1 Summary

This systematic review of systematic reviews investigated the effectiveness of lifestyle 2 weight management interventions for postnatal women. We systematically reviewed Medline 3 (PubMed), Embase, CINAHL Plus, The Cochrane Library and Scopus from 2000 until 4 January 2018, to identify systematic reviews of randomised controlled trials that evaluated 5 6 the effectiveness of behavioural lifestyle interventions for weight management in postnatal 7 women. Results were summarised both descriptively and statistically using a mega metaanalysis of data from randomised controlled trials included in previous systematic reviews. 8 9 Nine systematic reviews met our inclusion criteria. Overall the reviews concluded that lifestyle interventions involving physical activity and/or dietary changes resulted in a 10 reduction in postnatal weight. Results from the overall mega meta-analysis confirmed this 11 finding with a mean difference of -1.7kg (95% CI -2.3, -1.1). Findings for subgroup analyses 12 gave mean differences of -1.9kg (95% CI -2.9, -1.0) for combined diet and physical activity 13 interventions, -1.6kg (95% CI -2.1, -1.2) for physical activity only interventions, and -9.3kg 14 (95% CI -16.5, -2.1) for diet only interventions (one study). Heterogeneity varied from 0% to 15 68%. Interventions involving lifestyle interventions appeared to be effective in reducing 16 weight in postnatal women, although these findings should be interpreted with some caution 17 due to statistical heterogeneity. 18

19 Introduction

Obesity is a key contributor to many chronic co-morbidities including type 2 diabetes, cardiovascular disease (1), stroke, as well as a number of types of cancers such as colorectal and breast cancer (1-3). These conditions can be life threatening, detrimental to quality of life and expensive to treat.

The obesity epidemic is affecting all populations, including women of reproductive age.
Recent national surveys reported that approximately 66%, 56% and 58% of women in the

United States of America, Australia and England, respectively either have overweight (body 26 mass index (BMI) between $25-30 \text{kg/m}^2$) or obesity (BMI over 30kg/m^2) (4-6). This means 27 28 that most women already have overweight when they become pregnant. A period of notable weight gain for many women occurs during and after pregnancy (7, 8). Studies have reported 29 that among women who have a healthy BMI prior to pregnancy, 30% have overweight one 30 year after giving birth (9, 10). Of women who have overweight prior to conception, 44% have 31 32 obesity 1 year after giving birth, while 97% of women with obesity prior to pregnancy remain so at 1 year postnatally. On average women gain about 14-15kg during pregnancy and at 1 33 year after birth 5-9kg is retained (8, 11). Some women are able to return to their pre-34 pregnancy weight after childbirth, but the amount of weight women retain postnatally varies 35 considerably and many women never lose all of the weight gained during pregnancy (11, 12-36 15). 37

The weight gained, and then retained after pregnancy, tends to be centrally located on the 38 body, which is an independent risk factor for the development of cardio-metabolic diseases 39 such as diabetes and coronary artery disease (16, 17). Additionally, women are at risk of 40 gaining more weight during each successive pregnancy, increasing their likelihood of 41 42 complications during any future pregnancies, as well as developing obesity in later life (13, 18-19). Evidence also shows an association between postnatal weight and poor mental 43 44 health, which may adversely affect the behaviour and the family as a whole (20-22). This highlights the need for low cost and acceptable interventions to be designed and tested to help 45 women successfully lose and manage their weight after giving birth. It is not clear which 46 behavioural intervention approaches might be most successful in helping women lose weight, 47 although in non-pregnant population strategies such as goal setting, self-monitoring of 48 weight, calorie counting, attending a commercial weight loss programme, support from a 49 dietician and physical activity have evidence of effectiveness (23, 24). 50

51 *Objective*

52 Many studies, using a variety of methodological designs, have tested a range of weight-loss 53 interventions during the postnatal period (9, 25). Many of these studies have since been 54 included in systematic reviews of interventions for postnatal weight management. The 55 purpose of this systematic review is to both descriptively and statistically (using a mega 56 meta-analysis) summarise the findings of systematic reviews of randomised controlled trials 57 (RCTs) that have examined the effectiveness of behavioural lifestyle interventions for weight 58 loss in postnatal women.

