Creative interventions for symptoms of postnatal depression: A process evaluation of implementation

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ABSTRACT

Background: This article is a process evaluation of a three-arm randomised controlled trial (RCT) comparing the effects of creative interventions on symptoms of postnatal depression in new mothers.

Methods: Analyses of quantitative evaluation data from 91 participants and qualitative interviews and focus groups with 80 participants and 3 members of staff.

Results: Key assumptions of the project, including how the delivery of the intervention was achieved and what the intervention involved are explored. Data suggest that the intervention was delivered as planned with a high level of fidelity. Key uncertainties surrounding the project, in particular unanticipated challenges that had to be overcome during the project are also discussed and simple recommendations for improvement are made.

Conclusion: This process evaluation aims to illuminate the outcome and mechanisms data from the RCT and enable organisations or individuals to ascertain the feasibility of establishing their own singing classes for women with symptoms of postnatal depression.

KEYWORDS

Arts in health; postnatal depression; mental health; process evaluation; singing

Background

Postnatal depression (PND) affects at least 12.9% of new mothers, with symptoms including fatigue, anhedonia, insomnia and irritability (Boath & Henshaw, 2001; Morrell et al., 2009). However, challenges surround the fact that there is still no complete treatment solution. Although pharmacological treatment has had positive results, these are hampered by low uptake and adherence amongst mothers, while psychotherapy has produced mixed results as well as a similar challenges around low uptake or delayed treatment (Bledsoe & Grote, 2006; Cooper, Murray, Wilson, & Romaniuk, 2003; Milgrom, Negri, Gemmill, McNeil, & Martin, 2005; Morrell et al., 2009).

However, many mothers engage in community group activities with their babies, such as attending mother-infant play groups. Such activities have been identified as ways of relaxing mothers, providing good sources of social interaction, decreasing the monotony of each day and also providing a sense of personal fulfilment for mothers (Feeley, Bell, Hayton, Zelkowitz, & Carrier, 2016). Yet, to date there is little data as to whether such activities can impact positively on symptoms of PND. More specifically, there is also a growing body of evidence demonstrating the effects of community group singing on mental health (Clift & Morrison, 2011; Coulton, Clift, Skingley, & Rodriguez, 2015). Singing to new babies is practised in cultures around the world, and research has demonstrated valuable benefits such as improving mother-infant interaction and reducing distress in babies (Mualem & Klein, 2013; Nakata & Trehub, 2004; Vlismas, Malloch, & Burnham, 2013). The benefits of singing for maternal mental health remain largely unknown, however. Indeed, a systematic literature review of the effects of music on PND from 2012 found that "regardless of the extensive search of the literature there were no journal articles citing any research which related to the use of music as an intervention for women specifically with postnatal depression", summarising that "a large silence in the literature exists and further research is required to be conducted to determine music's effectiveness as an intervention for PND" (Terry & Terry, 2012).

Consequently, a three-arm randomised controlled trial (RCT) was carried out to compare the effects of different types of creative community group activities on symptoms of PND. Mothers were randomised into either receiving 10-week programmes of group singing classes with their babies, 10-week programmes of creative play classes with their babies or 10-weeks of usual care (a wait-list control group). Some previous studies have questioned whether there is any specific benefit of *music* or whether the social interaction provided by participation in a music intervention is in fact the cause of improvements in mental health (Crawford, Lewis, Brown, & Manning, 2013; Dingle, Brander, Ballantyne, & Baker, 2013). Consequently, this three-arm design not only allowed us to explore the effects of two different types of creative community group activities, but also provided a non-music social intervention as a point of comparison for the singing group.

The research findings regarding the outcomes of the RCT are published separately (Fancourt & Perkins, in press). The main outcome finding was that mothers who took part in the singing classes had the fastest improvements in their symptoms of PND (compared with those in a group play condition or control group). This effect was particularly seen for mothers with more serious symptoms of PND, amongst whom those in the singing group dropped below the threshold for symptoms of PND a month earlier than those in the other two groups. In addition, separate analyses exploring the mechanisms by which singing classes led to these effects are

underway. These mechanisms data are being considered in their own right as they were planned as a central research question in the study protocol and were approached with their own set of research tools. Key findings include that there were similar environmental, social and activity-specific mechanisms across both singing and play conditions but that there were stronger emotional mechanisms in the singing group, including feelings of achievement for the mother, immersion in the activity and bonding with the baby, as well as additional musical and social aspects of the singing activity itself. These could hold the key to the changes found in the singing but not the play group.

