

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

Article

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

5

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46 **Abstract**

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

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

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

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

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

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90 **Background**

91 **Overview and Rationale:** The NSPCC, in collaboration with University College London
92 the University of Reading, the Yale Child Study Center and the Yale School of Nursing, is
93 initiating a multi-site study of the effectiveness of a targeted prevention programme that
94 incorporates well established principles of home visiting with a more comprehensive
95 package of care for the developing mother-infant relationship. The programme
96 represents an important opportunity to advance the UK's provision of evidence-based
97 support for at-risk families and to intervene effectively in the intergenerational cycle of
98 disadvantage. The Minding the Baby[®] (MTB) programme is an interdisciplinary
99 intervention that was developed and tested by a team of researchers and clinicians at
100 the Yale Child Study Center and Yale School of Nursing [1]. MTB combines many of the
101 benefits of home visiting programmes – particularly their relative cost-effectiveness,
102 client acceptability and accessibility – with a coherent, evidence-based clinical
103 dimension that is informed by, and directly targets, well studied mechanisms of risk in
104 early child development. In focusing on key domains of parent-child relationships where
105 disturbances are known risk factors for later child maladjustment, particularly the
106 sensitivity of parental care, the security of infant-parent attachment and the parent's
107 capacity to reflect on the child as an autonomous agent with needs, feelings and
108 thoughts, the programme aims to combine best clinical practice in early prevention with
109 scientific evidence regarding the developmental processes that promote optimal child
110 outcomes. Currently, the UK health and social care systems offer a range of services to
111 young families targeting mental health or promoting family relationships from birth,
112 which are not always evidence-based and vary considerably from region to region.
113 Home visiting programmes are characterised by the presence of consistent and reliable
114 support figures with high quality training who are capable of addressing a broad range
115 of parenting concerns from the practical to the emotional [2]. The highly influential
116 Nurse Family Partnership model is a well-known example that has been found to be

117 effective for several important early child and maternal outcomes[3] . A notable
118 limitation of existing home visitation programmes, however, is the relative lack of focus
119 on supporting parent-child interaction and particularly attachment. This is a central
120 target of MTB [4, 5]. Longitudinal outcome studies clearly show that disturbances in the
121 quality of care can have lasting negative consequences for children’s development, and
122 the long-term social and financial costs associated with these poor outcomes are likely
123 to be considerable [6]. The potential value of effective early intervention focused on
124 sensitivity of care, particularly for parents experiencing multiple social adversities,
125 therefore cannot be overstated.

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

133

134 **Background and significance**

135 Although rates of teenage pregnancies have been dropping in the UK over the last 10
136 years, it remains the case that such pregnancies are greatly over-represented in low-
137 income urban populations [7]. The many environmental stressors that these young
138 parents face (poverty, single parenthood, social isolation and poor educational
139 achievement [8]) are often amplified by personal histories of abuse, depression and
140 post-traumatic stress (PTSD) [9, 10]. These parents may find themselves not only having
141 to deal with their own developmental needs but also trying to take on the complex roles
142 and responsibilities of parenting. It is perhaps not surprising that young parents living
143 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](#)].

170 The MTB programme brings together both these models, providing a holistic
171 intervention that not only addresses maternal mental health issues but also health,
172 attachment and life course outcomes for mother, child and family. Thus MTB aims to
173 bring together health, developmental, attachment and mental health approaches. By
174 incorporating both nursing and mental health approaches, MTB serves to address some
175 of the more complex needs of mothers and families at risk.

176

177 **Attachment and Reflective Functioning:**

178 It is firmly established in the attachment field that the quality of the infant's attachment
179 to their primary caregiver is robustly related to a range of child outcomes [5, 26]. MTB
180 builds on this evidence and makes the promotion of secure attachment a primary
181 clinical objective as a means of bringing about positive changes in the infant's social,
182 emotional and cognitive development. Originally, Ainsworth and colleagues [27]
183 suggested that a mother's ability to respond sensitively to her child's cues would be
184 crucial for the development of secure mother- infant attachment. Later research [28]
185 empirically tested this hypothesis and found broad support for the role of sensitivity in
186 secure attachment. Furthermore, recent work has highlighted the role of the mother's
187 own mental state with respect to attachment – referred to as her internal working
188 model (IWM) of attachment, in shaping the sensitivity of care, and thus her child's
189 attachment security [29]. These attachment representations are thought to shape how a
190 parent perceives their child and, accordingly, how they respond to the child's behaviour,
191 cues and communications [30].

192 A critical feature of the way in which parents think about their children is their ability to
193 consider the child's thoughts, feelings and beliefs, and to treat the child therefore as an
194 individual with a mind. Crucially, research indicates that this ability not only to think of
195 the child as an individual with their own thoughts and feelings, but also to understand

196 and make a causal connection between the child's behaviours and their underlying
197 feelings and experiences, is crucial in the development of a secure attachment [31, 32].
198 This capacity has been termed by Fonagy and colleagues as 'mentalization' or 'reflective
199 functioning' (RF) [33]. Slade and colleagues' research in this area has demonstrated
200 consistent relationships between mother's ability to mentalize, maternal behaviour, and
201 child attachment [34, 26, 31].

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

206

207 **Minding the Baby®: An Interdisciplinary Approach**

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

211 The UK MTB clinical team includes two qualified practitioners: a nurse or health visitor
212 and a social worker who are both highly trained and supervised in particular techniques
213 and developmental approaches tailored for working with vulnerable young mothers.

214 The nurse provides advanced levels of practical parenting support including individual
215 and family health assessments, nutrition advice and family planning. The social worker
216 provides mental health support to mother and baby, in-home assessment and
217 intervention for mild to moderate mental health problems like depression, anxiety and
218 post-traumatic stress symptoms the mother might be affected by. Crucial to the success
219 of the MTB programme is the mother's relationship with the MTB practitioners. Their
220 engagement and fostering of on-going relationships with these at-risk first-time young

221 mothers, as well as having the professional expertise that matches their complex health,
222 social and mental health needs, is aimed to diminish attrition from the programme. This
223 kind of integrative model is considered to be crucial for maximising both parental and
224 child outcomes across a range of domains.

