The NSPCC UK Minding the Baby® (MTB) home visiting programme, supporting young mothers (aged 14- 25) in the first two years of life: study protocol for a randomized controlled trial

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Abstract

Background: Young mothers living in low income urban settings often are exposed to significant and chronic environmental difficulties including poverty, social isolation and poor education and typically also have to cope with personal histories of abuse and depression. Minding the Baby® (MTB) is an interdisciplinary home visiting programme developed to support first time young mothers, which integrates primary care and mental health approaches into a single intensive intervention from the last trimester of pregnancy to the child's second birthday. The primary aim of the intervention is to promote caregiver sensitivity, and, secondarily, to promote both child and maternal socio-emotional outcomes

Methods/Design: This is a multi-site randomised controlled trial (RCT) with a target recruitment of 200 first time adolescent mothers (<26 years old). 100 participants will be randomised to the MTB group and they will receive the MTB programme in addition to the usual services available in their areas. Those participants not allocated to MTB will receive Treatment as Usual (TAU) only. Researchers will carry out blind assessments at Baseline (before the birth of the baby), and outcome assessments around the child's first and second birthdays. The primary outcome will be the quality of maternal sensitivity and the secondary outcomes will focus on attachment security, child cognitive/language development, behavioural problems, postponed childbearing, maternal mental health and incident of child protection interventions.

Discussion: This study evaluates the Minding the Baby® programme in the UK. In particular, this RCT explores the effectiveness of this integrative approach, which focuses on maternal mental issues as well as parent-infant interaction, parental concerns and developmental outcomes.

Trial registration: ISRCTN08678682 (date of registration 03/04/2014)

Keywords: Minding the Baby®, home-visiting programme, first-time mothers, attachment, reflective functioning

Background

Overview and Rationale: The NSPCC, in collaboration with University College London the University of Reading, the Yale Child Study Center and the Yale School of Nursing, is initiating a 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 is an interdisciplinary intervention that was developed and tested by a team of researchers and clinicians at the Yale Child Study Center and Yale School of Nursing [1]. MTB combines 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 scientific evidence regarding the developmental processes that promote optimal child outcomes. Currently, the UK health and social care systems offer a range of services to young families targeting mental health or promoting family relationships from birth, which are not always evidence-based and vary considerably from region to region. Home visiting programmes are characterised by the presence of consistent and reliable support figures with high quality training who are capable of addressing a broad range of parenting concerns from the practical to the emotional [2]. The highly influential Nurse Family Partnership model is a well-known example that has been found to be

effective for several important early child and maternal outcomes[3] . A notable limitation of existing home visitation programmes, however, is the relative lack of focus on supporting parent-child interaction and particularly attachment. This is a central target of MTB [4, 5]. Longitudinal outcome studies clearly show that 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 likely to be considerable [6]. The potential value of effective early intervention focused on sensitivity of care, particularly for parents experiencing multiple social adversities, 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 ability to mentalize 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

Although rates of teenage pregnancies have been dropping in the UK over the last 10 years, it remains the case that such pregnancies are greatly over-represented in low-income urban populations [7]. The many environmental stressors that these young parents face (poverty, single parenthood, social isolation and poor educational achievement [8]) are often amplified by personal histories of abuse, depression and post-traumatic stress (PTSD) [9, 10]. These parents may 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 young parents living in these circumstances are more susceptible to mental health problems and may

144 struggle to become responsive nurturing parents [11, 12]. Social disadvantage more
145 generally represents a broad but very reliable marker of a host of contextual,
146 psychological and developmental risk factors that have well-established negative
147 impacts on the quality of parenting and on child development [13-15]. The Minding the
148 Baby® (MTB) programme is aimed at supporting young parents facing multiple social
149 stressors, and raising their first infant in adverse social circumstances, in order to
150 promote positive parenting, raise rates of secure attachment, and improve child
151 developmental outcomes.
152

