25 participants withdrew consent following allocation to the POW group compared with 3 withdrawals in the standard care group. Again, these differences have the potential to influence the results and are not fully investigated.

Impact on guideline

The results of this trial indicate some beneficial effects of additional lay support for pregnant women. However, the significant effect on depression symptoms is limited to the subgroup of women with 2 or more social risk factors. From this trial, it remains unclear how generalisable this result is to the wider antenatal population.

The inclusion of mother-to-infant bonding as an outcome is relevant to NICE guideline CG192 because the guideline contains recommendations and a research recommendation on this area. However, the relevance of the significant effect is limited because this is a secondary outcome in the trial and the guideline considers interventions specifically designed with a focus on the mother–baby relationship.

NICE guideline CG192 is unlikely to be impacted by the results of this study because of the above limitations in generalisability and applicability to recommendations. Also, because the guideline does not specify types of psychosocial interventions recommended for this population, lay support is unlikely to be added to the recommendations based on the results of this trial.

Treating specific mental health problems in pregnancy and the postnatal period – interventions for depression

We selected the systematic review and meta-analysis by Daley et al. (2015) for a full commentary because it includes a population relevant to the guideline and investigates an intervention not fully covered in NICE guideline CG192 recommendations.

What the guideline recommends

NICE guideline CG192 (recommendations 1.8.1 and 1.8.3) recommends facilitated self-help for subthreshold to moderate depression and cognitive behaviour therapy (CBT) for moderate to severe depression in pregnancy and the postnatal period.

Although exercise is not specified as an intervention in the recommendations, it can form a component of both facilitated self-help and CBT during the behavioural elements of the interventions.

Methods

The Daley et al. (2015) systematic review and meta-analysis investigated the effects of exercise on antenatal depression. The search strategy identified randomised controlled trials (RCTs) of exercise as an intervention compared with any comparator. For inclusion in the review, exercise interventions were required to last for 6 weeks or more. Exercise when provided in conjunction with other interventions was also included within the review search. Trials with exercise as an intervention for either prevention or treatment of antenatal depression were included. For trials of treatment, pregnant women with a diagnosis or those identified at risk of depression were eligible for inclusion. For exercise as prevention, non-depressed pregnant women were also eligible for inclusion. Change in depression score from baseline to the final antenatal follow-up was the primary outcome. All included trials measured depression using the Centre for Epidemiological Studies depression scale (CES-D).

For the overall meta-analysis, all trial data were pooled with no distinction between populations or exercise intervention types. A prespecified subgroup analysis was performed comparing non-depressed with depressed or at risk populations. A further subgroup analysis was performed comparing aerobic with non-aerobic (yoga and tai chi) exercise interventions.

Results

The systematic review identified a total of 6 RCTs meeting the inclusion criteria. The trials included participants aged 14 to 38 years, recruited from 16 weeks' gestation and with a total 348 pregnant women completing follow-up. One trial included a population of non-depressed women and evaluated an aerobic exercise intervention. The other 5 trials included women either at risk or depressed at baseline and evaluated non-aerobic exercise interventions. In all the included trials, exercise was used as a single intervention compared with standard prenatal care, wait-list control, parenting education sessions or social support as comparator groups. One trial included

3 treatment arms that was analysed as 2 separate comparisons within the meta-analysis. This gave a total of 7 comparisons for inclusion in the review.

The meta-analysis indicated a significant reduction in depression scores for exercise compared with controls (standardised mean difference [SMD] −0.46, 95% CI −0.87 to −0.05, p=0.03). However, the I^2 test for heterogeneity (68%) indicated that inconsistency across studies may be important.

No significant differences in depression scores were found in subgroup analyses comparing non-depressed with depressed women (p=0.32, I^2=68%). Also, no significant differences in depression scores were found for the subgroup comparing aerobic with non-aerobic exercise interventions (p=0.32, I^2=68%).

Strengths and limitations

Strengths

The target population in the study is directly relevant to the population in NICE guideline CG192. The study clearly defines the population as pregnant women either at risk of depression or depressed in the antenatal period. The further inclusion of non-depressed pregnant women is a relevant addition for the investigation of exercise as a preventative intervention.

The evaluation of exercise interventions in this population is highly relevant to NICE guideline CG192. Although there are no explicit recommendations for exercise as a treatment in this guideline, evidence was assessed during guideline development and this study will add to this evidence base.

The primary outcome of depression symptoms is considered a critical outcome in NICE guideline CG192. Also, the use of the CES-D as an outcome measure for depression symptoms is recognised in the guideline.

Methodologically, this study is generally well reported with the use of an appropriate risk of bias tool and multiple authors to assess the quality of the included trials.

