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Supporting young mothers (aged 14- 25) in the first two years of life: A Randomized Control Trial (RCT) of the NSPCC UK Minding the Baby (MTB) Home Visiting Programme.

Short Title: Evaluation of the NSPCC UK Minding the Baby Programme

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Overview and Rationale:

The NSPCC, in collaboration with University College London and the University of Reading, is initiating an ambitious multi-site study of the effectiveness of a targeted prevention programme that incorporates well established principles of home visiting with a more comprehensive package of care for the developing mother-infant relationship. The programme represents an important opportunity to advance the UK's provision of evidence-based support for at-risk families and to intervene effectively in the intergenerational cycle of disadvantage. The Minding the Baby (MTB) programme represents a unique intervention that integrates many of the benefits of home visiting programmes – particularly their relative cost-effectiveness, client acceptability and accessibility – with a coherent, evidence-based clinical dimension that is informed by, and directly targets, well studied mechanisms of risk in early child development. In focusing on key domains of parent-child relationships where disturbances are known risk factors for later child maladjustment, particularly the sensitivity of parental care, the security of infant-parent attachment and the parent's capacity to reflect on the child as an autonomous agent with needs, feelings and thoughts, the programme aims to combine best clinical practice in early prevention with the best scientific data regarding the developmental processes that promote optimal child outcomes. Currently, the UK health and social care systems offer limited services to young families targeting mental health or promoting family relationships from birth. Routine care for at-risk parents can vary from enhanced health visiting to postnatal support groups to family therapy. The type and length of treatment often depends on where the parent lives and as a result the treatment offered sometimes does not adequately address the needs of the parent. What tends to be either absent or left to chance in routine care are consistent and reliable key figures that are capable of addressing a broad range of parenting concerns from the practical to the emotional, with the aim to promote a positive parent-child relationship. Several influential policy documents from government departments and third sector organizations have repeatedly called for such early intervention. Longitudinal outcome studies clearly show that major disturbances in the quality of care can have lasting negative consequences for children's development, and the long-term social and financial costs associated with these poor outcomes are considerable. The potential value of effective early intervention therefore cannot be overstated.

This randomized clinical trial will test the hypothesis that an intensive home visiting programme focused on promoting young parents' sensitive attunement to their infants and their capacity to reflect on their baby's thoughts, feelings and needs, will lead to improvements in the sensitivity of parenting at age 2 years compared to parents who receive routine care. The study will also examine several secondary hypotheses, including that the programme will increase offspring rates of secure attachment, improve cognitive and behavioural outcomes and promote maternal mental health.

BACKGROUND AND SIGNIFICANCE

A large percentage of first-time mothers living in low-income urban communities are adolescents [1]. The many environmental stressors that these young parents face (poverty, single parenthood, social isolation and poor educational achievement [2]) are often amplified by personal histories of abuse, depression and post-traumatic stress (PTSD)[3-5]. These parents find themselves not only having to deal with their own developmental needs but also trying to take on the complex roles and responsibilities of parenting. It is perhaps not surprising that these young parents are more susceptible to mental health problems and typically struggle to become responsive nurturing

parents [6, 7]. Social disadvantage more generally represents a broad but very reliable marker of a host of contextual, psychological and developmental risk factors that have well-established negative impacts on the quality of parenting and on child development [8-10]. The Minding the Baby (MTB) programme is aimed at supporting young parents facing multiple social stressors, and raising their first infant in adverse social circumstances, in order to promote positive parenting and improve child developmental outcomes.

The MTB programme was developed by an interdisciplinary team at the Yale School of Nursing, the Yale Child Study Centre and a community health centre. MTB is an intensive and preventive home visitation intervention for young parents and their first babies. MTB primarily evolved out of two distinct home visiting models that originated in the US; the Nurse Family Partnership (NFP) and the infant-parent psychotherapy model. The NFP model, developed by David Olds and colleagues ([11] is typically delivered by experienced public health nurses with extensive training in the NFP program, who conduct frequent home visits to high-risk first-time mothers and their infants beginning at the end of the second trimester of pregnancy, continuing through to the child's second birthday. The NFP has repeatedly been shown to promote a range of positive health, parenting, developmental and life course outcomes in high risk populations in long-term studies [11-20]. The infant-parent psychotherapy model has major advantages in working with parents who have significant mental health problems, often as a result of on-going trauma. Although this model has been less rigorously tested than the NFP programme, it has been found to have improved rates of infant attachment security, and the development of a healthy and resilient mother-child relationship [21], both of which are prognostic indicators of longer-term positive developmental outcomes in the child [22].

The MTB programme brings together both these models, providing a holistic intervention that not only addresses maternal mental health issues but also the evolving parent-infant relationship, practical parenting concerns and developmental outcomes. By incorporating both nursing and mental health approaches, MTB serves to address some of the more complex needs of mothers and families at risk.

Attachment and Reflective Functioning:

It is firmly established in the attachment field that the quality of the infant's attachment to their primary caregiver is robustly related to a range of child outcomes [23, 24]. MTB builds on this evidence makes the promotion of secure attachment a primary clinical objective as a means of bringing about positive changes in the infant's social, emotional and cognitive development. Originally, Ainsworth and colleagues [25] suggested that a mother's ability to respond sensitively to her child's cues would ultimately lead to the development of a healthy and secure mother- infant attachment. Later research [26] empirically tested this hypothesis and found broad support for the role of sensitivity in secure attachment. Furthermore, recent work has highlighted the role of the mother's own mental state with respect to attachment – referred to as her internal working model(IWM) of attachment, in shaping the sensitivity of care, and thus her child's attachment security [27]. These attachment representations are thought to shape how a parent perceives their child and, accordingly, how they respond to the child's behaviour, cues and communications[28].

A critical feature of the way in which parents think about their children is their ability to consider the child's thoughts, feelings, emotions and beliefs, and to treat the child therefore as an individual with

a mind. Crucially, research indicates that this ability not only to think of the child as an individual with their own thoughts and feelings, but also to understand and make a causal connection between the child's behaviours and their underlying feelings and experiences, is crucial in the development of a secure attachment [29, 30]. This capacity has been termed by Fonagy and colleagues as mentalization or reflective functioning (RF). Slade and colleagues' extensive research in this area has demonstrated consistent relationships between maternal RF, child attachment, and maternal behaviour [24, 31, 32].

THE MTB programme is rooted in this developmental theory and, at its core, the MTB programme aims to increase the parent's capacity to think about their child and reflect upon his/her thoughts, feelings and emotions, and to respond in a sensitive and attuned way to the child's cues and communications.

Home Visiting Interventions

Home visiting interventions have grown substantially in the last few years with their common overall objective being to promote the quality of life of both the mother and child in the first two years. Although the overall objectives of home visiting programmes are broadly similar, the interventions themselves vary greatly in terms of the content, organization and focus. Variations in the targeted outcomes, populations and theoretical underpinnings all drive diversity of treatment [17, 33, 34] and as such, comparisons among them are difficult to make. Nonetheless, home visiting evaluation studies have suggested a range of beneficial outcomes across different programmes, including child outcomes such as a reduction in incidences of child abuse and neglect [35, 36] levels of internalising and externalising problems [37, 38], numbers of accident and emergency visits [39],hospitalisations [40, 41] and immunisation rates [42],and maternal outcomes such as improvement in parental knowledge of child rearing and child development [43], the number of subsequent pregnancies and employment[18] and finally maternal psychological health [44, 45].

A recent meta-analysis has helped highlight some key aspects of home visiting programmes for at-risk families. Nievar and colleagues[46]indicated that intensive home visiting programmes with at least three visits per months were more than twice as effective as less intensive programmes. Interestingly, there was no significant difference between programmes being carried out by professionals versus paraprofessionals. However, overall, most programmes showed an increase in positive maternal behaviour with a greater success in maternal behaviour for those with more frequent home visits.