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

230

231 **Aims and Objectives**

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

235 Aim 2: The secondary aims of the study are to measure the effects of the MTB
236 programme in relation to a) maternal outcomes including maternal mental health,
237 maternal reflective functioning (RF) and postponed subsequent child bearing; and b)
238 infant outcomes including incidents of child protection intervention, attachment
239 security to the parent, cognitive and language development and behavioural problems.

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

242

243 **Methods**

244 **Design:**

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

251

252 **Outcome measures:**

253 *Primary outcome:* The primary outcome is the quality of parenting, operationalized as
254 maternal sensitivity [[27](#)]. Maternal sensitivity will be measured at ages 1 and 2 and will
255 be treated as a continuous score, with both time-points included in the primary analysis.
256 In order to measure parenting sensitivity at ages 1 and 2, we will use several short tasks
257 from our existing studies of attachment and another on-going clinical trial. The first task
258 focuses on mother-infant interaction in the context of free-play. Known as the ‘three-
259 boxes procedure’, the mother shows the child experimenter-provided toys in three
260 containers in a set order [[37](#), [38](#)] [[39](#)]. The second is a procedure pioneered by Smith
261 and Pederson [[38](#)]. In this task, mother and infant are left to explore a relatively empty
262 room, while the mother must also complete a distracting questionnaire. Another task
263 involves brief observations, one focusing on book sharing and the other on a difficult to
264 manipulate toy. Finally, we are using a separate joint book-reading observation in which
265 the content of the book involves strong attachment related scenarios. In each case,
266 maternal sensitivity will be rated, using NICHD Sensitivity Scales [[40](#)], an observation
267 tool. The scales describe and assess four dimensions on the adult side (sensitivity,
268 structuring, nonintrusiveness, and nonhostility) and two dimensions on the child side

269 (responsiveness and involvement with the caregiver). Dimensions are measured on a
270 scale, with scores between 1 and 7. Scales will be standardized and summed to yield a
271 total score across all tasks for the main analysis. The use of specific contexts for mother-
272 infant interactions will also allow us to determine whether the intervention is changing
273 the particular processes associated with each domain of child development in tertiary
274 analyses.

275 Secondary outcomes

276 *Child attachment security*, measured with the Attachment Q-Set (AQS: [41]), which will
277 be administered at Year 2. The AQS is based on a set period of observation of children
278 aged 1 – 5 in the home environment. The AQS consists of a set of 90 cards with a
279 specific behavioural characteristic described on each card that is age-appropriate. The
280 cards are used as a standard vocabulary to describe the behaviour of a child in a home
281 setting, with an emphasis on secure-base behaviour. The researcher who has observed
282 the parent and child ranks the cards into several piles from “most descriptive of the
283 subject” to “least descriptive of the subject.” The Q-set provides a score along a
284 continuum of secure to insecure. The Q-set has shown good convergent and
285 discriminate validity [42] and is a strong predictor of later developmental outcomes
286 [43].

287 *Child cognitive and language development* will be assessed at year 2 using the Bayley
288 Scales of Infant and Toddler Development, third edition [44]. The Bayley-III is an
289 assessment individually administered that evaluates the child’s mental and motor
290 development. The Scales are administered when children are between the ages of 2
291 months and 42 months. This yields two separate continuous scales representing overall
292 Cognitive Development and Language Development. The Bayley-III is a standardized
293 instrument and the Cognitive Scales and Language Composite correlate respectively
294 ($r=.79$) and ($r=.82$) with the WPPSI-III Full Scale IQ, reported for children aged 28-42
295 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.

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

334 *Additional outcome measures*

335 *Infant Behaviour Questionnaire Revised (IBQ- R; [53])* is a parent- report questionnaire
336 that ask parents to rate the frequency of specific temperament-related behaviour's
337 observed over the past week (or sometimes 2 weeks). The IBQ-R assesses the child's
338 temperament on six dimensions including activity level, sooth ability, fear, smiling and
339 approach behaviours. Parents rate the frequency of specific temperament related
340 behaviours on a scale 1 to 7. The IBQ-R has demonstrated good internal consistency
341 reliability and convergent validity[54]. The IBQ-R will be administered at the 1 and 2-
342 year follow-ups.

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

348 *Maternal Sense of Mastery* is measured by the Pearlin and Schooler 7-item scale.

349 Women are asked to measure the degree to which they perceive they can control their

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

354 *Norbeck Social Support Questionnaire (NSSQ)* [57] [58] measures multiple functional
355 dimensions of social support: (a) affect, (b) affirmation, and (c) aid. Participants are
356 instructed to list first names or initials for each significant person in their lives who
357 provides personal support to them. Participants are asked to identify their relationship
358 with the individual and finally use a 5-point rating scale to describe the amount of
359 support available from each person. The NSSQ has shown to be a valid and reliable
360 measure of all three functional types of social support as well as total network support
361 [59]. It will be administered at baseline, 1 and 2-year follow ups.

362 *Parent Development Interview - Revised (PDI)*[60] is a 20 question interview that assesses
363 parents' representations of their child, their relationships with them, and particularly
364 their capacity to reflect on their child's mental states. Transcribed interviews are scored
365 for Reflective Function. Initial studies testing the validity of this measure have linked it
366 to adult attachment, child attachment, and parental behaviour both in normal and drug
367 using samples [34, 30, 61, 4, 62] [4] [63]. RF is scored on a scale of 1-9 with higher
368 scores indicating greater levels of RF. It will be administered at 1 and 2-year follow-ups.