However, alongside the outcomes and mechanisms data, important questions remain. The singing and play classes are examples of 'complex' interventions in that multiple components were required to interact in order to achieve the desired results (Craig et al., 2008). Given this inherent complexity, it is challenging to be able to evaluate the data from the study without a comprehensive understanding of precisely what the intervention involved, the context within which it was implemented and the degree of fidelity to the original protocol with which it was carried out. Without this information, gaining a full picture of the impact of the workshops is not possible.

In the last few years, there has been a growing awareness of this challenge in researching and interpreting the results of so-called 'complex' interventions (Moore et al., 2015). As a result, although RCTs remain the gold standard for the establishing the effectiveness of interventions, studies involving complex interventions are increasingly incorporating process evaluations alongside outcomes data. Process evaluations can simultaneously provide further details on an intervention and its causal assumptions, identify whether the intervention was implemented as planned, elucidate how contextual factors influenced the running or outcomes of the intervention and consider the mechanisms by which an intervention achieved its desired effects. Figure 1 taken from the Medical Research Council (MRC) process evaluation guidance shows how elements of process evaluation, including its context, implementation and mechanisms of effect, work together with the intervention itself and its outcomes (Moore et al., 2015).

[INSERT FIGURE 1 ABOUT HERE]

This process evaluation aimed to explore the issue of *implementation* in relation to the study in question. Implementation refers to how an intervention is carried out. Understanding potential supporters or barriers to the implementation process can help to identify whether an intervention was delivered as planned. This is particularly important when dealing with complex interventions in which there are multiple interlocking components all central to the success of the intervention. Important considerations are what resources were required to deliver the intervention, whether the intervention followed the initial protocol, the dosage of the intervention that was received by participants, whether the intervention had to be adapted in any way to meet the requirements of different contexts, whether it reached the intended audience, and what the key challenges that arose were and whether they could be avoided in the future (Moore et al., 2015). This process evaluation aimed to explore these issues relating to implementation in detail as a way of illuminating the outcome and mechanisms data that are published separately, also providing a richer understanding of what was involved in running the intervention to enable external organisations or individuals to ascertain the feasibility of establishing their own future singing classes for women with symptoms of PND.

Research approach and methodology

Research questions

Following the MRC guidance for process evaluations, this process evaluation aimed to look at both the practicalities around implementation (the assumptions of the project) and identify and examine project challenges (uncertainties of the project) (Moore et al., 2015):

- Key assumptions of the project:
  - How delivery was achieved
  - What was delivered and whether it was actually delivered, received and appraised by the correct target group as planned
- Key uncertainties:
  - Identifying the unanticipated challenges that arose from the project
  - Recommendations for future improvements

Research methods

In order to answer the research questions, five types of data collection were involved:

- Evaluation forms collected from 100% of participants who completed involvement in the intervention(n=91; 89% of total participants who took part in the singing and creative play workshops). These involved a combination of Likert-rated responses and qualitative feedback directly assessing the intended workshop objectives as well as gathering more general evaluation of the workshops and points for improvement.
- Focus group interviews carried out with a subset of participants from the singing, creative play and control groups (n=80). These took place immediately after the interventions finished (or after the usual care period in the case of the control group) in order to gain fresh information before participants forgot key points.
- Individual interviews carried out with the two workshops leaders. These took place six weeks after the end of the six months of workshop cycles.
- An individual interview carried out with the project coordinator six weeks after the end of the six months of workshop cycles.
- Anonymous eligibility data taken from the study screening log and attendance recorded by the project coordinator through a register completed at each session.

There has been debate as to whether it is better to have separate teams or the same team analysing process evaluation and outcome data (Moore et al., 2015). However, as the main aim of this process evaluation was to illuminate study outcomes and provide practical information as to the implementation and potential future development of creative workshops for PND, the same team were involved in the analysis and write-up of both sets of data. Similarly, there has been significant debate as to the merits of analysing evaluation data before, after or simultaneously with outcome data (Munro & Bloor, 2010). Quantitative process data were initially analysed prior to outcomes data to assess whether there were any obvious deviations that would influence the interpretation of outcomes data. Following this check, qualitative process data and the write-up of all process data occurred alongside outcome and mechanisms data.