The Nurse Family Partnership (NFP) is one of the most well-studied home visiting programmes. The NFP has robustly demonstrated positive outcomes for both parent and child in multiple long-term studies [20, 47, 48]. In particular, a 15 year RCT follow-up study of NFP found significant differences in both parent and child outcomes compared to controls, including a 79% reduction in rates of child abuse and neglect [49]. The positive findings that have emerged from high quality RCTs of the NFP programme has led the UK government to offer FNP (Family Nurse Partnership in the UK) to young vulnerable first time mothers in a wide range of localities. The key difference between the UK and the US is that FNP in the UK will act as a support system alongside the routine support for new mothers offered already by the National Health Service. Despite the NFPs success, an important limitation expressed by Olds and colleagues is that the mothers who would benefit most from home visits, i.e. those who are extremely disadvantaged, are the ones who are most resistant to them. This

pattern has also been found in the UK [50]. It has been suggested by the MTB Yale group that this is possibly due to the fact that it is these parents who are likely to be experiencing more mental health difficulties and, as such, a nurse based intervention, where interveners may not have the necessary mental health qualifications, may not be enough to tackle this problem.

Selma Fraiberg pioneered the use of home based infant-parent psychotherapy as a means of addressing mental health and relational difficulties in high-risk mothers and infants [51].Although there are many mental health–focused home visiting programmes, only two have been extensively researched. Lieberman and colleagues replicated Fraiberg's model, and demonstrated that intensive parent-infant psychotherapy after one year is effective at both ameliorating attachment insecurity and improving maternal outcomes [21]. Similarly, Heinicke and colleagues [52-54]demonstrated that interventions in which mothers received home visiting services by trained mental health professionals displayed improved mother-child interactions, infant attachment status and led parents to encourage more autonomous and task orientated behaviours from their children. This approach thus shows promise in improving outcomes across the domains of parent-infant relationships, maternal mental health, parenting and child development outcomes.

Minding the Baby: An Integrative Approach

As described above, existing programs have tended to focus either on the practical and coping aspects of parenting or upon the emotional health of the mother-child dyad and the quality of the attachment relationship. Minding the Baby aims to address both these elements of parenting.

The UK MTB clinical team includes a nurse or health visitor and a social worker or other suitably qualified practitioner who are both specially trained and supervised in specific skills and developmental approaches for working with young mothers. The former provides advanced levels of practical parenting support including individual and family health assessments, nutrition advice and family planning. The latter is trained in infant mental health, attachment, infant-parent psychotherapy, and parent treatment, provides a range of mental health related services to mother and baby including in-home evaluation and treatment for common maternal mental health problems (depression, anxiety, post-traumatic stress symptoms).The young mother's relationship with the MTB practitioners is critical to the success of the program. Their engaging and fostering on-going relationships with these at-risk first-time young mothers, as well as having the professional expertise that matches their complex health, social and mental health needs, helps diminish attrition from the programme. This kind of integrative model is critical to providing support for the child's and mother's overall development, and for the development of positive health, attachment and mental health outcomes in both mother and child (See figure 1).

Following the Yale model, the UK MTB program is guided by the following principles: 1) it is based on well-established developmental theories; 2) it is based on lessons learned from previous programs 3) it is embedded in systems of community health care; 4) it uses an interdisciplinary team approach; 5) it is a relationship-based model 6) it matches the intensity of home-based services with the level of complexity and need in at-risk families; and 7) it involves well-supervised clinicians.

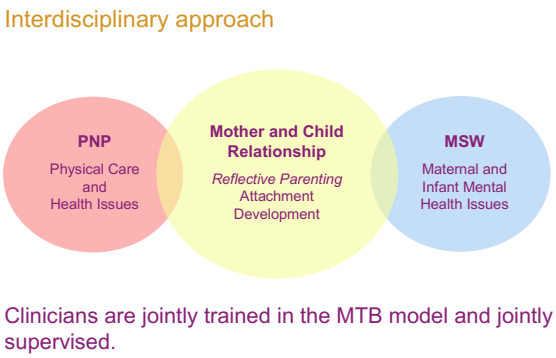


Figure 1

Yale Pilot Data

A pilot study by the Yale group consisting of 55 mothers in the intervention group compared to 35 in the control revealed some promising findings. Firstly, not only was there a retention rate of 90% in the intervention group but the mean number of home visits per family was 93 out of 108 over a 27 month course. Initial findings of parent-infant interactions were very encouraging with 76% of infants in the intervention group being classified as secure at the 12 months assessment. Interestingly, these dyads had previously being classified as having 'disrupted' relationships at the 4 month visit- a marker for later insecurity- however, it appears that participation in MTB seemed to override this trajectory. In addition, none of the intervention group mothers had experienced a second birth during the 24 month window whereas 17% of the control group mothers had given birth to a second child and, finally, 30% of the intervention mothers (vs. no control mothers) were still breastfeeding at the 6 and 12 month time points. Although these results are extremely encouraging, at the time of this pilot the control group attachment scores and reflective functioning (RF) scores were not available for comparison. Recent follow up data from this pilot study also revealed significant benefits of MTB relative to TAU in teacher-reported child externalizing behavioural problems at age 3-5 years[38].

C. Aims and Objectives

Aim 1: The primary aim of this study is to demonstrate that participation in the MTB programme can improve the quality of parenting and specifically the degree of maternal sensitivity.

Aim 2: The secondary aim of this study is to measure the effects of the MTB programme in relation to a) maternal outcomes variables including, maternal mental health, maternal reflective functioning (RF) and postponed subsequent child bearing; and b) infant outcome variables including verified accounts of child abuse and neglect, attachment security to the parent, cognitive and language development and behavioural problems.

Aim 3: A further key secondary aim is to assess the cost benefit/effectiveness of the MTB programme in order to sustain future programmes.

D. Methods

Design:

This is a multi- site randomised controlled trial, with randomization at the case level. This trial will utilize a two group experimental design, with random allocation to either an experimental or control condition. Allocation will be by minimisation, controlling for maternal age, maternal depression and study site. Minimisation will be necessary to limit the impact of factors that could influence treatment response. The independent variables are group (experimental intervention versus treatment as usual controls) and time (pregnancy/baseline, 1 year and 2 year). Dependent variables include a) *maternal variables* such as sensitivity, reflective functioning (RF) and competence; and b) infant variables including attachment status, cognitive/language development, maltreatment status and behavioural problems.

Proposed outcomes:

Primary outcome: The primary outcome is the quality of parenting operationalized as maternal sensitivity (Ainsworth et al., 1978).

Secondary outcomes: Key secondary outcomes will be attachment security, child cognitive/language development, behavioural problems, postponed childbearing, maternal mental health, and incidence rate of child maltreatment. A further key secondary endpoint measure will be the total service costs from post-randomization to 2 year outcome.

Study sites:

The trial will be conducted across three UK sites, Sheffield, York and Glasgow. The trial co-ordinator will be based in a central office in Leeds. The Trail Management Group (TMG) consisting of the PIs, collaborators and the trial coordinator will oversee all three sites.

Intervention sessions and all research assessments will be carried out in the participants' homes.

Sample size

A minimum of 120 participants (60 in each arm) will enter into the evaluation. The sample size calculation is motivated by the effect size estimates on the primary outcome (maternal sensitivity) and the attachment outcome at 1 year.

Power Analysis: We based our power analyses on previous interventions aimed at improving parenting sensitivity. The overall meta-analytic average for sensitivity-focused intervention trials in Bakermans-Kranenburg's (2003) review was d = .44. A sample size of 122 provides 80 to detect such an effect. Note that our original sample size projections aimed to obtain power on binary secure-versus insecure attachment as a secondary outcome, yielding a target sample size of 200. However, recruitment problems were encountered that made this target sample size unachievable. In November, 2015 the Trial Steering Committee agreed a revised target sample size of N = 120 based on the primary outcome analyses above. This adjusted target was agreed prior to any outcome measurements were collected.

