1 2 3 4 5 6 7 8 9	 P, Batallones R, Andrighetti H, Austin J. A matched cohort study of postpartum placentophagy: impact on mood, energy, vitamin B12 levels, and lactation. <i>Journal of Obstetrics and Gynecology Canada</i>, 2 41(9): 1330-7 which has been published in final form at: https://doi.org/10.1016/j.jogc.2019.02.004 The work is licensed under the Creative Commons Attribution-NonCommercial-NoDerivatives 4.0 International License. To view a copy of this license, visit https://creativecommons.org/licenses/by-nc-nd/4.0/ or send a letter to Creative Commons, PO Box 1866, Mountain View, CA 94042, USA. 				
10	A matched cohort study of postpartum placentophagy in women with a history of mood				
11	disorders: no evidence for impact on mood, energy, vitamin B12 levels, or lactation				
12					
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37 Dr. Austin reports grants and personal fees from CIHR, grants and personal fees from Michael

38 Smith Foundation, personal fees from Canada Research Chair, personal fees and non-financial

- 39 support from BC Mental Health & Substance Use Services, non-financial support from BC
- Women's Health Research Institute, during the conduct of the study; grants from Pfizer Canada,
 outside the submitted work.
- 41 42
- 43 All other authors: Declarations of interest: none.
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- 45
- 46 Abstract
- 4748 Objective: Though empirical studies investigating its effective
- 48 Objective: Though empirical studies investigating its effects are scarce, postpartum
 49 placentophagy is increasing in popularity due to purported benefits for mood, energy, lactation,
- and overall nutrition. Therefore, we sought to test the hypotheses that women who consumed
- 51 their placenta (placentophagy exposed, PE) would have: 1) less depressive symptoms, 2) more
- 51 unch placenta (placentophagy exposed, FE) would have: 1) less depressive symptoms, 2) more 52 energy, 3) higher B12 levels, and 4) less pharmaceutical lactation support during the postpartum
- 52 than women who did not consume their placenta (non placentophagy exposed, NE).
- 54 **Methods:** Using data from a large, longitudinal study of gene x environment effects involving
- 55 perinatal women with a history of mood disorders, we identified PE cohort and matched them
- 56 4:1 (by: psychiatric diagnosis, psychotropic medication use, supplementation, income, and age)
- 57 with an NE cohort from the same dataset. We investigated differences between PE and NE
- 58 cohorts with respect to: scores on the Edinburgh Postnatal Depression Scale (EPDS) and Sleep-
- 59 Wake Activity Inventory (SWAI), B12 levels, and use of pharmaceutical lactation support 60 (Canadian Taskforce Classification II-2).
- 61 **Results:** Our sample of 138 (28 in PE cohort, matched to 110 in NE cohort) provided 80%
- 62 power at $\alpha = 0.0125$ to detect an effect of moderate magnitude (which can be used to
- 63 approximate an effect of clinically significant magnitude). There were no differences in EPDS
- or SWAI scores (p=.28, and p=.39, respectively), B12 levels (p=.68), or domperidone use (p=1)
- 65 between PE and NE cohorts.
- 66 **Conclusion:** These data provide no support for the idea that postpartum placentophagy
- 67 improves mood, energy, lactation, or plasma B12 levels in women with a history of mood68 disorders.
- 69
- 70
- 71
- 72
- 73 Keywords: placentophagy, placenta, postpartum depression, lactation, postpartum energy,
- vitamin B12
- 75

76 Introduction

77 78 Recent media coverage of celebrities engaging in postpartum placentophagy [1] has been accompanied by increasing popularity of the practice in the broader population [2-4]. Rationale 79 80 for the practice is typically based on anecdotal reports of benefits derived from the hormones 81 and nutrients contained in the placenta [5-10]. Though consumption of placenta 82 (frozen/dehydrated, ground and encapsulated, or ingested in a less processed form, e.g. cooked 83 [11]) is often cited as beneficial to women's mood, energy, general nutrition, and lactation, 84 empirical studies regarding human placentophagy and any of these outcomes are scarce and 85 limited [12-14]. As placentophagy is not without significant (potentially life-threatening) risks 86 [9,15], data are needed regarding its potential benefits, in order to provide evidence-based 87 guidance regarding this practice. 88 The purpose of this study was to empirically investigate the effect of postpartum

placentophagy on maternal mood, energy, micronutrients, and lactation. Because women engage in placentophagy due to its purported beneficial effects on these outcomes [3], we aimed to test the hypotheses that in the postpartum, women who consumed their placenta (placentophagy exposed, PE) would have: 1) less depressive symptoms, 2) more energy, 3) higher plasma B12 levels, and 4) less pharmaceutical lactation support, than a matched cohort of women who did not consume their placenta (non placentophagy-exposed, NE).