The aim was to determine whether lifestyle interventions have been successful in helping 59 women lose weight, and if data allow, to further identify which types of interventions have 60 been successful. When several systematic reviews have performed a meta-analysis, a mega 61 meta-analysis is useful because it provides a comprehensive statistical summary of all the 62 evidence. A mega meta-analysis is also useful when previous systematic reviews have not 63 been able to perform meta-analysis or subgroup analyses because of a lack of trials. The 64 results of this systematic review of systematic reviews will help to provide direction and 65 context for the design of future weight management interventions for postnatal women and 66 will contribute to the evidence base for the development of clinical guidelines. 67

68 Methods

The protocol for this systematic review of systematic reviews was registered in 2017 in the
International Prospective Register of Systematic Reviews (PROSPERO), trial registration
number CRD42017072475.

72 Information sources, search strategy and eligibility criteria for systematic reviews

A comprehensive systematic search of the literature was conducted using the following
databases: MEDLINE (PubMed), Embase, CINAHL Plus, The Cochrane Library and Scopus.
The search terms used included postnatal, obesity, BMI, diet therapy, physical activity

therapy, body weight, systematic reviews, meta-analyses and derivatives of these search 76 terms. A sample search strategy is shown in the Supplementary Information. Databases were 77 78 searched from January 2000 to January 2018. We applied this date restriction as it coincided with the introduction of better reporting standards for research, particularly for RCTs and 79 systematic reviews. The criteria for the inclusion and exclusion of systematic reviews are 80 shown in Table 1. In summary, to be eligible for inclusion, systematic reviews had to include 81 82 RCTs and/or quasi RCTs that had assessed the effectiveness of behavioural lifestyle weight management interventions, namely diet and physical activity interventions or a combination 83 84 of these, in any format, context and setting, and against any comparator. A wide range of definitions are typically used when referring to the postnatal period, but for the purpose of 85 this systematic review of systematic reviews the postnatal period is defined as used by the 86 87 authors of the included systematic reviews, which typically starts immediately after childbirth and lasts until 2-3 years after giving birth. 88

89 *Screening and data extraction*

The titles and abstracts of potentially eligible systematic reviews were screened by two 90 91 independent researchers (JAF, HMP or AJD). When insufficient information was available from the title or abstract, full-text articles were retrieved and considered for inclusion. The 92 full-text articles of potentially eligible systematic reviews were further screened for eligibility 93 by two independent reviewers (JAF and either HMP or AJD) with any disagreements 94 discussed with a third reviewer until consensus reached. Two reviewers independently 95 extracted data from the eligible systematic reviews (JAF and either HMP or AJD) and any 96 disagreements were discussed with a third reviewer until consensus reached. Data extracted 97 for the systematic reviews included author and year of publication, dates of literature search 98 for studies included in the review, participant inclusion criteria, intervention and comparator 99 inclusion criteria, description of studies included in the review, results of any meta-analyses 100 performed, main conclusions of review and any additional comments. 101

102 *Quality assessment of systematic reviews*

103 The AMSTAR tool (26) was used to assess the quality of the included systematic reviews. 104 This was performed independently by two reviewers (JAF, HMP or AJD) and any 105 disagreements were discussed with a third reviewer until consensus reached. A third reviewer 106 was consulted on two occasions to discuss the scoring of some points on the AMSTAR tool.

107 Mega meta-analysis

108 We aimed to statistically summarise weight change data reported in the original RCTs within109 the included systematic reviews.

For inclusion in the mega meta-analysis, RCTs within the included systematic reviews had to 110 have reported data on body weight in a format that would allow us to perform statistical 111 112 synthesis. We excluded RCTs that only reported comparisons between two types of diet 113 and/or two physical activity interventions. Trials that had recruited women antenatally, but then offered an intervention postnatally, or which tested interventions that took place both 114 antenatally and postnatally were eligible for inclusion in the mega meta-analysis as long as a 115 postnatal weight had been reported at baseline as well as at follow up (baseline weight used 116 in mega meta-analysis was first reported postnatal weight). Studies that were included in 117 previous systematic reviews that were not RCTs were excluded from the mega meta-analysis. 118 In addition, we excluded interventions shorter than three weeks as these are unlikely to have 119 120 any longer term impact on weight.