Recruitment:

Recruitment will take place at three UK sites; York, Sheffield and Glasgow. Participants in York and Sheffield will be screened if they live within a defined geographical area around each site of approximately 15 miles of the city centre (the precise geographical boundaries will vary in each site). Due to the fact that the Family Nurse Partnership (FNP) is available to first-time parents at Sheffield and Glasgow the recruitment strategy will vary slightly across sites.

***Consent**:*

Overview: Formal consent into this study will be taken by a member of the UCL research team. Prior to this, consent to be contacted by the research team will be obtained by research midwives in antenatal clinics, by health, social care or voluntary sector professionals or provided by interested families directly.

Consenting procedures

Primary entry-point into the study: At all three sites potentially eligible expectant mothers will be informed about the Minding the Baby Study during an antenatal appointment in the hospital or in the community. During this appointment expectant mothers will be given a participant information sheet and a short leaflet and a research midwife or member of the antenatal care team will provide a brief explanation of the study. Potential participants will then be followed up by a research midwife, who will check eligibility, provide them with written information about the study again (Participant Information Sheet and a contact leaflet) and will verbally explain their involvement. This will usually be done in person at the 20-week scan appointment, but may also be done by telephone (with written material sent by post) or during another antenatal appointment. Potential participants will be encouraged to ask questions about the study and if necessary talk to others about it, before they provide their consent to be contacted by the research team. If requested, a member of the Minding the Baby clinical team can be made available to answer questions about the service. Note that in cases where research midwife cover is not sufficient to see all potential participants, a hospital-approved member of the study team may undertake the explanation of the study and obtain verbal consent to contact at this stage. If expectant mothers would like time to consider their participation or to discuss it with others before providing consent to be contacted, the research midwife or approved researcher will offer to call the potential participant by telephone after a few days. If expectant mothers are then happy to consent to be contacted by the research team, this will be obtained verbally, and formal written consent to participation in the study will be obtained by the research team during an initial home visit. In some cases, expectant mothers may be missed during the earlier antenatal appointment, in which case research midwives or an approved researcher will approach them for the first time at the 20-week scan, screen for eligibility, explain the study and obtain verbal consent to be contacted, as above.

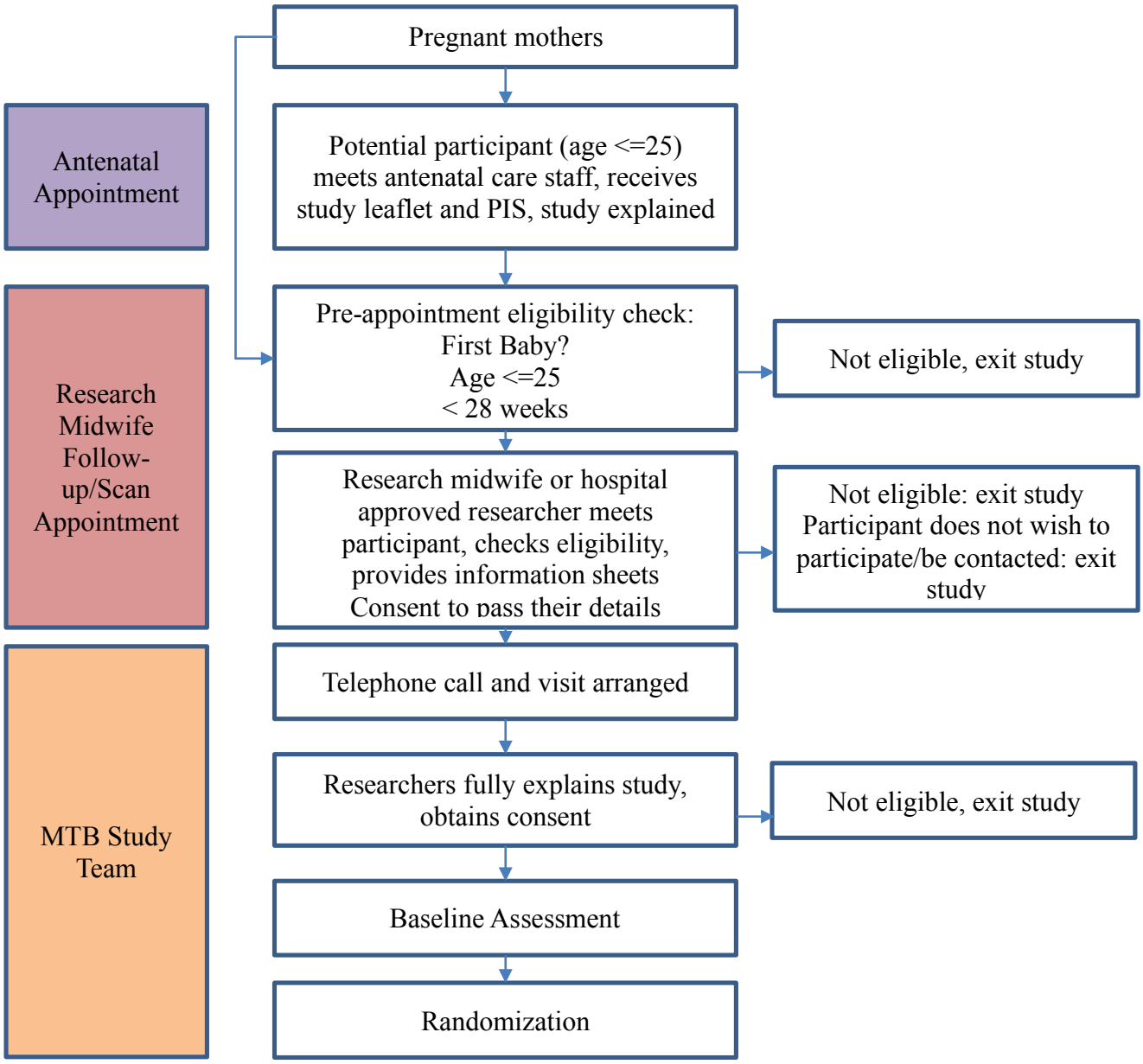
Once consent to be contacted has been obtained, a member of the research team will then contact the potential participant in order to make an appointment and visit them. At the visit the researcher will explain the research study in detail, answer any further questions they might have, and, if they are willing to take part, obtain their full written consent. As above, if requested, a member of the clinical team will be made available to answer any questions participants may have about the clinical service during this visit. At this research appointment baseline assessments will be carried out for all consenting participants. If participants require further time to consider their participation, the

researcher will arrange to call them after a few days, and arrange a further visit (for consenting and baseline assessment) if necessary.

Alternative entry-points into the study: At all three sites posters, 'Contact leaflets' and Patient Information Sheets will be placed in antenatal waiting rooms so that expectant parents can read about the study while they wait for their antenatal appointment. Families who are interested in taking part in the study may self-refer by filling in a contact leaflet and leaving it in a designated box which will be provided at the clinic. These forms will then be collected by the research midwives, and passed to the research team who will then get in touch to arrange a visit, following the same informed consent procedures described above. Similar contact leaflets and Participant Information Sheets will also be distributed to community midwives and other health, social care and voluntary-sector professionals (e.g., GPs, local authority housing officers, Shelter) in the area so that if they know of mothers meeting the eligibility criteria they can make them aware of the study. Such mothers would be directed to the research team's contact telephone number, or contact leaflets can be sent to the research team, who will then call the participant. Professionals working with families, having obtained verbal consent, may also contact the research team on behalf of the family. When speaking to potential participants, community referrers may request that a member of the clinical team be made available to answer any questions potential participants may have about the clinical programme. In the case of community midwifery, sites may decide either to request that community midwives notify the research midwives, who will speak to potential participants in order to provide further information, answer questions and obtain consent to contact (as described above in the primary entry point section), or they may choose to send contact forms directly to the research team for them to make contact (dependent on local circumstances). Once the research team has obtained confirmation of a participant's wish to be contacted, the research team would then arrange an initial visit, where the expectant mother would be informed about the study, given an opportunity to ask questions and consented in the standard way described above.

