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A pragmatic randomized controlled trial to evaluate the effectiveness of a facilitated exercise intervention as a treatment for postnatal depression: the PAM-PeRS trial

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1 **A pragmatic randomised controlled trial to evaluate the effectiveness of a facilitated**
2 **exercise intervention as a treatment for postnatal depression: the PAM-PeRS trial**

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36

37

38 **Abstract**

39 **Background:** Postnatal depression affects about 10-15% of women in the year after giving
40 birth. Many women and healthcare professionals would like an effective and accessible non
41 pharmacological treatment for postnatal depression.

42 **Methods:** Women who fulfilled the ICD-10 criteria for major depression in the first six
43 months postnatally were randomised to receive usual care plus a facilitated exercise
44 intervention or usual care only. The intervention involved two face to face consultations and
45 two telephone support calls with a physical activity facilitator over six months to support
46 participants to engage in regular exercise. The primary outcome was symptoms of depression
47 using the Edinburgh Postnatal Depression Scale (EPDS) at six month post-randomisation.
48 Secondary outcomes included EPDS score as a binary variable (recovered and improved) at
49 six and 12 month post-randomisation.

50 **Results:** 146 women were potentially eligible and 94 were randomised. 34% reported
51 thoughts of self-harming at baseline. After adjusting for baseline EPDS, analyses revealed a -
52 2.04 mean difference in EPDS score, favouring the exercise group (95% CI: -4.11 to 0.03,
53 $p=0.05$). When also adjusting for pre-specified demographic variables the effect was larger
54 and statistically significant (mean difference=-2.26, 95% CI:-4.36 to -0.16, $p=0.03$). Based on
55 EPDS score a larger proportion of the intervention group were recovered (46.5% versus
56 23.8%, $p=0.03$) compared with usual care at six months follow-up.

57 **Conclusions:** This trial shows an exercise intervention that involved encouragement to
58 exercise and to seek out social support to exercise may be an effective treatment for women
59 with postnatal depression, including those with thoughts of self-harming.

60

61 **Keywords:** exercise, postnatal, postpartum, depression, primary care

62

63 **Introduction**

64 Postnatal depression affects about 10-15% of women in the year after birth (O'Hara et
65 al., 1996; Gaynes et al., 2005) with symptoms including low mood, fatigue, anxiety, thoughts
66 of self harming and poor mother-infant interactions (Beck, 1992, 1995; Murray, 1992; Cooper
67 et al., 1995; American Psychiatric Association, 2000). Current treatments recommended for
68 postnatal depression include antidepressants and psychological therapies (National Institute
69 for Health and Care Excellence [NICE], 2007). There are some risks in taking antidepressants
70 and reluctance amongst new mothers to take them (Turner et al., 2008; Turner et al., 2010).
71 Although non pharmacological interventions can be effective (Dennis et al., 2007; Morrell et
72 al., 2009; Sharp et al., 2010) there can be long waiting lists to access treatment and they can
73 be costly. Exercise has the potential to address barriers associated with traditional treatments:
74 it is free, accessible and is without stigma or side effects (Daley et al., 2007; Lewis et al.,
75 2014).

76 The American College of Obstetrics and Gynecology, (2002) and NICE (2007) in
77 England have stated that self help strategies such as exercise should be considered as a
78 treatment for postnatal depression, although this guidance from NICE was based on evidence
79 at the time from trials that had recruited general populations and two small trials of women at
80 risk of postnatal depression. A systematic review with meta-analysis by the trial authors
81 found five small trials in women at risk of postnatal depression, but no samples with *clinically*
82 defined depression (Daley et al., 2009). The review showed that exercise significantly
83 reduced postnatal depression scores relative to comparators, but significant heterogeneity was
84 present and the effect size became non-significant when the trial that included exercise with
85 social support was excluded (Armstrong et al., 2003). We recently updated this review
86 (Blamey et al., 2012) and no further trials that had recruited women with clinically diagnosed
87 depression have been published.

88 It remains uncertain therefore whether exercise reduces symptoms of postnatal
89 depression and a high quality trial in women with clinically diagnosed depression was
90 considered essential. Following a pilot trial this RCT evaluated the effectiveness of a
91 facilitated exercise intervention as a treatment for postnatal depression alongside any usual
92 care compared with a group who only received usual care (Daley et al., 2008). The study was
93 purposively designed as a pragmatic trial where women were eligible for inclusion regardless
94 of whether they were receiving or not receiving other specific treatments (i.e. antidepressants
95 or psychological intervention) because it would not have been safe or ethical to interrupt or
96 withdraw usual care and test exercise alone until there is evidence that exercise is likely to
97 provide benefit in this population. We hypothesised that participants receiving the exercise
98 intervention would report lower depressive symptoms scores at follow up than those receiving
99 usual care.

100 **Design and overview**

101 **Setting and participants**

102 147 family medicine practices in Birmingham, UK were invited to assist with
103 recruitment, 67 agreed. Recruitment commenced in April 2010 and follow up completed in
104 April 2013. Women were eligible if they were within six months of giving birth, aged 18
105 years or more and had an ICD-10 diagnosis of a major depressive episode (WHO, 2011),
106 following initial screening using the Edinburgh Postnatal Depression Scale (EPDS) (Cox et
107 al., 1987) and a clinical diagnostic interview (Lewis et al., 1992). Women with a diagnosis of
108 mixed anxiety and depression were also eligible. Patients were excluded if they were
109 pregnant again, experiencing psychotic symptoms or dependent on illicit drugs or alcohol.
110 Women needed to be currently inactive (not meeting the current guidelines for physical
111 activity) (DOH, 2011).