Data were extracted by two independent reviewers (HMP and JAF) with any disagreements referred to a third reviewer (AJD). Review Manager, version 5.3 (27) was used to statistically summarise data from RCTs across all included systematic reviews. Data regarding weight change was summarised using mean difference in weight in kilograms. If this was presented using other metrics, a conversion calculation into kilograms was performed. When trials within reviews only published baseline and follow-up weight data, a weight change calculator(28) was used to calculate the weight change and the associated standard deviations.

We expected some heterogeneity due to the variability in the type of interventions tested in 128 RCTs, therefore a random effects model was used in the mega meta-analyses. The I² value 129 was calculated as a measure of heterogeneity (29, 30). Subgroup analyses were performed to 130 131 compare the type of lifestyle intervention (diet only, physical activity only or diet and physical activity), intervention duration ((3-12 weeks or > 12 weeks) and length of follow up 132 (≤ 12 weeks, 13 weeks–6 months and > 6 months)). The threshold of 12 weeks was chosen 133 for intervention duration as this is the typical timespan used in lifestyle interventions. The 134 effect of lifestyle interventions in women with or without a history of gestational diabetes 135 mellitus (GDM) was also assessed. 136

A funnel plot was conducted to investigate the possibility of publication bias due to samplesize.

139 **Results**

The searches identified 1291 potentially eligible articles. After the removal of duplicates and screening, nine systematic reviews of RCTs were eligible for inclusion in the systematic review of reviews (see PRISMA flow diagram in Figure 1). Further details of the full papers excluded and reasons for their exclusion are summarised in Table S1.

144 Description of included systematic reviews

The characteristics of the nine included systematic reviews are summarised in Table 2 and described below. The reviews were published between 2008 and 2017 and included RCTs with publication dates between 1994 and 2016. The majority of trials in the systematic reviews were conducted in the USA, with the remaining trials conducted in Australia, Canada, Greece, Iran, Japan, Malaysia, Sweden, Taiwan and Thailand (Table 2 and Table S2). All of the included systematic reviews scored as either medium or high quality, except
for the review by Kuhlman et al. (31) which was also the oldest included systematic review
(details of the AMSTAR scoring for each included systematic review are listed in Table S3).

Seven of the nine systematic reviews had performed meta-analyses (32-38), while two 153 reported only a narrative synthesis (31, 39). No systematic review included exactly the same 154 155 RCTs. Each systematic review included between two and 33 RCTs, and there was overlap in the RCTs included (see Table S2). Twenty-two RCTs were included in more than one 156 systematic review. Overall, there were 48 unique RCTs in the nine included systematic 157 reviews. The definition of the postnatal period also varied between systematic reviews. Three 158 defined this as up to 12 months after childbirth (32, 34, 38), one up to 18 months (36), one up 159 to 24 months (36). The remaining four systematic reviews stated that they included studies 160 with postnatal women, but did not define the postnatal period (31, 33, 37, 39). 161

Two of the systematic reviews placed no restrictions on the type of postnatal women they included from studies (34, 35). However, three reviews included only women who either have overweight and/ or have obesity (33, 36, 38), one systematic review only included women with a history of gestational diabetes (39) and one included only healthy women (32). Two did not report if they placed any restrictions on the type of postnatal women they would include (31, 37).

The scope of the included systematic reviews varied. Five of the reviews included studies that investigated the effectiveness of lifestyle interventions both during pregnancy and the postnatal period (31-33, 37, 38). However, as the review authors performed analyses for these populations separately, they were eligible for inclusion in this review of reviews. Two reviews focused exclusively on e-health technology interventions (37, 38). One review restricted its inclusion criteria to physical activity only interventions (32) while one focused on postnatal lifestyle interventions to prevent type 2 diabetes (39). The remaining five systematic reviews focused on different diet and physical activity modification interventions(31, 33-36) (see Table 2).

177 Mega meta-analysis of weight data

While there were 48 unique RCTs included in the systematic reviews, 13 did not report weight-related data, therefore only 35 of these were considered potentially eligible for inclusion in the mega meta-analysis. However, two were published in Chinese (40, 41) and therefore excluded. This meant 33 unique trials were eligible for inclusion in the metaanalysis. In addition to the above exclusion, a further 11 RCTs were excluded from the mega meta-analysis, mostly due to a lack of useable reported weight data (other reasons for exclusion are given in Table S4).

