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2	Ef	fectiveness of psychological interventions to reduce alcohol consumption among
3		pregnant and postpartum women: a systematic review
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25 ABSTRACT

26 Purpose: To synthesise the available evidence on psychological interventions to reduce
27 alcohol consumption among pregnant and postpartum women.

Methods: Six electronic databases were searched to identify controlled studies targeting pregnant and postpartum women who drink or are at-risk of drinking due to previous patterns of alcohol use. Controlled quantitative studies such as randomised controlled trials and quasiexperimental studies were included. The search was limited to peer-reviewed articles in English. The methodological quality of studies was assessed using the Cochrane risk of bias tool. A narrative synthesis of the findings was conducted.

Results: In total, 12,610 records were screened, and 11 studies were eligible for inclusion (9 with pregnant women, 2 with postpartum women). All studies were randomised controlled trials. Five studies had positive or partially-positive primary outcomes of reductions in drinking or abstinence, and their interventions ranged from multi-session brief interventions to self-help manuals based on cognitive behavioural components. All studies showed considerable methodological limitations.

40 **Conclusions:** Psychological interventions may be effective in promoting abstinence or 41 reducing alcohol consumption among pregnant and postpartum women. Interventions that 42 demonstrated some efficacy showed higher level of engagement with pregnant women 43 compared to studies which delivered interventions in a single session. Paucity of evidence, 44 inconsistency of outcomes, large heterogeneity in the interventions, and methodological 45 weaknesses limit the ability to make final conclusions about the overall effectiveness of these 46 interventions. Findings highlight the need for better quality research on this topic.

48 Keywords

49	Alcohol, pregnant women, postpartum women, psychological interventions.
50	

65 INTRODUCTION

66 The global prevalence of alcohol use in pregnancy is approximately 10%, with large variations of 0-

67 60% seen across countries and regions (Popova et al. 2017). Alcohol consumption during pregnancy

68 has been linked to harm for the developing embryo and foetus and to adverse pregnancy outcomes 69 including increased risk of miscarriage, still-birth, preterm delivery, sudden infant death, and low 70 birthweight (Bailey and Sokol 2011). The most severe consequences of alcohol use during pregnancy 71 are the Fetal Alcohol Spectrum Disorders (FASD) (Bertrand et al. 2004) which includes Fetal Alcohol 72 Syndrome (FAS), recognisable by the presentation of morphological anomalies, pre- and/or post-natal 73 growth retardation, and neurodevelopmental abnormalities (Institute of Medicine; Committee to 74 Study Fetal Alcohol Syndrome 1996). Although the literature has focused mainly on the adverse 75 effects of heavy alcohol use and binge drinking during pregnancy, the effects of light-to-moderate 76 alcohol consumption have also been investigated (Henderson et al. 2007; Patra et al. 2011; Mamluk 77 et al. 2017).

After birth, maternal alcohol consumption continues to expose the infant to the negative effects of
alcohol through breastfeeding. Healthcare recommendations therefore advise breastfeeding women
to avoid drinking alcohol entirely as a precaution, or otherwise minimise consumption (Royal College
of Obstetricians and Gynaecologists 2018).

82 The aforementioned negative consequences of pre- and post-natal alcohol use make this behaviour 83 an important target for intervention. Current guidelines recommend the use of brief interventions for 84 hazardous alcohol consumption in pregnant and postpartum women in primary care (NICE 2014; WHO 85 2014). Brief interventions are opportunistic interventions developed for use in non-specialist settings 86 to reduce alcohol consumption and prevent alcohol-related harms through time-limited assistance 87 (usually a single session) (Center for Substance Abuse Treatment 1999; Kaner et al. 2018). These 88 interventions adopt a preventative approach and include provision of feedback about the risks of 89 continued heavy drinking, information on harms associated with alcohol use, and motivational 90 enhancement for alcohol reduction. Brief therapies go beyond brief interventions and offer more 91 extensive support (at least 6 sessions) and are more appropriate for people with heavier and 92 potentially more harmful patterns of drinking (Center for Substance Abuse Treatment 1999).

