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Effect of a lipid-focused dietary intervention in pregnant people with pre-gestational overweight/obesity on maternal and fetal outcomes: study protocol for a multicenter randomized trial

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32	Abstract (265 words)
33	Introduction: Pregnant people with overweight or obesity are at higher risk of
34	delivering large-for-gestational-age (LGA) babies and suffering from other adverse
35	pregnancy outcomes. Diet-based interventions have the potential to reduce adverse
36	birth outcomes, especially to decrease LGA babies. We aim to evaluate the effect
37	of lipid-focused diet intervention in pregnant people with overweight or obesity on
38	maternal and fetal outcomes through a randomized control trial.
39	Methods and analysis: A multicenter randomized controlled trial has been
40	designed with the involvement of three hospitals in Beijing, China.
41	Women with a BMI>=24.0kg/m2 will be recruited before 12 weeks' gestation.
42	Women (n=1215) will be randomized 1:1:1 into three arms: 1) Online education
43	arm. 2) Diet checklist and 'one-page flyer' arm. 3) Routine antenatal education.
44	The primary outcome LGA will be recorded at birth. Dietary behaviors and
45	psychosocial factors of pregnant people will be collected through questionnaires
46	before and after the 6-month intervention. Breastfeeding and complementary food
47	supplementation of infants and young children will be collected through
48	questionnaires, and children's physical development indicators and taste tests will
49	be carried out 3 years after delivery.
50	Ethics and dissemination: This study has received ethical approval from the
51	Capital Medical University Ethics Committee and other study centers. Informed
52	consent will be introduced to pregnant people and their consent obtained. The

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53	findings will be reported in relevant national and international academic conferences
54	and peer-reviewed publications.
55	Trial registration: The trail is registered ChiCTR2300071126
56	Keywords: Study protocol, Pregnancy, Overweight or obesity, Diet lipid, Large
57	for gestational age
58	Article Summary
59	Strengths and limitations of this study
60	> This study is a cause-and-effect randomized controlled study.
61	> Study includes a large sample size that will be able to detect small differences.
62	> The pre-experiments have already shown this approach to have beneficial effects
63	for participants.
64	> due to the characteristics of the study design, participants are aware of the
65	intervention they receive.
66	> The women to be included in the study are being recruited from different
67	research centers and receive different levels of routine maternal education.
68	
69	INTRODUCTION (3377 words)
70	Large for gestational age (LGA) is defined as a newborn who weighs above the
71	90th percentile of newborns for the same gestational age. The incidence of LGA in
72	China is about 10.1% ¹ , and the incidence is higher among pregnant people who have
73	overweight or obesity. Studies have shown that LGA can have adverse effects on both

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74	pregnant people and infants. Women who give birth to LGA are more likely to have a
75	cesarean delivery, birth canal injury, and postpartum hemorrhage ² . Neonates born
76	with LGA have an increased risk of shoulder dystocia, clavicle fractures, brachial
77	plexus injury, and increased admissions to the neonatal intensive care unit ² . Follow-
78	up studies have also shown that people born with LGA are at an increased risk of
79	early obesity, metabolic disease, giving birth to LGA ³⁻⁵ . The person who gives birth to
80	LGA babies is associated with many risk factors in adulthood, including overweight
81	and obesity, gestational diabetes mellitus (GDM), lack of physical activity during
82	pregnancy, and a high intake of sugar and fat ⁶ . The incidence of LGA in overweight
83	and obese pregnant people is 2.30 times and 2.53 times that of normal-weight
84	pregnant people, respectively ^{1,7} .
85	The role of diet in overweight or obese women and LGA
86	Pregnant people undergo special physiological changes, and their nutrition needs
87	are also different. Many countries have established separate dietary guidelines for
88	pregnant people, including China ⁸ . However, a 2015 dietary survey of pregnant
89	people in eight major cities in China showed that the average energy intake during
90	pregnancy was 2098 Kcal, with fat contributing to 36.4% (median 37.7%) of total
91	energy, exceeding the recommended amount of 25%-30% ⁹ . A 2016 study in Shaanxi,
92	China, sorted foods into five major groups and analyzed the energy sources of
93	pregnant people from these different food groups. The main sources of energy for
94	pregnant people were snacks (19%), meats (16%), and edible oil (11%), while the

95	main sources of fat were cooking oil (25%), meats (24%) and nuts (16%) ¹⁰ . A recent
96	2021 dietary survey of pregnant people in Shanghai, China, found that 66.6% of the
97	total surveyed had poultry and meat intake above the recommended level, and 46.3%
98	had oil intake above the recommendation ¹¹ . Dietary fat plays an important role in
99	maintaining health as one of the three macronutrients, but excessive fat intake can
100	lead to many adverse health outcomes, especially for pregnant people. Previous
101	studies have indicated that high fat, high saturated fatty acid, and low polyunsaturated
102	fatty acid in diet may be risk factors for GDM ¹² . In the case of maternal overnutrition
103	and insulin resistance, high levels of triglyceride are hydrolyzed by placental lipase
104	into free fatty acids and enter the fetus ¹³ . Fetal exposure to excess free fatty acids may
105	result in lipid storage due to limited fatty acid oxidation capacity, leading to a higher
106	risk for adverse pregnancy outcomes.
107	Decreasing the LGA through diet intervention
108	Many previous studies have investigated the effect of dietary interventions on
109	health outcomes. A prospective cohort study showed that pregnant people with better
110	dietary fat quality (low saturated fatty acids, high polyunsaturated fatty acids) had a
111	lower incidence of LGA ¹⁴ . The intervention aiming to prevent LGA and reduce birth
112	weight, pregnant people who had overweight or obesity received a low-glycaemic,
113	low-saturated fat diet and guidance on physical activity. The intervention reduced the
114	incidence of LGA and GDM significantly ¹⁵ . In another intervention, focusing solely
115	on a low glycemic index diet did not reduce the incidence of birth weight, and fat

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116	intake was positively correlated with obese neonates ¹⁶ . Which might be due to the fact
117	that when recommending a low-carb diet there also must be a focus not exceeding
118	saturated fat recommendation as often low-carb foods are replaced with foods high in
119	saturated fat ¹⁷ . Nevertheless, meta-analyses have indicated that controlling saturated
120	fatty acid intake for the general population might improve their metabolic status and
121	reduce the risk of cardiovascular disease ^{18,19} . However, a low-fat diet alone did not
122	achieve a better outcome in chronic disease prevention than a Mediterranean diet,
123	which is a moderate-fat but mostly monounsaturated diet ²⁰ . This might be due to the
124	complexity of the dietary components of a dietary pattern. Increasing or decreasing a
125	single nutrient without considering the overall macronutrient distribution of foods
126	could have a negative impact on health outcomes, as the health effects of foods cannot
127	be predicted by their content of any single nutrient group ²¹ . Some studies have
128	suggested discontinuing any macronutrient-restricting interventions, especially a low-
129	carb ketogenetic diet or any diet characterized by excess saturated fatty acids for
130	pregnant people ²² . Although previous studies have proven dietary interventions are
131	effective in lowering the incidence of LGA, there is no randomized clinical trial
132	investigating the efficacy of a dietary intervention that focuses on controlling the fat
133	intake of pregnant people who have overweight or obesity.
134	Psychosocial determinants associated with eating behaviors
135	Pregnant people's dietary patterns are influenced by many factors, such as
136	predetermined biological factors, early exposure and experience, psychosocial factors,