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

375 *PTSD Checklist-Civilian (PCL-5)* [66]. This is a 20-item PTSD screen that is closely based
376 on the DSM-V criteria for PTSD. Participants rate each item from 0 (not at all) to 4

377 (extremely) to indicate the degree to which they have been bothered by the index
378 symptom in the past month. The PCL-C has shown good psychometric properties, high
379 rates of internal consistency, test-retest reliability and is highly correlated with other
380 measures of trauma symptoms [67]. It will be administered at baseline, 1 and 2-year
381 follow-ups

382 *State-Trait Anxiety Inventory (STAI)* [68] is a 40 item questionnaire that uses a 4- point
383 Likert scale to address both state and trait anxiety. The construct and concurrent
384 validity of the measure has been robustly demonstrated [69, 68]. It will be administered
385 at baseline, 1 and 2-year follow-ups.

386 *Adult Quality of Life (QoL)* – The EuroQol EQ-5D 3 level (EQ-5D-3L) is a health related
387 questionnaire assessing the quality of life through five dimensions (mobility, self-care,
388 usual activities, pain/discomfort, anxiety/depression). Each dimension is scored by
389 choosing one of three responses. The responses recorded are based on levels of severity
390 (no problems/some or moderate problems/extreme problems). Utility scores will be
391 calculated for each mother at each time point based on the algorithm developed by
392 Dolan [70]. Utility scores at each time point will be used to calculate total quality
393 adjusted life years (QALYs) for the duration of the trial calculated as the area under the
394 curve adjusting for baseline. It will be administered at baseline, 1 and 2-year follow-ups.

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

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

404 NSSQ), and paternal competence (i.e., SM and PSI), and the Treatment Experience
405 Questionnaire (TEQ) for fathers in the MTB group.
406 In Table 2 mother and child outcome measures are summarised and the time points of
407 their administration reported.

408

409 **Sample size**

410 A minimum of 200 participants (100 in each arm) will enter into the evaluation. The
411 sample size calculation is motivated by the effect size estimates on the primary outcome
412 (maternal sensitivity) and the attachment outcome at 1 year.

413 *Power Analysis:* We based our power analyses on previous interventions aimed at
414 improving parenting sensitivity. The overall meta-analytic average for sensitivity-
415 focused intervention trials in Bakermans-Kranenburg's (2003) review was $d = .44$ which
416 is equivalent to a correlation of $r = .22$. If we assume 4 covariates and a single df test of
417 treatment effect, with a reduced model R-squared of .15 and a full model r-squared of
418 .20, then 129 participants would be required for 80% power at $\alpha = .05$. Bakermans-
419 Kranenburg further reported that the meta-analytic average of randomized studies was
420 $d = .36$ ($r = .18$), which for the equivalent analysis and power would require a sample
421 size of 190. We also computed power to detect effects on attachment security. We
422 estimated the effect size based on meta-analytic data, based on the assumption that the
423 MTB intervention would be effective in enhancing parental sensitivity: such studies
424 yield average effect sizes of $d = .45$ in the aforementioned meta-analysis [73] and hence
425 the power for this outcome would be equivalent to that for sensitivity or greater.

426

427 **Recruitment:**

428 Recruitment will take place at three UK sites; York, Sheffield and Glasgow. Participants
429 in York and Sheffield will be screened if they live within a defined geographical area
430 around each site of approximately 15 miles of the city centre (the precise geographical
431 boundaries will vary in each site).

432

433 ***Consent:***

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

438

439 *Consenting procedures*

440 **Primary entry-point into the study:** At all three sites potentially eligible expectant
441 mothers will be informed about the Minding the Baby Study during an antenatal
442 appointment in the hospital or in the community. During this appointment expectant
443 mothers will be given a participant information sheet and a short leaflet and a research
444 midwife or member of the antenatal care team will provide a brief explanation of the
445 study. Potential participants will then be followed up by a research midwife, who will
446 check eligibility, provide them with written information about the study again
447 (Participant Information Sheet and a contact leaflet) and will verbally explain their
448 involvement. This will usually be done in person at the 20-week scan appointment, but
449 may also be done by telephone (with written material sent by post) or during another
450 antenatal appointment. If expectant mothers are then happy to consent to be contacted
451 by the research team, this will be obtained verbally, and formal written consent to

452 participation in the study will be obtained by the research team during an initial home
453 visit

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

458

459 **Alternative entry-points into the study:** At all three sites, posters, 'Contact leaflets'
460 and Patient Information Sheets will be placed in antenatal waiting rooms so that
461 expectant parents can read about the study while they wait for their antenatal
462 appointment. Families who are interested in taking part in the study may self-refer by
463 filling in a contact leaflet and leaving it in a designated box which will be provided at the
464 clinic. These forms will then be collected by the research midwives, and passed to the
465 research team who will then get in touch to arrange a visit, following the same informed
466 consent procedures described above. Similar contact leaflets and Participant
467 Information Sheets will also be distributed to community midwives and other health,
468 social care and voluntary-sector professionals (e.g., GPs, local authority housing officers,
469 Shelter) in the area so that if they know of mothers meeting the eligibility criteria they
470 can make them aware of the study. Such mothers would be directed to the research
471 team's contact telephone number, or contact leaflets can be sent to the research team,
472 who will then call the participant. Professionals working with families, having obtained
473 verbal consent, may also contact the research team on behalf of the family. Once the
474 research team has obtained confirmation of a participant's wish to be contacted, the
475 research team would then arrange an initial visit, where the expectant mother would be
476 informed about the study, given an opportunity to ask questions and consented in the
477 standard way described above.

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

489

490 **Eligibility criteria:**

491 1. Inclusion:

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

499

500 2. Exclusion

- 501 • Expectant mothers with a psychotic illness

- 502 • Expectant mothers with substance abuse disorders/ chronic drug
- 503 dependence
- 504 • Expectant mothers with profound or severe learning disabilities
- 505 • Expectant mothers who would require the use of an interpreter
- 506 • Expectant parents with a life-threatening illness
- 507 • Expectant parents whose baby is expected to be born with a life
- 508 threatening illness or profound disability
- 509 • The expectant mother has been accepted in a Family Nurse Partnership
- 510 Service (See Recruitment above)

511

512 **Scope of consent to participation**

513 Consent forms signed by the mother will include permission to access health and social
514 care records, remaining in effect for three years (with the provision of course that
515 families may withdraw this consent at any time). Ethical issues are discussed in greater
516 depth below, but we note at this point that in addition to obtaining consent to access
517 medical and social care records, the recruiter will be obliged to explicitly explain the
518 limits of confidentiality in the event that a child protection concern arises. For those not
519 consenting to participate, we will nevertheless endeavour to obtain anonymised
520 summary data from primary care services to characterise these cases, as prior work by
521 our group has found that these missing cases over-represent populations in most need
522 [\[74\]](#). For any families that drop out of the clinical project after randomization, we will
523 endeavour to retain them in the research study in order to minimise bias. In addition,
524 even families who drop out of the research study will be asked whether permission can
525 remain to access their medical and social care records so that data on child health
526 outcomes can nevertheless be obtained. Those who are allocated to the treatment arm

527 and later decide to withdraw from the research will still be able to receive MTB
528 treatment if they wish to.