112 *Patient identification and diagnosis of depression*

113 Women who had recently given birth and who lived within two primary care trusts in
114 Birmingham were identified from the Child Health System (CHS), a centralised computer
115 registration system of all new births in the areas which allowed systematic identification of
116 women in the 67 participating family medicine practices. Every two weeks the CHS
117 completed search lists of new births in participating practices and mailed the trial information
118 letter and EPDS to these women. Women were sent this at 10-14 weeks after birth and there
119 were several reasons for this; many women feel overwhelmed when they have a new baby to
120 care for and may be less inclined to participate in a research study in the first few weeks of
121 giving birth. Having a contact date of 10-14 weeks, rather than shortly after giving birth,
122 gave women the chance to get into a routine with their baby before committing to a long term
123 research study. Symptoms of depression in some cases can resolve naturally after a period of
124 adjustment to the baby and this study was focused on identifying those women who would
125 need assistance with resolving their depression. Women who scored 10+ on this first EPDS
126 (EPDS-1) then completed a second EPDS (EPDS-2) two weeks later by telephone to rule out
127 the possibility of transient depression. Women who scored 13+ on EPDS-2 then completed
128 the Clinical Interview Schedule-Revised (CIS-R) (Lewis, 1994; Jenkins et al., 1997) at a
129 home visit to ensure they met the ICD-10 criteria for experiencing a major depressive
130 episode.

131 *Other recruitment methods*

132 Women who presented with depression after six weeks, but within six months of
133 giving birth were also able to participate via referral from their GP or health visitor. Health
134 professionals from two perinatal mental health community services were also able to refer
135 women. Women identified in these ways also had to meet all the study entry criteria as
136 previously described.

137 **Outcomes, process measures and allocation of participants to trial groups**

138 The primary outcome was difference in mean EPDS score (adjusted for baseline)
139 between the groups at six month follow-up. We used the EPDS as our primary outcome of
140 symptoms of depression so that we could compare the results with other postnatal depression
141 treatment trials as the use of the EPDS is standard practice within postnatal depression
142 research. It can be very difficult to obtain high follow up in women with postnatal depression
143 and using the EPDS, rather than a clinical interview, was considered to provide the best
144 opportunity to achieve high follow up rates.

145 Secondary outcomes were difference in mean EPDS score at 12 month follow up and
146 rates of improved and recovered responses on the EPDS at follow up. Participants completed
147 the SF-12 (Ware et al., 1996), EQ-5D (Brooks, 1996), a body image subscale (Kumar et al.,
148 1984) the subjective vitality scale (Bostic et al., 2000) and items relating to perceived social
149 support (Sallis et al., 1987; Singleton et al., 2003) and self-efficacy for exercise (Sallis et al.,
150 1988) were also completed. Body weight and height were measured objectively. Physical
151 activity was measured by self report (IPAQ-short) (Craig et al., 2003) and objectively using
152 the Actiheart device.

153 During intervention weeks 4, 8, 12, 16, 20 the intervention group were asked to
154 complete exercise diary logs as previously used in our pilot trial (Daley et al., 2008). Logs
155 were completed with the physical activity facilitator (PAF) in person, over the telephone or
156 sent/returned by post.

157 **Randomisation, concealment and blinding**

158 An internet randomisation service was used to allocate participants to the trial groups
159 and was concealed from researchers involved in recruiting and randomising participants. The
160 allocation sequence was generated using a computer programme with random permuted
161 blocks of size 10. Participants were randomised into one of two trial groups (50:50 split) and
162 further randomised for wearing the Actiheart or not (60:40 split). The randomisation was

163 stratified by EPDS score (13-16 and 17+). The person delivering the intervention was not
164 involved in recruiting participants. Participants, researchers and those delivering the
165 intervention could not be blinded to group allocation. The primary outcome, EPDS score,
166 was completed by postal questionnaire (along with other secondary outcomes).

167 **Data collection**

168 Eligible women were asked to provide written informed consent. At baseline and six
169 and 12 month post randomisation follow up, the questionnaires were mailed to participants
170 and collected at home visits by the research team or returned by post. Those randomised to
171 wear the Actiheart had the device fitted at the home visit. The research team collected the
172 Actiheart from these participants and the IPAQ was then completed. Participants who had
173 worn the Actiheart at baseline were asked to wear it again at follow up. Participants were
174 asked to wear it the Actiheart for three consecutive days and to then complete the IPAQ.

175 **Intervention**

176 A detailed description of the six month intervention can be found in the published
177 protocol (Daley et al., 2012). The initial goal (weeks 1-12) was for participants to progress
178 towards accumulating 30 minutes of moderate intensity exercise on three days per week.
179 During weeks 13-24 participants were encouraged to work towards accumulating 30 minutes
180 of moderate intensity exercise on 3-5 days per week. Similar to our pilot trial (Daley et al.,
181 2008) the intervention involved two face to face personalised exercise consultations (during
182 months 1 and 2) and telephone calls (during months 3 and 4). The face to face consultations
183 were centred on equipping women with the skills, knowledge and confidence needed to
184 participate in regular exercise and were delivered by a PAF in participants homes.
185 Consultations lasted between 40-60 min. Participants were given a pedometer. Four weeks
186 later participants had a second consultation centred on the prevention of relapse back to an
187 inactive lifestyle and/or improving maintenance of an active lifestyle. Telephone support

188 calls (15-20 minutes) were made during months three and four of the intervention.