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137	and environmental factors ²³ . Previous studies have shown that lifestyle interventions
138	and nutrition education addressing various determinants based on psychosocial
139	theories could lead to positive changes in pregnant people's diet and physical activity
140	levels ²⁴ . A healthy lifestyle is beneficial for both pregnant people and their offspring.
141	Pregnant people are at a special life stage with a clear and urgent need for a healthy
142	dietary pattern and a strong motivation to improve their offspring's health. Therefore,
143	pregnancy is an excellent period for intervention. The theory of planned behavior
144	(TPB) show in the figure 1, was first proposed as a theory of reasoned action in 1975
145	to predict an individual's intention to engage in a behavior at a specific place and
146	time ²⁵ . The TPB has been successful in predicting and explaining a wide range of
147	intentions and behaviors, including diet, smoking, drinking, breastfeeding, and
148	substance use. It mainly focuses on enhancing the motivation of participants and takes
149	into account the impact of attitudes, perceived norms, and self-efficacy on the
150	formation of behavioral intention. The determinants of this model have been studied
151	extensively and found to be related to behaviors in more than 50 cultures, and thus has
152	good generalizability and can be used cross-culturally. Many intervention studies
153	based on the TPB model have also been effective in leading to positive changes in
154	eating habits and nutrition status, such as increasing fruit and vegetable intake ²⁶ ,
155	reducing unhealthy snack intake ²⁷ , and increasing calcium-rich foods ²⁸ .
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For this study, we have developed a multi-component nutrition education intervention based on the extended TPB model^{23,29}, shown in Figure 1, focusing on controlling fat intake, and improve the quality of diet lipid based on a balance diet. The primary aim is to assess whether the intervention will reduce the risk of delivery of an LGA infant for pregnant people who have overweight or obesity. **METHODS AND ANALYSIS** Study design This is a Multicenter RCT, 1:1:1 ratio, parallel, open-blind. The study design adheres to the SPIRIT quality standard criteria for RCT. Participating centers include Fuxing Hospital Affiliated to Capital Medical University, Xuanwu Hospital Capital Medical University and Beijing Haidian District Maternal and Child Health Care Hospital, all in Beijing, China. The specific process can be seen in Figure 2 and the time line was shown in Table 1. Table1. Timeline of intervention and information collection.

Time point	Enrolment and allocation		Post-allocati	on	Delivery	Postp	artum
·	Before 11weeks	11-12 weeks	26-28 weeks	34-36 weeks		42 days postnatal	3 years postnatal
Enrollment:	\checkmark						
Eligibility screen	\checkmark						
Informed consent	\checkmark						
Allocation	\checkmark						
Interventions:							
OEA		\checkmark	\checkmark	\checkmark			
NOA		\checkmark	\checkmark	\checkmark			
RAC		\checkmark	\checkmark	\checkmark			
Assessments:							
Baseline data:							
Sociodemographic data		\checkmark					
Medical history		\checkmark					

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	Food frequency	\checkmark	\checkmark			
	questionnaire	7	N			
	TPB questionnaire related	•	•			
	to diet	V	V			
	Food and tasty preference	1	1			
	and sensitive	v	v			
	Breastfeeding data				\checkmark	
	Primary outcome:			,		
				v		
	Mantel pregnancy					
	outcome (Mode of					
	delivery, Pregnancy			,		
	complications, and			v		
	gestational weight gain					
	and so on)					
	Fetal outcome(birth					
	weight, placenta weight,			\checkmark		
	SGA, preterm, Apgar					
	score, etc.)				-1	
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173	Ethical approval					
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3 4 5	184	Fasting plasma glucose (FPG) \geq 5.6 mmol/L at the first antenatal visit, > 12 weeks'
6 7	185	gestation, pre-existing type 1 or type 2 diabetes, fetal malformations including
8 9 10	186	chromosomal abnormalities or structural malformations detected by ultrasonography,
11 12 13	187	fetal congenital infections or abnormalities, restricted diet (including vegans and due
14 15 16	188	to medical conditions), conditions that might affect intervention or follow-up
17 18	189	(including physical activity restrictions, medical conditions or medications), unwilling
19 20 21	190	or unable to give informed consent
22 23 24	191	
25 26	192	Intervention
27 28 29	193	Eligible participants will be randomized into three groups: online nutrition
30 31 32	194	education (Group 1); nutrition checklist and 'One-page flyer' for self-learning (Group
33 34 25	195	2); routine antenatal education without any intervention (Group 3).
36 37	196	Group 1: Online nutrition education arm (OEA)
38 39 40	197	The first intervention group will receive 6 sessions of 1-h nutrition education by
41 42 43	198	video-conferencing. The course design was based on the TPB model and followed the
44 45	199	DESIGN Procedure ²³ of Contento and Koch. Two graduate students majoring in
46 47 48	200	nutrition will lead the course. The overall goal of the course is to promote a balanced
49 50 51	201	diet with a focus on controlling fat intake. The general goal can be further broken
52 53	202	down into three specific behavioral change goals: choosing the right food to eat,
54 55 56	203	cooking healthily, and reading nutrition labels so they can identify the healthy
57 58 59 60	204	packaged food.

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Group 2: Nutrition checklist and	'One-page flyer'	' arm	(NOA)
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206	The nutrition checklist was adapted from the FIGO checklist ³⁰ , which only requires
207	2-min to complete and is a very efficient way to assess the nutrition status of pregnant
208	people ³¹ . The checklist includes four parts. Part 1: self-reported special dietary habits
209	(e.g., vegan, food allergy); part 2: self-reported height, weight, and BMI; part 3: 17
210	questions related to dietary habits with a focus on fat intake (most are yes or no
211	questions); part 4: grading criteria and interpretation of the checklist result. The 'one-
212	page flyer' is an A4 paper-sized dietary instruction flyer. It is based on the theory of
213	planned behavior, including information on the adverse effects of a high-fat diet
214	during pregnancy on mother and baby at the top of the page (outcome
215	expectation), choosing healthy snacks, reading food labels, specific cooking tips using
216	less oil (knowledge and skills), information on diet management aiming to increase
217	confidence (perceived behavior control and self-efficacy), guidance on establishing
218	specific and feasible behavior change goals (goal-setting using SMART theory). The
219	checklist and "one-page" flyer are distributed to the participants by physicians at their
220	monthly pregnancy check-ups. Pregnant people can self-identify their nutrition
221	problems and make behavioral changes by following the guidance in the 'one-page
222	flyer'.
223	Criteria for discontinuing or modifying allocated interventions
224	Not applicable due to the nature of the interventions.

226	Strategies to improve adherence to interventions
227	Adherence to the online education sessions will be assessed by class attendance
228	from sign-ins and visual scansof video conference attendees. The treatment will be
229	considered complete if at least four out of the six sessions are attended. Adherence to
230	the dietary guidelines will be assessed by an improvement of ≥ 3 points of their total
231	scores of the 17-itemnutrition checklist compared to their total initial score. The study
232	population will be sorted according to adherence to the dietary guidelines, depending
233	on the score: ≥ 12 high adherence, $6 - 11$ moderate adherence, and < 6 low adherence.
234	Biomarkers of compliance will be evaluated by changes in weight, blood lipids, and
235	blood lipidomics.
236	
237	Relevant concomitant care permitted or prohibited during the trial
238	Women who participate in this trial cannot participate in another trial.
239	
240	Provisions for post-trial care
241	No post-trial care is needed since this is an educational intervention.
242	
243	Outcomes
244	Adverse pregnancy outcomes:
245	Primary outcome:

246	The primary outcome will be the prevalence of LGA at birth, defined as newborns
247	with a birth weight above the 90 th percentile according to local standards.
248	Secondary outcomes:
249	Neonatal: Macrosomia (birth weight \ge 4000 g), SGA (birth weight below the 10th
250	percentile for gestational age) or low birth weight (birth weight \leq 2500 g), preterm
251	birth (< 37 weeks' gestation), low Apgar score (Apgar <7).
252	Maternal: GDM (diagnosed by local criteria or OGTT), gestational hypertension
253	(defined as >20 weeks' gestation, elevated blood pressure [systolic BP \ge 140 mm Hg
254	or diastolic BP \geq 90 mm Hg] in the absence of proteinuria), cesarean section rate, birth
255	canal injury rate, shoulder dystocia rate, maternal insulin treatment rate, maternal
256	weight gain during pregnancy (maternal weight gain generally refers to maternal
257	weight at delivery minus pre-pregnancy weight), preeclampsia (defined as >20 weeks'
258	gestation, new-onset hypertension [systolic blood pressure ≥140 mm Hg or diastolic
259	blood pressure ≥90] mm Hg] and new-onset proteinuria [300 mg protein intake within
260	24 hours or urine protein/creatinine ratio 0.3 mg/dL], or in the absence of proteinuria,
261	new-onset hypertension with new-onset thrombocytopenia, renal insufficiency,
262	impaired liver function, pulmonary edema, or cerebral or visual impairment),
263	perinatal mortality (fetuses or neonates death at > 28 weeks' gestation - within 7 days
264	of postpartum)
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266	Changes in dietary behaviors