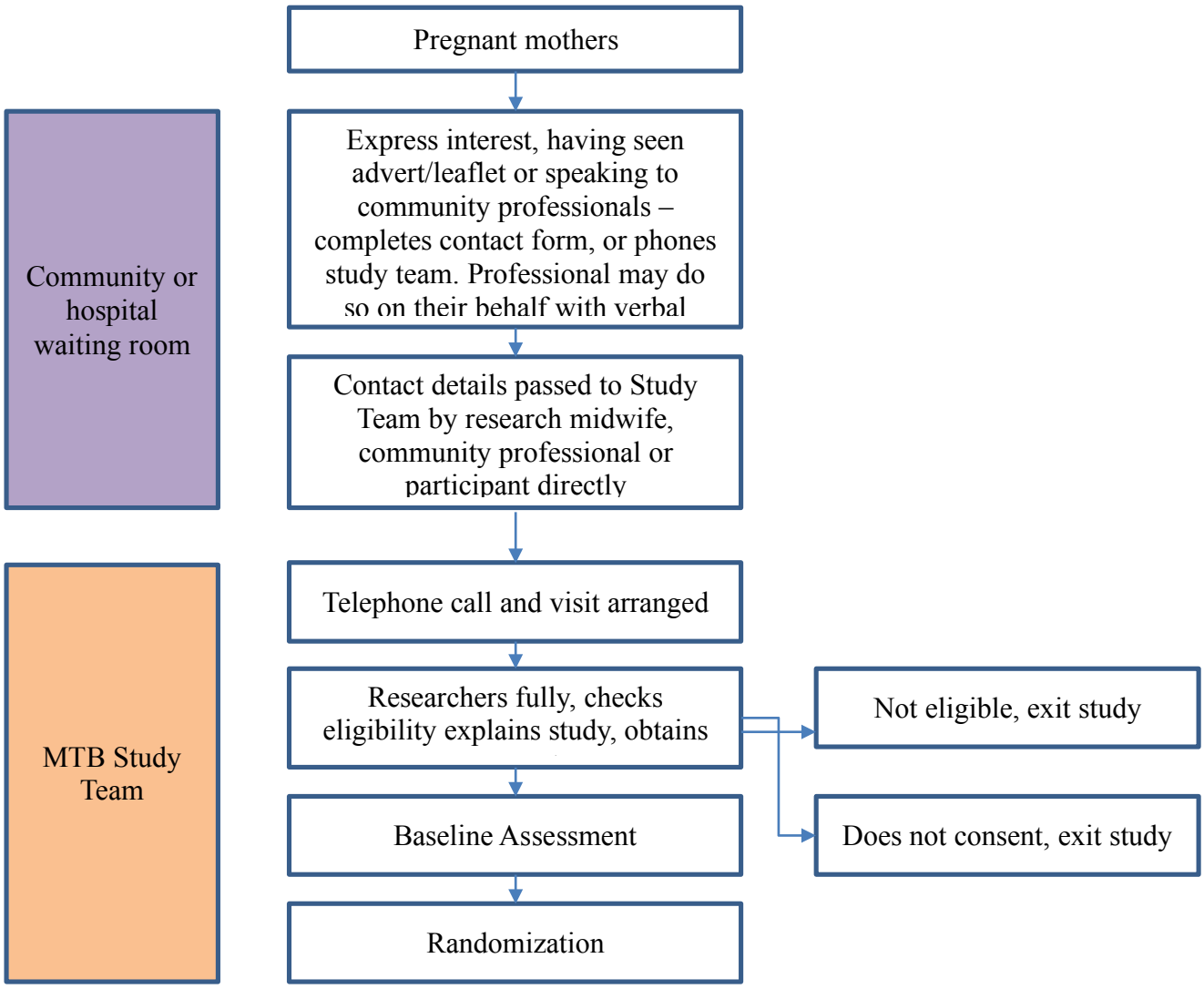
Sheffield and Glasgow Sites: FNP is being offered as a clinical service to all mothers under the age of 20 at the Sheffield and Glasgow sites. Both FNP and MTB have similar entry criteria and a similar set of intervention procedures and as such it will not be possible for parents to be involved in both programmes. As mentioned above, participants are recruited to the MTB trial at their 20 week scanning appointment. Both Sheffield and Glasgow FNP enroll parents into the programme up until 20 weeks gestation and as such, the MTB trial will not interfere with client accessibility to the FNP treatment. However, participants will be excluded if they are receiving services from FNP. This criterion is necessary to ensure the integrity of the Treatment as Usual arm of the trial. Participation in FNP will be recorded in the mother's notes, so that the research midwife is able to selectively recruit non-FNP participants.

Figure 2A: Recruitment flow-chart – primary entry point through antenatal clinics



Note: not all pathways into the study are shown, see section on consenting procedures

Figure 2B: Recruitment flow-chart – secondary entry point through community and/or self-referral



Eligibility criteria:

1. Inclusion:

- Women expecting their first baby AND
- Aged 19 or under OR aged between 20 to 25 and any of the following 1) currently eligible for means-tested benefits (or someone they live with and depend up such as a partner or parent, is eligible for means tested benefits), 2) not entitled to employer maternity pay, 3) living in a postcode falling within the highest quintile of social deprivation as defined by national government statistics or living in sheltered accommodation.

2. Exclusion

- Expectant mothers with a psychotic illness
- Expectant mothers with substance abuse disorders/ chronic drug dependence
- Expectant mothers with profound or severe learning disabilities
- Expectant mothers who would require the use of an interpreter
- Expectant parents with a life-threatening illness
- Expectant parents whose baby is expected to be born with a life threatening illness or profound disability
- The expectant mother has been screened for participation and accepted in a Family Nurse Partner Service (See Recruitment above)

  Note: we have defined the means tested benefit criterion as applying to either the woman herself or to a person living with her who she depends upon (e.g. a parent or partner).

Scope of consent to participation

Consent forms signed by the mother will include permission to access health and social care records, remaining in effect for three years (with the provision of course that families may withdraw this consent at any time). Ethical issues are discussed in greater depth below, but we note at this point that in addition to obtaining consent to access medical and social care records, the recruiter will be obliged to explicitly explain the limits of confidentiality in the event that a child protection concern arises. For those not consenting to participate, we will nevertheless endeavour to obtain anonymised summary data from primary care services to characterise these cases, as prior work by our group has found that these missing cases over-represent populations in most need [55]. For any families that drop out of the clinical project after randomization, we will endeavour to retain them in the research study in order to minimise bias. In addition, even families who drop out of the research study will be asked whether permission can remain to access their medical and social care records so that data on child health outcomes can nevertheless be obtained. Those who are allocated to the treatment arm and later decide to withdraw from the research will still be able to receive MTB treatment if they wish so.

Gillick Test

Working in partnership with those who have parental responsibility for participants who are under the age of 16 is an important consideration and will be pursued where possible, obtaining both

signatures of consent where a young parent is interested in participating. However, there are times when this may not be appropriate or goes against the wishes of the young parent in which case the Gillick principle will be applied.

There is no age laid down in the Gillick case when a minor becomes Gillick competent. The underlying principle of the law is that parental right yields to the child/young person's right to make his/her own decisions when s/he reaches a sufficient level of understanding to be capable of making up his/her mind on the matter requiring decision. Young parents would be considered eligible to participate without the knowledge of those who have parental responsibility for them if they understand the purpose and nature of the study and of the MTB programme and they cannot be persuaded to inform those who hold parental responsibility for them.

