Effects of lay support for pregnant women with social risk factors on infant development and maternal psychological health at 12 months postpartum

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1 **Effects of lay support for pregnant women with social risk factors**

2 **on infant development and maternal psychological health at 12**

3 **months postpartum**

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13

14 **Abbreviations**

15 ELSIPS: Evaluation of Lay Support in Pregnant women with Social risk

16

Abstract

Background: The ELSIPS (Evaluation of Lay Support in Pregnant Women with Social Risk) RCT showed that lay support for women with social risk had a positive effect on maternal mental health and mother-infant bonding. This exploratory study examined whether these observed benefits would impact infant development at 1 year. **Methods:** A sub-sample of women whose infants were under one year who had participated in the ELSIPS RCT which randomised women to receive either standard care or the services of a Pregnancy Outreach Worker (POW), and who were contactable, were eligible to participate in the follow up. At home visits, the Bayley Scales of Infant Development (3rd Edition) and standardised measures of depression, self efficacy, mind-mindedness and bonding were completed.

Results: 486 women were eligible for follow up, of whom 154 agreed to participate. 61/273 were successfully followed up in the standard maternity care arm and 51/213 in the POW arm. Women who completed follow up were less depressed and had higher selfefficacy scores at 8-12 weeks postpartum than those who did not complete follow up. There were no significant differences in maternal outcomes, infant cognitive development, receptive communication, expressive communication, fine motor development or social/emotional functioning between groups at 12 month follow up. Infants of mothers who received the POW intervention had significantly better gross motor development than infants whose mothers received standard care (p<0.03). **Conclusions:** The provision of lay support to women with social risk may facilitate infant gross motor skill development at one year but there were no other demonstrable benefits. The effects of the intervention may be underestimated given that those women who completed follow up had better mental health than the original study sample.

Introduction

Maternal and child health outcomes for disadvantaged and minority families continue to fall behind those with more advantaged backgrounds [1,2,3]. Severe maternal morbidities are more likely in non-white ethnic groups, with preexisting health conditions and poorer access to health services being risk factors for higher morbidity [4]. Women with complex social risk factors such as domestic violence and substance abuse are more likely to seek antenatal care later and fail to stay in regular contact with health services during pregnancy [4]. The differences in health behaviors and outcomes between socially advantaged and disadvantaged women and children are mediated by a number of factors including lack of social support [5,6], lack of education [7,8] and poor living environment [9].

Inequalities in health are not limited to physical functioning; for example women with higher socioeconomic status have lower rates of depression [10]. Postpartum depression (PPD) is characterized by low maternal mood within the year after childbirth [11] and is associated with reduced sensitivity in interaction and emotional withdrawal [12,13]. The effects on child development include adverse child physical, social and emotional developmental outcomes such as poor cognitive development and greater likelihood of insecure attachment [13-17]. Depressed women are less likely to develop warm, loving feelings towards their children [18-20] and failure to bond has implications for the subsequent relationship. Disordered bonding is characterized by a significant lack of maternal feeling; hostility toward the infant, lack of responsiveness to the infant's needs, and sometimes, harm or neglect [21,22]. Depression is also associated with reduced maternal 'mentalising' and vocalizations about infant emotion and cognition [23]. This characteristic is called 'mind-mindedness'; the mother's tendency to view her child as an

63 individual with a mind of its own [24,25]. There is significant individual variation in mothers'

64 mind-mindedness, and poorer mind-mindedness is associated with poorer infant cognitive

65 development [26] and less secure attachment [27,28]. Mind-mindedness is also associated

66 with parenting stress and child emotional and behavioural problems and has been

67 highlighted as an important target for interventions [29]. The ability to appropriately

68 comment on infant mental states and processes facilitates infant cognitive and

69 socioemotional development via increased maternal sensitive responsiveness [30].