93 Past systematic reviews have evaluated the evidence around non-pharmacological interventions for 94 alcohol use in pregnancy but have had considerable limitations. A Cochrane review examined the 95 effectiveness of psychological and educational interventions for the reduction of alcohol use among 96 pregnant women as well as women planning pregnancy, but only Randomised Controlled Trials (RCTs) 97 were considered for inclusion (Stade et al. 2009). While Gilinsky et al. (2011) expanded the eligible 98 study designs to include non-Randomised Controlled Trials (non-RCTs), they limited the population to 99 all pregnant women attending antenatal care and to interventions delivered in that setting. In 2013, 100 Gebara et al. (2013) conducted a review specifically focused on brief interventions for women, with 101 pregnant women as a sub-population. Other than the limited scope of intervention type, the review 102 restricted the publication years of their search (2006-2011). Finally, Fergie et al. (2018) reviewed the 103 literature on behavioural support interventions for alcohol and other drug use in pregnancy. Their 104 review was limited to RCTs, and their main aim was to examine the behavioural change techniques 105 utilised in the interventions.

106 In summary, these earlier systematic reviews all had significant limitations that prevent any one of 107 these reviews from providing an all-encompassing summary of the evidence for psychological 108 interventions to address alcohol use among pregnant and postpartum women. For example, past 109 systematic reviews limited their scope to interventions delivered in antenatal care only (Gilinsky et al. 110 2011) or brief interventions only (Gebara et al. 2013). Study designs were limited to randomized 111 controlled trials (Stade et al. 2009; Fergie et al. 2018), and those systematic reviews which included 112 quasi-experimental studies as well (Gilinsky et al. 2011; Gebara et al. 2013) had other limitations (e.g. 113 excluding postpartum women, limited scope of literature search). We define the postpartum period 114 as up to six months post childbirth, the recommended period for breastfeeding (WHO 2003; Romano 115 et al. 2010). Postpartum women are an important population group to be targeted along with 116 pregnant women. Previous reviews also had a narrow focus on intervention effectiveness, providing 117 little information of the content, structure and delivery format of the interventions. This information 118 is essential in order to enable decision-making around the feasibility of implementing the

interventions in real-world contexts. The aim of this systematic review is to complement earlier reviews on the topic by identifying, describing, and evaluating psychological interventions for the reduction of alcohol consumption among both pregnant and postpartum women. The objectives of this review are to (1) synthesise the evidence on the effectiveness of psychological interventions; (2) to describe the content of the psychological strategies; and (3) to summarise the delivery platform, the delivery agent (health care provider), and their training.

125

126 METHODS

127 This systematic review was conducted according to PRISMA guidelines (Moher et al. 2009). The 128 PRISMA checklist is included in Appendix 1. A protocol for this review was registered on the 129 international prospective register of systematic reviews (PROSPERO) (Registration number: 130 CRD42019141595).

131

132 Eligibility Criteria

133 We included studies which focused on pregnant and/or postpartum women who consumed any 134 amount of alcohol during pregnancy or six months postpartum. We also included studies of pregnant 135 women who were at-risk of alcohol consumption during pregnancy or in the postpartum period due 136 to previous patterns of alcohol use that were potentially harmful. No restrictions for inclusion were 137 applied to the age of women, or the number of weeks of gestation at which pregnant women were 138 enrolled. Studies which enrolled women after the six months post-partum period were excluded. We 139 included studies which measured alcohol consumption or its risk-level via validated screening tools, 140 clinician assessments or biological measures. We included studies which delivered a psychological 141 (non-pharmacological) intervention explicitly aimed at the reduction of alcohol consumption 142 (reduction and/or abstinence). Interventions addressing co-morbidities including illicit drug-use were

eligible for inclusion if the intervention was explicitly aimed at the reduction of alcohol consumption.
We only included controlled quantitative studies such as RCTs or non-RCTs (quasi-experimental
studies) where the intervention was compared to either one or more control groups. Our inclusion
and exclusion criteria are described in Appendix 2.