529

530 **Randomization**

531 Eligible consenting participants will be randomised on a 1:1 basis by the randomisation
532 centre (supervised by Peter Fonagy) at a separate site, who will manage randomization.

533 Monitoring of data quality and integrity will be done separately by David Wellsted,

534 study statistician. Together they will act as DMEC and will have power to break

535 confidential ID codes should ethical concerns arise. A computer-generated adaptive

536 minimisation algorithm [75] that incorporates a random element will be used with the

537 following balancing factors: treatment centre, maternal age (<20 vs >=20) and current

538 depressive symptomatology (<10 versus >=10 on the EPDS). These minimization

539 factors have been selected because previous research has shown that these factors are

540 associated with poorer outcomes on some of our dependent measures or are highly

541 plausible treatment modifiers. Once a family has been approach and consented to take

542 part, anonymised screening data will be sent to the randomisation centre by the trial

543 coordinator. The randomisation centre will send the results of the randomization to the

544 local clinical manager within 72 hours, ensuring that the research team is fully blind to

545 the condition that the family is allocated to. Participants will be informed about their

546 group allocation, as blinding to a psychosocial treatment of this nature is not possible.

547 The outcome assessors will be blind to the participants' allocation. During training, all

548 RAs will be briefed regarding the importance of blindness to condition, and RAs will

549 record any instances where the participating family discloses condition inadvertently,

550 so that the impact of this can be examined in the data analysis. Coding of the primary

551 outcome will be done independently from videorecordings by raters who have no

552 contact with the participants.

553

554 **Planned intervention**

555 *Minding the Baby*[®]:

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

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

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

568

569 Parental care and health education

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

578

579 Child health and development

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

587

588 Mother's health

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

595

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

597 Mental health promotion

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

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

608

609 Infant/Child and family assessment and intervention

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

620

621 *Treatment as Usual (TAU):*

622 TAU will be the standard care available in the local community, which will be
623 determined by the needs of each family and the local service provision. The first line of
624 services are provided at primary care level by universally available professionals such
625 as GPs, health visitors and midwives. For individuals who require more support after
626 birth the help they can receive will vary depending on where they live and the degree of
627 their needs. In general, TAU is often a package of support from family support workers,
628 enhanced health visiting, social worker or midwifery services (listening visits), one to
629 one support from clinical psychologists (provided through local CAMHS services),

630 psychotherapists or counsellors, postnatal support groups, crèches providing respite,
631 parenting education workshops, peer-supported groups, home visiting services, child
632 psychiatry and family therapy. The Service Users and Support (SUS) questionnaire will
633 be used to check what usual care services both groups of participants receive during the
634 trial.

635

636 **Intervention Fidelity:**

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

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

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

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

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

- 654 5) Specially trained supervisors will undertake model fidelity monitoring
655 by random sampling of families at each site and discussing the outcomes with
656 the relevant sites at compliance visits.
- 657 6) All practitioners' regular supervision by Yale trained local UK
658 supervisors. These specially trained supervisors meet monthly via phone with
659 the Yale MTB trainers.
- 660 7) Regular disciplinary and interdisciplinary supervision will be provided
661 by special trained supervisors and the Yale MTB team (in addition to supervision
662 provided as usual by the practitioners' line managers).

663

664 **Participant Retention**

665 Dropping out of treatment is common in prevention studies in the perinatal period [76].
666 In one of the key studies of the Nurse-Family Partnership programme, active refusals to
667 participate in the trial ran at approximately 20% (with a further 20% passively
668 dropping out by not responding to mailed invitations to participate), which is higher
669 than the estimates from the Yale pilot study [23]. However, it is notable that a much
670 smaller proportion refused to participate in the research evaluation once they had
671 agreed to randomization (3.8%). From the outset of the FNP study to the 2-year
672 outcome phase, a further 21% were lost to follow up. In the UK, the Family-Nurse
673 Partnership programme had an initial uptake rate of 83% of eligible families, and a later
674 drop-out rate of 15%. We thus aim to over-recruit by 15% to take attrition into account,
675 leading to initial intake target of N = 240, so that 100 per arm is achieved at the year 2
676 outcome point. An overview of participant timeline is presented in Table 1.

677

678 **Data Management**

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

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

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

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

702

703 **Data transfer:**

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

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

724

725 **Data Analysis:**

726 The primary outcome, maternal sensitivity, is an average of several ordinal scores, and
727 is typically found to be approximately normally distributed. **The primary analysis will be**
728 **a regression analysis testing group differences in mean sensitivity at year 1, after**

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

735 Where there are missing data, we will be evaluated either by multiple imputation or a
736 sensitivity analysis determined by the pattern of missing data. In doing so, we will
737 follow the procedures and guidance outlined by Sterne and colleagues [78].
738 Mediation analyses of change mechanisms (e.g. age 12-months maternal sensitivity
739 mediating treatment effects on age 2 attachment) will be tested using bootstrap
740 methods described by MacKinnon and Dwyer[79] and Preacher and Hayes[80].