189 Information leaflets were mailed in months three, four, five and six of the intervention to
190 further encourage exercise participation.

191 **Usual care comparator**

192 Usual care could have included women spontaneously consulting their GP and given
193 active treatment or just consultation to discuss symptoms, or informal counselling from their
194 health visitor or referral by their health visitor to the GP, or that they consulted no one and
195 had no treatment. The usual care group were sent the study "*Looking after yourself*" leaflet at
196 baseline and exercise was not further encouraged beyond receipt of this single leaflet.

197 **Sample size and statistical analyses**

198 A sample size of 83 patients randomised to each group (n=166) would be sufficient to
199 detect a 1.95 (SD =3.9, Heh et al., 2008) unit difference in EPDS score between the groups at
200 the six month follow-up with 90% power, 5% significance level. This increased to 104 in
201 each arm when allowance was made for a 20% dropout rate at six month follow-up (n=208).
202 When considered as a continuous variable two EPDS points is considered a moderate effect
203 size change (0.5 SD) (Matthey, 2004).

204 All analyses used the intention to treat principle, whereby participants were analysed
205 in the group to which they were randomised. All participants that had complete data for the
206 EPDS at 6 months were included in the primary analysis. The primary analysis compared
207 mean EPDS score at six month post randomisation follow-up between trial groups, adjusting
208 for baseline scores using analysis of covariance. EPDS-2 score was used as the baseline
209 score. Similar analyses were conducted for the secondary outcomes (except physical activity)
210 adjusting for baseline outcome score and baseline EPDS. Secondary analyses adjusted for
211 baseline score, baseline EPDS and covariates (age, baseline weight and ethnicity) again using
212 analysis of covariance. To explore longer term effects, a repeated measures mixed model

213 analysis of the primary and secondary outcomes was undertaken, comparing groups across the
214 follow ups. Adjustments were made for covariates as previously described. Bootstrapped
215 analyses (1000 repetitions) were performed where residuals were non-normally distributed.

216 To assess clinically meaningful change on the EPDS following the principles of
217 Jacobson and Truax (1991), analysis of the proportion of women per group who were
218 'recovered' (i.e. a reduction in EPDS score of four points or more plus scored less than 13
219 points) versus not recovered (Matthey, 2004) was conducted using Chi-squared tests.
220 Categorising data in this way provides a better indication of whether real changes have
221 occurred at the level of the individual participant (refer to Jacobson and Truax 1991 and
222 Matthey 2004 for a more detailed discussion). In addition, in order that we could compare
223 our findings with other previous postnatal depression treatment trials we compared those who
224 improved (i.e. proportions below 13 on the EPDS) versus not improved.

225 The IPAQ results were negatively skewed and comparison between the groups was
226 undertaken using quantile regression analysis, with baseline physical activity included as a
227 covariate. All statistical analysis was carried out using SAS version 9.2 and Stata version 12.

228 **Results**

229 Study invitations and EPDS-1 were sent by CHS to 9983 women and 1068 were
230 returned (10.7%). An additional 82 women recruited via other methods completed EPDS-1.
231 Of these, 436/1150 (37.9%) scored 10+ on EPDS-1, of whom 146/436 (33.5%) scored 13+ on
232 EPDS-2 two weeks later and were offered a home visit to diagnose depression using the CIS-
233 R and to assess other eligibility criteria. Of these 146 women, 100 (68.5%) were fully eligible
234 and 94 were randomised (Figure 1). The characteristics of responders and non-responders to
235 EPDS-1 were similar in terms of age, deprivation (McLennan et al., 2011) and ethnicity.

236 **Randomisation and participants' baseline characteristics**

237 Our sample size calculation indicated that 166 participants needed to be recruited,
238 rising to 208 with 20% loss to follow up. We did not meet this target and 94 participants were
239 randomised to the exercise plus usual care group (n=47) or the usual care only group (n=47).
240 Table 1 describes the baseline characteristics which shows a good balance between groups on
241 these variables, although more usual care participants were receiving
242 counselling/psychological support than the intervention group (21% versus 7%). The
243 majority of participants lived in the two highest deprivation quartiles (74/94, 79%) and 37%
244 (35/94) were of non-white ethnicity. The questionnaire assessments (EPDS and/or CIS-R)
245 showed that a large proportion of participants had thoughts of self-harming (32/94, 34%). 17
246 (18.1%) participants were diagnosed on the CIS-R with a severe depressive episode, 50
247 (53.2%) moderate severe episode, 15 (15.9%) mild episode and 12 (12.8%) were diagnosed
248 with mixed anxiety and depressive disorder. These diagnoses were balanced across groups.

249 **Information about follow up**

250 Rates of breastfeeding, risk of self harm, use of antidepressants and counselling (and
251 both treatments) at six and 12 month post randomisation (supplementary Table 1). More
252 usual care participants were also receiving psychological support at follow up than in the
253 exercise group.

254 At six months post randomisation 85/94 (90.4%) participants completed follow up for
255 the primary outcome and at 12 months post randomisation the follow up rate was 79/94
256 (84.0%). Participants lost to follow up tended to be marginally younger compared to those
257 who were followed up but were similar in terms of group allocation, baseline mean EPDS
258 score, deprivation quartile score (McLennan et al., 2010) and ethnicity.