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148 Search terms and strategy

Search terms were structured around alcohol use, pregnancy, and psychological interventions, and included study-design terms. Medline, Embase, Global Health, PsychInfo, Cinahl Plus and Web of Science were searched until August 2020. No restrictions were applied to study setting but only English peer-reviewed articles were included. The complete search strategy for Medline is included in Appendix 3. The database search was complemented by handsearching of reference lists of included articles. Studies included in past systematic reviews on this topic were also assessed for eligibility (Stade et al. 2009; Gilinsky et al. 2011; Gebara et al. 2013; Fergie et al. 2018).

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157 Analyses and quality appraisal

The methodological quality of the included studies was assessed using the revised Cochrane Risk of Bias tool (RoB 2.0) (Sterne et al. 2019), a tool specifically developed to assess the risk of bias of RCTs at the study and the outcome level. It was initially planned that the methodological quality of nonrandomised controlled trials would be assessed using the Cochrane ROBINS-I tool (Sterne et al. 2016), but no studies with this design were identified. The findings of this systematic review were summarised through a narrative synthesis following Popay's guidelines (Popay et al. 2006).

164

165 **RESULTS**

166 Search Results

A total of 12,610 records were identified. After screening titles and abstracts, 79 full-text articles were assessed for eligibility. The PRISMA flow diagram in Figure 1 below presents the number of records considered at each stage of the review. A second reviewer screened 10% of the full-text articles, and any disagreements around inclusion were either resolved by consensus or discussed with a third independent party.

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176 General Characteristics of Studies

177 A total of 11 studies, including 2,198 women (1,840 pregnant; 358 postpartum) were included in this 178 review (Reynolds et al. 1995; Handmaker et al. 1999; Chang et al. 1999, 2005; O'connor and Whaley 179 2007; Fleming et al. 2008; Tzilos et al. 2011; van der Wulp et al. 2014; Rubio et al. 2014; Ondersma et 180 al. 2015, 2016). Nine of the included studies enrolled pregnant women (Reynolds et al. 1995; 181 Handmaker et al. 1999; Chang et al. 1999, 2005; O'connor and Whaley 2007; Tzilos et al. 2011; Rubio 182 et al. 2014; van der Wulp et al. 2014; Ondersma et al. 2015), and two studies enrolled women in the 183 postpartum period (Fleming et al. 2008; Ondersma et al. 2016). Three of the 11 studies identified in 184 this review were not included in previous systematic reviews on this topic: two of the newly identified 185 studies enrolled pregnant women (Rubio et al. 2014; Ondersma et al. 2015) and one study enrolled 186 postpartum women (Ondersma et al. 2016). All studies were conducted in high-income settings, with 187 10 studies from the USA, and one from the Netherlands (van der Wulp et al. 2014). Nine of the studies 188 were individual RCTs, while two studies were cluster-randomised (O'connor and Whaley 2007; van 189 der Wulp et al. 2014). Three of the RCTs were pilot studies with a sample size of 50 or below 190 (Handmaker et al. 1999; Tzilos et al. 2011; Ondersma et al. 2015).

- Table 1 summarises the study characteristics and findings of the included studies. Appendix 4 contains
 an extended table with additional study and population characteristics including further demographic
 information on the included study population.
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- 195

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197 Study Populations

198 There was large variability in the inclusion criteria applied regarding alcohol use. Among studies with 199 pregnant women (n=9), two enrolled women who reported any alcohol consumption (Reynolds et al. 200 1995) or at least one drink (Handmaker et al. 1999) in the month of pregnancy prior to enrolment; 201 two studies enrolled women that had consumed any amount of alcohol since pregnancy recognition 202 (O'connor and Whaley 2007; van der Wulp et al. 2014); while one study required specific quantity-203 frequency thresholds of consumption for the periods before and after pregnancy recognition (Rubio 204 et al. 2014). In the remaining four studies (Chang et al. 1999, 2005; Tzilos et al. 2011; Ondersma et al. 205 2015), a positive T-ACE (Tolerance, Annoyance, Cut down, and Eye opener) score (2 or above) was 206 used to detect prenatal risk drinking. The T-ACE is a widely used and validated four-item alcohol 207 screening test developed for use with pregnant women (Sokol et al. 1989).