In a further attempt to reduce bias in the data collection or analysis of process evaluation data, quantitative and qualitative process evaluation questions were selected by the research team at the start of the workshops and remained unchanged throughout the six months of data

collection. All process evaluation forms for participants were completed after completion of all the core research data so as to avoid prompting responses to the core research questions. In addition, reflective interviews with the leaders and project coordinator took place after all workshops and data collection were complete to avoid contaminating or inadvertently altering the running of the workshops. No process evaluation data were analysed until all workshops and other data collection were complete, again to avoid any changes being made to the way the project was being run. The leaders and workshops assistants who led the workshop sessions were not involved in any data analysis or write-up.

Analyses

Quantitative data were analysed statistically using SPSS version 23.0 using a combination of descriptive statistics and either one-way analyses of variance (ANOVAs) or Mann-Whitney U Tests for comparing the differences between the three groups in evaluation responses for linear and ordinal data respectively. Qualitative data were analysed using thematic analysis, with units of meaning that emerged strongly or across multiple different respondents identified and clustered into sub-themes, with cross-checking from a second researcher.

Results

Key assumptions

How delivery was achieved

Participants. Mothers aged 18 or over up to 40 weeks post-birth were recruited to the project. Women were recruited through midwives, doctors, perinatal psychiatrists, health visitors and GPs in the Greater London area, as well as through social media, leaflets and by a research assistant in children's centres and in the local community. Mothers who were interested in taking part were asked to complete an online registration form that took demographic and availability details and assessed potential symptoms of PND using the Edinburgh Postnatal Depression Scale (EPDS) (Cox, Holden, & Sagovsky, 1987). Scores were checked by a member of the research team and women scoring 10 or higher (indicative of potential symptoms of PND; Gibson, McKenzie-McHarg, Shakespeare, Price, & Gray, 2009) were deemed as eligible for a place on the project. The EPDS score was selected as the eligibility criteria rather than a specific diagnosis of PND in recognition of the fact that some mothers do not seek professional support when experiencing symptoms of PND, either because they are not aware that this is what they are experiencing or because of concerns about being labelled with a mental health condition. Women were excluded if their baby was outside the specified age range, if a healthcare professional advised that the intervention was not suitable for them, if they did not or could not provide informed consent or if they lived outside the Greater London area so were unable to attend the workshops.

These participants were assigned randomly to either 10 weeks of group singing classes, 10 weeks of creative play classes or 10 weeks of usual care (with a 10-week singing class subsequently offered as a thank you once all research participation was complete). Both the singing and creative play classes were offered in different locations in London and on different weekday afternoons with two different times available. So to avoid presenting women with places on classes that they could not make due to prior commitments (such as work or collecting other children from nursery), women were asked to indicate their preferred location and their days and time of preference in case they were randomised to one of the two conditions requiring

class attendance. Once they had been randomised, and if they were randomised to one of the two conditions requiring class attendance, a member of the research team ensured that each woman was assigned to the class nearest to her at a time she could make. This step was designed to reduce high levels of drop out yet maintain a randomised allocation. Mothers scoring 8 or 9 on the EPDS were given one opportunity to rescreen a minimum of two weeks later. They were not told why they were being given a rescreen in order to avoid biasing their responses, but were simply informed that further details were required. If women were eligible for the programme, they were sent an email confirming their place and providing details of the location, date and time of their workshops, alongside a list of frequently asked questions and a guidance sheet on where they could seek further support about PND.

Additionally, the study was approved by an NHS Research Ethics Committee [15/SS/0160]. Women provided informed consent to take part and, if they agreed, their GPs were notified by letter of their participation in the study. The protocol also included specific steps that should be taken if it was identified during the study, either through face to face contact or through high responses on any of the study questionnaires (including a particularly high EPDS score or a high score on the individual EPDS item asking about thoughts of self-harm), that women appeared to require further support. These steps included speaking with the mother in question, reminding her about services available to her and her baby, and providing further correspondence to her GP so that she could receive appropriate professional guidance.

The final sample included 134 mothers with an average age of 35 years (SD 4 years, range 22-47). Their babies had an average age of 20 weeks (SD 9 weeks, range 3-40). The majority (76%) were white British, 71% were married and for 89% of them this was their first baby. Participants were well matched between the three groups across all demographic variables including considerations of whether mothers were receiving any medication or psychological support alongside involvement in the study. Full demographic details and the breakdown between groups are provided in the results paper (Fancourt & Perkins, in press).