259 **Primary outcome**

260 After adjusting for baseline scores, analyses revealed a -2.04 point mean difference in
261 EPDS score, favouring the exercise intervention group (95% CI: -4.11 to 0.03, p=0.053).

262 When adjusting for baseline EPDS score and pre-specified demographic variables, the mean
263 difference increased and was statistically significant (-2.26, 95% CI, -4.36 to -0.16, p=0.03).
264 Tables 2 and 3.

265 **Secondary outcomes**

266 At six months significantly more of the intervention group were considered
267 'recovered' and no longer a case (46.5% versus 23.8%, p=0.03) compared to usual care. By
268 12 months, the proportions considered 'recovered' (i.e. a reduction in EPDS score of four
269 points or more plus scored less than 13 points) had increased in both groups (51.2% versus
270 36.8%) but the difference between the groups was reduced and not statistically significant.
271 Table 4.

272 The exercise group had significantly higher social support scores than usual care at six
273 months in both adjusted models however the effect was not sustained at 12 months. In the
274 fully adjusted analysis there was some evidence of a difference in vitality scores at 6 months,
275 favouring the exercise group (p=0.054), but this effect was not significant at 12 months
276 (p=0.09). The exercise group reported significantly lower social support at 12 months for
277 exercise-family rewards scores (p=0.04) than usual care when adjusting for baseline score,
278 but there was no significant difference between the groups in the fully adjusted model (Tables
279 2 and 3).

280 There were no significant differences between the groups on any of the physical
281 activity outcomes derived from the IPAQ (supplementary table 2). Only eight participants
282 (8.5%) wore the Actiheart and provided useable data for analyses at both six and 12 months
283 follow up. These data are therefore not reported since they do not provide reliable
284 information on which to base any conclusions (see discussion later) but it is available from
285 the first author on request.

286 **Intervention implementation and adherence to the intervention goals**

287 Delivery of the various intervention components was very high; 41/47 (87%)
288 participants received all four individual contacts (two consultations and two telephone support
289 calls, 43/47 (91.4%), 44/47 (93.6%) and 46/47 (97.9%) received at least three, two and one
290 respectively of the individual intervention contacts.

291 A total of 163/235 (69.4%) (i.e. 47 participants x 5 logs) of the exercise logs were
292 completed by the intervention group, with the majority (40/47) completing at least 3/5 logs.
293 Only four participants failed to complete a single log. In the logs participants reported
294 completing an overall average of 146 (SD=142) min of moderate/vigorous exercise. The
295 exercise group reported increased levels of exercise over the course of the intervention; in
296 logs one to five participants reported means per week of 161.1, 217.5, 203.2, 222.5 and 245.0
297 min of moderate/vigorous exercise respectively (range equates to 23-35 min per day). The
298 most common types of exercise reported were brisk walking with pram, brisk walking without
299 pram, exercise DVDs, Wii fit workouts, jogging and swimming.

300 **Discussion**

301 Women diagnosed with postnatal depression and randomised to a facilitated home
302 based exercise intervention for six months reported lower mean EPDS scores than those
303 randomised to usual care only. Depressed women were twice as likely to report a clinically
304 meaningful change in their EPDS score (i.e. 'recovered') at six months follow up if they had
305 been randomised to the exercise intervention. These results emerged despite the fact that
306 substantially more (between two-three fold higher) usual care participants were receiving
307 psychological support at baseline and six month follow up than the exercise group. The
308 benefits of the intervention were seen only at six months follow up but given the longer term
309 adverse effects of postnatal depression for the mother and the development of the baby this is
310 the most critical time to offer treatment.

311 The magnitude of the difference in mean EPDS scores between the groups was of a
312 moderate size (Affonso, 2000; Matthey, 2004). This is smaller than the overall size found in
313 our meta analysis (Daley et al., 2009) of exercise for postnatal depression (-4.00 EPDS points,
314 95 % CI: -7.64 to -0.35), but which largely included small studies with high drop-out and less
315 stringent inclusion criteria than used here. In particular, none of the previous trials had
316 recruited women with a *clinical diagnosis* of depression after giving birth. These findings
317 should however be considered in light of the relatively low response (11%) to the initial
318 invitation letter meaning it is possible that women who were more motivated to be active
319 were recruited to the trial.

320 Our findings are broadly comparable with those reported for other types of treatments
321 for postnatal depression. In the RESPOND trial (n=254) (Sharp et al 2010), which initially
322 randomised women to antidepressants or non-directive counselling but which also allowed
323 women to stop one treatment and start the other or add the other treatment to the first one,
324 reported the proportion of women improving (scoring 13 or less on the EPDS) was 62% for
325 antidepressants and 51% for listening visits 18 weeks after randomisation. These proportions
326 are similar to the proportions considered as improved (56%) and recovered (47%) in our study
327 at six months follow up. The PONDER trial (Morrell et al., 2009) compared the effectiveness
328 of health visitors providing psychological support for one hour per week over eight weeks
329 compared to usual care in women (n=418) considered at risk of postnatal depression (EPDS
330 ≥ 12). The difference in EPDS score between the groups in was 2.1 points (95% CI -3.3 to -
331 0.9) (adjusted) favouring the intervention group, very similar to our reported mean group
332 difference and confidence intervals.