Randomization

Eligible consenting participants will be randomised on a 1:1 basis by Peter Fonagy and a research assistant in a separate site, who will manage randomization and act as DMEC (Data Management and Ethics Committee). Monitoring of data quality and integrity will be done separately by David Wellsted, study statistician. The DMEC will however have power to break confidential ID codes should ethical concerns arise. A computer-generated adaptive minimisation algorithm that incorporates a random element will be used with the following stratification factors: treatment centre, maternal age (<20 vs >=20) and current depressive symptomatology. These strata have been selected because previous research has shown that these factors are associated with poorer outcomes on some of our dependent measures or are highly plausible treatment modifiers. Minimisation should ensure that there will be an even distribution of family characteristics across the two arms of the trial. Once a family has been approach and consented to take part, anonymised screening data will be sent to the DMEC by the trial coordinator. The DMEC will send the results of the randomization to the local clinical manager within 72 hours, ensuring that the research team is fully blind to the condition that the family is allocated to. During training, all RAs will be briefed regarding the importance of blindness to condition, and RAs will record any instances where the participating family discloses condition inadvertently, so that the impact of this can be examined in the data analysis.

Planned intervention

Minding the Baby:

Minding the Baby is a home-visiting programme that helps vulnerable or high risk first time mothers aged 14-25. The programme has been developed by the Yale Child Study Centre and Yale School of Nursing, with the main focus being on the parent-child relationship. The MTB programme is delivered by an interdisciplinary MTB team of highly skilled practitioners, a nurse or health visitor experienced in parental, perinatal and paediatric roles and a social worker or other suitably trained practitioner trained in mental health assessment and intervention.

Mothers are visited weekly at home from the third trimester until the child's first birthday, and then fortnightly until their second birthday. The two MTB practitioners' visits are alternated weekly. Visits can be increased as required, particularly in times of crisis.

The health practitioner's role will focus primarily but not exclusively on the following:

Parental care and health education

- Reinforcement of good nutrition and foetal brain development
- Premature labour prevention
- Labour plan development
- Anticipation of new-born behaviour, needs, and ways of communicating
- Breast-feeding education/lactation support

Child health and development

- Assess child's development
- Promote health; diagnose and treat illness
- Education regarding environmental safety and injury prevention
- Anticipatory guidance and parenting skills

Mother's health

- Safe sex/family planning
- Assess and treat maternal physical and mental health in collaboration with primary care provider
- Smoking cessation, nutrition/exercise
- Stress reduction and on-going health concerns

The social/therapeutic role will focus primarily but not exclusively on the following:

Mental health promotion

- Assessment: gathering psychosocial history; exploring with mother feelings about her pregnancy, connection to unborn child, exploration of experience of being parented, and parental intentions
- Perinatal depression and anxiety: ruling out diagnostic criteria and on-going mental status examination
- Parent-infant psychotherapy: relationship-based; using video as a clinical strategy; learning to read baby's cues and develop responsive care-giving practices

Infant/Child and family assessment and intervention

- Dyadic play and developmental guidance: building play skills of baby and mother; guiding developmental expectations; supporting mother in developing her own intuitiveness
- Family intervention: couples' and family counselling
- Legal/court systems: care proceedings, contact disputes, child protection systems
- Crisis intervention
- Case management and supportive approaches: life skills, education/employment

Treatment as Usual (TAU):

The TAU will be carried out as it would normally be provided. This is a standard care package which will be determined by the needs of each family and the local service provision. The first line of services will be provided at primary care level by universally available professionals such as GPs, health visitors and midwives. For individuals who require more support after birth the help they can receive will vary depending on where they live and the severity of their needs. In general, TAU is often a package of support from family support workers, enhanced health visiting, social worker or

midwifery services (listening visits), one to one support from clinical psychologists (provided through local CAMHS services), psychotherapists or counsellors, postnatal support groups, crèches providing respite, parenting education workshops, peer-supported groups, home visiting services, child psychiatry and family therapy.

In two out of the three trial sites FNP is running as part of the standard NHS care package. Participants who are randomly allocated to TAU in the MTB trial at either of these sites will have already been identified as not being eligible to take part in FNP. This will either be because FNP are unable to take new referrals (due to a full caseload) or because the potential participant does not meet the FNP inclusion criteria. As such, the participant will receive the standard NHS care package, excluding FNP that is offered in their area.

Intervention Fidelity:

Adherence to the MTB intervention protocol will be achieved in the following ways:

1) All participant contact will be guided by the written intervention manual
2) All clinicians will be trained using the standardised Yale training materials
3) All MTB practitioners will record detailed information regarding their direct and indirect contact with families
4) Regular supervision will be provided by special trained supervisors and the Yale MTB team (in addition to supervision provided as usual by the practitioners' line managers).
5) Adherence will be checked on a random sample of 20% of families using video recordings of home visits.

Participant Adherence

Dropping out of treatment is common in prevention studies in the perinatal period [56]. In one of the key studies of the Nurse-Family Partnership programme, active refusals to participate in the trial ran at approximately 20% (with a further 20% passively dropping out by not responding to mailed invitations to participate), which is higher than the estimates from the Yale pilot study [57]. However, it is notable that a much smaller proportion refused to participate in the research evaluation once they had agreed to randomization (3.8%). From the outset of the FNP study to the 2-year outcome phase, a further 21% were lost to follow up. In the UK, the Family-Nurse Partnership programme had an initial uptake rate of 83% of eligible families, and a later drop-out rate of 15%. We aim for a rate of clinical enrolment that includes a 13 % and 20% drop out rate, to ensure a randomized sample of 140 cases. With a maximum further 15% attrition, we are left with a margin of error of approximately 10 cases in each arm to meet our minimum sample size target of 60 per arm at the year 2 outcome point.

Retention in the study, and particularly in the TAU group, is a key priority. Regular follow-up telephone calls and birthday and festival greeting cards, letters, and newsletters will be used in order to maintain good collaborative relationships with both arms of the study. Also, GPs, health visitors, and members of the antenatal care team will be contacted when necessary, so that family contact details are up to date.

Time requirement per participant:

		Study Period				
		Post Allocation				
TIMEPOINT	Pre-Baseline	Baseline	6 Month	Year 1	18 months	Year 2
RECRUITMENT:						
Eligibility screen	x					
Informed consent	X					
Allocation		X				
RESEARCH ASSESMENT:						
Questionnaires		X	x	x	x	x
Reflective Functioning				x		
Maternal sensitivity				x		x
Developmental Assessment						x
Attachment Security				x		x
Overall participant time involvement	15 mins	1hr	15 mins	2hrs	15 mins	2hrs

Research Measures:

Schedule for administering Research interviews and Instruments:

Subject	Variables	Pregnancy	6 Months	12 Months	18 Months	24 Months
Mother and Child	**Demographics**	**Demographic form**				
Mother and Child	**Quality of life**	**EQ-5D**		**EQ-5D, WCHMP**		**EQ-5D, WCHMP**
Mother	**Mental Health**	**EPDS,STAI, PCL-5**		**EPDS,STAI, PCL-5**		**EPDS,STAI, PCL-5**
Mother	**Support**	**NSSQ, SUS**	**SUS –by telephone**	**NSSQ, SUS**	**SUS – by telephone**	**NSSQ, SUS**
Mother	**Treatment Experience**			**TEQ**		**TEQ**
Mother	**Reflective Functioning**			**Parent Development Interview**		
Mother	**Maternal Competence**	**MSM**		**MSM, PSI**		**MSM PSI**
Child	**Abuse and Neglect**			**Health Records**		**Health Records**
Child	**Attachment Status**			**Q-Sort**		**Q-Sort**
Child	**Development**			**IBQ-R**		**Bayley Scales, CBCL**
Child	**Health**			**Health**		**Health**

	outcomes			**Record Review**		**Record Review**
Mother-child Dyad	**Quality of relationship**			**Sensitivity Scale**		**Sensitivity Scale**

Acronyms: EPDS – Edinburgh Postnatal Depression Scale; STAI – Spielberger State-Trait Anxiety questionnaire; SF-12 Quality of Life Questionnaire, Short-Form; NSSQ Norbeck Social Support Questionnaire; SUS Service Use and Support Questionnaire; TEQ – Treatment Experience Questionnaire; MSM – Maternal Sense of Mastery; PSI Parenting Stress Index; IBQ-R- Infant Behaviour Questionnaire Revised; CBCL- Child Behaviour Check List

Measures:

Parental sensitivity: In order to measure parenting sensitivity at ages 1 and 2, we will use several short tasks from our existing studies of attachment and another on-going clinical trial. The first task is derived from the influential NICHD Study of Early Child Care [58], which to date is the largest study ever to investigate the parenting antecedents of attachment security and insecurity. The task focuses on mother-infant interaction in the context of free-play. Known as the 'three-boxes procedure', the mother shows the child experimenter-provided toys in three containers in a set order, and the video-recorded interaction is coded along several dimensions, including the mother's positive regard of the child, intrusiveness and sensitivity. The scales have proved to be consistently predictive of a range of emotional and cognitive outcomes in later development [e.g. 59, 60]. The second is a procedure pioneered by Smith and Pederson [61]. In this task, mother and infant are left to explore a relatively empty room, while the mother must also complete a distracting questionnaire. The mother must therefore divide her attention between competing demands, which appears to strengthen the predictive validity of sensitivity assessments. Finally, we also propose to incorporate two short tasks that we are using in another clinical trial of postnatal depression, in which we are seeking to understand the specificity of effects of particular aspects of parental care for particular developmental outcomes. To do this, we deliberately arrange the assessment context to elicit domain-relevant parenting. For cognitive outcomes, we have used a specially designed task to elicit the parent's capacity to support the child's attention and regulation and to be actively and contingently involved in the child's interest and efforts to engage with cognitive tasks. The task involves brief observations, one focusing on book sharing and the other on a difficult to manipulate toy. For the behavioural problems domain, we have found that a challenging task in which the child is not permitted to touch a desirable toy to be a powerful way of eliciting variation in parents' capacities to sensitively set limits and manage negative affect in the child. Finally, we are using a separate joint book-reading observation in which the content of the book involves strong attachment related scenarios, and mothers are invited to talk to the baby about what is happening in the story. In addition to yielding data on mother-infant synchrony, itself a well validated predictor of attachment [27], this task also elicits rich variations in how parents manage attachment related emotions, and in particular, how the parent is able to communicate maternal RF within an intimate child-rearing interaction. In each case, maternal sensitivity will be rated, giving comparability with the Yale project, but the use of specific contexts for mother-infant interactions will also allow us to determine whether the intervention is changing the particular processes associated with each domain of child development. We believe these additional analyses could yield important data on treatment mechanisms.

Attachment Q- Set (AQS;[62]is based on a set period of observation of children aged 1 – 5 in the home environment. The AQS consists of a set of 90 cards with a specific behavioural characteristic described on each card that is age-appropriate. The cards are used as a standard vocabulary to describe the behaviour of a child in a home setting, with an emphasis on secure-base behaviour. The researcher who has observed the parent and child ranks the cards into several piles from ‘‘most descriptive of the subject’’ to ‘‘least descriptive of the subject.’’The Q-set provides a score along a continuum of secure to insecure. The Q-set has shown good convergent and discriminate validity [63] and is a strong predictor of later developmental outcomes [64].

Bayley Scales Infant Development, Second Edition [65] is an assessment-based measure that describes a child's (between the ages of 2 months and 42 months) mental and motor functioning and includes a behavior rating scale. The Scales require about 45 minutes and must be administered by a trained and experienced evaluator. The mother is present during the evaluation and may assist in the presentation of various items and activities to the child. The Bayley was standardized on a national sample of 1262 infants and children and correlates (r=.57) with the Stanford Binet reported for children aged 24-30 months. The split half reliability coefficients are reported as ranging from .81-.93 on the Mental Scale and .68 to .92 on the Motor Scale [65].

Child Behavioural Problems (CBCL; [66]) is a parent-report questionnaire and is valid for children from 18 months and older. It assesses internalizing (i.e., anxious, depressive, and over-controlled) and externalizing (i.e., aggressive, hyperactive, noncompliant, and under controlled) behaviours. The CBCL is one of the most widely-used standardized measures in child psychology for evaluating maladaptive behavioural and emotional problems [67].

Edinburgh Post-Natal Depression Scale (EPDS [68])is a ten item questionnaire screening for post-natal depression. EPDS is a well validated measure of depression [69]that may be used within 8 weeks postpartum but has also been applied for depression screening during pregnancy [70].

Infant Behaviour Questionnaire Revised (IBQ- R; [71]) is a parent- report questionnaire that ask parents to rate the frequency of specific temperament-related behaviour's observed over the past week (or sometimes 2 weeks). The IBQ-R assesses a range of dimensions including activity level, soothability, fear and approach behaviours. The IBQ has demonstrated good internal consistency reliability and convergent validity [72].

Infant Health Outcome indicators will be collected through a Record Review of the infant's paediatric health record. Variables will include birth outcomes, the number of routine paediatric visits attended, immunizations up to date or delayed, number of Accident & Emergency (A&E) room visits, number of A&E visits for injuries or ingestions, number of hospitalizations, any major or chronic health problem, number of Social Services referrals and number of times the infant has had an open Social Services case.

Maternal Sense of Mastery measured by the Pearlin and Schooler 7-item scale that asks participants to respond to the extent that they feel some control over their life's chances, as opposed to feeling ruled by fate [73]. Responses indicating agreement to disagreement are based on a 7-point scale. Higher scores indicate higher sense of mastery. This scale has been used widely with similar samples of young women [74]. Mastery scores were negatively correlated with depression scores and positively correlated with self-esteem scores [75].

Norbeck Social Support Questionnaire (NSSQ [76, 77]) measures multiple functional dimensions of social support: (a) affect, (b) affirmation, and (c) aid. Participants are instructed to list first names or initials for each significant person in their lives who provides personal support to them. Participants are asked to identify their relationship with the individual and finally use a 5-point rating scale to describe the amount of support available from each person. The NSSQ has shown to be a valid and reliable measure of all three functional types of social support as well as total network support [78]

Parent Development Interview - Revised (PDI;[79]) is a 20 question interview (Appendix B) that assesses parents' representations of their relationships with their child. The interview takes approximately 45 minutes to administer and parents are asked to describe their experience of the child, their relationship with the child, their own internal experience of parenting, and the child's reactions to normal separations, routine upsets, and parental unavailability. Many of the questions that directly explore the child's behaviour or feelings are followed with probes aimed at evaluating how the mother experiences and represents the dynamics of the relationship between herself and her child. Transcribed interviews are scored for RF. Initial studies testing the validity of this measure have linked it to adult attachment, child attachment, and parental behaviour both in normal and drug using samples [80-83], [24, 84].RF is scored on a scale of 1-9 with higher scores reflecting higher levels of RF.

Parenting Stress Inventory (PSI) Short Form[85] is a 36-item questionnaire that measures stress level experienced within the parenting role. Rated on a five-point scale, the measure contains three subscales pertaining to parenting stress. The Difficult Child (DC) subscale assesses the degree to which parents are bothered by behavioral characteristics of their children that make them difficult to manage. The Parent-Child Dysfunctional Interaction (P-CDI) subscale focuses on the degree to which parents are satisfied with their children's abilities to meet their expectations. The Parental Distress (PD) subscale determines the distress parents feel as a function of personal factors directly related to parenting. The PSI subscales have demonstrated concurrent validity with the full-length PSI [86]

PTSD Checklist-Civilian (PCL-5)[87] This is a 20-item PTSD screen that is closely based on the DSM-V criteria for PTSD. Participants rate each item from 0 (not at all) to 4 (extremely) to indicate the degree to which they have been bothered by the index symptom in the past month. The measure can be scored in two ways: participants can be evaluated in light of their overall score, which is highly correlated with a PTSD diagnosis, or individual variables that align with DSM criteria can be assessed. The PCL-C has shown good psychometric properties, high rates of internal consistency, test-retest reliability and is highly correlated with other measures of trauma symptoms [88].