153 The MTB programme is the result of an interdisciplinary collaboration between Yale
154 School of Nursing and Yale Child Study Centre. MTB is an intensive and preventive home
155 visitation programme for young first time parents. MTB primarily evolved from two
156 home visiting models that originated in the US; the Nurse Family Partnership (NFP) and
157 the infant-parent psychotherapy model. David Olds and colleagues developed the Nurse
158 Family Partnership programme [3], which involves home visits by highly trained nurses
159 to vulnerable high-risk for time mothers. Home visits begin at the end of the second
160 trimester of pregnancy and continue through the child's second birthday. Extensive
161 research on the effectiveness of the NFP programme in high risk population showed
162 improved health, parenting and developmental outcomes [16-23, 2, 3]. A different
163 emphasise is on the infant-parent psychotherapy model which was developed to protect
164 infants and help parents with mental health problems, often as a result of on-going
165 trauma. Although this model has been less rigorously tested than the NFP programme,
166 positive child outcomes were found. In particular, this programme appears to supports
167 the development of healthy mother-child relationships and secure attachment [24], both
168 of which are prognostic indicators of longer-term positive developmental outcomes in
169 the child [25].

The MTB programme brings together both these models, providing a holistic intervention that not only addresses maternal mental health issues but also health, attachment and life course outcomes for mother, child and family. Thus MTB aims to bring together health, developmental, attachment and mental health approaches. 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 [5, 26]. MTB builds on this evidence and 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 [27] suggested that a mother's ability to respond sensitively to her child's cues would be crucial for the development of secure mother- infant attachment. Later research [28] 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 [29]. 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 [30].

A critical feature of the way in which parents think about their children is their ability to consider the child's thoughts, feelings 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 [31, 32]. This capacity has been termed by Fonagy and colleagues as 'mentalization' or 'reflective functioning' (RF) [33]. Slade and colleagues' research in this area has demonstrated consistent relationships between mother's ability to mentalize, maternal behaviour, and child attachment [34, 26, 31].

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, and feelings, and to respond in a sensitive and attuned way to the child's cues and communications.

Minding the Baby®: An Interdisciplinary Approach

The home visiting intervention programmes presented above have mostly focused on either the practical aspects of parenting or the quality of mother-child relationship and attachment. Minding the Baby® aims to address both these elements of parenting.

The UK MTB clinical team includes two qualified practitioners: a nurse or health visitor and a social worker who are both highly trained and supervised in particular techniques and developmental approaches tailored for working with vulnerable young mothers. The nurse provides advanced levels of practical parenting support including individual and family health assessments, nutrition advice and family planning. The social worker provides mental health support to mother and baby, in-home assessment and intervention for mild to moderate mental health problems like depression, anxiety and post-traumatic stress symptoms the mother might be affected by. Crucial to the success of the MTB programme is the mother's relationship with the MTB practitioners. Their engagement and fostering of 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, is aimed to diminish attrition from the programme. This kind of integrative model is considered to be crucial for maximising both parental and child outcomes across a range of domains.

Following the Yale model, the UK MTB is grounded in well-established developmental research, builds on the experience of similar successful programme, is a relationship-based model, delivers a flexible model of care design to match the varying and often complex needs of at-risk families, and has a robust, manualized system of training and supervision.

Aims and Objectives

Aim 1: The primary aim of this study is to test whether participation in the MTB programme leads to improvements in the quality of parenting and specifically the degree of maternal sensitivity.

Aim 2: The secondary aims of the study are to measure the effects of the MTB programme in relation to a) maternal outcomes including maternal mental health, maternal reflective functioning (RF) and postponed subsequent child bearing; and b) infant outcomes including incidents of child protection intervention, 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.

Methods

Design:

This is a multi-site randomised controlled trial, with randomization at the case level. This trial will utilize a two-arm design, with random allocation to either MTB plus treatment as usual or a Treatment as Usual only control condition. Allocation will be by minimisation, controlling for maternal age, maternal depression and study site. Figure 1 shows a flow chart of the study design, and the SPIRIT checklist is presented in Additional file 1 [35, 36].

Outcome measures:

Primary outcome: The primary outcome is the quality of parenting, operationalized as maternal sensitivity [27]. Maternal sensitivity will be measured at ages 1 and 2 and will be treated as a continuous score, with both time-points included in the primary analysis.