333 The exercise intervention group also had higher social support scores at six months
334 indicating that they felt more supported than usual care. Exercise can provide a reason for
335 engaging with others and as part of this intervention participants were encouraged to find

336 social support, to ask friends/family to support them with their exercise. Findings suggest the
337 intervention group were able to achieve this and plausibly benefitted from doing so. This is
338 important because women with postnatal depression can become isolated at a time when they
339 need support the most. Exercise may be a vehicle by which these women (and health
340 professionals responsible for their care) can engage others in their social networks to offer
341 support. Moreover, most forms of exercise typically involve some level of engagement or
342 connection with others, whether that is by attending exercise groups/classes or taking a walk
343 in the local community for example.

344 No significant differences between the groups at follow up were recorded for self-
345 reported physical activity; there are several plausible explanations for this. Usual care may
346 have over reported their exercise which is common in the general population. The
347 intervention group however were taught how to accurately assess and report their exercise as
348 a way of self-monitoring their progress so were made more aware of what constitutes
349 different intensities of exercise, potentially resulting in this group reporting their exercise
350 more accurately than usual care. As individuals can increase their exercise without
351 professional support, usual care may have increased their exercise following informed
352 consent. It is also possible that the intervention group did not achieve higher exercise levels
353 compared to usual care.

354 We are not able to corroborate the self-reported exercise data using data from the
355 Actiheart (objective assessment) because so few women were prepared to wear the device at
356 follow up. Many participants found the Actiheart uncomfortable and/or it interfered with
357 breastfeeding so removed it. However, the logs completed by the exercise group throughout
358 the intervention showed that this group reported increasing their exercise levels over time and
359 maintained participation in at least 150 minutes of moderate/vigorous intensity exercise per
360 week. A real increase in exercise may explain the significant improvements in psychological

361 outcomes for the women in the intervention group relative to usual care, but other
362 mechanisms are also possible. It is possible the improvements in psychological outcomes are
363 due to non-specific effects associated with the contacts with the PAF, which may have been
364 perceived as therapeutic by women. It may also have been that the PAF acted as a
365 mechanism for women to seek out additional social support to help them with their exercise
366 endeavours, and it is this social support that facilitated improvement in their mental health.

367 **Strengths and limitations of the study**

368 The response rate was relatively low and whilst we did not meet our recruitment target
369 the size of difference seen in EPDS score exceeded the pre-specified effect size in our sample
370 size calculation. Several alternative strategies were used during the trial to try and improve
371 recruitment but with varied success. To facilitate recruitment future trials will need to involve
372 several centres and/or recruit over several years. A very recent trial of depression (Krusche et
373 al., 2014) found that an intensive advertisement campaign that targeted community settings
374 (e.g. adverts on buses, social media and regular radio adverts) was very cost effective. Our
375 trial had minimal involvement from mass media and in future trials this might be a useful
376 supplement to the recruitment strategies used here. This is the largest exercise RCT of any
377 postnatal women considered to be depressed and the only study to recruit women with a
378 clinical diagnosis of depression. This study was extremely rigorous in determining a
379 diagnosis of depression, using a two stage process that resulted in an ICD-10 diagnosis of a
380 major depressive episode or mixed anxiety and depression, rather than only a high score on a
381 screening questionnaire as used in all previous studies. The effect of the intervention on
382 EPDS score are in line with larger high quality studies that have evaluated other treatments
383 for postnatal depression, providing reassurance about the robustness of our findings.

384 At baseline most women were experiencing a severe/moderate depressive episode and
385 34% reported thoughts of self-harming demonstrating recruitment of those women clearly in

386 need of intervention. A large proportion of participants were of non-white ethnicity (37%)
387 and/or living in the two highest IMD deprivation quartiles (79%); typically these populations
388 are very difficult to recruit to mental health treatment trials. Loss to follow up was very low
389 (6% at 6 months, 16% at 12 months). We are not able to be certain of the exact mechanism of
390 effect by which the intervention improved outcomes but we do know the intervention group
391 achieved the behavioural goals asked of them during the exercise intervention. Nevertheless,
392 this trial provides the first steps of evidence and the foundation for further studies on this
393 question in women with clinically defined postnatal depression. Studies that focus on
394 investigating potential mechanisms of effect in this population are needed.

395 **Conclusions**

396 This trial contributes new evidence to indicate that a facilitated exercise intervention
397 that involved encouragement to exercise and to seek out social support to exercise may be an
398 effective treatment for women experiencing postnatal depression, including those at risk of
399 self-harming.

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408

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Contributors:

417 AD, KJ, CM, AR, DS, KT, MM and IJ were responsible for the initial proposal, secured
418 funding for the study and drafted the original protocol. RB and SC also contributed to
419 drafting the published protocol. AD as the principal investigator had overall management
420 responsibility for the study. RB as trial coordinator was responsible for the day to day
421 conduct of the study. SC delivered the intervention. RB prepared the data from the actihearts
422 for analysis. AR conducted the sample size calculations, wrote the analysis plan and
423 conducted the statistical analyses. AD wrote the initial draft of the manuscript with assistance
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427 Favourable ethical opinion was granted for this study by the Birmingham, East, North and
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Data sharing

430 Additional data can be obtained from the corresponding author for the purposes of secondary
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432