741

742 **Additional Data Analysis:**

743 *Economic Evaluation:*

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

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

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

752 2) Costs of the use of other resources: we will use a self-completed Service User
753 and Support (SUS) questionnaire to collect other health and social care and out of
754 pocket costs for clients in the MTB and the control group. The retrospective self-
755 completed questionnaire will provide information on resources accessed during the last
756 6 months. The SUS will be completed at enrolment, 6 months after the baby is born by
757 telephone and at each outcome assessment (infant age 1 and 2). Resource use will be
758 costed using Personal Social Services Unit (PSSRU) and national datasets wherever
759 possible.

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

763 Incremental cost effectiveness ratio (ICER): The incremental cost effectiveness ratio
764 (ICER) is the mean cost per mother/child in the intervention minus the mean cost per
765 patient the control group divided by the mean incremental gain per mother/child in
766 outcomes from the intervention compared to controls. If an intervention has a lower
767 cost to society and better outcomes it is considered dominant and likely to be adopted
768 by a decision maker if the evidence is satisfactory. If the intervention has higher cost to
769 society but is associated with better outcomes the decision maker needs adequate
770 information to determine if they are willing to pay the additional cost per outcome
771 gained.

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

- 774 • Maternal sensitivity
- 775 • Infant QoL using the Warwick Child Health and Morbidity Profile[[81](#), [20](#)].

776 • Parental QoL using the EQ-5D, which is a brief questionnaire that measures
777 generic health related quality of life from the patient's point of view. EQ – 5D scores can
778 be converted to preference based utility scores that can be used to calculate quality
779 adjusted life years (QALYs) for use in cost effectiveness analyses using an algorithm
780 developed by Dolan [70].

781 • Mother-infant attachment

782 As the ICER does not easily allow for normal statistical tests we will use bootstrapping
783 methods, replications of the statistic of interest by sampling with replacement from the
784 original data, to calculate the confidence interval for the ICER. We will also use this data
785 and the net-monetary benefit approach to calculate the probability that MTB is cost
786 effective compared to the control group for a number of values of willingness to pay per
787 gain in outcome or the cost effectiveness acceptability curve (CEAC)[19]. This provides
788 more information to decision makers to help them decide if the outcomes achieved as a
789 result of the intervention are worth the additional cost.

790 Lifetime Model: Poor parent-child relationships, child abuse and neglect can have long
791 term negative impacts on children, their families and society. Poor parenting has
792 repeatedly been identified as being associated with antisocial behaviour and severe
793 behavioural problems [22, 23]. A long-term follow-up study of children with conduct
794 disorder suggested that the cost of unresolved conduct disorders can exceed £1 million
795 over an individual's lifetime [2]. There are obviously further costs and benefits to realise
796 as a result of preventing each case of child abuse and neglect. The ICERs proposed above
797 do not capture the full lifetime costs and outcomes that may be realised as a result of
798 MTB. As part of the project, we would therefore aim to investigate developing a decision
799 analytical model that uses information available from the evaluation as well as
800 published data sources to determine the cost-effectiveness of MTB over the lifetime of
801 the children.

802

803 **Data Monitoring:**

804 *Data Monitoring*

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

812 *Trial Steering Committee*

813 A Trial Steering Committee will be used to monitor the progress of the project and
814 advise the research team on matters arising during subsequent phases of the study. The
815 TSC will meet 6-monthly and perhaps more regularly during the preparatory and final
816 stages of the formal evaluation. The group will be made up of representatives from the
817 NSPCC, researchers, a statistician, service users and /or carers, and representatives of
818 professional/ provider organisations, including a link person from at least two local
819 clinical teams.

820

821 **Ethical Considerations:**

822 This trial has received a multi-site ethics approval from the NHS Health Research
823 Authority (NRES) Research Ethics Committee (London-Dulwich, the United Kingdom)
824 (REC reference: 13/LO/1651; IRAS project ID: 135643; protocol version 6.0,
825 11/01/2016). R&D approval is in place at all three sites. A formal amendment is needed

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

828

829 **Discussion**

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

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

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

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

853

854 **Trial status**

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

856

857 **List of abbreviations**

858 MTB: Minding the Baby®; NSPCC: National Society for the Prevention of Cruelty to
859 Children; RF: Reflective Functioning; PTSD: Post-Traumatic Stress Disorder; NFP: Nurse
860 Family Partnership; DMEC: Data Management and Ethics Committee; CAMHS: Child and
861 Adolescent mental Health Services; ICER: Incremental Cost Effectiveness Ratio; CEAC:
862 Cost Effectiveness Acceptability Curve; NRES: National Research Ethics Services; EPDS:
863 Edinburgh Postnatal Depression Scale; STAI: Spielberger State-Trait Anxiety
864 questionnaire; EQ-5D – EuroQol EQ-5D 3 level ; NSSQ: Norbeck Social Support
865 Questionnaire; SUS: Service Use and Support Questionnaire; TEQ: Treatment Experience
866 Questionnaire; MSM: Maternal Sense of Mastery; PSI : Parenting Stress Index; IBQ-R:
867 Infant Behaviour Questionnaire Revised; CBCL: Child Behaviour Check List.

868

869 **Declarations**

870 ***Ethical approval and Consent to participate***

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

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

878

879 *Consent to Publish*

880 Not Applicable

881

882 *Availability of supporting data*

883 Not Applicable

884

885 *Funding*

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887 of Cruelty to Children (NSPCC: contract number: 20130116).

888

889 **Competing Interests**

890 The authors declare that they have no competing interests.

891

892 **Authors' contributions**

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

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

904

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910 interpretation of the data, writing of the manuscript and in the decision to submit the
911 manuscript for publication.

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915

916 **References**

917 1. Sadler LS, Slade A, Close N, Webb DL, Simpson T, Fennie K, Mayer LC. Minding the
918 Baby: Enhancing reflectiveness to improve early health and relationship outcomes in an
919 interdisciplinary home visiting program. *Infant Mental Health Journal*. 2013;34(5):391-
920 405.