70 Another important predictor of maternal functioning is self efficacy; the extent to which

71 individuals regard their lives as under their own control [31]. Depression is associated with

72 reduced perceptions of personal control [32]. Self efficacy plays a crucial role in parenting

73 behaviour and infant psychosocial risk [33, 34]. Self efficacy is a primary predictor of

74 parenting behavioural competence in mothers of young infants, over and above the effects

75 of depression and social support [35]. Given that perceived control over life events has

76 been suggested to underlie social inequalities in health, interventions that seek to increase

77 self efficacy have the potential to improve social, physical and mental health outcomes for

78 mothers and their infants.

79 Research has begun to assess the efficacy of a variety of types of support for women with

80 high social risk during and after pregnancy, including lay support. Lay support is provided by

81 community workers or peers who are not health professionals but whose role is to provide

82 social and practical support, for example, to access existing care pathways. A Cochrane

83 review of psychosocial and psychological interventions for preventing postpartum

84 depression included seven lay interventions, and demonstrated that they were not

85 significantly different from professionally delivered interventions in their ability to reduce

86   risk of depression [36]. However, the review called for further trials of the efficacy of lay

87   support because of the small number of eligible studies, the lack of trials examining

88   individual lay interventions targeting mood, and the lack of detail concerning the nature of

89   the lay individuals delivering the intervention [36]. The Evaluation of Lay Support in

90   Pregnant Women with Social Risk (ELSIPS) study [37] aimed to evaluate whether using lay

91   Pregnancy Outreach workers (POW), could benefit maternal and infant health outcomes in

92   nulliparous women with a number of social risk factors. POWs were trained by an

93   independent Community Interest Company to deliver individual case management for

94   women identified by the midwifery team as having social risk. The service included home

95   visits, and aimed to encourage antenatal attendance and healthy lifestyles and facilitate

96   access to existing services (e.g. benefits, housing). The POW's role was also to provide

97   support to mothers to improve their psychological health, including depression, self efficacy

98   and bonding. Most contacts between POWs and the women in the trial took place

99   antenatally (77%), with 27% being face to face contact and half of contacts lasting between

100   1-2 hours (see http://dx.doi.org/10.1136/bmjopen-2015-009203 [38] for full trial details).

101   The trial found modest positive effects on maternal mental health at 8-12 weeks

102   postpartum, particularly in those women with greater social risk [38] and a significant

103   benefit for mother-to-infant bonding. Measuring the potential impact of these effects on

104   infant development is important given the cumulative duration and timing effects of

105   maternal depression on infant outcomes [39].

106   This study aimed to follow up a subsample of families within the ELSIPS trial to evaluate

107   infant and maternal outcomes at one year postpartum. The aims were 1) to examine

108   whether the service had a positive impact on the cognitive, social, emotional and physical

109   development of the infant at 12 months and 2) to examine whether the POW service had an

110   effect on maternal depression, mind-mindedness, self efficacy and bonding at 12 months

111   postpartum.

Materials and Methods

113   ELSIPS was a randomised controlled trial (RCT) in nulliparous women with social risk, which

114   compared standard maternity care with the addition of referral to a lay Pregnancy Outreach

115   Worker (POW) support service. The POWs worked alongside community midwives offering

116   individualised support to encourage engagement with health and social care services, from

117   randomisation (before 28 weeks gestation) until 6 weeks after birth. Primary outcomes

118   were engagement with antenatal care and maternal depression at 8-12 postnatal weeks,

119   using the Edinburgh Postnatal Depression Scale (EPDS [40]). Self efficacy and mother-to-

120   infant bonding was also measured at 8-12 weeks. Details of the original ELSIPS trial have

121   been previously published [37, 38]. 1324 women participated in the original trial, 662

122   receiving the intervention and 662 standard care.

Study oversight

124   Ethical approval from South Birmingham Ethics Committee (10/H1207/23). Participants in

125   the original trial received a separate information leaflet for the follow up study and signed a

126   consent form specific to the follow up study before participation.

127

Follow up Study Design

129 We followed up a subsample of women and infants in both trial arms to evaluate the effect

130 of the intervention at 12 months postpartum on the primary outcome of infant

131 development (measured by the Bayley Scale of Infant and Toddler Development-III [41]).