Leaders. All classes were provided by professional workshop leaders. An advertisement was placed for leaders to run ‘creative interventions’; both singing classes and creative play classes. Applicants had a range of experience working in hospital, community and school settings including with a range of ages from young babies up to older adults. The majority of the experience listed by applicants was from running music or mixed-arts workshops, although it was a selection criterion that applicants also had experience leading non-musical play activities. Two leaders were selected, both of whom split their time 50:50 between leading singing and play classes to ensure that leader personality did not become a variable in participant responses. The leaders also liaised with one another and the wider project team in planning the classes to ensure that the groups received comparable activities.

The leaders were supported by one or two assistants, recruited from students studying at the Royal College of Music (RCM), in collaboration with the RCM Creative Careers Centre. The assistants helped with practicalities such as preparing the room for sessions and welcoming mothers, as well as supporting the class activities, such as accompanying the singing on musical instruments or supporting mothers to engage with their babies in creative play. In addition, there was a project coordinator present at all classes who was the first contact point for mothers throughout the project, kept a check on attendance rates, contacted participants who missed a session to check if they were alright, supported data collection on the relevant weeks, supported

mothers as needed in the sessions, ensured smooth running of the classes with the venue, and monitored risk.

Staff involved in the project underwent training prior to the workshops starting. This training included an introduction to the research from the research team (but crucially not involving the specific hypotheses of the research study); and an overview of PND, advice on how to tackle potentially sensitive situations and safeguarding training on how to spot and report mothers or babies who might be at risk, all provided by a professional perinatal health visitor. Additionally, the project coordinator underwent health and safety and enhanced infant first aid training. All staff were required to have a current criminal record check (Disclosure and Barring Service certificate; DBS), and to sign an agreement confirming they would adhere to the project's 'Vulnerable Adults and Children Protection Policy and Procedure'.

Location. The classes were provided in Children's Centres in London, in the boroughs of Hammersmith & Fulham and Kensington & Chelsea. Children's Centres are government-run community locations in the UK that give help and advice on child and family health, parenting and training to parents of children under the age of five. Some centres also provide early learning and day-care for pre-school children. Children's Centre activities are provided free of charge.

The Children's Centres provided the venue free of charge for the workshops, including the workshops within their programme of activities. The spaces used for the classes were relatively small rooms that comfortably seated 12 mothers and babies plus the workshop leader, assistant and project coordinator. Spaces all had natural light and open floor space where play mats and cushions could be laid out. The Children's Centres had pushchair storage, changing facilities and trained staff on site as extra support for the project.

Some of the mothers were already familiar with the Children's Centre where their workshops took place through attending for baby weigh clinics or other assessments or activities. Other mothers were new to the venue. However, as Children's Centres are a well-known resource amongst London mothers, participants were largely familiar with the role and purpose of Children's Centres before attending the classes.

What was delivered

The intervention. Both the singing and creative play classes were delivered face-to-face in groups of an initial size of 10-13 mothers and lasted one hour. In order to enrol a large sample of women, the 10-week blocks of singing classes and play classes were run multiple times over a 6-month period. Classes took place on a weekly basis on weekday afternoons either from 2-3pm or 3.30-4.30pm, with the allocation of singing and play workshops to these two slots counterbalanced over the course of the project. Mothers were invited to sit in a circle on the floor surrounded by soft play cushions and mats. Both classes started with welcomes: the singing class involved a welcome song that was used at the start of every week, introducing the babies and mothers to one another; and the play class involved the mothers introducing their babies and telling the rest of the group a development that the baby had achieved since the last session.

Following these introductions, the singing classes involved learning songs from around the world, ranging from short vocal exercises that used 'motherese' style noises and sound effects (including sound baths where the mothers sang a sustained note providing a relaxation

technique), to simple lullabies that could be picked up very quickly and sung in basic harmonies or rounds, to longer or more complex songs that were learnt gradually over the weeks. Songs were a mix of relaxing in style, with mothers encouraged to hug or stroke their babies as they sung, to energetic, with mothers standing and moving with their babies, bouncing their babies in their arms. Some songs were accompanied by maracas, drums, hand chimes and other simple instruments that the mothers and babies could play together and also a combination of guitar and ukulele was used for a small number of songs. Mothers also worked to write some of their own songs over the weeks, developing lyrics together on the subject of their babies or experiences of motherhood and creating simple melodies. Recordings of the group singing the songs together were made and uploaded to private online platforms or onto CDs for the mothers to listen to at home.