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267	Changes in dietary behaviors will be assessed by a dietary behavior questionnaire,
268	which was adapted from previous FFQs ^{32,33} . The questionnaire includes questions on
269	the intake and frequency of consumption of different categories of foods, in particular
270	high fat foods.
271	We will also assess knowledge and skills related to cooking habits that can reduce
272	fat and reading nutrition labels to choose low fat foods when shopping. Behaviors
273	related to adherence to the dietary guidelines will be assessed by the 17-item nutrition
274	checklist.
275	
276	Changes in psychosocial determinants based on the TPB model
277	A questionnaire was developed to assess the changes in the four components related
278	to diet behavior (reducing fat intake, cooking healthily, and reading nutrition
279	labels.)of TPB before and after the intervention. The questionnaire was based on
280	previous studies ^{26,34} , and content validity has been confirmed by experts in nutrition.
281	Attitudes, perceived norms, self-efficacy, self-depictions, and behavioral intention
282	were assessed as the mean of the statements under each component measured on 5-
283	point unipolar (+1 to +5) scales.
284	
285	Postpartum follow-up
286	Breastfeeding and complementary foods added will be investigated 42 days after
287	delivery through a questionnaire to be developed. Children are followed again at 3

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288	years of age for diet, taste preferences, and growth and development. Children's diets
289	will be assessed by a food frequency questionnaire based on a previous study ³² . Taste
290	preferences will be assessed by the TASTY scale, which was developed by
291	pediatricians to determine children's dietary taste preferences based on facial
292	expressions ³⁵ . Children's growth and development will be assessed by their weight,
293	height, sitting height, and body composition, measured by body weight meter,
294	mechanical height/sitting height meter, and body composition analyzer, respectively.
295	Other measures
296	A baseline survey is used to collect information on participants' demography,
297	lifestyle (e.g., sleep, physical activity), and medical and family history.
298	Sample size
299	The RCT used the incidence of LGA as the primary outcome. The incidence of
300	LGA in the general population is about 10.1%, while the incidences for pregnant
301	people who have overweight or obesity are 1.87 and 3.99 times higher than those of
302	the normal weight. Therefore, we estimated that 30% of women in our study would
303	have LGA deliveries without intervention. For a 30% reduction in the incidence from
304	an estimated 30% of LGA to 21%, 368 women will be recruited, assuming a type 1
305	error of 5% and a power of 80%. Allowing for a 10% dropout, 405 women will be
306	needed for each of the three arms, with an overall sample size of 1215 participants for
307	the study.
308	
309	Recruitment

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310	At the first prenatal check-up, all eligible pregnant people will be introduced to the
311	purpose of the study, the intervention, and the potential benefits and risks. Women
312	who agree to participate, after obtaining written informed consent, will be randomized
313	into the three different groups. Randomization will be performed by using a computer
314	system that randomly assigns participants into one of the three groups: (1) online
315	nutrition education + nutrition checklist and flyer (2) nutrition checklist and flyer for
316	self-learning, and (3) usual care without any intervention.
317	
318	Randomization
319	Allocation
320	The computer system (http://www.jerrydallal.com/random/randomize.htm)
321	generates randomization sequences based on the need of the study. The participants
322	are divided into four categories based on whether they are > 35 years old and have a
323	BMI \geq 28 kg/m2 (the cutoff between overweight and obesity in China), and are
324	randomized under each category. The name of the intervention group, the number of
325	groups, and the sample size for each group is entered into the system to generate the
326	allocation plan. Participants in different groups will receive different invitation links
327	for their intervention to have unified management.
328	
329	Concealment mechanism
330	Allocation concealment is ensured as the randomization code is not released until
331	the participants have met the eligibility and signed informed consent. The allocation is
332	performed automatically by the computer without human control. Participants will

3		
4 5	333	receive a new inclusion number after the groups are formed, and the number is also
6	004	
7 8	334	used as a participant ID for the intervention lessons.
9	335	
10 11	336	Implementation
12 13	337	The enrollment of the participants will be done by doctors who do not have
14 15 16	338	information on group allocation, as the randomization happens after the recruitment.
17 18 19	339	Participants are first divided into different categories according to the plan and then
20 21	340	randomized into three groups by research assistants of the study using the computer
22 23 24	341	program.
25 26 27	342	Doctors will distribute the nutrition checklist and one-page flyer to participants.
28 29 30	343	Research assistants will provide guidance on how to use these materials.
31 32	344	Online nutrition education sessions will be delivered by two research assistants who
33 34 35	345	are Ph.D. students majoring in Nutrition. The course content and study materials have
36 37 38	346	been reviewed by experts in nutrition.
39	347	
40 41	348	Blinding
42 43	349	Due to the nature of the study design, it is not possible to blind participants or
44 45 46	350	researchers in the study regarding the intervention type.
47	351	
48 49	352	Procedure for unblinding if needed
50 51	353	Not applicable, and the trial will not be blinded.
52 53 54	354	Statistical analysis
55 56 57 58 59 60	355	This study population will be defined according to the following methods

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356	The Intention-To-Treat Population (ITT), is defined as the result of the initial
357	random grouping, regardless of whether all interventions were completed. Modified
358	Intention to Treat Population (mITT) is defined as the removal of the absence of a
359	primary outcome, such as stillbirth or intrauterine death of the newborn, congenital
360	malformations, etc. Population Per Protocol(pp) is PP was defined as including only
361	those with good compliance with the intervention for analysis.
362	The following are compliance criteria:
363	Online Education Group: Course participation who have completed 4 lessons
364	(>67%) will be considered good adherence. Overall: the difference between the
365	dietary adherence score and the pre-intervention survey results is not less than -3
366	points. mITT analysis will be used for pre-randomization, baseline analysis, and
367	primary and secondary efficacy variable analysis. The primary outcome analysis will
368	be based on ITT for the preliminary analysis and PP for the comparison of robustness.
369	Research centers, corresponding obstetricians, or nutrition physicians will be
370	analyzed as categorical variables for subgroup analyses.
371	Patient and public involvement
372	Before the official start of the study, we will have a pilot study which includes a
373	process evaluation and interviews with obstetricians, dietitians, and pregnant people.
374	The comments and recommendations on the intervention plan from these populations
375	will be used to revise and improve the final intervention. During the intervention, the

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376	intensity and completeness of the intervention, as well as the acceptability and
377	satisfaction of pregnant people, will be recorded.
378	Discussion
379	Whether in China or around the world, the epidemic trend of overweight and
380	obesity is very serious. LGA is widely recognized as a risk factor for overweight and
381	obesity in children. The main objective of this study was to investigate the
382	effectiveness of controlling dietary fat intake in preventing and reducing the
383	occurrence of LGA.
384	This study includes two interventions to reduce dietary fat intake in pregnant
385	people, an online intervention based on a dietary guidance course and an intervention
386	based on a dietary instruction checklist and a one-page flyer. Both interventions
387	deliver the same content based on different pathways. Our aim was to compare the
388	effectiveness of the two interventions relative to routine outpatient visits, to help
389	analyze the effectiveness of dietary fat management for reducing LGA and other
390	adverse pregnancy outcomes in pregnant people with overweight and obesity, and to
391	test whether the new, low-cost intervention 'One-page flyer', which is easily scaled up
392	in busy clinical work, reduces the risk of adverse pregnancy outcomes in pregnant
393	people. The intensity of the "one -page flyer" is much lower than online sessions, but
394	even a small effect will benefit wider dissemination and achieve results on a wider
395	scale.