- 921 2. Olds D, Henderson CR Jr, Kitzman HJ, Enckerode JJ, Cole RE, Tatelbaum RC. Prenatal
922 and infancy home visitation by nurses: recent findings. *The Future of Children*.
923 1999;9(1):44-65.
- 924 3. Olds D, Kitzman H, Cole R, Robinson JA. Theoretical foundations of a program of home
925 visitation for pregnant women and parents of young children. *J Community Psychol*.
926 1997;25(1):9-25.
- 927 4. Slade A. Parental reflective functioning: An introduction. *Attachment and Human*
928 *Development*. 2005;7(3):269-81.
- 929 5. Goldberg S. *Attachment and Development*. London: Arnold; 2000.
- 930 6. Ordway M, Sadler LS, Dixon J, Close N, Mayes L, Slade A. Lasting effects of an
931 interdisciplinary home visiting program on child behavior: preliminary follow-up
932 results of a randomized trial. *J Pediatr Nurs*. 2014;29(1):3-13.
- 933 7. Ermisch J. Does a 'teen-birth' have longer-term impacts on the mother? Suggestive
934 evidence from the British Household Panel Study. IDEAS Working Papers Series from
935 RePEc. 2003.
- 936 8. Swann C, Bowe K, McCormick G, Kosmin M. Teenage pregnancy and parenthood: a
937 review of reviews Great Britain: NHS Health Development Agency; National Institute for
938 Health and Clinical Excellence 2003.
- 939 9. Lesser J, Koniak-Griffin D. The impact of physical or sexual abuse on chronic
940 depression in adolescent mothers. *J Pediatr Nurs*. 2000;15(6):378-87.
- 941 10. Pearlin L, Menaghan EG, Lieberman MA, Mullan JT. The Stress Process. *J Health Soc*
942 *Behav*. 1981;22(4):337-56.
- 943 11. Sadler L, Anderson SA, Sabatelli RM. Parental competence among African American
944 adolescent mothers and grandmothers. *J Pediatr Nurs*. 2001;16(4):217-33.
- 945 12. Sadler LS, Swartz MK, Ryan-Krause P. Supporting adolescent mothers and their
946 children through a high school-based child care center and parent support program. *J*
947 *Pediatr Health Care*. 2003;17(3):109-17.
- 948 13. Singh G, Ghandour RM. Impact of neighborhood social conditions and household
949 socioeconomic status on behavioral problems among US children. *Maternal and Child*
950 *Health Journal*. 2012;16(1):158-69.
- 951 14. Brooks-Gunn J, Duncan GJ. The effects of poverty on children. *The Future of Children*.
952 1997;7(2):55-71.
- 953 15. Sellström E, Bremberg S. The significance of neighbourhood context to child and
954 adolescent health and well-being: A systematic review of multilevel studies.
955 *Scandinavian Journal of Public Health*. 2006;34(5):544-54.
- 956 16. Olds D, Robinson J, O'Brien R, Luckey DW, Pettitt LM, Henderson CR, et al. Home
957 visiting by paraprofessionals and by nurses: a randomized, controlled trial. *Pediatrics*.
958 2002;110(3):486-96.
- 959 17. Kitzman H, Olds DL, Henderson CR Jr, Hanks C, Cole R, Tatelbaum R, et al. Effect of
960 prenatal and infancy home visitation by nurses on pregnancy outcomes, childhood
961 injuries, and repeated childbearing: A randomized controlled trial. *JAMA: The Journal of*
962 *the American Medical Association*. 1997;278:644-52.
- 963 18. Kitzman H, Olds DL, Sidora K, Henderson CR, Hanks C, Cole R, et al. Enduring effects
964 of nurse home visitation on maternal life course: A 3 year follow up of a randomised
965 trial. *JAMA: The Journal of the American Medical Association*. 2000;283(15):1983-9.
- 966 19. Olds D, Henderson CR Jr, Phelps C, Kitzman H, Hanks C. Effects of prenatal and
967 infancy nurse home visitation on government spending. *Med Care*. 1993;31(2):156-74.
- 968 20. Olds D, Henderson CR Jr, Cole R, Eckenrode J, Kitzman H, Luckey D, et al. Long-term
969 effects of nurse home visitation on children's criminal and antisocial behaviour: 15 year
970 follow-up of a randomised controlled trial. *JAMA: Journal of the American Medical*
971 *Association*. 1998;280(14):1238-44.
- 972 21. Olds D, Hill P, Robinson J, Song N, Little C. Update on home visiting for pregnant
973 women and parents of young children. *Curr Probl Pediatr*. 2000;30(4):107-41.