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435

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437

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595 **Table 1: Baseline characteristics of randomised participants**

| | Exercise (N=47) | Usual care (N=47) |
|---|----------------------------|------------------------------|
| | n (%) | n (%) |
| Age (years) mean (sd) | 31.7 (5.3) | 29.3 (5.7) |
| EPDS [0-30] mean (sd) | 17.3 (3.0) | 17.5 (3.7) |
| EPDS score* 13-16 | 20 (43) | 20 (43) |
| 17+ | 27 (57) | 27 (57) |
| Thoughts of self-harming | 14 (30%) | 18 (38%) |
| IMD quartile 1 (least deprived) | 3 (6) | 4 (9) |
| 2 | 7 (15) | 6 (13) |
| 3 | 13 (28) | 9 (19) |
| 4 (most deprived) | 24 (51) | 28 (60) |
| Ethnic origin | | |
| White | 27 (57) | 32 (68) |
| Mixed | 3 (6) | 2 (4) |
| Indian | 3 (6) | 3 (6) |
| Pakistani | 7 (15) | 5 (11) |
| Bangladeshi | 1 (2) | 0 (0) |
| Black-African | 2 (4) | 1 (2) |
| Black-Caribbean | 0 (0) | 1 (2) |
| Chinese | 1 (2) | 0 (0) |
| Other | 3 (6) | 3 (6) |
| Number of children mean (sd) | 2.2 (1.2) | 2.2 (1.4) |
| Number with children aged 2-5 years | 25 (53) | 22 (47) |
| Number with children aged over 5 yrs | 14 (30) | 12 (26) |
| Other occupants - Husband | 40/45 (89) | 41/47 (87) |
| Relative | 7/30 (23) | 6/26 (23) |
| Step-children | 1/25 (4) | 2/23 (9) |
| Age of baby at randomisation (days) mean (sd) | 117.3 (26.5) | 121.8 (27.9) |
| Height (m) mean (sd) | 1.63 (0.06) | 1.64 (0.06) |
| Weight (kg) mean (sd) | 76.2 (13.4) | 76.8 (17.0) |
| BMI mean (sd) | 28.8 (5.0) | 28.5 (5.8) |
| Smoker | 9/46 (20) | 9/47 (19) |
| Experiencing long term illness | 7/47 (15) | 7/47 (15) |
| Prescribed antidepressants before or during pregnancy | 18/39 (46) | 12/37 (32) |
| Currently taking antidepressants | 10/46 (22) | 10/47 (21) |
| Currently having counselling/psychological support | 3/46 (7) | 10/47 (21) |
| Currently taking antidepressants plus having counselling/psychological support | 1(2) | 6(13) |
| Employment status: | | |
| Paid | 17/46 (37) | 25/47 (53) |
| Self employed | 0/46 (0) | 2/47 (4) |
| Unemployed | 7/46 (15) | 5/47 (11) |
| Student | 1/46 (2) | 2/47 (4) |
| Looking after home/family | 20/46 (43) | 13/47 (28) |

| | | |
|--|---------------|-------------|
| Sick/disabled | 0/46 (0) | 0/47 (0) |
| Other | 1/46 (2) | 0/47 (0) |
| Years living in area median (IQR) | 5 (2 to 10.5) | 4 (2 to 10) |
| Have practical help at home | 35/47 (74) | 36/46 (78) |
| Have contact with local people with a baby | 22/47 (47) | 27/44 (61) |
| Have someone to talk to | 39/47 (83) | 35/46 (76) |
| Have help from husband [0-10] mean (sd) | 5.4 (3.3) | 5.7 (2.7) |
| Currently breast feeding | 16/47 (34) | 20/46 (44) |
| Type of delivery | | |
| Normal vaginal | 27/47 (57) | 31/46 (67) |
| Instrumental vaginal | 6/47 (13) | 6/46 (13) |
| Elective caesarean | 7/47 (15) | 5/46 (11) |
| Emergency caesarean | 7/47 (15) | 4/46 (9) |
| Exercise per wk pre-pregnancy (hours) median (IQR) | 0 (0 to 5) | 0 (0 to 4) |

596 *Stratification variable. Higher score on EPDS indicates high levels of probable depression