3 4 5	396	China is a developing country with a large population, and the BMI of residents
6 7 8	397	continues to rise, especially in rural areas. If dietary fat interventions are demonstrated
9 10 11	398	in this study to work, it can help optimize obstetric visits during pregnancy. If the
12 13	399	'One-page flyer' intervention reduces the incidence of adverse pregnancy outcomes in
14 15 16	400	pregnant people, it is likely that this intervention may be used by obstetricians as a
17 18 19	401	more cost-effective and convenient intervention.
20 21 22	402	Data Availability Statement
22 23 24	403	
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36 37 38	408	College, Columbia University, New York, NY 10027, USA.
39 40 41	409	³ Department of Obstetrics and Gynecology, the Eighth Clinical Medical College, Fu
42 43	410	Xing Hospital, Capital Medical University, Beijing, China.
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416 platform support. We would also like to thank the Ethics Committee of Capital417 Medical University.

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419 Haiyan, Isobel Contento, Pamela Koch, and Sun Shengzhi gave design comments and

420 feedback on the scheme. Yadi Zhang and Xiaoge Gao drafted and wrote the protocol,

421 and Huanling Yu, Isobel Contento, and Pamela Koch review edit. All authors

422 contributed to the research project.

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424 (Effects and mechanisms of gestational diabetes mellitus affecting intestinal microbial

425 colonization through modulation of offspring intestinal immune cell composition,

426 KZ202210025039).

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428 **Patient and public involvement** Patients and/or the public were not involved in the

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430 Methods section for further details.

431 **Patient consent for** publication Not required.

432 **Provenance and peer review** Not commissioned; externally peer reviewed.

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Figure 1. Extended Theory of Planned Behavior /Reasoned Action Approach

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DOA

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Appointment

with health

trainer

followed by

6 monthly

sessions

DECLINED

Routine antenatal care

BMI, age and pregnancy outcomes

recorded (if agreed)

Session 1: No more fat 1

Session 2: No more fat 2

Session 3: Eat out smartly

Session 4: Cook healthily

Session 6: Read the label

3 year Follow-Up:

Mother: Questionnaire: diet

assessment(FFQ), diet checklist, IPAQ-S,

PSQI, TPB-Q.

Anthropometry Samples: blood

Child: medications and supplements

Questionnaire: feeding and growth,

early care/education; sleep and activity

Session 5: Choose the

right snacks





SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Check	Section/item	Item No	
Page 1	Title	1	
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		2b	
	Protocol version	3	
Page 23	Funding	4	
	Roles and responsibilities	5a	
		5b	
		5c	
		5d	
Page 4	Introduction		
Page 4	Background and rationale	6a	
		6b	
Page 9	Objectives	7	
Page 9	Trial design	8	
Dago 0	Study potting	0	
Page 9	Study setting	9	
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14	Fage 19	Allocation concealment mechanism	100
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24			18b
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47 48		Protocol amendments	25
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50 51			26b
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53 54		Confidentiality	27
55		Declaration of interests	28
56 57		Access to data	29
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59 60		Anciliary and post-trial care	30

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Dissemination policy	31a
	31b
	31c
Appendices	
Informed consent materials	32
Biological specimens	33

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license. Koerterien ont

BMJ Open

The lipid-focused dietary education in pregnant women: study protocol for an open-label, parallel, randomized, intervention study addressing the adverse pregnancy outcomes

Journal:	BMJ Open
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7	2	an open-label, parallel, randomized, intervention study addressing the adverse
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10	3	pregnancy outcomes
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word count: 4385

3 4 5	32	Abstract (273 words)
6 7 8	33	Introduction : The incidence of infants who are large-for-gestational-age
9 10	34	(LGA) continues to increase in China, and its detrimental effects has received
12 13	35	increasing attention. Diet-based interventions have the potential to reduce adverse
14 15 16	36	birth outcomes, especially to decrease infants who are LGA. We aim to evaluate
17 18 19	37	the effect of lipid-focused diet education based on the theories of behavior change
20 21	38	in pregnant women on maternal and offspring outcomes through a randomized
22 23 24	39	control trial.
25 26 27	40	Methods and analysis: An open-label, parallel, multicenter randomized
28 29 30	41	controlled trial has been designed with the involvement of three hospitals in
31 32	42	Beijing, China.
33 34 35	43	Pregnant women will be recruited before 12 weeks' gestation, and randomized
36 37 38	44	1:1:1 into three arms: 1) Online education arm. 2) Diet checklist and 'one-page
39 40	45	flyer' arm. 3) Routine antenatal education. The primary outcome LGA will be
41 42 43	46	recorded at birth. Demographic, physical activity, sleep, and medical history
44 45 46	47	information will be collected through questionnaires and case cards prior to
47 48	48	enrolment. Dietary behaviors and psychosocial factors of pregnant women will be
49 50 51	49	collected through questionnaires at enrolment, at 24-28W and 34-36W of gestation.
52 53 54	50	Breastfeeding and complementary food supplementation of infants and young
55 56 57 58 59	51	children will be collected through questionnaires, and children's physical
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52	development indicators will be assessed and taste tests will be carried out 3 years					
53	after delivery.					
54	Ethics and dissemination: The study has received ethical approval from the					
55	Capital Medical University Ethics Committee and other study centers. Informed					
56	consent will be introduced to pregnant women and their consent obtained. The					
57	findings will be reported in relevant national and international academic conferences					
58	and peer-reviewed publications.					
59	Trial registration: The trail is registered ChiCTR2300071126					
60	Keywords: Study protocol, Pregnancy, Diet lipid, Large for gestational age,					
61	Theories of behavior change					
62	Protocol version: V2.					
63	Article Summary					
64	Strengths and limitations of this study					
65	 (Strengths) This study is a cause-and-effect randomized controlled study. 					
66	(Strengths) This study includes a large sample size that will be able to detect					
67	small differences.					
68	➤ (Strengths) The pre-experiments have already shown this approach to have					
69	beneficial effects on participants.					
70	 (Limitations) Due to the characteristics of the study design, participants are awar 					
71	of the intervention they receive.					

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72	(Limitations) People to be included in the study are being recruited from different
73	research centers and will receive different levels of routine maternal education.
74	
75	INTRODUCTION (1278 words)
76	Large for gestational age (LGA) is defined as a newborn who weighs above the
77	90th percentile of newborns for the same gestational age. The incidence of infants
78	who are LGA in China is about 10.1%[1], and the incidence is higher among pregnant
79	women with high gestational weight gain [adjusted OR 4.45 (95% CI 2.49-7.99)][2].
80	Studies have shown that LGA can have adverse effects on both pregnant women and
81	infants. People who give birth to an infant who is LGA are more likely to have a

82 cesarean delivery, birth canal injury, and/or postpartum hemorrhage[3]. Infants who

- 83 are LGA have an increased risk of shoulder dystocia, clavicle fractures, brachial
- 84 plexus injury, and/or increased admissions to the neonatal intensive care unit[3].
- 85 Follow-up studies have also shown that infants who are LGA are at an increased risk
- 86 of early obesity, metabolic disease, giving birth to LGA[4-6]. People who give birth
- 87 to infants who are LGA or gain excessive weight during pregnancy are associated
- 88 with many risk factors in adulthood, including being overweight and obesity,
- 89 gestational diabetes mellitus (GDM), lack of physical activity during pregnancy, and a
- 90 high intake of sugar and fat[2, 7].

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The role of diet in gestational weight gain and the incidence of LGA

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92	Pregnant women undergo special physiological changes, and their nutrition
93	needs are also different. Many countries have established separate dietary guidelines
94	for pregnant women, including China[8]. However, a 2015 dietary survey of pregnant
95	women in eight major cities in China showed that the average energy intake during
96	pregnancy was 2098 Kcal, with fat contributing to 36.4% (median 37.7%) of total
97	energy, exceeding the recommended amount of 25%-30% [9]. A 2016 study in
98	Shaanxi, China, sorted foods into five major groups and analyzed the energy sources
99	of pregnant women from these different food groups. The main sources of energy for
100	pregnant women were snacks (19%), meats (16%), and edible oil (11%), while the
101	main sources of fat were cooking oil (25%), meats (24%) and nuts (16%)[10]. A
102	recent 2021 dietary survey of pregnant women in Shanghai, China, found that 66.6%
103	of the total surveyed had poultry and meat intake above the recommended level, and
104	46.3% had oil intake above the recommendation[11]. Dietary fat plays an important
105	role in maintaining health as one of the three macronutrients, but excessive fat intake
106	can lead to many adverse health outcomes, especially for pregnant women. Previous
107	studies have indicated that high fat, high saturated fatty acid, and low polyunsaturated
108	fatty acid in diet may be risk factors for GDM, excessive weight gain and LGA[12-
109	14]. In the case of maternal overnutrition and insulin resistance, high levels of
110	triglyceride are hydrolyzed by placental lipase into free fatty acids and enter the
111	fetus[15]. Fetal exposure to excess free fatty acids may result in lipid storage due to
112	limited fatty acid oxidation capacity, leading to a higher risk for adverse pregnancy

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113 outcomes, including LGA[13, 16]. Observational study shows that maternal free fatty 114 acid levels in early pregnancy are significantly associated with childhood overweight 115 or obesity[17].