The play classes involved creative activities ranging from storytelling and introducing different sensory objects to the babies, to creating simple crafts such as mobiles, pom-pom balls, and hand and foot prints of the babies in salt dough to messy play involving paints and water. As with the singing classes, the play classes combined relaxing activities seated in a circle with mothers encouraged to hug or stroke their babies, with energetic activities, such as standing and swinging babies in slings. Mothers also worked to create larger pieces of art with their babies such as hand trees, where mothers created stencil outlines of their baby's hands which formed leaves on the tree and wrote aspirations for their babies in the hand-prints. Mothers were able to take home the crafts that they had made together.

Fidelity

The MRC guidance on process evaluations for complex interventions recommends that an assessment of whether an intervention is delivered as planned considers four criteria: fidelity (whether the intervention was delivered as intended; also referred to as integrity), dose (the quantity of intervention implemented), adaptations (whether the intervention had to change in a way that undermined its fidelity) and reach (whether the intended audiences came into contact with the intervention, and how) (Moore et al., 2015). The initial protocol for the study stated:

> "The singing group will receive 10 weeks of group singing with their child led by a professional workshop leader for 1hr per week plus standard care. The play group will receive 10 weeks of group play for them and their child led by a supervisor for 1hr week plus standard care. The control group will receive standard care with no additions."

Regarding fidelity, this was indeed what was delivered. The running of both the play and the singing workshops went smoothly: the correct number of workshops was delivered for each of the groups of mothers and there was no change in the location or timing of workshops. There were a small number of sessions (10 out of the overall 100 classes delivered over the duration of the research) where the planned leader was ill, but due to the structure of two main leaders and a number of assistants, these classes were covered from within the leader/assistant pool without a change to the running of the intervention.

A wider consideration was whether the intervention was also true to the initial aim of creating a positive experience for mothers who attended. To explore this, the evaluation forms asked mothers to rate how well the intervention was tailored to them and their babies, the likelihood that they would recommend the classes, and to provide an overall rating for the workshops (see

Table 1). In the singing group, 87.8% of the mothers agreed that the classes were well tailored while 66.7% of the play group agreed (a statistically significant difference; Z=-3.48, p=.001). However, 19% of the creative play respondents neither agreed nor disagreed, suggesting that it was not a simple question for mothers to respond to. In the focus groups, this was brought up with some of the mothers reporting that even though they enjoyed the creative play classes, that they felt their baby was too young to get the maximum benefit. One mother in the play group summarised the issue: "I think the music workshop is a bit more suitable for babies up to a year. As they understand and respond better to sounds than to arts and crafts". Nevertheless, as the classes were aimed at improving the mothers' wellbeing, this did not in itself suggest a lack of fidelity to the original aims in the play group but does suggest that the singing classes were particularly well designed in appealing both to mother and baby.

We also asked the mothers to provide an overall rating for the workshops out of a possible score of 10. Both classes received strong scores, with the singing group scoring 8.8/10 and the play group scoring 7.6/10, but this was still a statistically significant difference ($F_{1,89}$=11.76, p=.001). Furthermore, regarding the likelihood to recommend the classes, 100% of the singing classes and 90.5% of the play classes reported that they were very likely to recommend the intervention, or had even recommended the intervention already. However, again there was still a significant difference between groups (Z=-2.50, p=.013). Across all three of these measures, sensitivity analyses that excluded women who had stopped attending the workshops after just one session (but still continued to provide research data) did not affect the significance of results.

As well as these quantitative data, we provided free-response boxes for mothers to describe the project. A range of positive comments arose from the women involved. These coded onto several key themes that were mentioned across both play and singing classes. For example, a number of mothers referred to making new friends, with one mother calling the project "an invitation to join a tribe of mothers" (singing mother). Mothers in both classes also referenced having "a new tool for looking after my baby" (singing mother) and said that the classes "opened up new avenues to play" (play mother) with their babies. Bonding and relaxation came through in feedback from both classes, with one mother commenting that the classes "help you bond and enjoy your baby as well as relax and feel human again" (play mother). The effect of the classes on happiness, self-esteem and competence was also mentioned from both classes, with mothers commenting on how the classes helped them as mothers "to feel important" (singing mother) as well as describing how "the project helped me to be a better mum, [a] happy mum!" (singing mother). Another aspect that emerged from the qualitative feedback was the effect of all of these aspects on coping with postnatal challenges, with one mother writing "It's very encouraging for mothers who have battled with issues during their pregnancy and after having delivered, with their babies" (play mother), and another mother mentioning the importance of "meeting mums that (sic) I have a connection with on a level beyond usual interests" (singing mother). One mother quite simply called it "a lifeline" (singing mother). These qualitative data suggest that the classes were well received by mothers, supporting the wider conclusion that the intervention was delivered with integrity.