Service Use and Supports Questionnaire (SUS) an inventory for collecting information about the services that mother and child have used over the previous 6-months.This will allow us to see what sort of input each family in the study has had from various professionals and voluntary agencies. Parents are also asked to note down the single most helpful service they have accessed over the previous six months. This questionnaire will be administered at baseline, 6-months (by telephone) 12-month assessment, 18-months (by telephone)and finally again at the 24 month assessment.

State-Trait Anxiety Inventory (STAI[89] is a 40 item questionnaire that uses a 4- point likert scale to address both state and trait anxiety. The construct and concurrent validity of the measure has been robustly demonstrated[89, 90].

Adult Quality of Life (QoL) – The EQ-5D is a health related questionnaire assessing the quality of life through five dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression). Each dimension is scored by choosing one of three responses. The responses recorded are based on levels of severity (no problems/some or moderate problems/extreme problems). The EQ- 5D is stated to be the preferred instrument for NICE [91].

Child Quality of Life (QoL) - Warwick Child Health and Morbidity Profile(WCHMP)[92]measure parent-reported health and morbidity in infancy and childhood in a ten item survey. The WCHMP has shown to be reliable and valid with low inter-observer variation. [92]

Additional Data Collection:
Father Involvement:

While this trial is primarily focused on outcomes associated with parent and child functioning, there is great value in also determining the impact the programme might have on fathers. Consequently, where possible we aim to collect selected outcome measurements from fathers. Recruitment of fathers will take place after mothers have consented to their involvement in the study. Once maternal consent has been obtained, the research team will contact mothers to ask if they are happy for the researchers to send the child's father an invitation to participate. If mothers agree verbally on the telephone, the research team will send an information sheet regarding fathers' potential involvement in the study by post prior to the baseline visit. A contact telephone number will be included in the information sheet so that the father can ask any questions they may have. The researcher will bring the father questionnaire set to the baseline visit, and leave the questionnaires and consent form for fathers to complete and return by stamped addressed envelope. If fathers are present on the day of the visit they will be able to complete the consent form and questionnaires in person. The same procedure will be followed at the first and second outcome assessments. The questionnaires given to the fathers are detailed below:

Father questionnaire set

Subject	Variables	Baseline	12 Months	24 Months
Father and Child	**Quality of life**	**EQ-5D**	**EQ-5D**	**EQ-5D**
Father	**Mental Health**	**EPDS,STAI, PCL-5**	**EPDS,STAI, PCL-5**	**EPDS,STAI, PCL-5**
Father	**Support**	**NSSQ**	**NSSQ**	**NSSQ**
Father	**Treatment Experience**		**TEQ**	**TEQ**
Father	**Paternal Competence**	**SM**	**SM, PSI**	**SM PSI**

Acronyms: EPDS – Edinburgh Postnatal Depression Scale; STAI – Spielberger State-Trait Anxiety questionnaire; SF-12 Quality of Life Questionnaire, Short-Form; NSSQ Norbeck Social Support Questionnaire; TEQ – Treatment Experience Questionnaire; MSM – Maternal Sense of Mastery; PSI Parenting Stress Index

E. Data Management:

Data collection:

The data will be collected by experienced research assistants who have been trained to work with high-risk populations. Necessary safe guarding policies will be in place to ensure the safety of the research assistant collecting the data. In particular, contact information of the assessment location will be left with another member of staff before leaving for the assessment. Regular contact with the RA will be maintained at the start and end of the assessment. In situations where an RA feels immediate danger RA's will be instructed to follow safe-guarding policies to call the police.

Regular supervision with the trial management team, coordinator and the Principal Investigators will ensure the reliability of data collection. Where necessary the RAs will be fully trained and certified in administering and coding research measures.

All coding will be supervised by the Principal Investigators. Where standardized coding measures are required the RAs will undertake full training courses and complete necessary reliability checks. The data will be coded by an RA who does not know the family and will be blind to the subject status (intervention or control). Inter-rater reliability will be established for all instruments.

Every week, questionnaire data collected the previous week will be coded, verified and double-entered directly into secure web databases. Audio interviews will be transcribed and video-taped material downloaded, any personal identifiable information will be removed and the data stored on a secure server ready for coding. To check the reliability of the process, 10% of the records will be randomly selected and will be reviewed, coded and entered independently by research assistants for calculation of inter-rater agreement rates. The databases will be compared and checked for errors before transferring to an SPSS (v. 21.0) file for analysis.

Data transfer:

In the study, all participant data as outlined previously in this protocol will be collected in accordance with the participant consent form and participant information sheet. All participant data will be appropriately sent to Dr. David Wellsted for statistical analysis, and UCL will act as the data controller of such data for the study. Professor Pasco Fearon will be responsible for the processing, storage and disposal of all participant data in accordance with all applicable legal and regulatory requirements, including the Data Protection Act 1998 and any amendments thereto.

Data will be stored on a secure server dedicated exclusively to this project that has encrypted access. Only the research team will have access to the data and to information identifying participants. Research data and personally identifying data will be stored in separate, web-accessible, secure databases. All research data will be stored in locked filing cabinets in each site. Consent forms will be stored separately from the research data in locked filing cabinets in each site. Risks to subject confidentiality will be minimized by adopting suitable data storage procedures in accordance with best practice guidelines and in accordance with the Data Protection Act. Subjects will be assigned ID numbers. The master ID list that links subject names with ID numbers will be kept on a highly secure password-protected server. All information concerning allocation to condition (TAU or MTB) will be held securely by the DMEC. Clinical records and other relevant clinical information regarding participants in the MTB arm will be held by the NSPCC, following their standard governance protocols.

Archiving
UCL and each participating site recognise that there is an obligation to archive study-related documents at the end of the study. The Chief Investigator confirms that he will archive the study master file at UCL for 20 years from the study end.

Data Analysis:

The primary outcome, maternal sensitivity, is an average of several ordinal scores, and is typically found to be approximately normally distributed. The primary analysis will be a regression analysis testing group differences in mean sensitivity, after adjustment for baseline characteristics. Clustering by therapist and site will be allowed for by computing robust standard errors (Roberts, 1999). Continuously distributed secondary outcomes will be treated in the same manner. Rates of child maltreatment will be described by a Kaplan-Meier graph and summarised by the proportions of children with file-verified abuse or neglect by 2 years. The primary analysis for this outcome will be Cox regression, adjusting for key baseline characteristics.

Where there are missing data, we will use multiple imputation methods which under reasonable assumptions yield less biased and more powerful estimates of parameters. In doing so, we will follow the procedures and guidance outlined by Stern and colleagues [93]. Mediational analyses of change mechanisms (e.g. age 12-months maternal sensitivity mediating treatment effects on age 2 attachment) will be tested using bootstrap methods described by MacKinnon and Dwyer [94] and Preacher and Hayes [95].

Additional Data Analysis:

Economic Evaluation:

We propose conducting a cost effectiveness analysis of Minding the Baby (MTB) relative to the control condition from a broad societal perspective. The aim of cost benefit and cost effectiveness analyses are to provide information to decision makers about whether the benefits derived from an intervention are worth its costs. Within health and social care there are limited resources available that can be allocated to interventions and hence it is up to decision makers, be they policy makers or commissioners, to decide how best to allocate resources to achieve the maximum beneficial outcomes for society. The key difference between a cost benefit analysis and a cost effectiveness analysis is that a cost benefit analysis compares the intervention to the control by converting all outcomes to monetary units so that the benefits of the intervention can be directly compared to the costs. When benefits exceed the costs the intervention is considered cost beneficial. Cost benefit analyses are not commonly used to evaluate health and social care interventions due to difficulties associated with providing a monetary valuation of the outcomes. It is our view that this is particularly true of MTB, as we are not aware of any studies that provide a direct valuation of mother-infant relationships, attachment or the prevention of abuse or neglect. Infant Quality of Life (QoL) also is difficult to attach a monetary value to. It would be possible to derive such values using methodology set out in the Treasury Green Book (HM Treasury 2012) and other reference sources [96] but we currently consider this outside of the remit of the study, although it is something we are willing to explore. Instead, we propose a number of cost effectiveness analyses which will provide an incremental cost per outcome gained of MTB compared to controls.