Similar variability regarding inclusion criteria and definition of alcohol-related risk was seen among the two studies targeting postpartum women. The Healthy Moms study considered any consumption of alcohol in the previous 28 days of the postpartum period as high risk (Fleming et al. 2008), while the other study assessed risk based on alcohol consumption in the 12 months prior to the pregnancy (along with a positive T-ACE score postpartum) (Ondersma et al. 2016). Pregnant and postpartum women in the included studies were identified in routine care and were not seeking treatment for an alcohol use disorder.

215 Intervention Content and Delivery

216 Most of the identified studies aimed to test the effectiveness of a particular intervention for the 217 reduction of alcohol use, with this intervention mainly described as a brief intervention (Chang et al. 218 1999, 2005; O'connor and Whaley 2007), motivational interview (Handmaker et al. 1999), or as having 219 elements of both (Fleming et al. 2008; Tzilos et al. 2011; Rubio et al. 2014; Ondersma et al. 2015, 220 2016). One study compared two different types of brief intervention (health counselling and 221 computer-tailored feedback) against usual care (van der Wulp et al. 2014), while another study 222 described its intervention as a Cognitive-behavioural therapy-based self-help manual (Reynolds et al. 223 1995). All of the studies were individually delivered – no group interventions were identified.

224 All the studies were delivered in healthcare settings. Most were delivered within routine prenatal or 225 postpartum services, with the exception of one study where the intervention was delivered during an 226 inpatient childbirth hospital stay (Ondersma et al. 2016). Four of the included studies used computer-227 based delivery of the interventions (Tzilos et al. 2011; van der Wulp et al. 2014; Ondersma et al. 2015, 228 2016). For studies that used face-to-face delivery, the most common delivery agents were medical 229 professionals such as physicians (Chang et al. 1999, 2005; Fleming et al. 2008), nurses or midwives 230 (Chang et al. 2005; Fleming et al. 2008; Rubio et al. 2014; van der Wulp et al. 2014), or clinical 231 psychologist (Handmaker et al. 1999). One study had nonmedical professionals (nutritionists) as 232 delivery agents (O'connor and Whaley 2007). Only one study used non-professional providers (lay 233 counsellors) to deliver the intervention, but did not describe the lay counsellor educational or 234 professional background (Rubio et al. 2014). One study described the delivery agents as health 235 educators within obstetric clinics, but also did not specify their professional background (Reynolds et 236 al. 1995).

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Table 2 summarises the content and delivery of each intervention as reported in the studies.

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242 Alcohol Use Outcomes

243 In studies with pregnant women, only two included studies showed positive results in their primary 244 outcomes at follow-up, demonstrating significantly higher rates of abstinence in the intervention 245 group compared to the control group (Reynolds et al. 1995; O'connor and Whaley 2007). The 246 interventions in these studies were multi-session 10-to-15-minute workbook-driven brief intervention 247 delivered by nutritionists at every prenatal care visit if the woman continued to drink (O'connor and 248 Whaley 2007), and a 9-day CBT-based self-help manual delivered to women attending prenatal care 249 (Reynolds et al. 1995). Two other studies demonstrated partially positive alcohol-use outcomes in 250 favour of the intervention group. Handmaker et al. (1999) showed significant reductions in peak blood 251 alcohol content compared to control, yet no significant between-group differences in total alcohol 252 consumption or days of abstinence. The intervention used in this study was a 1-hour motivational 253 interview preceded by an hour-long alcohol assessment. Van Der Wulp et al. (van der Wulp et al. 2014) 254 demonstrated an effect in favour of a 2-session computer-tailored feedback intervention compared 255 to usual care for the abstinence outcome at 6 months, yet average weekly alcohol consumption was 256 only significantly lower among those women whose drinking level was low-to-average at baseline. 257 One of the two identified studies with postpartum women showed significant reductions in all primary 258 alcohol use outcomes, as well as statistically significant differences between groups favouring the 259 intervention (Fleming et al. 2008). In this study (Healthy Moms study), the intervention was delivered 260 in two sessions by physicians or nurses at obstetric practices, and consisted of a workbook-based 15-261 minute brief intervention followed by two behaviour change reinforcement phone calls.