All the included RCTs reported that they objectively assessed weight, except for the RCT by Youngwanichsetha et al. (42), which did not clearly state that weight-related data were objectively collected. Therefore the mega meta-analysis included data from 22 unique RCTs and 1553 postnatal women and demonstrated that overall women randomised to a lifestyle intervention had significantly lower body weight at last follow up than comparators (mean difference of -1.7kg (95% CI -2.3, -1.1) (Figure 2).

Most RCTs included in the reviews did not report data by weight status and those that did reported it inconsistently or in a format that could not be used in the mega meta-analysis, therefore a sub-group analysis on the basis of weight status was not possible.

194 Subgroup analyses

195 *Intervention type (Figure 2)*

196 When analyses were restricted to combined physical activity and diet interventions trials the

197 mean change in weight was -1.9kg (95% CI -2.9, -1.0, P<0.01, I²=62%, 16 comparisons)

198 relative to comparators. Analysis of physical activity only interventions resulted in a weight

change of -1.6kg (95% CI -2.1, -1.2, P<0.01, 9 comparisons) relative to comparators and no heterogeneity (I²=0%). There was only one study in the diet only subgroup analysis (43) and this showed that the dietary intervention significantly reduced postnatal weight (MD = -9.3kg (95% CI -16.5, -2.1, P=0.01) relative to comparators.

203 Intervention duration (Figure 3)

The mean weight change for participants who received interventions of between 3-12 weeks duration was -2.6kg lower than the comparator group (95% CI -3.6, -1.6, P<0.01, I²=68%, 12 comparisons). In the analysis where only trials greater than 12 weeks duration were included, participants who received an intervention were 1.5kg lighter than comparators at follow up (95% CI -2.5, -0.6, P=0.002, I²=24%, 12 comparisons).

209 *History of GDM (Figure 4)*

When analysis was restricted to trials that had included only women without a history of GDM the intervention group lost 1.8kg more than comparators at follow up (95% CI -2.5, -1.1, P<0.01 and I²=54%, 21 comparisons). When the analyses were repeated for women with a history of GDM participants who received an intervention were 1.6kg lighter than comparators at follow up (95% CI -2.9, -0.2, P=0.02, I²=17%, 5 comparisons).

215 *Length of follow up (Figure 5)*

The mean weight change for participants at follow up 12 weeks or less was -2.0kg lower than the comparator group (95% CI -2.8, -1.1, P<0.01, $I^2=54\%$, 8 comparisons). At follow up between 13 weeks and six months, participants who received an intervention were 1.5kg lighter than comparators at follow up (95% CI -2.6, -0.4, P=0.006, I²=24%, 10 comparisons), while at more than six months follow up, participants who received an intervention were 1.9kg lighter than comparators at follow up (95% CI -3.4, -0.5, P=0.01, I²=56%, 8 comparisons). The funnel plot (Figure S1) displayed some asymmetry, suggesting the possibility of somebias, due to a lack of published studies with larger sample sizes.

225 Discussion

This systematic review of systematic reviews of RCTs has comprehensively and 226 227 systematically synthesised both descriptive and statistical evidence of the effects of lifestyle interventions for postnatal weight management for the first time. Nine systematic reviews 228 that had included RCTs were eligible for inclusion in this review of reviews. Overall these 229 reviews concluded that lifestyle interventions were effective in reducing weight in postnatal 230 women. Based on the current available evidence, pooled results in our mega meta-analysis 231 also showed that lifestyle interventions significantly reduced weight in postnatal women by -232 1.7kg (95% CI -2.3, -1.1) relative to comparators at follow up. Interventions that involved 233 both diet and physical activity interventions, physical activity alone and dietary interventions 234 alone were all effective, relative to comparators, although there was only one trial in the diet 235 236 only analysis. In women with a history of GDM postnatal weight was -1.6kg (95% CI -2.9, -0.2) lower than comparators, and lifestyle interventions appeared as effective in women with 237 and without a history of GDM (1.6kg versus 1.8kg respectively). Interventions of shorter 238 duration (3-12 weeks) appeared to be more effective in reducing postnatal weight than longer 239 interventions, although this may be the result of recidivism where it becomes harder to lose 240 and maintain weight over time in longer interventions and which therefore have longer follow 241 up assessments. The AMSTAR scores for the systematic reviews increased in line with the 242 year of publication and coincided with the transition of QUORUM (44) to PRISMA (45) and 243 244 requirements from journals for better reporting of trials and systematic reviews (46).