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 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 [37, 38] [39]. The second is a procedure pioneered by Smith and Pederson [38]. In this task, mother and infant are left to explore a relatively empty room, while the mother must also complete a distracting questionnaire. Another task involves brief observations, one focusing on book sharing and the other on a difficult to manipulate toy. Finally, we are using a separate joint book-reading observation in which the content of the book involves strong attachment related scenarios. In each case, maternal sensitivity will be rated, using NICHD Sensitivity Scales [40], an observation tool. The scales describe and assess four dimensions on the adult side (sensitivity, structuring, nonintrusiveness, and nonhostility) and two dimensions on the child side

(responsiveness and involvement with the caregiver). Dimensions are measured on a scale, with scores between 1 and 7. Scales will be standardized and summed to yield a total score across all tasks for the main analysis. 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 in tertiary analyses.

Secondary outcomes

Child attachment security, measured with the Attachment Q-Set (AQS: [41]), which will be administered at Year 2. The AQS 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[42] and is a strong predictor of later developmental outcomes [43].

Child cognitive and language development will be assessed at year 2 using the Bayley Scales of Infant and Toddler Development, third edition [44]. The Bayley-III is an assessment individually administered that evaluates the child's mental and motor development. The Scales are administered when children are between the ages of 2 months and 42 months. This yields two separate continuous scales representing overall Cognitive Development and Language Development. The Bayley-III is a standardized instrument and the Cognitive Scales and Language Composite correlate respectively (r=.79) and (r=.82) with the WPPSI-III Full Scale IQ, reported for children aged 28-42 months. Bayley-III is also UK validated [45] .

296 *Behavioural problems* will be assessed with the Child Behaviour Checklist (CBCL[46])
297 questionnaire, at Year 2. This consists in a 100 items parent-report questionnaire and is
298 valid for children from 18 months and older. CBCL measure yields three age-normed
299 scales of Internalizing Problems (i.e., anxious, depressive, and over-controlled),
300 Externalizing Problems (i.e., aggressive, hyperactive, noncompliant, and under
301 controlled) and Total Problems. Parents record responses with: 0 (Not true, as far as I
302 know), 1 (Somewhat or Sometimes true), or 2 (Very true or Often true). The analysis
303 will focus on the Total Problem scale. The CBCL is one of the most widely-used
304 standardized measures in child psychology for evaluating maladaptive behavioural and
305 emotional problems [47].
306 *Postponed child bearing* will be assessed at each follow up when mothers will be asked
307 about their pregnancy status. The number of months from baseline to the next
308 pregnancy will be used for analysis.
309 *Maternal mental health* will be measured with the Edinburgh Post-Natal Depression
310 (EPDS: [48]) questionnaire which will be administered at baseline, Year 1 and Year 2.
311 EPDS is a ten-item questionnaire screening for post-natal depression. Mothers'
312 responses are on a scale 0 to 3, and a score is calculated adding individual items. All 3
313 total scores from will be entered into the analysis, with change from baseline being the
314 outcome of interest. EPDS is a well validated measure of depression [49] that may be
315 used within 8 weeks postpartum but has also been applied for depression screening
316 during pregnancy [50].
317 *Child Quality of Life* will be assessed at Year 1 and Year 2 follow ups with the Warwick
318 Child Health and Morbidity Profile (WCHMP) questionnaire [51]. This consists in a 10-
319 item survey where parents are asked to report on health and morbidity in infancy and
320 childhood. The WCHMP has shown to be reliable and valid with low inter-observer
321 variation [51]. An incremental cost effectiveness ratio (ICER) will be calculated and the
322 two groups of mothers compared.