262

263 Risk of Bias Assessment

264 The studies had several methodological weaknesses. Most studies described an adequate computer-265 generated randomisation, with the exception of three studies where the randomisation was not 266 described (Reynolds et al. 1995; Handmaker et al. 1999; O'connor and Whaley 2007). Through the 267 use of time-matched computer-delivered control conditions, three studies (Tzilos et al. 2011; 268 Ondersma et al. 2015, 2016) were able to blind personnel (e.g. care providers, investigators) from the 269 interventions that were delivered to the participants, thus decreasing the risk of performance bias. 270 The majority of studies described blinded outcome assessments. More than half the studies had low 271 attrition (<20%) (Reynolds et al. 1995; Chang et al. 1999, 2005; Fleming et al. 2008; Tzilos et al. 2011; 272 Ondersma et al. 2015), and two studies imputed missing data using appropriate statistical methods 273 (van der Wulp et al. 2014; Ondersma et al. 2016). Further risk of bias assessments are presented in 274 Table 3.

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278 DISCUSSION

279 Based on the available evidence, psychological interventions may be effective in promoting 280 abstinence or reducing alcohol consumption among pregnant and postpartum women. The ability to 281 draw conclusions on the effectiveness of the identified interventions is hindered by several factors. 282 First, a low number of studies (eleven) were identified. Of these, only four studies with pregnant 283 women (Reynolds et al. 1995; Handmaker et al. 1999; O'connor and Whaley 2007; van der Wulp et 284 al. 2014) and one study with postpartum women (Fleming et al. 2008) showed positive or partially 285 positive outcomes for alcohol use. Second, studies included women 'at risk' of alcohol consumption 286 based on pre-pregnancy drinking behaviour; these women were included in an effort to reduce 287 underreporting of alcohol consumption and to predict future risk (Chang et al. 1999, 2005; Tzilos et 288 al. 2011; Ondersma et al. 2015). This may have resulted in the inclusion of pregnant women who 289 were not drinking at baseline as well as women who had a relatively low average alcohol consumption 290 at baseline, which may have attenuated the treatment effect. Third, characteristics of the control 291 group may have contributed to a lack of treatment effect. In studies where reductions in alcohol use 292 were observed in both study arms, it was speculated that the receipt of a comprehensive alcohol 293 assessment, or even a briefer alcohol screen, may have led to the reduction of alcohol consumption 294 in the control arm with pregnant (Chang et al. 1999, 2005; Ondersma et al. 2015) and postpartum 295 women (Ondersma et al. 2016). Another factor to consider when discussing effectiveness of 296 interventions is the use of self-reported outcome measures. Due to social stigma around alcohol 297 consumption in pregnancy and during breastfeeding, self-reported outcomes are susceptible to 298 underreporting (Ernhart et al. 1988; Lange et al. 2014; Oni et al. 2018). Outcome assessments in 299 studies at baseline may have also been highly susceptible to recall bias as participants were asked to 300 recall details of their alcohol consumption over long follow-up periods of up to 12 months prior to 301 the pregnancy.

302 The majority of psychological interventions consisted of brief interventions, motivational interviews 303 or had elements of both. Despite this similarity, there was considerable variability in the content and 304 strategies employed in these interventions including the number and duration of sessions. This points 305 to a lack of standardisation of what brief and motivational interventions consist of in practice. In the 306 case of interventions for postpartum women, the fact that only one of two identified studies showed 307 positive outcomes in the intervention group (Fleming et al. 2008) precludes us from drawing any 308 conclusions other than suggesting that brief interventions based on the principles of motivational 309 interviewing may be effective in reducing alcohol use among postpartum women, and that further 310 research is urgently needed among this population. However, among pregnant women, we observed 311 that interventions that showed some efficacy were longer in duration and required more frequent 312 engagement with intervention content compared to studies or brief interventions typically delivered 313 in a single session. For example one of the brief interventions involved brief but multiple contacts in 314 repeated sessions (O'connor and Whaley 2007), and the other one consisted of a 9-session self-help