132 Selection criteria were applied systematically and researchers were blind to participant

133 group membership at the point of decisions regarding eligibility for follow up.

134 The secondary outcomes for the follow up were maternal depressed mood, mind-

135 mindedness, self efficacy and maternal bonding. Infant weight and length were also

136 recorded.

137 The researcher conducting home visits and collecting and entering all data was blind to

138 group membership and maternal social risk factors.

139 **Participants**

140 We followed up women whose infants were between 11-13 months between June 2012 and

141 June 2013. This was a pragmatic sample; participants who could be included were limited

142 due to funding and time constraints. Women were eligible if they had returned an 8-12

143 week questionnaire in the original trial, and gave birth to a live infant after 1st June 2011.

144 Women were not eligible if they had been approached to engage in other additional

145 research or evaluations of the trial (e.g. qualitative analyses), if we did not have accurate

146 contact information, if they did not speak English, or if the GP felt that participation was

147 inappropriate. Of the original sample of 1324 mother and baby pairs, this left a potential

148 pool of 486 participants. See Fig 1.

149

150 **Figure 1. Consort diagram for the ELSIPS follow up**

151

152

153   When infants were aged 7 to 11 months, their mothers were invited to participate by

154   sending a patient information leaflet and reply slip to their home. Once the reply slip was

155   returned to the study office, the mother was telephoned to confirm participation, or the

156   mothers were called directly by the researcher when their child approached 11 months old

157   to book a home visit and check eligibility.

158   155 mothers were engaged in total, representing 11.7% of the original trial sample. In total,

159   8.5% of the original sample were successfully followed up. Home visits could not be

160   completed in 43 cases, due to the mother not being present at the agreed appointment (n=

161   41) or the child exceeding the age cut off by the time of booking (n=2). If a mother did not

162   attend an arranged appointment, two further attempts were made to contact her to re-

163   arrange. If a mother did not attend a second appointment, a final attempt was made to re-

164   arrange the appointment but no further contact was made after this point.

165 **Measures**

166   **Primary Outcome: Infant Development.**

167   ***Bayley III Scale of Infant and Toddler Development (Bayley-III).*** The Bayley III

168 measures the mental, motor and behavioural development of infants from one to 42

169 months of age across 5 subscales: cognitive, language, motor, social/ emotional and

170 adaptive behaviour [38]. It takes 45-60 minutes to complete. The Bayley Scale is a widely

171 used, internationally recognised, extensively evaluated, standardised, reliable and valid gold

172 standard for early childhood assessment [42].

173   The cognitive, language and motor scales are administered by the researcher (in this

174   case a psychologist) who has attended accredited training. The Cognitive Scale assesses the

175   infant's information processing and play skills. The Language Scale is composed of receptive

176   communication (infant's preverbal behaviour, social referencing and verbal comprehension)

177   and expressive communication (infant's preverbal communication skills, including gestures).

178   The Motor Scale is split into fine motor (ability to manipulate objects, reaching, grasping and

179   visual tracking) and gross motor (how well the child can move his /her torso and limbs,

180   balance and static positioning).

181   The social/emotional and adaptive behaviour questionnaires are completed by the

182   caregiver. The Social Emotional Scale assesses the social and emotional functioning of the

183   child reported by the caregiver, identifying whether key social-emotional milestones have

184   been reached. The Adaptive Behaviour Scale assesses the child's skills in behavioural

185   autonomy and responses to his/her environmental context.

186   **Secondary Outcomes: Maternal cognition and emotion**

187   ***Maternal Mind-mindedness Interview.*** Maternal mind-mindedness can be

188   measured by the mother's use of mental state language in descriptions of her child [26]. All

189   mothers were asked to 'describe (your baby's name) for me', and responses were audio-

190   recorded, transcribed and coded by two trained independent coders (both psychologists,

191   both trained in mind-mindedness coding) blinded to group allocation and social risks. The

192   mind-mindedness interview has established reliability, validity and feasibility [43].