245 *Comparison with the literature*

246 Despite some variation in the inclusion and exclusion criteria adopted by the nine included247 systematic reviews, all reviews reported that lifestyle interventions reduced postnatal weight.

This is consistent with the findings of reviews involving other adult populations (47). The 248 mega meta-analysis showed that lifestyle interventions to date have been moderately 249 effective in helping women lose about 1.7kg of weight in the postnatal period, but weight loss 250 does not have be large to be important for health. This reduction in weight is similar to that 251 reported by several of the meta-analyses reported in the included systematic reviews, 252 demonstrating consistency of results (32, 33, 36). Clinical guidance from the National 253 254 Institute for Health and Care Excellence (NICE) in England suggests that weight loss of approximately 2kg is clinically important for health (48) and can contribute towards an 255 256 effective reduction in the risk of cardiovascular disease and type II diabetes mellitus (49). Modelling has also shown that even if a small amount of weight is lost, this weight loss 257 remains cost effective if the weight regained occurs on a lower weight trajectory (50). 258 Furthermore, as the relationship between obesity and mortality is linear even small amounts 259 of weight loss may be clinically important (49, 51, 52). 260

It is important to set the results of this study in context with other types of weight loss interventions that postnatal women may choose to use. Evidence suggests that commercial weight loss programmes are an effective intervention for weight loss and people attending these types of programmes will lose on average about 5kg (24), which is substantially higher than our pooled estimate here (-1.7kg).

Three trials in the mega meta-analysis reported weight loss (relative to comparators) of the same magnitude or greater than reported for commercial weight loss programmes (43, 53, 54), but these trials all involved very intensive and expensive interventions that would be difficult for health care services to fund for the large number of women who need to lose weight after having a baby. The study by O'Toole et al. (53) involved an individually structured diet and physical activity intervention developed by a dietician and a physiologist. Participants were asked to record their daily food consumption in a food diary and attended

weekly group sessions for the first 12 weeks, then once every two weeks for two months and 273 then once a month until one year postnatal. The other two trials with weight loss greater than 274 4.5kg in the mega meta-analysis (43, 54) also involved intensive and/or lengthy interventions 275 involving behaviour modification counselling, motivational interviewing or specialised 276 dietetic support, none of which can be easily implemented at a population or community 277 health level. Additionally, all three of the trials reporting effects greater than 4.5kg 278 279 randomised very small numbers of participants (ranged from 23-57 participants) (43, 53, 54) and their estimates may therefore be susceptible to bias. 280

Taken together this raises the question of whether it might be more useful to refer or 281 encourage postnatal women, who wish to lose weight, to a commercial weight loss 282 programme since this may be more effective and provision is already in place for women to 283 attend such programmes, both during and after pregnancy. Some even promote their 284 programme as being suitable for all, including pregnant and breastfeeding women (55) or 285 from six weeks after childbirth (56). Furthermore, a very recent trial in the UK (23) found 286 that referral of adult patients with obesity to commercial weight management programmes by 287 family doctors during routine consultations can be an effective weight loss intervention. 288 Nevertheless, postnatal women are a unique subgroup of the population with many 289 challenges and barriers that may impact their ability to consistently attend commercial weight 290 291 loss programmes, for example, availability of childcare, child feeding and sleeping patterns. Future research should address this question. 292

Research evidence has been inconsistent on the preference of postnatal women for different types of weight management interventions with some reporting that women prefer to attend group-based sessions (57, 58), while others found that home-based interventions are preferred due to issues such as time constraints, convenience and childcare requirements (59, 60). A recent systematic review that compared self-help interventions (such as printed materials,

internet, mobile phone apps, etc.) with controls in general populations reported a significant 298 effect favouring the interventions at six months follow up (-1.9kg (95% CI -2.9, -0.8)) (61). 299 Self-help interventions are attractive because they are low cost, varied, flexible and can be 300 tailored to the specific needs of the individual. Given many postnatal women might find it 301 difficult to attend more formal weight loss programmes and some have expressed a 302 preference for home-based programmes, self-help interventions for postnatal weight loss are 303 304 worthy of consideration. Particularly as the effect estimate (-1.9kg (95% CI -2.9, -0.8)) in self-help interventions is similar to the result in our mega meta-analysis (-1.7kg (95% CI -2.3, 305 306 -1.1), in which the interventions tested, typically, involved professional support and/or more resource intensive interventions than self-help interventions. 307