We have chosen a societal perspective to the analysis, rather than the perspective of a particular government department or commissioner because:

- The costs and benefits associated with improving mother-infant relationships and potentially reducing incidences of child abuse and neglect affect a number of government agencies and third sector organisations. The government departments that could be directly affected by MTB include Communities and Local Government, Department of Health and Department of Work and Pensions although other government departments may indirectly reap costs of benefits.

- A large proportion of the financial burden associated with outcomes linked to poor mother-infant relationships and attachment falls on the families [14] and hence we would explicitly like to include these costs and outcomes in our data collection and analysis.

Cost information: We propose two elements to the cost component of the cost effectiveness analysis:

1) Cost of MTB: this will include fixed costs associated with the resources required to run the service as well as variable costs associated with training, staffing and related consumables. We will calculate a bottom up costing of the service and calculate a weighted cost per case based on the caseload of each practitioner.

2) Costs of the use of other resources: we will use a self -completed Service User and Support (SUS) questionnaire to collect other health and social care and out of pocket costs for clients in the MTB and the control group. The retrospective self-completed questionnaire will provide information on resources accessed during the last 6 months. The SUS will be completed at enrolment, 6 months after the baby is born by telephone and at each outcome assessment (infant age 1 and 2). Resource use will be costed using Personal Social Services Unit (PSSRU) and national datasets wherever possible.

We will provide summary statistics of the costs for the MTB and control group as well as a comparison of the total cost per patient to society of MTB compared to controls for the duration of the study.

Incremental cost effectiveness ratio (ICER): The incremental cost effectiveness ratio (ICER) is the incremental cost of the intervention compared to the control group divided by the incremental gain in outcomes from the intervention compared to controls. If an intervention has a lower cost to society and better outcomes it is considered dominant and likely to be adopted by a decision maker if the evidence is satisfactory. If the intervention has higher cost to society but is associated with better outcomes the decision maker needs adequate information to determine if they are willing to pay the additional cost per outcome gained.

We propose calculating a number of ICERs for MTB compared to controls and propose using the following outcomes in the denominator of the ICER for different analyses:

- Maternal sensitivity

- Infant QoL using the Warwick Child Health and Morbidity Profile [15].

- Parental QoL using the SF-12, which is a brief questionnaire that measures functional health and well-being from the patient's point of view.SF-12 scores can be converted to preference based utility scores that can be used to calculate quality adjusted life years (QALYs) for use in cost effectiveness analyses using an algorithm developed by Brazier & Roberts [16].

- Mother-infant attachment

As the ICER does not easily allow for normal statistical tests we will use bootstrapping methods, replications of the statistic of interest by sampling with replacement from the original data, to calculate the confidence interval for the ICER. We will also use this data and the net-monetary benefit approach to calculate the probability that MTB is cost effective compared to the control group for a number of values of willingness to pay per gain in outcome or the cost effectiveness acceptability curve (CEAC) [97]. This provides more information to decision makers to help them decide if the outcomes achieved as a result of the intervention are worth the additional cost.

Lifetime Model: Poor parent-child relationships, child abuse and neglect can have long term negative impacts on children, their families and society. Poor parenting has repeatedly been identified as being associated with antisocial behaviour and severe behavioural problems [17, 18]. A long-term follow-up study of children with conduct disorder suggested that the cost of unresolved conduct disorders can exceed £1 million over an individual's lifetime [19]. There are obviously further costs and benefits to realise as a result of preventing each case of child abuse and neglect. The ICERs proposed above do not capture the full lifetime costs and outcomes that may be realised as a result of MTB. As part of the project, we would therefore like to investigate developing a decision analytical model that uses information available from the evaluation as well as published data sources to determine the cost-effectiveness of MTB over the lifetime of the children.

Data Monitoring:

Data Monitoring and Ethics Committee (DMEC)

An independent DMEC will be established to review the safety and ethics of the trial and will meet prior to the start of recruitment and annually thereafter. Detailed reports will be prepared by the statistician for the DMEC to monitor safety data, recruitment and drop-out rates. The formal statistical interim analysis of the primary outcome will be reported to the DMEC after the end of the first outcome phase.

Trial Steering Committee

A Trial Steering Committee will be used to monitor the progress of the project and advise the research team on matters arising during subsequent phases of the study. The TSC will meet 6-monthly and perhaps more regularly during the preparatory and final stages of the formal evaluation. The group will be made up of representatives from the NSPCC, researchers, a statistician, service users and /or carers, and representatives of professional/ provider organisations, including a link person from at least two local clinical teams. Service users and carers will be drawn from local groups and/or national organisations. In addition to supporting the design and management of the study, the TSC would also have the opportunity to comment upon and inform the final project report.

International Advisory Group

An International Advisory Group of experts in the field of attachment and prevention research will be used in this study. The group will consist of Professor Marinus van IJzendoorn and Professor Marian Bakermans-Kranenburg, from the University of Leiden and Professor Jude Cassidy from the University of Maryland in the USA, who are world-leaders in both these fields, and have exceptional experience in all aspects of controlled trials focused on early parent-child relationships. Collectively, the International Advisory Group will ensure that the study maximises its potential from the point of view of both science and practice, and will also create a valuable forum in which to promote the study's findings and consider future advancements of the project's aims. The group will participate in remote meetings via teleconference, having been sent detailed documentation in advance focusing on key issues identified by the investigators for discussion. Members of the Trial Steering Committee, and any other interested key stakeholders, would also be invited to attend these meetings, which we anticipate would take place twice-yearly.

Ethical Considerations:

This study will have multi-site ethics approval from the NHS REC. R&D approval will be in place at all three sites.

Safeguarding Policy:

A safeguarding protocol for the study will be drawn up, and the research teams will take all concerns about safeguarding to the attention of the Chief Investigator on the day that the concern arises. The CI will take responsibility in assessing the degree of risk to both the parent and child and make the necessary steps in ensuring their safety. The CI will consult with an independent safeguarding consultant before making a decision and will follow standard safeguarding policy, notifying local safeguarding boards where a child protection concern is deemed to be present. The NSPCC have their own safeguarding policies and as such, the Minding the Baby practitioners will follow their own procedures regarding concerns for the welfare of the parent and child. The DMEC will act as the bridge between the clinical and research teams and will be informed immediately of situations where the clinical or the research team would need to know about the safeguarding event. This will enable adequate timing to break confidential ID codes and inform the necessary member of staff. Training in safeguarding will be provided for the evaluating team (ideally found locally or otherwise provided by members of the Trial Management Team).

Serious Adverse Events:

Given the at-risk nature of the target population for this project there is a realistic prospect of child protection incidents. In the event of a death associated in any way with the trial, the independent Data Monitoring and Ethics Committee would consider the implications for continuation of the trial. In addition it is possible that families (or indeed coroners) may wish to speak to someone representing the research project about such deaths as well as to local clinical staff who have provided treatment. If required the Trial Management team would be available for such meetings.

In the event of trial termination the Trail Management team will be responsible for the interim data collected and will decide, after consultation with the trial steering group, how this data is analysed and disseminated.

Participant Consent:

Regarding consent to take part in the trial, all participants will be agreeing to the research team having access to their health and social care records. It is therefore of exceptional importance that parents fully understand the limits of access (by whom, for what purposes, for what period) and their rights to withdraw consent. As such, all staff involved in the consenting process will be carefully trained, and provided with a detailed protocol and checklist to ensure a full and consistent consent process. Similarly, it will be essential that families properly understand the relationship between the evaluating and clinical teams, and the high degree of independence between the two. All data provided to the evaluating team will be treated in the strictest confidence and of course will not be accessible in any way by the clinical team or any other party. However, families will need to understand clearly that the evaluating team has legal obligations to report to relevant authorities should it become significantly concerned about the safety of the parent, the child or others. Families will be carefully advised regarding the limits of confidentiality in both spoken and written information regarding the study

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