193   ***Self report measures.*** Mothers completed three questionnaire measures, which had

194   also been completed at 8-12 weeks postpartum. These were:

195   *Edinburgh Postnatal Depression Scale* [40]: A 10 item self report questionnaire with 4

196   response options, designed to assess emotional wellbeing. A score of 13 or higher

197   suggests depression. The EPDS is the most frequently used measure of postnatal

198   depression, with good reliability, validity, specificity and sensitivity [44].

199   *Pearlin Mastery Scale* [31]: A 7 item index of self efficacy, with 4 point likert response

200   options (strongly agree to strongly disagree). Higher scores indicate higher self efficacy.

201   This scale has been used in many large scale studies to examine parents' self efficacy

202   [e.g. 45] (for example, the National Survey of Families and Households, as well as the

203   National Longitudinal Survey of Youth)

204   *Mother to Infant Bonding Scale* [46]: Seven expressions indicating the mothers feelings

205   toward her child, followed by a 4 point likert scale (Very much to Not at all). Higher

206   scores indicate poorer maternal to infant bonding. The scale is widely used with good

207   reliability and validity [47].

208   ***Length and weight*** Infant length and weight was measured using the SECA 210 Measure

209   Mat and the SECA 384 electronic scale.

Procedure

211   After informed consent, the mind-mindedness interview was conducted. Next, self-report

212   measures were completed. The infant's height and weight was measured by the researcher,

213   fully clothed for height measurement but clothes and nappy removed for weight

214   measurement.

215   The Bayley assessment was administered in the following order: Gross motor, fine motor,

216   cognitive, receptive communication and expressive communication. The child's age was

217   calculated and for premature babies, the adjusted age was calculated using gestation at

218   birth. Standard administration procedure was followed. On completion of the assessment

219   and questionnaire, the mother was given £20 in high street vouchers. The same researcher

220   conducted all measures in both arms of the trial.

221   **Data analysis**

222   **Bayley Scale scores**: Raw scores were summed for each subtest and converted into

223   scaled scores. Scaled scores were used to determine the child's performance against norms

224   from typically developing children (reference mean =10, SD= 3).

225   **Mind-mindedness**: After transcription, each comment was coded as mind-minded

226   (referring to a mental state), general, behavioural or physical. The percentage of mind-

227   related comments relative to the total number of comments was calculated. Inter-rater

228   reliability was calculated; 90.5% of the statements were coded in the same way by the two

229   coders, suggesting overall agreement was very good (Kappa = .86).

230   We examined differences in social risk and other characteristics between those participants

231   who did and did not complete the follow up study irrespective of eligibility for follow-up,

232   using independent sample t-tests. We also examined differences between those

233   participants who were eligible for the follow-up and who did or did not complete the study,

234   using independent sample t-tests. Differences between arms in outcomes were compared

235   using ANOVA where data were normally distributed and Mann Whitney U tests where the

236   data were significantly skewed. Differences between groups in the percentage of

237   participants who had an EPDS score ≥13 were analysed using chi-square. Analyses of

238   differences in self efficacy, depression and bonding at 1 year follow up were adjusted for a

239   group difference in gestational age (see below) with ANCOVA. Analysis of infant

240   developmental outcomes was not adjusted for gestation because the measures used to

241   assess infant development adjust for gestational age. Based on the sample available post

242   hoc power analyses showed that with 112 participants and alpha at .05, power of .95 was

243   available to detect effect sizes of .38 and larger; this corresponds to a difference between

244   arms of 1.14 Bayley scale points (mean score for Bayley scaled subscales is 10 and standard

245   deviation is 3). We also carried out pre-specified subgroup analyses of the women who had

246   2 or more social risks at baseline.