116 Decreasing the risk of LGA through diet intervention 117 Many previous studies have investigated the effect of dietary interventions on 118 health outcomes. A prospective cohort study showed that pregnant women with better 119 dietary fat quality (low saturated fatty acids, high polyunsaturated fatty acids) had a 120 lower incidence of LGA[18]. An intervention aimed at preventing LGA and 121 controlling birth weight provided guidance on a low-glycemic, low-saturated fat diet 122 and physical activity for pregnant women who were overweight or obese. The 123 intervention reduced GDM in pregnant women and the incidence of infants who are 124 LGA significantly[19]. In another trial, focusing solely on a low glycemic index diet 125 did not reduce the incidence of high birth weight, and fat intake was positively 126 correlated with neonatal central adiposity[20]. This might be due to the fact that when 127 recommending a low-carb diet, there also must be a focus on not exceeding the 128 saturated fat recommendation, as low-carb foods are often replaced with foods high in 129 saturated fat[21]. Moreover, meta-analyses have indicated that controlling saturated 130 fatty acid intake for the general population might improve their metabolic status and 131 reduce the risk of cardiovascular disease[22, 23]. However, a low-fat diet alone did 132 not achieve a better outcome in chronic disease prevention than a Mediterranean diet, 133 which is characterized by a moderate amount of fat intake but mostly 60 7 For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

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134	monounsaturated fat [24]. This might be due to the complexity of the dietary
135	components of a dietary pattern. Increasing or decreasing a single nutrient without
136	considering the overall macronutrient distribution of foods could have a negative
137	impact on health outcomes, as the health effects of foods cannot be predicted by their
138	content of any single nutrient group[25]. Some studies have suggested discontinuing
139	any macronutrient-restricting interventions, especially a low-carb ketogenetic diet or
140	any diet characterized by excessive saturated fatty acids for pregnant women .
141	Therefore, based on the Dietary Guidelines for Chinese Residents, this study aims to
142	control the amount of total dietary fat intake, improve the quality of dietary fat
143	(increase unsaturated fatty acids, decrease saturated fatty acids, and eliminate trans
144	fatty acids), and maintain a balanced dietary pattern. The main goal is to guide and
145	encourage pregnant women to change unhealthy dietary behaviors characterized by a
146	high-fat intake, which is supplemented by encouraging them to increase the
147	consumption of vegetables and fruits, whole grains, deep-sea fish and shrimp, nuts,
148	etc., and adjusting the frequency of eating. The intervention starts in early pregnancy,
149	as most women only visit the hospitals for dietary guidance when they realize they are
150	already pregnant, and their motivation to change is strong when they become mother-
151	to-be. Also, many pregnancies are unplanned in China, so it is more practical to start
152	the intervention in early pregnancy.
153	Psychosocial determinants associated with eating behaviors

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154	Pregnant women's dietary patterns are influenced by many factors, such as
155	predetermined biological factors, early exposure and experience, psychosocial factors,
156	and environmental factors[26]. Previous studies have shown that lifestyle
157	interventions and nutrition education addressing various determinants based on
158	psychosocial theories could lead to positive changes in pregnant women 's diet and
159	physical activity levels[27]. A healthy lifestyle is beneficial for both pregnant women
160	and their offspring[28]. Pregnant women are at a special life stage with a clear and
161	urgent need for a healthy dietary pattern and a strong motivation to improve their
162	offspring's health[29]. The theory of planned behavior (TPB) shown in Figure 1, was
163	first proposed as a theory of reasoned action in 1975 to predict an individual's
164	intention to engage in a behavior at a specific place and time[30]. The TPB has been
165	successful in predicting and explaining a wide range of intentions and behaviors,
166	including diet, smoking, drinking, breastfeeding, and substance use[31-34]. It mainly
167	focuses on enhancing the motivation of participants and takes into account the impact
168	of attitudes, perceived norms, and self-efficacy on the formation of behavioral
169	intention. The application of the TPB theory has been on the rise since it was first
170	introduced by Ajzen in 1985. As of 2010, more than 4,000 publications cited the
171	theory[35]. Many intervention studies based on the TPB model have also been
172	effective in leading to positive changes in eating habits and nutrition status, such as
173	increasing fruit and vegetable intake[36], reducing unhealthy snack intake[37], and
174	increasing calcium-rich foods intake[38].

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176	For this study, we have developed a multi-component nutrition education
177	intervention based on the extended TPB model[26, 39], as shown in Figure 1,
178	focusing on controlling total fat intake and improving the quality of diet lipids based
179	on a balanced dietary pattern. Outcome expectations, self-efficacy, and action goal
180	setting are the center of our focus. The primary aim is to assess whether the
181	intervention will reduce the risk of the delivery of an LGA infant for pregnant
182	women .
183	METHODS AND ANALYSIS
184	Study design
185	This is a multicenter, 1:1:1 ratio, parallel, open-blind RCT. The study design
186	adheres to the SPIRIT quality standard criteria for RCT. Participating centers include
187	Fuxing Hospital Affiliated to Capital Medical University, Xuanwu Hospital Affiliated
188	to Capital Medical University and Beijing Haidian District Maternal and Child Health
189	Care Hospital, all in Beijing, China. The specific process can be seen in Figure 2 and
190	the time line is shown in Table 1. The study commenced in May 2023 and is expected
191	to end in August 2024.
192	Table1. Timeline of intervention and information collection.
193	

The scient	Enrolment and allocation	Post-allocation			- D-11	Postpartum	
i ime point	Before	11-12	26-28	34-36	Delivery	42 days	3 years
	11weeks	weeks	weeks	weeks		postnatal	postnatal

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Enrollment:

Allocation

NOA

RAC

Interventions: OEA

Assessments: Baseline data:

Demographic

Current pregnancy health diet assessment(FFO),

> questionnaire Diet checklist

TPB questionnaire

IPAQ, PSQI Child Feeding and Development, Early Care,

Sleep and Activity Primary outcome : LGA、GDM

Ethical approval

Eligibility criteria

was obtained in all centers as well (Z2022SY077).

Second outcome : Mantel pregnancy outcome (Mode of delivery, Pregnancy complications, and gestational weight gain and so on) Fetal outcome(birth weight, placenta weight, SGA, preterm, Apgar score, etc.) Infant length and weight

Eligibility screen Informed consent

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NOA: Nutrition checklists and "One-page flyer" arm; OEA: Online education arm; IPAQ-S: International Physical Activity

Capital Medical University Ethics Committee approved the study. Ethical approval

Questionnaire - Short Form; PSQI: The Pittsburgh Sleep Quality Index; TPB-Q: Theory of planned behavior questionnaire.