[INSERT TABLE 1 ABOUT HERE]

Dose

Regarding dose, there was no set number of sessions outlined in the protocol that women were required to attend. This was deliberate, as part of the aim of the study was to assess whether mothers did indeed want to attend classes to support their symptoms of PND. All women were invited to attend the full 10-week block of classes and encouraged to keep returning, receiving a follow-up phone call if they missed a week without prior notice to encourage them to return. Analyses of attendance rates showed that women in the play sessions attended an average of 5.7 sessions (SD=2.8) out of the total 10 sessions. Women in the singing sessions had higher attendance: an average of 7.2 sessions (SD=2.6) out of the total 10 sessions. When analysed statistically, there was a significant difference in these attendance averages, indicating that a higher dose was received by the singing group ($Z=-2.50$, $p=.012$). When analysing this further, 9.5% of women who started the play group dropped out of the sessions after just one week, compared to just 2% of the women in the singing group. Only 57.1% of women in the play group attended more than half of the sessions (six classes or more), compared to 73.5% of the women in the singing group. Therefore there was evidence of greater adherence to the intervention in the singing group.

Adaptations

Regarding adaptations, the interventions did not appear to evolve from their original plans. The two leaders undertook significant pre-planning together and worked closely with the project team to ensure that the structure of the 10 weeks of classes was planned up front, and the majority of the activities were then repeated each time the 10-week block was run. Interviews with the leaders confirmed this consistency, with one leader explaining "I did essentially the same thing…we had a similar structure every week" (leader 1). However, both leaders referred to how the workshops naturally evolved as women got to know one another: "I found myself able, in all the groups, to step back more and more. It was deliberate. I wanted them to come forward and take some ownership" (leader 2). One leader also referenced the changes in the babies as they grew, meaning that the classes too had to evolve to continue to support their needs. However, the different personalities and small group sizes did mean that the feel of the sessions could be different, even if the activities remained consistent: "it very much depends on who turns up" (leader 1). Despite not consciously changing the format of the sessions, the leaders also acknowledged how much they learned themselves during the process, which led the sessions to evolve as new ideas were incorporated: "Play probably varied slightly more from the first group to the second and third because I learned a lot" (leader 1).

An important consideration of the project was whether the classes had similar ratings for the two leaders, or whether there was a variation at a leader level that might have impacted on the experience for mothers. Analyses that compared the responses of mothers who took part in singing classes led by the two different leaders showed no significant differences in overall evaluation of the sessions, nor in terms of how well mothers thought the workshops were tailored to them and their baby, nor their likelihood to recommend the classes ($p>.05$). Similarly, there was no significant difference between leaders on any of these measures in the play groups ($p>.05$), indicating that the groups were similarly delivered by the two leaders. Qualitative feedback from the mothers was highly complementary about both leaders, with both of their sensitivity, calmness and enthusiasm praised by mothers. Consequently, there were no marked adaptations from the original plan and no evidence that classes delivered by the two different leaders were differently received or valued.

Reach

Regarding reach, a total of 307 women were screened for participation in the study. Women were asked where they had found out about the project and results showed that face-to-face communication was by far the most effective, with 97% of mothers recruited this way: 23% at mum-and-baby classes in the local community, 21% at the local baby cinema screenings, 21% at the Children's Centres themselves, largely at baby-weigh clinics, 14% through friends or word-of-mouth and 18% through healthcare professionals at the local hospital, GP practice or through health visitors. Just 3% of mothers found out through social media, even through there was ample information on a range of websites, twitter, Facebook and newsletters, highlighting that this might not be the most effective recruitment strategy for this target population. Of the women who were screened, 153 were eligible to participate and 148 commenced the study. Of these, 43.7% of women had an EPDS of 10-12 (inclusive) and the remaining 56.3% had an EPDS of 13 or higher, demonstrating a relatively even split between milder and more moderate-severe symptoms of PND. This meant that 50% of people screened were eligible to take part. Given that PND is anticipated to affect around 13% of mothers in the UK, our high eligibility percentage suggests that our recruitment strategies were well designed to find women with symptoms of PND. Further, withdrawals from the study were limited to just 13 people, 9 of whom were lost to follow-up and 4 of whom withdrew consent (1 as a result of moving away). This represents just a 9.6% drop-out. The final number of women to provide complete datasets was therefore 135: singing (n=49), play (n=42) and usual care (n=44). However, it is to be noted that one participant was retrospectively excluded from the outcome analyses as she reported not answering the EPDS questions accurately.