247   SPSS software (IBM SPSS statistics version 21) was used for statistical analyses.

Results

Sample characteristics

250   Table 1 illustrates characteristics of participants followed and not followed from the original

251   trial. Of the 112 mothers visited, 62 infants were boys and 50 were girls. The follow up

252   sample was largely representative of the initial and eligible ELSIPS sample though there

253   were proportionately fewer Asian mothers in the follow up, due to the eligibility criteria of

254   good understanding of written and spoken English (46.6% of ineligible Asian mothers did not

255   speak English). There were no significant differences in social risk count, birth weight or

256   gestation between those who did and did not participate in follow up, irrespective of

257   eligibility. However, there was a significant difference in EPDS and self efficacy: women who

258   participated in follow up had significantly lower mean depression scores (t=2.94, df=1006,

259   p=.003) and reported greater self efficacy (t=-3.11, df= 975, p=.002) than those who did not

260   participate overall, and than those who were eligible but did not participate (depression

261   t=2.7, df=217, p=.007; self efficacy t=-2.8, df=220, p=.005). There was no significant

262   difference between those followed up and those not followed, irrespective of eligibility for

263   follow up, in proportions of EPDS ≥13.

Table 1. Baseline+ data for ELSIPS Follow Up Sample Compared to a) all participants who were eligible to be followed but who were not followed and b) all participants who were not followed

N= 1324	Followed Up	Eligible for follow up but not followed	Not Followed Up (overall sample)
Group total (%)	112 (8.5)	373 (28)	1212 (91.5)
Ethnicity			
White European (%)	80 (71.4)	241 (65)	609 (50.2)
African (%)	5 (4.5)	14 (3.7)	82 (6.8)
Caribbean (%)	12 (10.7)	20 (5.3)	58 (4.8)
Asian (%)	6 (5.4)	69 (18.4)	335 (27.6)
Other (%)	9 (8.0)	24 (6.4)	86 (7.1)
Middle Eastern (%)	0 (0.00)	5 (1.3)	42 (3.47)
Mean birth weight (sd)	3152 (632)	3199 (563)	3167.8 (617.3)
Mean Gestation in days (sd)	-2.5 (13.1)	-2.3 (14)	-3.6 (16.5)
Mean baseline EPDS score (sd)	5.7 (4.5)*	7.1 (5.4)	7.2 (5.4)
N(%) ≥13	10 (8.9)	54 (11.1)	138 (11.4%)

Mean baseline Self efficacy score (sd)	20.0 (2.7)*	19.2 (3.2)	19.0 (3.2)
Mean baseline MIB score (sd)	1.9 (.2)	1.9 (.2)	1.9 (.2)
Social risk count (sd)	2.3 (1.0)	2.2 (1.1)	2.2 (1.1)

264   *Followed up sample are significantly different from overall ELSIPS sample not followed

265   AND significantly different from sample eligible for follow up but not followed.

266   *$p \leq 0.05$ + At 8-12 weeks postpartum

267

268   Of the 112 women and infants included, 51 were from the POW service and 61 from the

269   standard care trial arms. Table 2 shows the descriptive statistics at 8-12 weeks for the

270   participants followed up in each arm. When comparing the sample by randomisation group,

271   there were no significant differences in demographic and anthropometric characteristics,

272   except that infants in the POW group had significantly fewer days of gestation (t=2.0, df

273   =111, p=.05). Analyses of maternal outcomes were therefore adjusted for gestation. There

274   were small differences in maternal mental health between the POW and control arms at 8-

275   12 weeks postnatal, with a trend towards a lower mean levels of depression (t=1.7, df=110,

276   p=.09) and significantly higher self efficacy scores (t=-2.2, df=109, p=.03) in the women who

277   had received the POW intervention. There were no significant differences between the POW

278   group and standard care group in the percentage of participants with EPDS scores ≥13.