Limitations

The meta-analysis indicated levels of heterogeneity in the results, which suggest potentially important inconsistencies across the included trials. The results should be interpreted cautiously with these inconsistencies in mind. Also, the number of included trials is relatively low, which did

not fully allow the investigation of subgroup analyses as planned. This was apparent in the analysis of non-depressed women and aerobic exercise, which were based on a single trial. The low number of trials did not allow for the comparison of specific exercise types, which may have been informative for developing guideline recommendations. The authors also note that the generally low quality of the included trials and wide confidence intervals limit the conclusions that can be made regarding the effectiveness of exercise interventions for this population.

Impact on guideline

The results of this study indicate some support for the use of exercise as a treatment for antenatal depression. However, the limitations of heterogeneity, small sample size and low quality of included trials result in uncertainty around the effects of exercise interventions for this population.

During the development of NICE guideline CG192, similar low-quality data were identified resulting in no specific recommendations for exercise interventions being made. Although this study will add to this evidence base, the limitations mean it is unlikely to impact on recommendations at this time. There remains uncertainty on the effectiveness of exercise interventions for the prevention and treatment of depression in an antenatal population.

How we made the decision

We check our guidelines regularly to ensure they remain up to date. We based the decision on surveillance 3 years after the publication of NICE's guideline on antenatal and postnatal mental health (NICE guideline CG192) in 2014.

For details of the process and update decisions that are available, see ensuring that published guidelines are current and accurate in developing NICE guidelines: the manual.

Evidence

We found 23 relevant studies in a search for randomised controlled trials and systematic reviews published between 1 April 2014 and 16 January 2017. We also included 6 relevant studies from a total of 37 identified by members of the guideline committee who originally worked on this guideline.

From all sources, we considered 29 studies to be relevant to the guideline.

We also checked for relevant ongoing research, which will be evaluated again at the next surveillance review of the guideline.

See appendix A: summary of evidence from surveillance for details of all evidence considered, and references.

Views of topic experts

We considered the views of topic experts, including those who helped to develop the guideline and other correspondence we have received since the publication of the guideline.

Views of stakeholders

Stakeholders commented on the decision not to update the guideline. See appendix B for stakeholders' comments and our responses.

Twelve stakeholders responded to the consultation not to update the guideline with 11 stakeholders providing comments. Of the stakeholders who commented on the proposal not to update the guideline: 5 agreed with the decision, 5 disagreed with the decision and 1 provided no answer. Stakeholders who disagreed suggested that carbamazepine, lithium and valproate can be

used with caution during breastfeeding that could impact on recommendation 1.9.8, which states: encourage women with a mental health problem to breastfeed, unless they are taking carbamazepine, clozapine or lithium (valproate is not recommended to treat a mental health problem in women of childbearing potential).

The comments were considered in detail. In terms of mental health conditions, valproate is only licensed for treating manic episodes in bipolar disorder when lithium is contraindicated or not tolerated. In developing the guideline, the committee was of the view that the evidence of significant harms (both congenital and neurodevelopmental) to the fetus associated with valproate was such that it should not be used in the acute or long-term treatment of a mental health problem in women of childbearing potential. This would also cover women that are breastfeeding.

During guideline development, evidence was also identified showing carbamazepine was associated with an increased rate of congenital harms, albeit not at the same level as valproate and not at a level that would preclude the use of carbamazepine in women of childbearing potential. However, the risk for harm associated with carbamazepine was greater than that observed for lamotrigine, and the committee recommended that carbamazepine is not offered for treating a mental health problem to women who are planning a pregnancy, pregnant or considering breastfeeding. No new evidence on valproate or carbamazepine use in women of childbearing potential or breastfeeding was identified through the surveillance review to change current guidance.

In terms of lithium, the British National Formulary states that lithium salts should be avoided when breastfeeding because of risk of toxicity in the infant. This information supports current recommendations.

A comment received through consultation suggested that NICE guideline CG192 should include recommendations on preventing postnatal post-traumatic stress disorder (PTSD), particularly through including information on what staff can do during labour to reduce the trauma to the woman. This is outside the scope of NICE guideline CG192, but is addressed by NICE's guideline on intrapartum care. An additional comment received through consultation asked NICE to consider postnatal PTSD separately from other kinds of PTSD. Neither NICE guideline CG192 nor the current surveillance review found evidence to support recommending postnatal-specific interventions for PTSD. Instead, NICE guideline CG192 recommends that women with PTSD that has resulted from a traumatic birth, miscarriage, stillbirth or neonatal death should be treated in line with NICE's guideline on PTSD. This area will be considered again at the next surveillance review of NICE guideline CG192.

See ensuring that published guidelines are current and accurate in developing NICE guidelines: the manual for more details on our consultation processes.

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