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202	Eligible participants will be pregnant women, include biological females who do
203	not identify as women.
204	The inclusion criteria are as follows:
205	Singleton pregnancy, natural insemination, < 12 weeks' gestation, signed informed
206	consent.
207	The exclusion criteria are as follows:
208	> 12 weeks' gestation, pre-existing type 1 or type 2 diabetes, fetal malformations
209	including chromosomal abnormalities or structural malformations detected by
210	ultrasonography, fetal congenital infections or abnormalities, restricted diet (including
211	vegans and due to medical conditions), conditions that might affect intervention or
212	follow-up (including physical activity restrictions, medical conditions or
213	medications), unwilling or unable to give informed consent
214	
215	Intervention
216	Eligible participants will be randomized into three groups: online nutrition
217	education (Group 1); nutrition checklist and 'One-page flyer' for self-learning (Group
218	2); routine antenatal education without any intervention (Group 3).
219	Group 1: Online nutrition education arm (OEA)
220	The first intervention group will receive 6 sessions of 1-h nutrition education by
221	video-conferencing (Table 2). The course design was based on the TPB model and
222	followed the DESIGN Procedure[26]of Contento and Koch. The DESIGN procedure
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223	is a simple, systematic, 6-step process that integrates food and nutrition science,
224	psychological theories, education principles, and communication skills. It provides a
225	framework for planning theory-based, behavior-focused nutrition education that
226	translates theory and evidence into activities, materials, group discussions, and social
227	media. Two graduate students majoring in nutrition will lead the course. The overall
228	goal of the course is to promote a balanced diet with a focus on controlling fat intake.
229	The general goal can be further broken down into three specific behavioral change
230	goals: choosing the right food to eat, cooking healthily, and reading nutrition labels so
231	they can identify healthy packaged food. According to the previous records of the
232	participating hospitals, over 95% of the pregnant women have a high-school degree
233	and all of them are literate, therefore would be able to comprehend the course content.
234	Table2. Course topics and behavioral strategies.

Them	Behavioral strategy	Diet topic
Session 1: No more fat 1	 Outcome expetations Factual knowledge and skill Self-efficacy/Perceive behavior control Analysis of pros and cons of change(Behavioral Intention) 	Benefits of balance diet Discovering your inadequate of their diet Identifying high-fat foods Use fists and hands to count food servings Overcoming the obstacles of a high-fat diet
Session 2: No more fat 2	 Negative outcomes of current behavior Perceived benefits Self-depictions Behavioral intention 	The Dangers of Trans Fatty Acids Knowing that a healthy cooked diet is just as tasty Knowing that the mother's diet affects the child

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		Learn to establish dietary goals
Session 3: Eat out smartly	 Negative outcomes of current behavior Knowledge and cognitive skills Perceived norms Self-efficacy 	understand how to choose foods wisely when dining out or ordering delivery online
Session 4: Cook healthily	 Perceived benefits Skills and ability Perceived barriers Behavioral intention 	learn the recipes for healthy cooking
Session 5: Choose the right snacks	 Perceived risk Food and nutrition knowledge Food preferences Self-efficacy 	understand the definition of ultra-processed foods, learn how to choose healthy snacks
Session 6: Read the label	 Perceived benefits Skills and ability Perceived norms Behavioral intention 	learn how to read nutrition labels and ingredient list

236 Group 2: Nutrition checklist and 'One-page flyer' arm (NOA)

The 17-item nutrition checklist was adapted from the FIGO checklist[40], which only requires 2 minutes to complete and is a very efficient way to assess the nutrition status of pregnant women[41]. This tool helps clinicians and pregnant women quickly identify imbalances in their dietary patterns. The checklist includes four parts. Part 1: self-reported special dietary habits (e.g., vegan, food allergy); Part 2: self-reported height, weight, and BMI; Part 3: 17 questions related to dietary habits with a focus on fat intake (most are yes or no questions); Part 4: grading criteria and interpretation of

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244	the checklist result. The 'one-page flyer' is an A4 paper-sized dietary instruction
245	flyer. It is based on the theory of planned behavior, including information on the
246	adverse effects of a high-fat diet during pregnancy on mother and baby at the top of
247	the page (outcome expectation), choosing healthy snacks, reading food labels, specific
248	cooking tips using less oil (knowledge and skills), information on diet management
249	aiming to increase confidence (perceived behavior control and self-efficacy),
250	guidance on establishing specific and feasible behavior change goals (goal-setting
251	using SMART theory). The checklist and "one-page" flyer are distributed to the
252	participants by physicians at their monthly pregnancy check-ups. Pregnant women
253	can self-identify their nutrition problems and make behavioral changes by following
254	the guidance in the 'one-page flyer'.
255	Criteria for discontinuing or modifying allocated interventions
256	Not applicable due to the nature of the interventions.
257	
258	Strategies to improve adherence to interventions
259	Adherence to the online education sessions will be assessed by class attendance
260	from sign-ins and visual scans of video conference attendees. We will set up an online
261	group chat for participants to remind them to attend before the start of each class, and
262	we will create a pre-class check-in e-form, post-class Q&A and evaluation e-form to
263	measure participation in the class. The treatment will be considered complete if at
264	least four out of the six sessions are attended. Adherence to the diet checklist and

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265	'one-page flyer' arm will be assessed by an improvement of ≥ 3 points of their total
266	scores of the 17-item nutrition checklist compared to their total initial score. The
267	study population will be sorted according to adherence to the dietary guidelines,
268	depending on the score: ≥ 12 high adherence, $6 - 11$ moderate adherence, and < 6 low
269	adherence.
270	
271	Relevant concomitant care permitted or prohibited during the trial
272	People who participate in this trial cannot participate in another trial.
273	
274	Provisions for post-trial care
275	No post-trial care is needed since this is an educational intervention.
276	
277	Outcomes
278	Adverse pregnancy outcomes:
279	Primary outcome:
280	The primary outcome will be the prevalence of LGA at birth, defined as the
281	newborns with a measured birth weight above the 90th percentile (P_{90}) of the same
282	sex for the same gestational age were evaluated as large for gestational age (Growth
283	standard for newborns by gestation in China, WS/T 800-2022).
284	Secondary outcomes:

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285	Neonatal: Birth weight, Macrosomia (birth weight \geq 4000 g), SGA (birth weight
286	below the 10th percentile for gestational age) or low birth weight (birth weight \leq 2500
287	g), preterm birth (< 37 weeks' gestation), low Apgar score (Apgar <7).
288	Maternal: GDM (GDM is diagnosed when the blood glucose value at any point in
289	time meets or exceeds the above criteria: fasting, 1 hour after oral glucose, and 2
290	hours after glucose thresholds of 5.1, 10.0, and 8.5 mmol/litre, respectively.),
291	gestational hypertension (defined as >20 weeks' gestation, elevated blood pressure
292	[systolic BP \geq 140 mm Hg or diastolic BP \geq 90 mm Hg] in the absence of proteinuria),
293	cesarean section rate, birth canal injury rate, shoulder dystocia rate, maternal insulin
294	treatment rate, maternal weight gain during pregnancy (maternal weight gain
295	generally refers to maternal weight at delivery minus pre-pregnancy weight),
296	preeclampsia (defined as >20 weeks' gestation, new-onset hypertension [systolic
297	blood pressure \geq 140 mm Hg or diastolic blood pressure \geq 90] mm Hg] and new-onset
298	proteinuria [300 mg protein intake within 24 hours or urine protein/creatinine ratio 0.3
299	mg/dL], or in the absence of proteinuria, new-onset hypertension with new-onset
300	thrombocytopenia, renal insufficiency, impaired liver function, pulmonary edema, or
301	cerebral or visual impairment), perinatal mortality (fetuses or neonates death at > 28
302	weeks' gestation - within 7 days of postpartum)
303	
304	Changes in dietary behaviors

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305	Changes in dietary behaviors will be assessed by a dietary behavior questionnaire,
306	which was adapted from previous FFQs[42, 43]. The questionnaire includes questions
307	on the intake and frequency of consumption of different categories of foods,
308	particularly high-fat foods.
309	We will also assess knowledge and skills related to cooking habits that can reduce
310	fat intake and reading nutrition labels to choose low-fat foods when shopping.
311	Behaviors related to adherence to the dietary guidelines will be assessed by the 17-
312	item nutrition checklist.
313	
314	Changes in psychosocial determinants based on the TPB model
315	A questionnaire was developed to assess the changes in the four components
316	(attitude towards behavior, subjective norm, perceived behavioral control, and
317	behavioral intention) related to diet behaviors (reducing fat intake, cooking healthily,
318	and reading nutrition labels) based on the TPB before and after the intervention. The
319	questionnaire was based on previous studies[36, 44], and content validity has been
320	confirmed by experts in nutrition. Attitudes, perceived norms, self-efficacy, self-
321	depictions, and behavioral intention will be assessed as the mean of the statements
322	under each component measured on 5-point unipolar (+1 to +5) scales.
323	The 17-item nutrition checklist, FFQ, and TPB-Q are undergoing pre-survey and
324	validation of validity.
325	Postpartum follow-up