308 *Physical activity and diet only interventions*

Our findings showed that both physical activity and diet only interventions can be effective in 309 310 reducing weight in postnatal women. Only one trial that recruited a small sample was eligible for inclusion in the diet only analysis highlighting the need for more studies on this 311 question in this population of women. The recent scientific report and systematic review by 312 the American Physical Activity Guidelines Committee concluded that there was insufficient 313 evidence to determine whether physical activity is associated with weight loss during 314 postnatal period. Our systematic review provides an up to date summary of the current 315 evidence by concluding physical activity interventions can play a role in reducing weight 316 after childbirth (-1.6 kg), relative to comparator groups (62). 317

318 *Strengths and limitations*

This review has a number of strengths and limitations that need to be considered when interpreting the findings. Our review focused only on systematic reviews that had included RCTs in order to summarise high quality evidence. Drawing together these findings in one place has generated a comprehensive evidence-based review of the effectiveness of lifestyle interventions for postnatal women. Data from this systematic review of systematic reviews can be used to guide the development and design of future interventions in this population, as well as future health policy for postnatal women. By performing a mega meta-analysis of previous meta-analyses, we have provided a quantitative estimate of the amount of weight loss that can be obtained from behavioural lifestyle interventions for weight loss in this population of women.

A limitation of some of the trials included in the individual systematic reviews was the broad range in the number of months postnatal women could be to meet the systematic review inclusion criteria. It was therefore not possible to determine the effect of the intervention in relation to the time it was initiated during the postnatal period. We excluded unpublished systematic reviews and we did not search grey literature. We were unable to include one systematic review (63) due to a lack of clarity regarding the inclusion and exclusion criteria and the authors did not respond to our request for more information.

Most of the trials within the included systematic reviews were conducted in America and 336 most participants were of white ethnicity, so the findings from the systematic reviews, and by 337 implication our findings, may not be generalisable to other ethnic groups. We did not contact 338 study authors of RCTs where there was unusable weight data because most were more than 339 five years old. As expected there was some overlap of trials between the nine included 340 341 systematic reviews. However, this is a particular advantage of performing a mega metaanalysis since each trial only contributes once to the overall pooled findings. In the overall 342 pooled estimate there was a moderate level of heterogeneity which is likely to be the result of 343 344 the variation in the types/content of interventions (64). This heterogeneity was only partially resolved by subgroup analyses. 345

There were limited data (one small trial) on diet only interventions and this remains animportant avenue for future research. The most recent RCT included in any systematic review

348 was published in 2015, highlighting the need now for more trials to test the feasibility and 349 effectiveness of novel lifestyle interventions for weight loss in postnatal women. Bias was 350 considered with the aid of a funnel plot (Figure S1). The asymmetry of the funnel plot 351 suggests the possibility of some bias, due to a lack of published studies with larger sample 352 sizes.

Our review did not find any RCTs that have tested an intervention embedded within routine health care appointments and this might be a pragmatic way to offer support to all postnatal women who wish to lose weight after having a baby. Evaluation of these types of interventions is an important direction for further research. The analysis involving women with a history of GDM only included five small trials, therefore this result should be interpreted as preliminary.

359 Conclusion

This systematic review of systematic reviews and mega meta-analysis of RCTs found that lifestyle interventions are moderately effective in reducing weight after childbirth. Clinical guidance for the care of postnatal women should be updated to reflect the findings of this review and the accompanying mega meta-analysis.

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367 List of figures and tables

- **Figure 1:** PRISMA flow diagram
- **Figure 2:** Mean difference in weight change (kg), intervention type subgroup analysis
- **Figure 3:** Mean difference in weight change (kg), intervention duration subgroup analysis
- **Figure 4:** Mean difference in weight change (kg), GDM subgroup analysis
- **Figure 5:** Mean difference in weight change (kg), length of follow up subgroup analysis
- **Table 1:** Inclusion and exclusion criteria for selection of systematic reviews
- **Table 2:** Characteristics of included systematic reviews

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