315 manual, which was preceded by a 10-minute educational session and followed up with a phone call 316 (Reynolds et al. 1995). Moderator analyses conducted in studies also revealed trends between 317 treatment effect and baseline drinking. A few studies showed that the intervention was significantly 318 more effective at maintaining abstinence among women who were abstinent at baseline (Chang et 319 al. 1999), while another study showed significantly higher quit rates among women with lower levels 320 of baseline alcohol consumption (Reynolds et al. 1995). Conversely, two studies revealed significantly 321 greater reductions of alcohol consumption among women in the intervention group with higher 322 levels of alcohol consumption at baseline (Handmaker et al. 1999; Chang et al. 2005). Further 323 research is needed among postpartum women to determine whether interventions show greater 324 efficacy at higher levels of engagement among women with higher levels of drinking.

325 Concerning the delivery of interventions, the fact that all the identified studies in this review were 326 conducted within a health care setting narrows the review to women who have recognised their 327 pregnancy and initiated prenatal care, and postpartum women who received clinic-based postnatal 328 care. Women who drink at higher levels may delay antenatal care of have late pregnancy recognition, 329 and therefore miss an opportunity for an alcohol use reduction intervention (Choi et al. 2014). This 330 points towards important considerations for the integration of alcohol use interventions within clinic-331 based care, particularly concerning the ability of those interventions to reach the pregnant and 332 postpartum women who need them most. Community outreach efforts and case-finding could 333 increase the number of pregnant and postpartum women engaged in clinic-based care, and thus 334 enhance the impact of the interventions embedded within prenatal and postnatal care. The 335 utilisation of computer-delivered interventions and interventions delivered by non-medical 336 professionals, health educators or lay counsellors provides insight into the potential feasibility of non-337 traditional delivery modalities and delivery agents that could also support the scalability of 338 interventions and their greater impact.

340 Limitations

Our study has a few limitations. The search was limited to published journal articles in English only, and we did not search for grey literature. Only one author (LS) was involved in the literature search and data extraction. However, any queries regarding inclusion of studies and data extraction were discussed with another author (DF) and 10% of the data extraction was verified. Due to the large variability in outcomes and content of psychological interventions, a meta-analysis was not conducted, and studies were synthesised narratively only.

347

348 Conclusions

349 Our findings point to some potentially effective psychological interventions and strategies for the 350 reduction of alcohol consumption among pregnant and postpartum women. Integration of alcohol 351 use interventions within prenatal care may be a first step in communities in which alcohol use among 352 pregnant women is common, but this needs to be complemented by community outreach efforts 353 and case-finding to promote earlier pregnancy recognition among vulnerable women who may not 354 initiate prenatal care on their own. Our review found that psychological interventions to reduce 355 alcohol use among pregnant and postpartum women were all implemented in high-income countries, 356 and shows that more research on psychological interventions is needed in more diverse and 357 international contexts. There may also be a need to conceptualise alcohol use on a spectrum of risk 358 levels as per World Health Organization (WHO) recommendations (WHO 2014). While self-help and 359 brief interventions may be a good first step for at-risk women, findings from this review suggest that 360 more extensive interventions (such as brief therapies) may be more effective for pregnant women 361 who engage in higher levels of drinking. Our review also elucidates the potential for the use of self-362 help strategies and computer-delivered interventions within the continuum of care for alcohol use. 363 We conclude that psychological interventions may be effective in promoting abstinence or reducing 364 alcohol consumption among pregnant and postpartum women, and that additional research is

- 365 required to develop contextually appropriate psychological interventions to reduce alcohol use in
- 366 pregnancy.
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- 368
- 369 Declarations
- 370
- 371 Funding
- 372 NA

373 Ethics approval

- 374 This study was performed in line with the principles of the Declaration of Helsinki. Approval
- 375 was granted by the Ethics Committee of the London School of Hygiene and Tropical Medicine.
- 376 Consent to participate
- 377 NA
- 378 Consent for publication
- 379 NA
- 380 Conflicts of interests
- 381 The authors declare that they have no conflicts of interests.

382 Availability of data and material

383 Data and materials of this systematic review can be obtained from the corresponding author.

384	Code availability
385	NA
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