95 Materials & Methods

We conducted a matched retrospective cohort study through secondary analysis of data
collected in the context of a Canadian prospective longitudinal study on perinatal

98 psychopathology in women (N=365) with a history of a psychiatric disorder (recruitment

99 described elsewhere [16]). The prospective longitudinal study from which data were drawn for

this investigation was observational in nature; no experimental interventions were provided toparticipants.

102 After providing informed consent, each participant completed demographic 103 questionnaires at enrolment (during pregnancy), and past history of a psychiatric diagnosis was 104 confirmed with the Structured Clinical Interview for the DSM IV [17]; women did not need to 105 be currently experiencing a perinatal mood episode to enrol in the study. At each of three 106 postpartum time-points (1-2 weeks postpartum, 1-2 months postpartum, and 3-4 months 107 postpartum), we administered instruments to measure depression and energy (see *Outcome* 108 Measures), and participants were explicitly asked to report all medications and 109 vitamins/supplements taken, including consumption of placenta in any form (encapsulated or 110 non-encapsulated (e.g., consumed as a food)). Rather than seeking to influence participants' 111 activities with regard to use of supplements (including placenta) or medications (e.g. 112 domperidone), we simply recorded each woman's reported practice. Blood was drawn at each 113 visit, after which plasma was separated from red blood cells by centrifugation, and frozen at -114 70°C for later analysis of B12. The study was approved by the University of British Columbia 115 Research Ethics Board (H06-70145).

116 Inclusion criteria and cohort matching

We extracted data related to all pregnancies where: women had consumed their placenta after delivery, and we had data from at least one study time-point after initiation of placentophagy (PE cohort). To increase power, given the limited number of women in the PE cohort, we attempted to match each participant in the PE cohort with four NE women – this allows control for variables that are known to be correlated with the outcomes, but that are not of direct interest to the study [18]. We matched our cohorts according to psychiatric diagnosis

123 and postpartum psychotropic medication use (i.e. taking a daily anti-depressant or mood 124 stabilizer), age, income level, and consumption of a postpartum multivitamin and B12 125 supplement (see Table 1). More specifically, women in the PE cohort were categorized 126 according to whether they used psychotropic medication and B12 supplements after they had 127 initiated placentophagy. NE women were categorized according to whether they used 128 psychotropic medications and B12 supplements after the postpartum time-point at which their 129 index PE woman initiated placentophagy. Women were included in the NE cohort only if 130 outcome data (described below) were available for at least one study time-point after their index 131 PE woman had initiated placentophagy. 132 **Outcome Measures** 133 Depression symptoms: Edinburgh Postnatal Depression Scale (EPDS) 134 The EPDS is a 10-item, self-administered, Likert scale-based questionnaire (each item is 135 rated by selecting from 4 options, scored from 0 to 3) that has been validated for prenatal use 136 [19]. Total scores range from 0 to 30, with higher scores indicating higher levels of depression. 137 To test the hypothesis that PE women would have less depressive symptoms than NE women, 138 we used highest postpartum EPDS score after initiation of placentophagy as our outcome 139 variable for PE women. For NE women, we used the highest postpartum EPDS score after their 140 index PE woman initiated placentophagy. This strategy allowed for potential differences in 141 timing of emergence of most severe symptomatology. 142 Energy: Excessive daytime sleepiness subscale of the Sleep-Wake Activity Inventory (SWAI) 143 The SWAI is a self-report measure of sleepiness, with a validated 9-item excessive 144 daytime sleepiness subscale [20] that we used in this study. Each item is scored on a Likert scale 145 (1=always to 9=never). Scores on the excessive daytime sleepiness subscale range from 9 to 81,

and lower scores indicate lower energy (i.e., a higher degree of daytime sleepiness). To test the
hypothesis that PE women would have more energy than NE women, we used the lowest
postpartum SWAI subscale score after initiation of placentophagy as our outcome variable for
PE women. For NE women we used the lowest postpartum SWAI subscale score after their
index PE woman initiated placentophagy. This strategy allowed for differences in timing of
emergence of the most severe symptoms.