Health and social care resource use will be collected throughout the study using the Service Use and Supports Questionnaire (SUS) [52]. This is a self-report questionnaire administered at baseline and every subsequent follow up, i.e., 6 months, Year 1, 18 months, and Year 2. Mothers are asked to note whether they had any input from professionals and voluntary agency in the previous 6 months, in four areas: 1) health services, 2) mental health services, 3) support services and 4) childcare services. Parents are also asked to note down the single most helpful service they have accessed over the previous six months. Costs are applied to service use at each time point. Total costs per patient will be calculated from the total across all follow-up points and adjusted for by baseline values. Unit cots will be obtained from the Personal Social Services Unit (PSSRU) nationally published reference costs and published studies.

Additional outcome measures

Infant Behaviour Questionnaire Revised (IBQ- R; [53]) 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 the child's temperament on six dimensions including activity level, sooth ability, fear, smiling and approach behaviours. Parents rate the frequency of specific temperament related behaviours on a scale 1 to 7. The IBQ-R has demonstrated good internal consistency reliability and convergent validity[54]. The IBQ-R will be administered at the 1 and 2-year follow-ups.

Infant Health Outcome Data will be collected at the end of the study through a review of the infant/toddler's health records. Data will be collected on birth outcomes, routine hospital visits, completeness of immunizations, Accident & Emergency (A&E) visits, presence of chronic health problems, number of Social Services referrals. Unit costs will be applied to calculate the cost per infant.

Maternal Sense of Mastery is measured by the Pearlin and Schooler 7-item scale. Women are asked to measure the degree to which they perceive they can control their

life's chances [55]. Responses are based on a 7-item scale (agreement to disagreement), and higher scores reflect greater level of mastery. This scale has been used extensively with similar samples of young women [56]. It will be administered at baseline, 1 and 2-year follow ups.

Norbeck Social Support Questionnaire (NSSQ [57] [58] *m*easures 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 [59]. It will be administered at baseline, 1 and 2-year follow ups.

Parent Development Interview - Revised (PDI[60] is a 20 question interview that assesses parents' representations of their child, their relationships with them, and particularly their capacity to reflect on their child's mental states. Transcribed interviews are scored for Reflective Function. 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 [34, 30, 61, 4, 62] [4] [63]. RF is scored on a scale of 1-9 with higher scores indicating greater levels of RF. It will be administered at 1 and 2-year follow-ups.

Parenting Stress Inventory (PSI) Short Form[64] is a 36-item questionnaire that measures stress level experienced within the parenting role. Rated on a five-point scale (agreement to disagreement), the measure contains three subscales pertaining to parenting stress. The PSI short-form subscales have demonstrated concurrent validity with the full-length PSI[65]. The PSI-SF will be administered at baseline, 1 and 2 year follow-ups.

PTSD Checklist-Civilian (PCL-5) [66]. 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 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 [67]. It will be administered at baseline, 1 and 2-year follow-ups

State-Trait Anxiety Inventory (STAI) [68] 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 [69, 68]. It will be administered at baseline, 1 and 2-year follow-ups.

Adult Quality of Life (QoL) – The EuroQol EQ-5D 3 level (EQ-5D-3L) 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). Utility scores will be calculated for each mother at each time point based on the algorithm developed by Dolan [70]. Utility scores at each time point will be used to calculate total quality adjusted life years (QALYs) for the duration of the trial calculated as the area under the curve adjusting for baseline. It will be administered at baseline, 1 and 2-year follow-ups.

Treatment Experience Questionnaire (TEQ). This is a 15-item feedback questionnaire based on questionnaires used for similar studies (e.g., [71, 72]. This will be given to participants in the MTB arm of the trial only, to record satisfaction with the service they have received. Parents are asked to rate the treatment on a 5-point scale (disagreement to agreement).

Father outcome measures: Where possible we aim to collect selected outcome measurements from fathers at baseline, Year 1 and Year 2 follow ups. Some of the outcome measures used for the mothers will be used for the fathers: quality of life (i.e., EQ-5D); mental health (i.e., EPDS, STAI and PCL-5), support and personal network (i.e.,

NSSQ), and paternal competence (i.e., SM and PSI), and the Treatment Experience Questionnaire (TEQ) for fathers in the MTB group.

In Table 2 mother and child outcome measures are summarised and the time points of their administration reported.