597

598 **Table 2: Baselines questionnaires and measurements**

| Outcomes | Intervention Mean (sd) | N | Usual care Mean (sd) | N |
|--|---------------------------|----|-------------------------|----|
| Questionnaires | | | | |
| Vitality scale [1-7] | 2.8 (0.7) | 46 | 2.8 (0.6) | 47 |
| PCS-12 [0-100] mean (sd) | 52.7 (7.9) | 47 | 51.0 (9.4) | 47 |
| MCS-12 [0-100] mean (sd) | 30.8 (7.9) | 47 | 31.2 (7.9) | 47 |
| EQ-5D [-0.59-1.0] mean (sd) | 0.68 (0.19) | 47 | 0.68 (0.22) | 46 |
| median (IQR) | 0.73 (0.62 to 0.81) | | 0.69 [0.69 to 0.85] | |
| MAMA (body image) [10-40] | 22.5 (4.4) | 44 | 22.0 (3.9) | 41 |
| Social support [8-24] | 20.1 (4.0) | 47 | 19.5 (4.4) | 47 |
| Social support and exercise | | | | |
| Family participation [10-50] mean (sd) | 15.1 (6.5) | 44 | 14.9 (5.4) | 44 |
| median (IQR) | 12 [10 to 20] | | 12.5 [10 to 20.5] | |
| Family rewards [3-15] mean(sd) | 3.4 (1.2) | 45 | 3.2 (0.8) | 45 |
| median (IQR) | 3 [3 to 3] | | 3 [3 to 3] | |
| Friends participation [10-50] mean (sd) | 13.0 (5.6) | 44 | 12.8(4.3) | 44 |
| median (IQR) | 10.5 [10 to 14] | | 10 [10 to 14] | |
| Exercise confidence | | | | |
| Sticking to it score [8-40] mean(sd) | 20.9 (5.9) | 37 | 19.7 (4.8) | 40 |
| Making time for it score [4-20] mean(sd) | 13.0 (3.4) | 35 | 11.8 (2.8) | 36 |
| IPAQ | | | | |
| Vigorous (MET-mins/wk) mean(sd) | 264.7 (762.9) | 47 | 163.6 (546.7) | 44 |
| median (IQR) | 0 [0 to 0] | | 0 [0 to 0] | |
| Moderate (MET-mins/wk) mean(sd) | 453.9 (927.9) | 46 | 59.1 (167.1) | 46 |
| median (IQR) | 0 [0 to 360] | | 0 [0 to 0] | |
| Walking (MET-mins/wk) mean(sd) | 950.5 (1089.6) | 43 | 895.1 (1106.6) | 44 |
| median (IQR) | 495 [198 to 1386] | | 585.8 [99 to 1254] | |
| Total (MET-mins/wk) mean(sd) | 1725.4 (1864.7) | 43 | 1122.1 (1242.9) | 43 |
| median (IQR) | 918 (396 to 3108) | | 594 (99 to 1254) | |
| Sitting (hrs/day) mean(sd) | 5 (4.1) | 32 | 5.3 (4.9) | 28 |
| median (IQR) | 4 [2.5 to 6] | | 4 [3 to 5] | |

599 Higher scores on all questionnaire based outcomes except EPDS and sitting time indicate
600 more positive health/behaviours
601
602

Exercise for postnatal depression

Table 3: Six and 12 month post randomisation follow up data for outcomes

| | Follow-up (months) post randomisation | Randomisation Group | | | | Difference in adjusted* means (95% CI) | p value | Difference in adjusted** means (95% CI) | p value |
|------------------------------|---|---------------------|----|---------------|----|---|---------|---|---------|
| | | Exercise | | Usual care | | | | | |
| | | mean (sd) | n | mean (sd) | n | | | | |
| Primary outcome: | | | | | | | | | |
| EPDS [0-30] | 6 | 12.51 (5.46) | 43 | 14.67 (4.86) | 42 | -2.04 (-4.11 to 0.03) | 0.053 | -2.26 (-4.36 to -0.16) | 0.035 |
| | 12 | 12.02 (5.29) | 41 | 12.55 (5.17) | 38 | -0.95 (-3.16 to 1.25) | 0.40 | -1.39 (-3.69 to 0.92) | 0.24 |
| Weight (kg) | 6 | 75.06 (13.20) | 42 | 77.36 (17.36) | 42 | 0.38 (-1.82 to 2.58) | 0.74 | 0.79 (-1.41 to 3.00) | 0.48 |
| | 12 | 75.40 (16.05) | 41 | 77.11 (18.39) | 38 | 1.39 (-2.12 to 4.91) | 0.44 | 1.36 (-2.36 to 5.09) | 0.47 |
| BMI (kg/m ²) | 6 | 28.61 (5.38) | 42 | 28.61 (5.98) | 41 | 0.17 (-0.67 to 1.01) | 0.69 | 0.22 (-0.61 to 1.06) | 0.45 |
| | 12 | 28.75 (6.99) | 41 | 28.77 (6.29) | 37 | 0.53 (-0.90 to 1.96) | 0.47 | 0.37 (-1.15 to 1.88) | 0.63 |
| PCS-12 [0-100] | 6 | 51.34 (9.02) | 42 | 51.59 (8.48) | 42 | -1.10 (-4.32 to 2.11) | 0.50 | -0.06 (-2.95 to 2.84) | 0.97 |
| | 12 | 52.16 (9.16) | 40 | 51.6 (8.57) | 38 | -0.49 (-3.76 to 2.78) | 0.77 | 0.10 (-3.17 to 3.37) | 0.95 |
| MCS-12 [0-100] | 6 | 41.45 (9.99) | 42 | 37.90 (10.30) | 42 | 3.38 (-0.74 to 7.51) | 0.11 | 3.45 (-0.78 to 7.69) | 0.11 |
| | 12 | 41.60 (12.13) | 41 | 41.02 (12.36) | 38 | 1.16 (-3.65 to 5.96) | 0.64 | 1.97 (-3.13 to 7.07) | 0.45 |
| EQ-5D # [-0.59- 1.0] | 6 | 0.78 (0.21) | 41 | 0.72 (0.22) | 41 | 0.07 (-0.02 to 0.15) | 0.12 | 0.07 (-0.02 to 0.15) | 0.11 |
| | 12 | 0.81 (0.21) | 40 | 0.78 (0.23) | 38 | 0.05 (-0.03 to 0.14) | 0.22 | 0.06 (-0.03 to 0.15) | 0.22 |
| MAMA (Body image) [10-40] | 6 | 23.73 (5.20) | 40 | 22.53 (4.10) | 40 | 0.53 (-1.01 to 2.07) | 0.50 | 0.60 (-0.93 to 2.14) | 0.44 |