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3 4 5	326	The feeding types and complementary foods added will be investigated 42 days
6 7 8	327	after delivery through a questionnaire to be developed. Children are followed again at
9 10	328	3 years of age for diet, taste preferences, and physical development. Children's diets
12 13	329	will be assessed by a food frequency questionnaire based on a previous study32.
14 15 16	330	Children's physical development will be assessed by their weight, height, sitting
17 18 19 20 21 22	331	height, and body composition, measured by body weight meter, mechanical
	332	height/sitting height meter, and body composition analyzer, respectively.
22 23 24	333	Other measures
25 26 27	334	A baseline survey is used to collect information on participants' demography,
28 29	335	lifestyle (e.g., sleep, physical activity), and medical and family history.
30 31	336	Sample size
32 33	337	The RCT uses the incidence of LGA as the primary outcome. The incidence of
34 35 36	338	LGA in the general population is about 11.0%[45], while the incidence in the
37 38 39	339	intervention group is expected to be 5.0%[46]. Assuming a type 1 error of 5% and a
40 41 42	340	power of 80%, 318 participants will be recruited. Allowing for a 20% dropout, 400
43 44	341	participants will be needed for each of the three arms, with an overall sample size of
45 46 47	342	1200 participants for the study[47].
48 49 50 51	343	$n = \frac{(z_{1-\alpha/2} + z_{1-\beta})^2 [p_1(1-p_1)/k + p_2(1-p_2)]}{(p_1 - p_2)^{-2}}$
52 53	344	Recruitment
54 55	345	At the first prenatal check-up, all eligible pregnant women will be introduced of the
50 57 58 59	346	purpose of the study, the intervention, and the potential benefits and risks. Participants
60		19

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lifestyle (e.g., sleep, physical activity), and medical and family history.
Sample size
The RCT uses the incidence of LGA as the primary outcome. The incidence of
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1200 participants for the study[47].
$n = \frac{(z_{1-\alpha/2} + z_{1-\beta})^2 [p_1(1-p_1)/k + p_2(1-p_2)]}{(p_1 - p_2)^2}$
Recruitment

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363 364 who agree to participate, after obtaining written informed consent, will be randomized into the three different groups. Randomization will be performed by using a computer system that randomly assigns participants into one of the three groups: (1) online nutrition education + nutrition checklist and flyer (2) nutrition checklist and flyer for self-learning, and (3) usual care without any intervention.

Randomization

Allocation

- 355 The computer system (http://www.jerrydallal.com/random/randomize.htm)
- generates randomization sequences based on the need of the study. The participants 356 357 are divided into four categories based on whether they are > 35 years old and have a 358 BMI $\geq 28 \text{ kg/m}^2$ (the cutoff between overweight and obesity in China), and are 359 randomized under each category. The name of the intervention group, the number of
 - 360 groups, and the sample size for each group is entered into the system to generate the
 - allocation plan. Participants in different groups will receive different invitation links 361
 - 362 for their intervention to have unified management.
 - Concealment mechanism

365 Allocation concealment is ensured as the randomization code is not released until 366 the participants have met the eligibility and signed informed consent. The allocation is 367 performed automatically by the computer without human control. Participants will receive a new inclusion number after the groups are formed, and the number is also 368

- 369 used as a participant ID for the intervention lessons.

1 ว		
2 3	371	Implementation
4 5 6	372	The enrollment of the participants will be done by doctors who do not have
7 8 9	373	information on group allocation, as the randomization happens after the recruitment.
10 11 12	374	Participants are first divided into different categories according to the plan and then
13 14 15	375	randomized into three groups by research assistants of the study using the computer
16 17	376	program.
18 19 20	377	Doctors will distribute the nutrition checklist and one-page flyer to participants.
21 22 23	378	Research assistants will provide guidance on how to use these materials.
24 25	379	Online nutrition education sessions will be delivered by two research assistants who
20 27 28	380	are Ph.D. students majoring in Nutrition. The course content and study materials have
29 30 31	381	been reviewed by experts in nutrition.
32	382	
33 34	383	Blinding
35 36	384	Due to the nature of the study design, it is not possible to blind participants or
37 38 39	385	researchers in the study regarding the intervention type. Therefore, the study is
40 41 42	386	blinded only to the clinical nurses responsible for grouping. Nurses responsible for
43 44 45	387	enrolment recruitment were unaware of the grouping.
46 47	388 389	Procedure for unblinding if needed
48 49 50	390	Not applicable, and the trial will not be blinded.
51 52 53	391	Statistical analysis
54 55 56 57 58 59	392	This study population will be defined according to the following methods
60		24

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393	The Intention-To-Treat Population (ITT), is defined as the result of the initial
394	random grouping, regardless of whether all interventions were completed. Modified
395	Intention to Treat Population (mITT) is defined as the removal of the absence of a
396	primary outcome, such as stillbirth or intrauterine death of the newborn, congenital
397	malformations, etc. Population Per Protocol(pp) is defined as including only those
398	with good adherence to the intervention for analysis.
399	The following are adherence criteria:
400	Online Education Group: Course participation who have completed 4 lessons
401	(>67%) will be considered good adherence. Nutrition checklist and 'One-page flyer':
402	the difference between the dietary adherence score and the pre-intervention survey
403	results is not less than -3 points. mITT analysis will be used for pre-randomization,
404	baseline analysis, and primary and secondary efficacy variable analysis. The primary
405	outcome analysis will be based on ITT for the preliminary analysis and PP for the
406	comparison of robustness.
407	The missing value treatment program follows CPMP/EWP/1776/99.
408	Missing values are filled in for the main variables only. The filling principles are as
409	follows:
410	Primary missing value imputation strategy: Worst case impute is used for the
411	primary outcome (the primary outcome was the occurrence of LGA, which was
412	defined as a birth weight greater than the 90th percentile of the mean weight of
413	children of the same gestational age and sex).

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3 4 5	414	Secondary missing value imputation strategy: a multiple filling of all data using
6 7 8	415	control group observations
9 10	416	The results of the primary analyses were based on worst-case impute, and the
11 12 13	417	results of multiple impute were sensitivity analyses.
14 15 16	418	Non-parametric tests were used for component variability of unordered categorical
17 18	419	variables, ordered categorical variables, non-normal continuous variables, and
19 20 21	420	parametric tests for normally distributed data.
22 23 24	421	Research centers, corresponding obstetricians, or nutrition physicians will be
25 26 27	422	analyzed as categorical variables for subgroup analyses. Demographic variables such
28 29	423	as age of the pregnant woman, number of births, level of education, and place of
30 31 32	424	domicile will be used for sensitivity analyses.
33 34 35	425	Patient and public involvement
36 37 38	426	Before the official start of the study, we will have a pilot study which includes a
39 40	427	process evaluation and interviews with obstetricians, dietitians, and pregnant women.
41 42 43	428	The comments and recommendations on the intervention plan from these populations
44 45 46	429	will be used to revise and improve the final intervention. During the intervention, the
47 48 40	430	intensity and completeness of the intervention, as well as the acceptability and
50 51	431	satisfaction of pregnant women, will be recorded. Patients and/or the public were not
52 53 54	432	involved in the design, or conduct, or reporting, or dissemination plans of this
55 56 57	433	research. Refer to the Methods section for further details.
58 59 60	434	Data Availability Statement

1 2		
3 4 5	435	Not applicable for a protocol as no data has been generated.
6 7 8	436	FIGURE LEGENDS
9 10 11	437	Figure 1. Extended Theory of Planned Behavior /Reasoned Action Approach
12 13	438	Figure 2. Study design including the screening, recruitment, randomization process,
14 15 16	439	and the conduct flow.
17 18 19	440	Note : IPAQ-S: International Physical Activity Questionnaire - Short Form; PSQI:
20 21	441	The Pittsburgh Sleep Quality Index; TPB-Q: Theory of planned behavior
22 23 24	442	questionnaire; NOA: Nutrition checklists and "One-page flyer" arm; OEA: Online
25 26 27	443	education arm.
28 29 30	444	
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471	
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Figure 1. Extended Theory of Planned Behavior /Reasoned Action Approach

230x113mm (150 x 150 DPI)

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Figure 2. Study design including the screening, recruitment, randomization process, and the conduct flow.