Table 2. ELSIPS Follow Up Sample Composition and Characteristics

	Trial Group		
	Standard	POW	total

ELSIPS sample			1324
Eligible to participate			486
Recruited (%)	61 (54.5)	51 (45.5)	112
Boy (%)	33 (55)	29 (55.8)	
Girl (%)	27 (45)	23 (44.2)	
Ethnicity			
White European (%)	46 (46.7)	34 (65.1)	
African (%)	1 (1.7)	4 (7.7)	
Caribbean (%)	5 (8.3)	7 (13.5)	
Asian (%)	4 (6.7)	2 (3.8)	
Other (%)	4 (6.7)	5 (9.6)	
Birthweight g (sd)	3199.5 (603.6)	3096.2 (665.7)	
Male Infant weight in kg at 12 months (sd)	10.3 (1.4)	10.1 (1.1)	
Female Infant weight in kg at 12 months (sd)	9.4 (1.3)	9.5 (1.4)	
Male Infant length in cm at 12 months (sd)	76.5 (2.9)	76.4 (2.3)	
Female Infant length in cm at 12 months (sd)	74.8 (2.6)	74.9 (3.9)	
Gestation in days (sd)	-0.5 (10.2)	-4.9 (15.5)*	
Social risk count (sd)	2.2 (1.1)	2.5 (0.9)	
Baseline EPDS mean (SD)	6.3 (4.6)	4.9 (4.2)t	
N (%) ≥13	7(11.4)	3 (5.8)	
Baseline Mastery (self efficacy) mean (SD)	19.5 (2.8)	20.6 (2.4)*	
Baseline Bonding mean (SD)	22.9 (1.5)	23.0 (1.2)	

279   t $p<.1$ *$p ≤ 0.05$ Baseline measures taken at 8-12 weeks postpartum.

Inferential analysis

There were no differences between intervention and control arms of the trial in maternal depression, bonding or self efficacy outcomes at 12 months postpartum (Table 3). Despite this, infants of the women who had received the POW intervention had significantly better gross motor skills than those who received standard care, with the infants in the POW arm scoring close to the scaled reference mean of 10. There were no other significant differences between the two groups of infants in developmental outcome. Scores of cognitive development and receptive communication were approximately one standard deviation lower than the scaled reference indicating below average performance of infants in both the POW and Control trial arms. Sub group analyses of women with 2 or more social risks showed that there were no significant differences in infant development between infants of women with 2 or more social risks in the POW (n=45) and control (n=43) arms of the trial, and no differences in the two groups of women in their longer term depression, self efficacy or bonding scores (see Supporting Information: S1-S2 Tables).

Table 3. Group Differences by Randomisation in the ELSIPS Follow Up Study at 12 months postpartum

Outcome variable	Treatment Group			AN(C)OVA/chi square
	Standard (n=61)	POW (n=51)	N	F/X2, *p-value*
Primary Outcome:				
Mean Bayley III Scale of Infant and Toddler Development Scaled Scores				
Cognitive Scale b	7.8 (1.8)	7.2 (2.4)	111	2.45, 0.12
Communication Scale b	14.6 (5.0)	15.2 (4.1)	111	0.37, 0.54
Expressive Communication b	8.3 (2.4)	8.7 (2.3)	111	0.82, 0.37
Receptive Communication b	6.7 (2.5)	6.7 (1.9)	111	0.01, 0.94
Motor Scale b	17.8 (4.2)	18.9 (4.4)	112	1.78, 0.19
Fine Motor b	9.2 (3.0)	8.9 (2.2)	112	0.30, 0.58

Gross Motor b	8.6 (3.0)	10.0 (3.2)	112	5.35, 0.02*
Social and Emotional Scale b	10.5 (3.2)	10.2 (3.2)	111	0.20, 0.66
Adaptive Behaviour Scale b	78.8 (17.8)	81.6 (13.9)	111	0.79, 0.38

Secondary Outcomes:

Edinburgh Postnatal Depression Score

N(%) ≥13	5 (8.1)	3 (5.8)	112	.25, .45
Mean (sd)	6.8 (4.9)	5.6 (4.6)	112	1.38, 0.24
Median (IQR, range)	6 (7, 0-26)	5 (5, 0-24)		0.12a