| | Follow-up (months) post randomisation | Randomisation Group | | | | Difference in adjusted* means (95% CI) | p value | Difference in adjusted** means (95% CI) | p value |
|---|---|---------------------|----|--------------|----|---|---------|---|---------|
| | | Exercise | | Usual care | | | | | |
| | | mean (sd) | n | mean (sd) | n | | | | |
| | 12 | 24.43 (5.18) | 37 | 23.94 (4.83) | 36 | -0.11 (-1.99 to 1.76) | 0.91 | -0.03 (-2.04 to 1.97) | 0.98 |
| Vitality [1-7] | 6 | 3.53 (0.95) | 39 | 3.18 (0.87) | 40 | 0.36 (-0.04 to 0.76) | 0.08 | 0.41 (0.007 to 0.82) | 0.054 |
| | 12 | 3.70 (1.11) | 41 | 3.48 (1.14) | 38 | 0.31 (-0.14 to 0.76) | 0.18 | 0.42 (-0.06 to 0.90) | 0.09 |
| Social support [8-24] | 6 | 20.80 (3.59) | 41 | 18.93 (4.93) | 41 | 2.10 (0.78 to 3.43) | 0.002 | 2.24 (0.93 to 3.54) | 0.001 |
| | 12 | 20.80 (3.68) | 40 | 19.73 (5.14) | 37 | 1.25 (-0.20 to 2.71) | 0.09 | 1.38 (-0.15 to 2.90) | 0.08 |
| Social support for exercise Family participation [10- 50] | 6 | 16.87 (7.44) | 38 | 15.48 (6.54) | 40 | 2.23 (-0.94 to 5.40) | 0.17 | 2.00 (-1.49 to 5.48) | 0.26 |
| | 12 | 16.88 (7.87) | 41 | 18.67 (9.53) | 36 | -0.95 (-4.28 to 2.38) | 0.58 | -0.88 (-4.30 to 2.54) | 0.62 |
| Family rewards and punishment [3-15] | 6 | 3.60 (1.68) | 40 | 3.55 (1.30) | 40 | 0.11 (-0.41 to -0.64) | 0.68 | 0.16 (-0.37 to 0.69) | 0.55 |
| | 12 | 3.46 (1.47) | 41 | 4.03 (1.65) | 38 | -0.54 (-1.06 to -0.02) | 0.04 | -0.42 (-0.96 to 0.11) | 0.12 |
| Friend participation [10- 50] | 6 | 16.57 (9.08) | 37 | 14.75 (8.11) | 40 | 1.62 (-2.12 to 5.37) | 0.40 | 2.18 (-1.85 to 6.20) | 0.29 |
| | 12 | 14.55 (7.13) | 38 | 16.73 (8.36) | 37 | -2.83 (-5.65 to -0.005) | 0.050 | -2.30 (-5.15 to 0.55) | 0.11 |

| | Follow-up (months) post randomisation | Randomisation Group | | | | Difference in adjusted* means (95% CI) | p value | Difference in adjusted** means (95% CI) | p value |
|--|---|---------------------|----|--------------|----|---|---------|---|---------|
| | | Exercise | | Usual care | | | | | |
| | | mean (sd) | n | mean (sd) | n | | | | |
| Exercise confidence ECS sticking to it [8-40] | 6 | 22.09 (7.93) | 33 | 20.22 (6.89) | 32 | 2.41 (-1.71 to 6.52) | 0.25 | 3.27 (-1.13 to 7.66) | 0.15 |
| | 12 | 23.29 (8.54) | 31 | 22.03 (8.24) | 30 | 0.88 (-3.30 to 5.07) | 0.68 | 2.03 (-2.52 to 6.57) | 0.38 |
| ECS making time for it [4-20] | 6 | 12.21 (4.26) | 34 | 11.07 (3.38) | 30 | 0.27 (-1.89 to 2.44) | 0.81 | 0.91 (-1.25 to 3.08) | 0.41 |
| | 12 | 12.81 (3.79) | 31 | 12.15 (4.35) | 26 | -0.73 (-1.43 to 2.90) | 0.51 | 1.32 (-1.03 to 3.68) | 0.27 |

* adjusted by baseline value and baseline EPDS

** adjusted by baseline value, baseline EPDS, age, weight and ethnicity

bootstrapped confidence intervals and p values

Higher scores on all questionnaire based outcomes except EPDS and sitting time indicate more positive health/behaviours

Exercise for postnatal depression

Table 4: Proportions improved and recovered on the EPDS six and 12 months post randomisation

| Outcome | Randomisation Group | | Difference (95% CI) | p value |
|---|---------------------|------------------|-------------------------|---------|
| | Exercise | Usual care | | |
| Improved at 6 months (EPDS score less than 13) | 24/43 (55.8%) | 16/42 (38.1%) | 17.7% (-3.2% to 38.6%) | 0.10 |
| Improved at 12 months (EPDS score less than 13) | 23/41 (56.1%) | 17/38 (44.7%) | 11.4% (-10.6% to 33.3%) | 0.31 |
| Recovered at 6 months (EPDS dropped by 4 points and score less than 13)* | 20/43 (46.5%) | 10/42 (23.8%) | 22.7% (3% to 42.4%) | 0.03 |
| Recovered at 12 months (EPDS dropped by 4 points and score less than 13)* | 21/41 (51.2%) | 14/38 (36.8%) | 14.4% (-7.3% to 36.0%) | 0.20 |

*Criteria for determining clinically important change (Jacobson and Truax 1991; Matthey 2004).