Sample size

A minimum of 200 participants (100 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 which is equivalent to a correlation of r = .22. If we assume 4 covariates and a single df test of treatment effect, with a reduced model R-squared of .15 and a full model r-squared of .20, then 129 participants would be required for 80% power at alpha = .05. Bakermans-Kranenburg further reported that the meta-analytic average of randomized studies was d = .36 (r = .18), which for the equivalent analysis and power would require a sample size of 190. We also computed power to detect effects on attachment security. We estimated the effect size based on meta-analytic data, based on the assumption that the MTB intervention would be effective in enhancing parental sensitivity: such studies yield average effect sizes of d = .45 in the aforementioned meta-analysis [73] and hence the power for this outcome would be equivalent to that for sensitivity or greater.

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).

***Consent**:*

Overview: Formal consent into this study will be taken by a member of the 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. 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

During the research home visit the researcher will explain the study in detail, answer any further questions they might have, and, if they are willing to take part, obtain their full written consent. At this research appointment baseline assessments will be carried out for all consenting participants.

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. 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 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 will be 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.

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 upon 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 accepted in a Family Nurse Partnership Service (See Recruitment above)

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 [74]. 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 to.

Randomization

Eligible consenting participants will be randomised on a 1:1 basis by the randomisation centre (supervised by Peter Fonagy) at a separate site, who will manage randomization. Monitoring of data quality and integrity will be done separately by David Wellsted, study statistician. Together they will act as DMEC and will have power to break confidential ID codes should ethical concerns arise. A computer-generated adaptive minimisation algorithm [75] that incorporates a random element will be used with the following balancing factors: treatment centre, maternal age (<20 vs >=20) and current depressive symptomatology (<10 versus >=10 on the EPDS). These minimization factors 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. Once a family has been approach and consented to take part, anonymised screening data will be sent to the randomisation centre by the trial coordinator. The randomisation centre 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. Participants will be informed about their group allocation, as blinding to a psychosocial treatment of this nature is not possible. The outcome assessors will be blind to the participants' allocation. 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. Coding of the primary outcome will be done independently from videorecordings by raters who have no contact with the participants.

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

- Practitioners provide ongoing support and information about maternal and infant nutrition and healthy child growth and development, including foetal and postnatal brain development. Support is given regarding the prevention of premature birth, and planning for labour and delivery. Practitioners also help pregnant women begin to anticipate and imagine life with a newborn, what its needs might be, how one interacts and communicates with a young infant. Practical and educational support is given to women pre- and postnatally regarding breast feeding.

Child health and development

- The health practitioners undertake routine assessments of the child's physical, cognitive and social development, and provide advice and guidance about the child health, including advice regarding the identification and treatment of illnesses. Practitioners also provide information and advice about a safe environment for the child to reduce incidents of injury. Finally, practitioners provide anticipatory and ongoing guidance about parenting of young infants and toddlers.

Mother's health

- Practitioners are trained to help women think about safe sex and future family planning, provide support and information regarding healthy lifestyles, including smoking cessation support and healthy nutrition and exercise. Practitioners also assist mothers in obtaining support when they experience physical or mental health difficulties (e.g., via primary care), or have ongoing problems with stress.

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

Mental health promotion

- Practitioners in this role are trained in psychosocial assessment, and will gather a detailed: psychosocial history; explore the mother's feelings about her pregnancy, her connection to unborn child, her own history of being raised, and her expectations about the parenting role. Practitioners are trained to identify and provide intervention (through direct working or signposting to others services as appropriate) for mental health problems antenatally and postnatally,

and are able to provide focused mother-infant dyadic interaction guidance, drawing on principles from parent-infant psychotherapy, and using video feedback to help mothers to be attuned to the infant's attachment cues, and promote sensitive interactions.

Infant/Child and family assessment and intervention

- As part of the dyadic work, practitioners also guide mothers in dyadic play and provide developmental guidance, helping to broaden mothers' repertoire of skills, teaching about typical developmental milestones and facilitating mothers' creativity in parenting and self-efficacy. Where indicated, the social-therapeutic practitioner will provide couples' and family counselling, and help families manage the complexities of formal, statutory/legal systems such as housing, disputes around contact, or child protection intervention. The practitioners offer a broad range of support to help families manage crises, and provide assistance in supporting the women's acquiring of key life skills through education and employment.