As part of the focus groups, we asked mothers why they had signed up to take part in the project. Many of the mothers joined specifically to support their mental health: "It just kind of seemed the right time… [I] definitely kind of had a lower mood and a lot of anxiousness having her [my baby]" (play mother). Specifically, some mothers discussed a fear about their wellbeing becoming worse, so saw the classes as a preventative measure: "I joined because my older sister had postnatal depression that became postnatal psychosis. I worried that I might suffer it similar way" (singing mother). However, for other mothers, they did not want to identify with having symptoms of PND. One mother commented that she was "curious to find how people would be" (care as normal mother) while another said that the focus on wellbeing rather than explicit mentions of PND in the publicity had appealed to her. Other mothers signed up for reasons outside supporting their mental health. Some were drawn by the fact that music was involved for some of the groups: "I just think music's so good for everyone, but it's, I think, really good for baby…I think it's just such a primal good thing to do really. And I really want her to be musical" (care as normal mother).

The RCM association also helped draw people in: "I thought it might be a bit more grown-up" (singing mother). For other mothers, the class was simply a way to fill the time: "the week can be very long, so wanting to just have somewhere else to go" (singing mother). Consequently, the classes did appear to attract women who were in need of support, but interestingly some of them did not explicitly mention their mental health or wellbeing for the reason they engaged. As women were asked this question in groups, some may have preferred not to disclose information about their mental health. However, the additional draws of music and the

opportunity to do a free activity ("It was free. I think that made a big difference because everything else is quite expensive" (play mother)) also appear to have been central in engaging mothers.

Key uncertainties

As recommended by the MRC guidelines, another key part of the process evaluation was identifying challenges that arose from the implementation of the project. We identified these challenges from the ground up, exploring qualitative responses from the mothers, the leaders and the project coordinator and identifying themes that emerged specific to each of these three groups. Following on from these challenges, we also identified recommended points for improvement in any future running of the workshops.

Challenges perceived by participants

One of the major challenges perceived by mothers was the space itself. Several mothers commented that they found the room quite cramped. The size of the space did vary between the Children's Centres. While all spaces were capable of holding up to 12 mothers and their babies plus the leader, assistant and project coordinator, some of the spaces were limited to this, meaning that prams had to be left in the communal area outside and there was little break-away room for mothers if they needed to leave the immediate circle of the activity.

Some mothers also raised challenges around fitting in the activity around their baby's nap schedule. However, other mothers found the timing fitted perfectly for them, highlighting that this could be an idiosyncratic problem.

Challenges perceived by workshop leaders

The leaders highlighted separate challenges to the participants. Both leaders mentioned the demoralising effect of drop-outs from the groups, even when drop-outs were down to logistical rather than personal factors: "There were mums that didn't come back and that's challenging, disappointing, and that affects the morale of the group…Learning that it's not a personal thing, remembering that it's not a personal thing. That was challenging" (leader 2).

The leaders also highlighted the emotional burden for them: "Knowing a woman is really struggling and that actually you can't do anything one-on-one, all you can do is be there. It's quite difficult to let that go because as people who work in the arts it's not often you see that" (leader 1).

The difficulties in planning for the project sessions was also discussed: "The bit that I found more difficult was second guessing myself about what people might want…My tendency was to over-prepare" (leader 1). However, as discussed above, this issue became less as the sessions went on and the groups settled into a rhythm. Furthermore, the preparation for the sessions perhaps led to the sessions being perceived as easy to run: "I found the easiest part of the project was delivering each session" (leader 1). However, the leaders also mentioned the additional challenges for running play sessions, which they both had less experience in, highlighting the importance of experience in a workshop leader: "In the creative play I felt I didn't have quite so many tricks up my sleeve. I was less flexible. I had to stick to what I'd planned" (leader 2).

Challenges perceived by the project coordinator

The project coordinator highlighted separate challenges again, the main one being around recruitment: “First of all, you're dealing with a lot of first time mums who are now in a completely different lifestyle. If they are feeling lonely some of them don't even want to admit it. Some of them are very reluctant to even take a flyer. Some mums didn't really want to engage with even the notion of having PND.” The project coordinator identified how support from organisations was key to recruitment, such as allowing flyering at events, facilitating social media and including details of the project on newsletters and websites, but that recruitment became harder if organisations were not willing to help with activities such as these.