152

153 Plasma vitamin B12

154 Plasma vitamin B12 (a nutrient present in abundance in the placenta, and that should 155 therefore present in women's plasma after placentophagy) was quantified using 156 chemiluminescent immunoanalysis, (using Abbott architect i1000, as described elsewhere [21]. 157 To test the hypothesis that PE women would have higher plasma B12 levels (continuous 158 variable) than NE women, we used lowest postpartum B12 measure after initiation of 159 placentophagy as our outcome variable for PE women. For NE women we used the lowest 160 postpartum B12 measure after their index PE woman initiated placentophagy. This strategy 161 allowed for differences in timing of fluctuation of B12 levels.

162

163 *Lactation: Use of Domperidone*

Domperidone is thought to enhance milk production, and is often used off-label for this purpose in Canada, despite limited data supporting its efficacy and some safety concerns [22-24]. To test the hypothesis that PE women would use less pharmaceutical lactation support than NE women, we categorized women according to whether they took domperidone for the

- 168 indication of poor milk production at any time in the postpartum after initiation of
- 169 placentophagy (or, for the NE cohort, after their index PE woman initiated placentophagy).
- 170

171 Analyses/power

Descriptive statistics were applied to demographic data. Data distributions of the highest EPDS scores, lowest SWAI excessive daytime sleepiness subscale scores, and lowest plasma B12 levels were assessed for normality using Shapiro Wilk tests. Mann-Whitney U tests were used for comparisons, as data were not normally distributed. We applied Fisher's Exact test to compare rates of domperidone use between PE and NE cohorts.

177 There were no pre-existing data from which to estimate the size of the effect of 178 placentophagy on the outcomes of interest, and therefore no data on which to base a power 179 calculation. We therefore conducted a compromise calculation (using G*power) to determine 180 the power of our available dataset to detect an effect of moderate magnitude (which can be used 181 to approximate an effect of clinically significant magnitude [25]). A significance threshold (α) 182 of p < 0.0125 was applied (to allow for four tests at a nominal overall significance level of 183 0.05). Common language (CL) effect sizes were calculated when applicable with values of 0.56, 184 0.64, 0.72 corresponding to small, moderate and large effect sizes, respectively [26]. All 185 analyses were performed using IBM SPSS Statistics version 24 (IBM Corp. Armonk, N.Y). 186 **Results** 187 We found that 28 of the 365 women in the larger study met inclusion criteria for our PE 188 cohort (27 used encapsulated placenta, the other ingested it raw and blended), and matched them 189 (according to the process described above) to an NE cohort of n=110 (we successfully made

190 four NE matches each for 26 of the PE cohort, and made three NE matches each for the

191	remaining two). One of the PE cohort did not complete the SWAI and was therefore excluded
192	from the analysis of energy levels (along with her NE matches). One of the PE cohort could not
193	be matched for B12 supplement use (due to the use of additional B12 supplements), and was
194	thus excluded from the analysis of plasma B12 levels. Demographic data are displayed in Table
195	1. Our dataset afforded 77% power to detect an effect of d=0.65.
196	
197	< <insert 1="" about="" here="" table="">></insert>
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199	Of the 28 women in the PE cohort, the majority (n=21) commenced consumption of their
200	placenta prior to the 1-2 weeks postpartum time-point, with the remaining seven initiating prior
201	to the 1-2 month time-point.
202	
203	Effect of placentophagy on depression symptoms
204	Highest postpartum EPDS scores for PE and NE cohorts are shown in Figure 1. There
205	were no significant differences in highest postpartum EPDS scores between cohorts (p=0.282,
206	CL effect size=0.57).
207	
208	< <insert 1="" about="" figure="" here="">></insert>
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210	Effect of placentophagy on energy
211	Lowest SWAI scores for the two cohorts are shown in Figure 2. There were no
212	significant differences in lowest postpartum SWAI scores between cohorts (p=0.389, CL effect
213	size=0.55).