Treatment as Usual (TAU):

TAU will be the standard care available in the local community, which will be determined by the needs of each family and the local service provision. The first line of services are 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 degree 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. The Service Users and Support (SUS) questionnaire will be used to check what usual care services both groups of participants receive during the trial.

Intervention Fidelity:

Adherence to the MTB intervention protocol will be achieved in close collaboration with the Yale team (including the primary developers) in the following ways:

1) All participant contact will be guided by the written intervention manual as well as other training materials.

2) All clinicians will receive extensive training in the MTB model via in person, taped, or videoconference training sessions led by the Yale MTB trainers. Yale MTB trainers include senior nurse and mental health supervisors and home visitors.

3) All MTB practitioners will record detailed information regarding their direct and indirect contact with families.

4) In order to ensure that home visits adhere to the Yale MTB intervention programme after each visit practitioners will complete a Home Visit Form. This aims to describe the visits in detail and compare them with the US MTB intervention home visits. In particular practitioners record the length, nature and focus of the visit and the families' level of engagement. It also summarises the focus of the visit, e.g., parenting, health, mental health etc., and the time spent on each topic.

5) Specially trained supervisors will undertake model fidelity monitoring by random sampling of families at each site and discussing the outcomes with the relevant sites at compliance visits.

6) All practitioners' regular supervision by Yale trained local UK supervisors. These specially trained supervisors meet monthly via phone with the Yale MTB trainers.

7) Regular disciplinary and interdisciplinary 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).

Participant Retention

Dropping out of treatment is common in prevention studies in the perinatal period [76]. 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 [23]. 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 thus aim to over-recruit by 15% to take attrition into account, leading to initial intake target of N = 240, so that 100 per arm is achieved at the year 2 outcome point. An overview of participant timeline is presented in Table 1.

Data Management

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 randomisation centre. Clinical records and other relevant clinical information regarding participants in the MTB arm will be held by the NSPCC, following their standard governance protocols.

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 at year 1, after

adjustment for baseline characteristics. Clustering by therapist and site will be allowed for by computing robust standard errors [77]. Continuously distributed secondary outcomes will be treated in the same manner. The risk of child protection intervention will be described using the Kaplan-Meier method and summarised by the proportions of children with child protection intervention over 2 years. The primary analysis for this outcome will be Cox regression, adjusting for key baseline characteristics.

Where there are missing data, we will be evaluated either by multiple imputation or a sensitivity analysis determined by the pattern of missing data. In doing so, we will follow the procedures and guidance outlined by Sterne and colleagues [78]. 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[79] and Preacher and Hayes[80].

Additional Data Analysis:

Economic Evaluation:

We will conduct a cost effectiveness analysis of Minding the Baby®(MTB) relative to the control condition from a broad societal perspective.

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 mean cost per mother/child in the intervention minus the mean cost per patient the control group divided by the mean incremental gain per mother/child 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[81, 20].

- Parental QoL using the EQ-5D, which is a brief questionnaire that measures generic health related quality of life from the patient's point of view. EQ – 5D 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 Dolan [70].

- 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)[19]. 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 [22, 23]. 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 [2]. 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 aim 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

The Trial Steering Committee will take the role of monitoring trial safety and data monitoring. The statistician will review the data on an on-going basis, including any adverse event records, and report this Trial Steering Committee (TST). Detailed reports will be prepared by the statistician for the TST to monitor safety/adverse event data, recruitment and drop-out rates. The formal statistical interim analysis of the primary outcome will be reported to the Trial Steering Committee 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.

Ethical Considerations:

This trial has received a multi-site ethics approval from the NHS Health Research Authority (NRES) Research Ethics Committee (London-Dulwich, the United Kingdom) (REC reference: 13/LO/1651; IRAS project ID: 135643; protocol version 6.0, 11/01/2016). R&D approval is in place at all three sites. A formal amendment is needed

for any modification of the protocol and requires approval by the NHS REC as well as the local R&D offices approval.