- 974 22. Olds D, Kitzman HJ. Review of research on home visiting for pregnant women and
975 parents of young children. *The Future of Children*. 1993;3(3):53-92.
- 976 23. Olds D. Prenatal and infancy home visiting by nurses: from randomized trials to
977 community replication. *Prev Sci*. 2002;3(3):153-72.
- 978 24. Lieberman A, Weston DR, Pawl JH. Preventive intervention and outcome with
979 anxiously attached dyads. *Child Dev*. 1991;62(1):199-209.
- 980 25. Cassidy J, Shaver PR. *Handbook of attachment: Theory, research, and clinical*
981 *applications*. 2nd ed. New York; London: Guilford Press; 2008.
- 982 26. Slade A. Parental reflective functioning: an introduction. *Attachment Human*
983 *Development*. 2005;7(3):269-81.
- 984 27. Ainsworth MDS, Blehar MC, Waters E, Wall S. *Patterns of attachment: A*
985 *psychological study of the strange situation*. New Jersey; New York ; London: Wiley;
986 1978.
- 987 28. Main M, Kaplan N, Cassidy J. Security in infancy, childhood, and adulthood: A move to
988 the level of representation. *Monogr Soc Res Child Dev*. 1985;50(1/2):66-104.
- 989 29. De Wolff M, van Ijzendoorn MH. Sensitivity and attachment: A meta-analysis on
990 parental antecedents of infant attachment. *Child Dev*. 1997;68(4):571-91.
- 991 30. Slade A, Belsky J, Aber JL, Phelps JL. Mothers' representations of their relationships
992 with their toddlers: links to adult attachment and observed mothering. *Dev Psychol*.
993 1999;36(3):611-19.
- 994 31. Slade A, Grienenberger J, Bernbach E, Levy D, Locker A. Maternal reflective
995 functioning, attachment, and the transmission gap: A preliminary study. *Attach Hum*
996 *Dev*. 2005;7(3):283-98.
- 997 32. Kelly K, Slade A, Grienenberger J. Maternal reflective functioning, mother-infant
998 affective communication, and infant attachment: exploring the link between mental
999 states and observed caregiving behavior in the intergenerational transmission of
1000 attachment. *Attach Hum Dev*. 2005;7(3):299-311.
- 1001 33. Fonagy P, Bateman A, & Bateman A The widening scope of mentalizing: A discussion.
1002 *Psychology and Psychotherapy*. *Psychology and Psychotherapy: Theory, Research and*
1003 *Practice*. 2011;84(1):98-110.
- 1004 34. Grienenberger J, Kelly K, Slade A. Maternal reflective functioning, mother-infant
1005 affective communication, and infant attachment: exploring the link between mental
1006 states and observed caregiving behavior in the intergenerational transmission of
1007 attachment. *Attach Hum Dev*. 2005;7(3):299-311.
- 1008 35. Moher D SK, Altman DG. The CONSORT statement: revised recommendations for
1009 improving the quality of reports of parallel-group randomized trials. *Ann Intern Med*.
1010 2001;134:657-62.
- 1011 36. Chan A-W TJ, Altman DG, Laupacis A, Gotzsche PC, et al. SPIRIT 2013 Statement:
1012 Defining standard protocol items for clinical trials. *Ann Intern Med*. 2013;158:200-7.
- 1013 37. Belsky J, Fearon RMP, Bell B. Parenting, attention and externalizing problems:
1014 testing mediation longitudinally, repeatedly and reciprocally. *J Child Psychol Psychiatry*.
1015 2007;48(12):1233-42.
- 1016 38. Smith P, Pederson DR. Maternal sensitivity and patterns of infant-mother
1017 attachment. *Child Dev*. 1988;59(4):1097-101.
- 1018 39. McElwain N, Booth-LaForce C. Maternal sensitivity to infant distress and nondistress
1019 as predictors of infant-mother attachment security. *J Fam Psychol*. 2006;20(2):247-55.
- 1020 40. Biringen Z, Robinson JL, Emde RN. Appendix B: The Emotional Availability Scales
1021 (3rd ed.; an abridge Infancy/Early Childhood Version). *Attach Hum Dev*. 2000;2(2):256-
1022 70.
- 1023 41. Waters E. The Attachment Q-Set. *Monogr Soc Res Child Dev*. 1995;60(2-3):234-46.
- 1024 42. van Ijzendoorn M, Vereijken CM, Bakermans-Kranenburg MJ, Riksen-Walraven JM.
1025 Assessing attachment security with the Attachment Q Sort: meta-analytic evidence for
1026 the validity of the observer AQS. *Child Dev*. 2004;75(4):1188-213.

- 1027 43. Fearon R, Bakermans-Kranenburg MJ, van Ijzendoorn MH, Lapsley AM, Roisman GI.
 1028 The Significance of Insecure Attachment and Disorganization in the development of
 1029 children's externalizing behavior: a meta-analytic study. *Child Dev.* 2010;81(2):435-56.
 1030 44. Bayley N. Bayley Scales of Infant and Toddler Development - Third edition. San
 1031 Antonio, TX: Harcourt Assessment; 2006.
 1032 45. Marlow N, Wolke D, Bracewell MA, Samara M. Neurologic and developmental
 1033 disability at six years of age after extremely preterm birth. *N Engl J Med.* 2005;352:1-11.
 1034 46. Achenbach T. Manual for the Child Behavior Checklist/4 - 18 and 1991 Profile.
 1035 Burlington, VT: University of Vermont Department of Psychiatry; 1991.
 1036 47. Ivanova M, Achenbach TM, Rescorla LA, Harder VS, Ang RP, Bilenberg N, et al.
 1037 Preschool psychopathology reported by parents in 23 societies: testing the seven-
 1038 syndrome model of the child behavior checklist for ages 1.5-5. *J Am Acad Child Adolesc*
 1039 *Psychiatry.* 2010;49(12):1215-24.
 1040 48. Cox J, Holden J, Sagovsky R. Detection of postnatal depression. Development of the
 1041 10-item Edinburgh Postnatal Depression Scale. *Br J Psychiatry.* 1987;150(6):782-6.
 1042 49. Cox J, Chapman G, Murray D, Jones P. Validation of the Edinburgh Postnatal
 1043 Depression Scale (EPDS) in non-postnatal women. *J Affect Disord.* 1996;39(3):185-9.
 1044 50. Murray D, Cox JL. Screening for depression during pregnancy with the edinburgh
 1045 depression scale (EDDS). *J Reprod Infant Psychol.* 1990;8(2):99-107.
 1046 51. Coe C. The development and validation of a measure off parent-reported child health
 1047 and morbidity: The Warwick Child Health and Morbidity Profile. *Child Care Health Dev.*
 1048 1996;22(6):367-79.
 1049 52. Byford S, Harrington R, Torgerson D, Kerfoot M, Dyer E, Harrington V, et al. . Cost-
 1050 effectiveness analysis of a home-based social work intervention for children and
 1051 adolescents who have deliberately poisoned themselves. Results of a randomised
 1052 controlled trial. *Br J Psychiatry.* 1999;174:56-62.
 1053 53. Kohnstamm G, Bates J, Rothbart M. Temperament in Childhood. Chichester: Wiley;
 1054 1989.
 1055 54. Parade S, Leerkes EM. The reliability and validity of the Infant Behavior
 1056 Questionnaire-Revised. *Infant Behavior and Development.* 2008;31(4):637-46.
 1057 55. Pearlin L, Schooler C. The structure of coping. *J Health Soc Behav.* 1978;19(1):2-21.
 1058 56. DeSocio J, Kitzman H, Cole R. Testing the relationship between self-agency and
 1059 enactment of health behavior. *Res Nurs Health.* 2003;26(1):20-9.
 1060 57. Norbeck J, Lindsey AM, Carrieri VL. The development of an instrument to measure
 1061 social suppor. *Nurs Res.* 1981;30(5):264-9.
 1062 58. Norbeck J, Lindsey AM, Carrieri VL. Further development of the Norbeck Social
 1063 Support Questionnaire: normative data and validity testing. *Nurs Res.* 1983;32(1):4-9.
 1064 59. Gigliotti E. A confirmation of the factor structure of the Norbeck Social Support
 1065 Questionnaire. *Nurs Res.* 2002;51(5):276-84.
 1066 60. Slade A, Aber JL, Bresgi I, Berger B, Kaplan M. The Parent Development Interview -
 1067 Revised. Unpublished Manuscript. New York, NY: The City University of New York 2004.
 1068 61. Levy DW, Truman S. Reflective functioning as mediator between drug use, parenting
 1069 stress and child behaviour. Quebec City, Canada: College of Problems of Drug
 1070 Dependence, 2002.
 1071 62. Slade A. Representation, symbolization and affect regulation in the concomitant
 1072 treatment of a mother and child: Attachment theory and child psychotherapy.
 1073 *Psychoanalytic Inquiry.* 1999;19:824-57.
 1074 63. Aber J, Belsky J, Slade A, Crnic K. Stability and change in mothers' representations of
 1075 their relationship with their toddlers. *Devevelopmental Psychology.* 1999;35(4):1038-
 1076 47.
 1077 64. Abidin R. Parenting Stress Index, Third Edition: Professional Manual. Odessa, FL:
 1078 Psychological Assessment Resources, Inc.; 1995.
 1079 65. Abidin R. Parenting Stress Index (PSI) Manual, Administration Booklet, and Research
 1080 Update. Charlottesville, VA: Pediatric Psychology Press; 1983.