A second challenge was around the coordination of many different people involved in the project, including staff at the venues, leaders, healthcare professionals, partners and the mothers themselves. It was paramount that external stressors or problems that arose over the course of the project (including very minor issues such as the timing of fire drills) were not brought into the sessions as this could have negatively affected participants and outcomes. Careful management and multitasking was therefore required to ensure that all elements of the project were delivered smoothly.

Recommended points for improvement

Based on the challenges outlined above, certain suggestions can be made for future practice. First, the venue itself is imperative to the success of the project. The Children’s Centres themselves, while successful in this project, may not be crucial. They certainly provided safe and familiar environments for mothers, and importantly they had baby changing facilities and a baby first-aider on site, as well as providing links to other community support services and healthcare professionals. However, the project coordinator explained that other venues could also work: “I do think if you have a church hall, or you had another sort of facility…which had the space and did have other staff on hand just in case something went wrong...Then it could happen there as well.” Evidently from the challenge highlighted by the mothers, the size and comfort of the room is paramount.

To reduce some of the emotional burden for workshop leaders and to assist with the planning of sessions to avoid concerns about over- or under-preparation, the workshop leaders suggested having formal debrief sessions for them with the project leads at the end of each session as a way of expressing any concerns or emotional challenges from the sessions: “It always demands a certain amount of energy, facilitating a group, but the level of sensitivity is a bit like working in a hospital. You're kind of heightened …I find it exhausting…more formal five minute debrief at the end of every session…really helps just to go ‘Bleugh!’…Let it all out. Then you don’t carry it home” (leader 2).

For the project coordinator, it is recommended that the amount of time needed for recruitment and project management is not underestimated. It is also advised not to try and reduce the staffing and conflate the roles of coordinator and leader or assistant. Each of the three roles had its own purpose and was essential to the running of the project. The leaders commented on the value of having an assistant in the session to support women individually in taking part and looking after their baby: “it all felt very well supported, the fact that there was an assistant…was fantastic” (leader 2). However, the coordinator’s role in the sessions (in addition to the coordinator’s wider role in project management and recruitment) was separate to this and revolved more around liaising with the venue, acting as the health and safety officer and checking on the wellbeing of the mothers to enable reporting back to healthcare professionals

if a woman required additional support. Consequently, it is strongly recommended that these three roles be maintained as separate entities.

There were also two further recommended points for improvement that emerged. Some of the mothers suggested having specific coffee time after the session each week to encourage people to spend more time together and get to know one another even better. This was also suggested by the workshop leaders and the workshop coordinator who recommended finding a local space where the mothers could meet up straight after the sessions. Finally, there was also the suggestion of having more formal resources for the mothers. CDs were distributed in the singing classes and a dropbox of recordings from the sessions created, but one of the leaders recommended "more formal resources…if there was funding to create the resource I think that could be really beneficial. It would, again, add to that sense of community" (leader 2).

Conclusions

The aim of this process evaluation was to explore the practical challenges of running the 'creative interventions for symptoms of postnatal depression' study and in particular to identify whether there were any challenges that may have confounded the interpretation of results.

Overall, this process evaluation does not find any evidence that the implementation of the intervention could affect the interpretation of results. Qualitative and quantitative data show that the workshops were delivered with a high level of fidelity, there were no indications of significant adaptations that could have confounded results, and the correct target demographic was reached. However, despite this, there was a discrepancy between evaluation responses to the singing and play groups, with the singing group consistently receiving stronger feedback and evaluation scores, and mothers attending more sessions on average (leading to a higher dose). It is possible that the singing classes were simply higher quality overall, perhaps as a result of leader experience, although it should be noted that both classes received very positive qualitative responses. The alternative interpretation is that the mothers were more interested in singing workshops and they were simply a better fit than creative play classes for this target demographic; indeed the music itself was reported as one of the draws to mothers signing up to the project. This, combined with the fact that the psychological results from the study showed significantly faster improvements in symptoms of PND in the singing group but not the play group (Fancourt & Perkins, in press), supports the recommendation that singing groups are likely the most effective of the two interventions and the one that should be considered for further research and practice.

This process evaluation also highlighted several challenges perceived by mothers, workshop leaders and the project coordinator. However, none of these challenges became an obstacle to the running of the workshops and some simple recommendations for improvements and future developments of the project have been made. It is hoped that by describing the implementation of this intervention study in this very close level of detail, this process evaluation will be of value to arts organisations, arts practitioners and healthcare institutions interested in taking this work forwards.

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