Discussion

The study protocol presented in this paper explains how Minding the Baby®, a programme aimed to support young vulnerable first-time parents with their baby, will be evaluated in a randomized trial in the UK. A key feature of this approach is the way in which it combines health input from community nurses with mental health input from social workers. Another key feature is the explicit focus on promoting sensitivity of parenting, and a model of change based on the assumption, supported by developmental research, that parental reflective functioning is critical in promoting sensitive and attuned interactions between mother and infant. The trial represents the first UK study of Minding the Baby®.

Minding the Baby® programme was developed at Yale University where a pilot trial produced encouraging results [1]. Positive outcomes emerged in relation to attachment as well as health and mental health outcomes. In particular, infants allocated to Minding the Baby group showed higher rates of secure attachment, and mothers showed improvements in maternal reflective functioning as well as positive health outcomes compared to the control group. Crucially, these outcomes appeared to be lasting as benefits continued to be observed when the children were seen at ages of 3 and 5.

We predict similar outcomes will emerge from this intervention in the UK. In particular mothers randomised to Minding the Baby group, compared to the mothers in the TAU group, are expected to show higher observed sensitivity as well as more secure attachment. Findings will be published in scientific journals, shared with stakeholders and will inform child and maternal health policy. The study will have important

implications for how the delivery of early intervention to families who are potentially at risk, especially during the crucial first months and years of life, from pregnancy to age 2.

Trial status

Recruiting of expectant mothers started in April 2014, and we are still recruiting.

List of abbreviations

MTB: Minding the Baby®; NSPCC: National Society for the Prevention of Cruelty to Children; RF: Reflective Functioning; PTSD: Post-Traumatic Stress Disorder; NFP: Nurse Family Partnership; DMEC: Data Management and Ethics Committee; CAMHS: Child and Adolescent mental Health Services; ICER: Incremental Cost Effectiveness Ratio; CEAC: Cost Effectiveness Acceptability Curve; NRES: National Research Ethics Services; EPDS: Edinburgh Postnatal Depression Scale; STAI: Spielberger State-Trait Anxiety questionnaire; EQ-5D – EuroQol EQ-5D 3 level ; 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.

Declarations

Ethical approval and Consent to participate

This study was approved by the NHS Health Research Authority (NRES) Research Ethics Committee (London-Dulwich, the United Kingdom) (REC reference: 13/LO/1651; IRAS project ID: 135643). The study was approved also at each site by the following R&D

offices: Learning and Research Centre, York Teaching Hospital NHS Foundation; Clinical Research Office, Sheffield Teaching Hospitals NHS Foundation Trust; Research and Development, West Glasgow Ambulatory Care Hospital. Informed written consent will be obtained from all participants.

Consent to Publish

Not Applicable

Availability of supporting data

Not Applicable

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Competing Interests

The authors declare that they have no competing interests.

Authors' contributions

EL participated in the study design, she is responsible for the set up, running and coordination of the trial, and prepared the manuscript. LM, RH, DW, SCT, KM, GR, RC and

PF participated in the study design and revised the manuscript. LM conceived the study and obtained the funding. RH contributed to the cost-effectiveness work. DW performed the statistical analysis. KM participated in recruitment and data collection. SCT participated in the set up of the study and preparation of the manuscript. GR and RC were responsible for managing the clinical delivery of the intervention, and the coordination of the research with the clinical teams. PF participated in the preparation of the manuscript. RMPF is the Principal investigator of the project, conceived and designed the trial, obtained the funding, and supervised the implementation of the study and prepared the manuscript. All authors read and approved the final manuscript.