- 1081 66. Weathers F, Litz B, Herman D, Huska J, Keane T. The PTSD Checklist (PCL):
1082 Reliability, Validity, and Diagnostic Utility. Paper presented at the Annual Convention of
1083 the International Society for Traumatic Stress Studies; San Antonio, TX1993.
1084 67. Ruggiero K, Del Ben K, Scotti JR, Rabalais AE. Psychometric properties of the PTSD
1085 Checklist—Civilian version. *J Trauma Stress*. 2003;16(5):495-502.
1086 68. Spielberger CD, Gorsuch RL, Lushene R, Vagg PR, Jacobs GA. Manual for the State-
1087 Trait Anxiety Inventory. Palo Alto, CA: Consulting Psychologists Press; 1983.
1088 69. Spielberger CD. State-Trait Anxiety Inventory: a comprehensive bibliography. Palo
1089 Alto, CA: Consulting Psychologists Press; 1989.
1090 70. Dolan P. Modeling valuations for EuroQol health states. *Med Care*. 1997;35(1):1095-
1091 108.
1092 71. Cooper P, Murray L, Wilson A, Romaniuk H. Controlled trial of the short and long
1093 term effect of psychological treatment of postpartum depression *The British Journal of*
1094 *Psychiatry*. 2003;182(5):412-19.
1095 72. Silove D, Parker G, Manicavasagar V. Perceptions of general and specific therapist
1096 behaviors. *J Nerv Ment Dis*. 1990;178:292-99.
1097 73. Bakermans-Kranenburg M, IJzendoorn, MH, van Juffer F Less is more: meta-analyses
1098 of sensitivity and attachment interventions in early childhood. *Psychol Bull*.
1099 2003;129(2):195-215.
1100 74. Murray L, Cooper P, Hipwell A. Mental health of parents caring for infants. *Archives*
1101 *of Women’s Mental Health*. 2003;6(2):s71-s7.
1102 75. Pocock SJ, Simon R. Sequential Treatment Assignment with balancing for prognostic
1103 factors in the controlled clinical trial. *Biometrics*. 1975;31(1):103-15.
1104 76. Brugha T, Wheatley S, Taub NA, Culverwell A, Friedman T, Kirwan P, Jones DR,
1105 Shapiro DA. Pragmatic randomized trial of antenatal intervention to prevent post-natal
1106 depression by reducing psychosocial risk factors. *Psychol Med*. 2000;30(06):1273-81.
1107 77. Roberts C. The implication of variation in outcome between health professionals for
1108 the design and analysis of randomised controlled trials. *Stat Med*. 1999;18:2605-15.
1109 78. Sterne JA, White IR, Carlin JB, Spratt M, Royston P, Kenward MG, et al. Multiple
1110 imputation for missing data in epidemiological and clinical research: potential and
1111 pitfalls. *BMJ*. 2009;338(b2393).
1112 79. MacKinnon D, Dwyer JH. Estimating Mediated Effects in Prevention Studies.
1113 *Evaluation Review*. 1993;17(2):144-58.
1114 80. Preacher K, Hayes AF. Asymptotic and resampling strategies for assessing and
1115 comparing indirect effects in multiple mediator models. *Behav Res Methods*.
1116 2008;40(3):879-91.
1117 81. McIntosh E, Clarke P, Frew E, Louviere J. Applied methods of cost-benefit analysis in
1118 health care. *Handbooks in health economic evaluation series*. Oxford: Oxford University
1119 Press; 2010.
1120 82. Della Jean D. Reliability and validity of the Emotional Availability Scale among
1121 Hispanic and African American mother-toddler dyads. United States - Illinois: Rush
1122 University; 2012.
1123 83. Belfer ML. Child and adolescent mental disorders: the magnitude of the problem
1124 across the globe. *Journal of Child Psychology and Psychiatry*. 2008;49(3):226-36.
1125 84. Wailoo A, Davis S, Tosh J. Benefits in cost utility analysis using the EQ-5D: School of
1126 Health and Related Research, University of Sheffield 2010.
1127 85. Guide to the methods of technology appraisal 2013. NICE. 2013. In: National
1128 Institute for Health and Care Excellence. 2013. <http://publications.nice.org.uk/pmg9>.
1129
1130 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)

1135

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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