Mother to Infant Bonding Score

Mean (sd)	1.4 (2.8)	1.0 (1.8)	111	0.30, 0.59
Median (IQR, range)	0 (2, 16-28)	0 (1, 16-28)		0.95 a

Pearlin Self efficacy Scale

Mean (sd)	23.1 (3.4)	23.7 (3.5)	111	0.83, 0.37
Median (IQR, range)	23 (6, 0-13)	24 (6, 0-8)		0.20 a

Proportion of Mind-minded Comments

Mean (sd)	25.7 (22.0)	27.0 (20.6)	111	0.17, 0.68
Median (IQR, range)	20.00 (39.28, 0-75)	25 (27.50, 0-75)		0.45a
Mean Baseline to Follow up change group differences				
Edinburgh Postnatal Depression Score (sd)	0.46 (5.25)	0.64 (5.08)	111	0.75, 0.39
Mother to Infant Bonding Score (sd)	-0.09 (3.13)	0.06 (2.03)	107c	0.10, 0.75
Pearlin Mastery Scale (self efficacy) (sd)	3.58 (3.53)	3.22 (3.36)	109d	1.72, 0.19

*$p \leq 0.05$. Main analyses use ANCOVA with gestation in days as covariate (gestation information missing n = 1), except: a Mann Whitney Test used to analyse group differences; b ANOVA used as Bayley scaled scores are calculated using infant adjusted age. c missing mother to infant bonding data at baseline (n=5); d missing self efficacy data at baseline (n=3). Baseline measures taken at 8-12 weeks postpartum.

Discussion

This study aimed to examine whether the POW service had a positive impact on infant development at 12 months and a sustained effect on maternal depression, self efficacy and bonding at 12 months postpartum. There was no evidence of sustained improvements in any aspect of maternal mental health in the sub-sample who completed follow up but infants of women who received the POW intervention had significantly better gross motor skills at 1 year than infants of women who received standard care. There were no other significant improvements in any other aspect of development in infants in the POW arm of the trial.

Gross motor skills include the assessment of general musculature, physical skills and coordination, and thus gross motor skills delay is often used as an indicator of developmental delay. The infants of women who received the POW support demonstrated gross motor skills in line with that expected of their age group using scaled reference scores. In contrast, their peers who did not receive the intervention demonstrated gross motor skill performance significantly below the norm for their age, consistent with their background of high social risk. In general, the infants performed less well than a same aged peer reference group, particularly in indices of cognitive and receptive communication development, for which they scored over one standard deviation below that expected of their age group (between the 9th and 16th percentile).

Delayed development of motor skills has been associated with later cognitive deficits such as dyslexia, ADHD and language impairment [48]. Specifically, gross motor skills (but not fine motor skills) measured from birth to 4 years have been shown to explain significant variance

317   in children's later cognitive performance, particularly working memory and processing

318   speed [49]. Therefore, whilst we did not demonstrate a significant effect of the intervention

319   on cognitive development at 12 months, it is possible that children whose mothers received

320   the POW intervention may show better longer term cognitive outcomes. This may be

321   particularly important in this group, who are showing signs of significant underperformance

322   in many areas of development.

323   The positive effects of the POW service on postnatal mental health are likely to have

324   benefitted maternal-infant interaction, given that self efficacy is associated with greater

325   parental competence [35] and that maternal depression is associated with less play, touch

326   and affection [12]. Therefore, one mechanism by which the POW service had positive

327   effects on infant gross motor outcome may be through better sensorimotor stimulation.

328   Another mechanism may be that of exposure to a less stressful uterine environment.

329   Maternal antenatal distress has previously been associated with poorer motor development

330   in infancy [50] and is a more important predictor of motor development than postnatal

331   distress. Aspects of distress clustered in the second and third trimesters, including anger,

332   pregnancy related stress and cortisol levels, have specific links to poorer infant psychomotor

333   development [51]. There are a number of other potential mechanisms linking improvements

334   in early postnatal mental health to better later infant gross motor outcomes, include greater

335   support from a less depressed mother to infant attempts at movement, as well as general

336   improvements in environmental stimulation (toys, opportunities) that increase children's

337   interest in their environment and motivate the development of movement and action.