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215	< <insert 2="" about="" figure="" here="">></insert>
216	
217	Effect of placentophagy on plasma vitamin B12 levels
218	Lowest postpartum plasma vitamin B12 levels for the two cohorts are shown in Figure 3. There
219	were no significant differences in lowest postpartum plasma vitamin B12 between cohorts
220	(p=0.685, CL effect size=0.53).
221	< <insert 3="" about="" figure="" here="">></insert>
222	
223	Effect of placentophagy on lactation
224	A small proportion of women used domperidone in the postpartum (total n=21), and the
225	proportion of women who used it was identical between cohorts (p=1.0, see Table 1).
226	
227	Discussion
228	This is the largest study to date – of which we are aware - to examine the effect of
229	postpartum placentophagy on mood and energy, and the first to use objective measures to
230	examine the effects of placentophagy on plasma vitamin B12 and lactation. We identified no
231	significant differences in depression symptomatology, energy levels, plasma vitamin B12 levels
232	(a nutrient that should be abundant in placenta) or the use of pharmaceutical lactation
233	supplements (domperidone) between matched cohorts of women who did and did not engage in
234	postpartum placentophagy – all of whom had a history of a mood disorder.
235	In a previous study, the most commonly reported motivation for women to engage in
236	postpartum placentophagy was to improve mood [3]. However, our data show that among

women with the greatest need for an intervention to improve postpartum mood (due to increased
risks for postpartum episodes associated with a history of a mood disorder [27,28]), there was
no significant difference in postpartum mood symptoms between women who consumed their
placenta, and those who did not. Similarly, we found no differences between the cohorts in
terms of energy levels.

242 These results are broadly in line with the little previous data that exists on this topic. One 243 small, randomized, placebo-controlled pilot trial investigated depression symptomatology (also 244 using the EPDS) and fatigue in 12 women who consumed their placenta, and 18 controls, and 245 also found no robust differences between groups [13]. In the current study, the differences 246 between groups were not statistically significant, and effect sizes were small (with the direction 247 of the effects in the opposite direction to that hypothesized (i.e. women in the PE cohort had 248 more depressive symptoms (higher EPDS scores) and lower energy (lower SWAI scores)) 249 Similarly, our data showing no effect of placentophagy on B12 levels are concordant 250 with findings related to other micronutrients that are primarily obtained through animal products 251 (and are thus likely to be present in the placenta): specifically, one study showed no effect of 252 placentophagy on iron [12]. Ceiling effects are possible, given that most women were also 253 taking a multivitamin, though this is not evident from the data (Figure 3).

While women in previous studies have self-reported that placentophagy increases milk production ^{3, 11, 14}, we found identical rates of use of domperidone (commonly prescribed in Canada to improve lactation in women with poor milk production). Given that the PE cohort may be enriched for those who eschew pharmaceutical interventions [3,5], our data may underestimate the need for lactation support in this cohort.

259

260 Conclusion

Our data provide no evidence to support the idea that placentophagy improves mood, energy, plasma vitamin B12, or lactation in the postpartum period – at least in women with a history of depression. Given concerns about serious and life-threatening risks that have been associated with placentophagy, these data can help inform risk-benefit discussions of placentophagy.

266 Limitations

267 Our study consisted of a cohort of women with a history of mood disorders and as such, 268 our data may not be generalizable to populations of postpartum women who do not have a past 269 history of mental illness. Though the study was adequately powered to detect effects of 270 moderate to large magnitude, the observed effect sizes of placentophagy on the outcomes of 271 interest were small/very small, suggesting that any difference that may be attributed to 272 placentophagy is too small to be clinically meaningful. However, to guide future studies on the 273 outcomes of postpartum placentophagy, our data indicate that sample sizes of N=620 for EPDS 274 and SWAI, and N=2476 for B12, would be required for studies to have 80% power to detect 275 effects of the size observed in this study. We could not conduct a power calculation for lactation 276 as the rates of domperidone use were identical between cohorts.

Although adequately-powered randomized, double-blind, placebo-controlled trials
represent the gold standard, our study utilized a matching technique (including matching for
demographic, psychiatric, and vitamin supplementation/medication use) that aims to mitigate
many of the confounding factors that would otherwise impact hypothesis interpretation. Further,
the data were collected in the context of a larger study in which the collection of data about
placentophagy was incidental; this serves to minimize the potential for participant bias