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Figure Legends

1131 Figure 1. Flow diagram of the study design

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1133 Additional files

1134 Additional file 1: The SPIRIT checklist (DOC 126 KB)

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1136 Table 1

1137 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 Classification				X		X
Overall time involvement	15 mins	1hr	15 mins	2hrs	15 mins	2hrs

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1140 Table 2

1141 Outcome Measures: Description and validity of Measures as well as time points of their
1142 administration.

Outcome Measures	Description of and Validity of Measures	Time points
Primary Outcomes		
Maternal Sensitivity	Emotional Availability Scales (EA). Observation of behaviours. Score 6 dimensions on a 1 to 7 scale. Validated for international use [82]	Year 1 and Year 2
Secondary Outcomes		
Child Attachment security	Attachment Q-Set (Q-Set). Observation of behaviours. Score on a continuum of secure to insecure. Good convergent and discriminate validity [42]	Year 2
Child Cognitive and Language development	Bayley Scales of Infant and Toddler Development Scales, third edition (Bayley-III). Individual administration. Continuous Scales produce scores. Validated for UK and Ireland use [45]	Year 2
Behavioural problems	Child Behaviour Checklist (CBCL).100-item questionnaire. Responses are on a scale 0 to 2. Validated for international use [47]	Year 2
Postponed child bearing	Mother asked about her pregnancy status. Number of months from baseline to the next pregnancy used for analyses. Extensive use with similar studies (e.g. [1])	6 month, Year 1, 18 month and Year 2
Maternal mental health	Edinburgh Post-Natal Depression (EPDS).10-item questionnaire. Responses are on a scale 0 to 3. Validated measure of depression [49]	Baseline, Year 1 and Year 2
Child Quality of Life	Warwick Child Health and Morbidity Profile (WCHMP). 10-items survey. An incremental cost effectiveness ratio (ICER) calculated Validated with low inter-observer variation [51]	Year 1 and Year 2
Health and social care resource use	Service Use and Support (SUS). 36 item questionnaire. Cost of services calculated with Personal Social Services Unit (PSSRU). Extensive use in clinical studies (e.g., [83])	Baseline, 6 month, Year 1, 18 month, and Year 2

Additional outcome measures		
Measurement of temperament	Infant Behaviour Questionnaire Revised (IBQ-R). 37 item questionnaire. Responses are on a scale 1 to 7. Good internal consistency reliability and convergent validity [54]	Year 1
Sensitivity Scale	Maternal and paternal sense of mastery (MSM). 7-item questionnaire. Responses are on a 7=item scale (agreement to disagreement). Extensive use with similar sample of young women [55]	Baseline, Year 1 and Year 2
Social support	Norbeck Social Support questionnaire (NSSQ). 9-item questionnaire. Responses are on a scale 0 to 4. Validity and reliability on all measures [59]	Baseline, Year 1 and Year 2
Infant Health outcome	Health records reviewed at the end of the study and data collected on different issues, including hospitalisation and Social Services referrals. Extensive use with similar studies (e.g. [1])	Year 1 and Year 2
Parental representation of their child	Parent Development Interview (PDI). 20-item interview. Scores are on a scale 1 to 9. Validity shows links to adult attachment, and child attachment [34, 30, 61, 62]	Year 1
Stress within the parenting role	Parental Stress Inventory Short Form (PSI-SF). 36-item questionnaire. Responses are on a 5-point scale (agreement to disagreement). Short forms show concurrent validity with the full length PSI [65]	Year 1 and Year 2
PTSD Checklist Civilian	Post Traumatic Stress Disorder (PCL-5). 20-item questionnaire Responses are on a scale 0 to 4. PCL-5 has good psychometric properties [67]	Baseline, Year 1 and Year 2
State and trait anxiety	State-Trait Anxiety Inventory (STAI). 40-item questionnaire. Responses are on a 0 to 4 scale. Strong construct and concurrent validity [69, 68]	Baseline, Year 1 and Year 2
Adult Quality of Life (QoL)	EuroQol EQ-5D 3 level (EQ-5D) 6-item questionnaire. Responses are on 0 to 2 scale. Extensive use for similar study (e.g. [84, 85])	Baseline, Year 1 and Year 2
Treatment experience	Treatment Experience Questionnaire (TEQ). 15-item questionnaire. Responses are on a 5-point scale. Based on questionnaires used in similar studies [71]	Year 1 and Year 2

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