338   Furthermore, improvements in bonding from mother to infant facilitate security of

339   attachment and thus may improve willingness to explore the environment. Improvements in

340 maternal pregnancy health (for example reductions in the use of drugs and/or alcohol

341 during pregnancy, reduced use of antidepressants during pregnancy) may also have

342 implications for improvements in infant gross motor development. However, we do not

343 have data from the ELSIPS study to enable us to examine these factors as mechanisms, so

344 these conclusions remain speculative.

345 One important limitation of this study was that the sample selected for follow up was

346 pragmatic, limited by financial and time restrictions, and a less diverse, less depressed and

347 more self- efficacious group were tested for longer term outcomes. Selection bias regarding

348 inclusion into the follow up study applied equally to both arms of the study but unobserved

349 selection mechanisms may have comprised the comparability of the study groups despite

350 the efforts of the investigators to apply selection criteria in both arms in a symmetrical way.

351 Thus the lack of representativeness of our follow up sample does pose significant limitations

352 on our ability to make conclusions about the effectiveness of the overall ELSIPS trial on later

353 infant outcome. Also, whilst there was a significant difference in self efficacy between the

354 follow up sample POW and standard care participants at 8-12 weeks, the differences in

355 depression at that time were slight. Therefore, it is possible that the effects of the

356 intervention on maternal mental health are relatively short term or that the measured

357 effects of the intervention on long term maternal mental health, bonding and infant

358 development may be underestimated. A further important limitation of the study is that of

359 multiple testing. We did not undertake Bonferroni correction for multiple testing given their

360 unnecessarily stringent effects because we did not want to increase the risk of type II error

361 in this relatively small sample. However, this raises the possibility that the only

362 improvement in infant development found in this study, that of gross motor development,

363   could be a spurious finding resulting from a type I error. Nevertheless the scale of the effect

364   (half a standard deviation difference between arms) suggests that this result is a clinically

365   significant one. Further work examining the effects of pre- and post-natal lay interventions

366   on longer term infant outcomes, and the precise mechanisms of action, is required.

367   There is a need for a greater range of support services for perinatal women with social risks,

368   including support in addressing economic and social needs, and these women express a

369   preference for services focused on empowerment of the women themselves [52]. The POW

370   service is an example of such a service, which shows positive effects on maternal mental

371   health and bonding in the short-term. Whilst the benefits of the POW service for infant

372   development are limited, there may be a benefit for infant gross motor outcomes in the

373   longer term.

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377

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380

381   **Conflict of Interest**

382   The authors declare no conflict of interest related to this work.

383

384   **Contributors' Statements**

385 Jackie Blissett contributed to conceptualization and design of the follow up study,

386 supervised data collection, conducted the initial analyses, drafted the initial manuscript, and

387 approved the final manuscript as submitted.

388 Sara Kenyon contributed to conceptualization and design of the follow up study, supervised

389 data collection, critically reviewed the manuscript, and approved the final manuscript as

390 submitted.

391 Emma Popo carried out the data collection, contributed to the initial analyses, contributed

392 to the draft of the initial manuscript, and approved the final manuscript as submitted.

393 Sophie Dann contributed to the design of the follow up study, supervised data collection,

394 critically reviewed the manuscript, and approved the final manuscript as submitted.

395 Christine MacArthur contributed to conceptualization and design of the follow up study,

396 critically reviewed the manuscript and approved the final manuscript as submitted.

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536

537

Supporting Information
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539

540   **S1 Table.** ELSIPS Follow Up Sample Composition and Characteristics

541   in Mothers with Two or More Social Risks Only.

542

543   **S2 Table.** Group Differences in Mothers with Two or More Social

544   Risks in the ELSIPS Follow Up Study at 12 months postpartum