283 influencing our self-reported outcome measures. All but one woman in the current study 284 ingested encapsulated placenta. It is possible that the mechanism of delivery matters, and 285 perhaps different outcomes could be observed with cohorts using less processed forms of 286 placenta or a standardized method of encapsulation, but, in this study, the datapoints from the 287 one woman who consumed her placenta raw were not outliers. We did not record data regarding 288 women's motivation(s) for placentophagy in our study, and did not match for variables other 289 than those listed above. Most women were also taking a daily multivitamin, raising the 290 possibility that the effect of placentophagy on B12 levels could be masked; however women are 291 advised to take vitamin supplements during the postpartum, [29] so our data actually provide 292 insight into the effect of placentophagy in a naturalistic context. 293 As domperidone is not routinely used by all women with lactation problems, often due to 294 its safety and efficacy concerns, we may underestimate the number of women with lactation 295 problems in our study. 296 297 298 299 300 301

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306 307	Acknowledgements
308	The authors thank Arianne Albert from the BC Women's Health Research Institute for her help
309	with the statistical analyses. The authors thank Roger Dyer and Janette King from the BC
310	Children's Hospital Research Institute for the B12 analyses, and the Translational Psychiatric
311	Genetics Group (TPGG) for their varied contributions, and the team's volunteers. The study was
312	funded by the Canadian Institute of Health Research (CIHR). JA was supported by the Canada
313	Research Chairs Program, and BC Mental Health and Substance Use Services.
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- 403

Table 1. Characteristics of women who engaged in placentophagy and a matched non-exposedcohort

407

	Placentophagy exposure (PE) (n=28)	Non-exposed (NE) (n=110)	Total (N=138)			
Demographics:						
Age - mean (SD)	32.7 (5.47)	31.0 (5.29)	31.3 (5.36)			
Psychiatric Diagnosis - n (%)		·				
Depression	24 (85.7)	94 (85.5)	118 (85.5)			
Bipolar disorder	4 (14.3)	16 (14.5)	20 (14.5)			
Annual Household Income - n (%)						
<\$20,000	4 (14.3)	9 (8.2)	13 (9.4)			
\$20,000 -40,000	5 (17.9)	16 (14.5)	21 (15.2)			
\$41,000 - 60,000	3 (10.7)	23 (20.9)	26 (18.8)			
\$61,000- 80,000	5 (17.9)	21 (19.1)	26 (18.8)			
\$81,000- 100,000	4 (14.3)	22 (20.0)	26 (18.8)			
>\$100,000	7 (25.0)	19 (17.3)	26 (18.8)			
Use of supplements and medicines						
^a Postpartum use of a daily psychotropic medication - n (%)	5(17.9)	16 (14.5)	21 (15.2)			
Postpartum use of daily multivitamin - n (%)	26 (92.9)	102 (92.7)	128 (92.7)			
^{b,d} Postpartum use of an additional vitamin B12 supplement - n (%)	2 (7.4)	6 (5.7)	8 (6.0)			
Outcomes:						
Highest postpartum EPDS score - mean (SD)	9.29 (5.17)	8.15 (4.78)	8.38 (4.86)			
^c Lowest postpartum SWAI score- mean (SD)	55.81 (9.23)	57.78 (11.29)	57.38 (10.90)			
^d Lowest plasma vitamin B12 (pg/mL) – mean	466.26 (165.90)	453.41 (205.92)	456.02 (201.25)			
Postpartum use of domperidone - n (%)	4 (14.29)	17 (15.45)	21 (15.21)			

408

409 ^a Initiated prior to time-point at which highest EPDS score was recorded

410 ^b Either as part of a vitamin B Complex or as a separate B12 supplement, initiated prior to time-

411 point at which lowest B12 was recorded

412 ^c PE cohort n=27 and NE cohort n=106 (1 from the PE cohort did not complete the postpartum

413 SWAI subscale of interest, and was excluded along with her NE matches)

⁴¹⁴ ^dPE cohort n=27 and NE cohort n=106 (1 from the PE cohort was taking additional vitamin B12

415 was excluded, due to no adequate NE matches)

418 Legends

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- 420
- 421 Figure 1. Comparison of highest postpartum EPDS score in women who consumed their
- 422 placenta (PE) and those who did not (NE).
- 423
- 424 Figure 2. Comparison of lowest SWAI daytime sleepiness subscale scores for cohorts of women
- 425 who consumed their placenta (PE) and those who did not (NE).
- 426
- 427 Figure 3. Comparison of lowest postpartum plasma vitamin B12 levels (pg/mL) in women who
- 428 consumed their placenta (PE) and those who did not (NE).