Note: IPAQ-S: International Physical Activity Questionnaire - Short Form; PSQI: The Pittsburgh Sleep Quality Index; TPB-Q: Theory of planned behavior questionnaire; NOA: Nutrition checklists and "One-page flyer" arm; OEA: Online education arm.

Figure 2. Study design including the screening, recruitment, randomization process, and the conduct flow.

210x267mm (150 x 150 DPI)

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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Check	Section/item	Item No
Page 1	Title	1
Page 4	 Trial registration 	2a
Page 4	Protocol version	3
Page 24	Funding	4
Page 23	Roles and responsibilities	5a
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Page 5	Background and rationale	6a
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Page 19	Sample size	14
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Page 16	Data collection methods	18a
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Page 21	Statistical methods	20a
NA	Data monitoring	21a
Page 16	Harms	22
Page 15	Auditing	23
Page 3	Research ethics approval	24
NA	Protocol amendments	25
Page 19	Consent or assent	26a
		26b
Page 24	Confidentiality	27
Page 24	Declaration of interests	28
Page 23	Access to data	29
Page 16	Ancillary and post-trial care	30
Page 24	Dissemination policy	31a
		31b
		31c
NA	Appendices	
	Informed consent materials	32
	Biological specimens	33

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "<u>Attribution-NonCommercial-NoDerivs 3.0 Unported</u>" license.

A lipid-focused dietary education intervention in pregnant women: study protocol for an open-label, parallel, randomized, intervention study addressing adverse pregnancy outcomes.

Journal:	BMJ Open
Manuscript ID	bmjopen-2023-076911.R2
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Primary Subject Heading :	Public health
Secondary Subject Heading:	Nutrition and metabolism, Epidemiology, Research methods
Keywords:	EPIDEMIOLOGIC STUDIES, Health Education, Primary Prevention, PUBLIC HEALTH, Obesity

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Word count: 4,720
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3 4 5	34	Abstract (273 words)
6 7 8	35	Introduction: The incidence of infants who are large-for-gestational-age (LGA) is
9 10	36	on the rise in China, and its detrimental effects on health has received increasing
12 13	37	attention. Diet-based interventions have the potential to reduce adverse birth
14 15 16	38	outcomes, particularly in decreasing the occurrence of LGA infants. We aim to
17 18	39	evaluate the effect of lipid-focused diet education based on the theories of behavior
20 21	40	change in pregnant women on maternal and offspring outcomes through a
22 23 24	41	randomized control trial.
25 26 27	42	Methods and analysis: We have designed an open-label, parallel, multicenter
28 29	43	randomized controlled trial in collaboration with three hospitals in Beijing, China.
30 31 32	44	Pregnant women will be recruited before reaching 12 weeks of gestation, and will
33 34 35	45	be randomized in a 1:1:1 ratio into three arms: 1) Online education arm, 2) Diet
36 37	46	checklist and 'one-page flyer' arm, and 3) Routine antenatal education. The
38 39 40	47	primary outcome LGA will be recorded at birth. Demographic information,
41 42 43	48	physical activity, sleep, and medical history will be collected through
44 45 46	49	questionnaires and case cards prior to enrolment. Questionnaires will also be used
40 47 48	50	to collected dietary behaviors and psychosocial factors of pregnant women at
49 50 51	51	enrolment, at 24-28 weeks and 34-36 weeks of gestation. Additionally, information
52 53 54	52	on breastfeeding and complementary food supplementation for infants and young
55 56	53	children will be obtained through questionnaires. Physical development indicators
57 58 59 60	54	of children and taste tests will be assessed three years after delivery.

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55	Ethics and dissemination: The study has received ethical approval from the Capital					
56	Medical University Ethics Committee and other collaborating study centers. Informed					
57	consent will be introduced to pregnant women and their consent obtained. The					
58	findings will be reported in relevant national and international academic conferences					
59	and peer-reviewed publications.					
60	Trial registration: The trail is registered ChiCTR2300071126					
61						
62	Keywords: Study protocol, Pregnancy, Diet lipid, Large for gestational age, Theories					
63	of behavior change					
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65 66	Protocol version: V3.					

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4 5	67						
6 7 8	68	Article Summary					
9 10	69	Strengths and limitations of this study					
12 13	70	 (Strengths) This study is a rigorous cause-and-effect randomized controlled 					
14 15 16	71	study.					
17 18 19	72	> (Strengths) This study includes a large sample size that will be able to detect					
20 21	73	small differences.					
22 23 24	74	(Strengths) The pilot study have already proven that prenatal nutrition					
25 26 27	75	education activities based on behavioral change theory have beneficial effects on					
28 29 30	76	participants.					
31 32	77	(Limitations) Due to the characteristics of the study design, participants are					
33 34 35	78	aware of the intervention they receive.					
36 37 38	79	(Limitations) People to be included in the study are being recruited from					
39 40 41	80	different research centers and will receive different levels of routine maternal					
41 42 43	81	education.					
44 45 46	82						
47 48 49	83	INTRODUCTION (1,360 words)					
50 51	84	Large for gestational age (LGA) baby is defined as a newborn weighing above the					
52 53 54	85	90th percentile of newborns for the same gestational age. In China, approximately					
55 56 57	86	10.1% of infants are classified as LGA[1], and the incidence is higher among					
58 59	87	pregnant women with high gestational weight gain[2]. Studies have shown that LGA					
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88	can have adverse effects on both pregnant women and infants. Maternal outcomes for
89	those giving birth to an LGA infant are more likely to have a higher risk of cesarean
90	delivery, birth canal injury, and postpartum hemorrhage[3]. Infants who are LGA
91	have an increased risk of shoulder dystocia, clavicle fractures, brachial plexus injury,
92	and increased admissions to the neonatal intensive care unit[3]. Follow-up studies
93	have also shown that LGA infants face an increased risk of early obesity, metabolic
94	disease, and giving birth to LGA offspring[4-6]. Individuals giving birth to LGA
95	infants or experiencing excessive weight gain during pregnancy are associated with
96	several risk factors in adulthood, including overweight and obesity, gestational
97	diabetes mellitus (GDM), lack of physical activity during pregnancy, and a high
98	consumption of sugar and fat[2, 7].
99	The role of dist in gestational weight gain and the incidence of LCA
00	The role of thet in gestational weight gain and the incidence of LGA
100	Several countries have established specific dietary guidelines for pregnant women,
100 101	Several countries have established specific dietary guidelines for pregnant women, including China[8]. However, a dietary survey conducted in 2015 among pregnant
100 101 102	Several countries have established specific dietary guidelines for pregnant women, including China[8]. However, a dietary survey conducted in 2015 among pregnant women in eight major cities in China showed that the average energy intake during
100 101 102 103	Several countries have established specific dietary guidelines for pregnant women, including China[8]. However, a dietary survey conducted in 2015 among pregnant women in eight major cities in China showed that the average energy intake during pregnancy was 2098 Kcal, with fat accounting for 36.4% (median 37.7%) of the total
100 101 102 103 104	Several countries have established specific dietary guidelines for pregnant women, including China[8]. However, a dietary survey conducted in 2015 among pregnant women in eight major cities in China showed that the average energy intake during pregnancy was 2098 Kcal, with fat accounting for 36.4% (median 37.7%) of the total energy, exceeding the recommended amount of 25%-30% [9]. A 2016 study in
100 101 102 103 104 105	Several countries have established specific dietary guidelines for pregnant women, including China[8]. However, a dietary survey conducted in 2015 among pregnant women in eight major cities in China showed that the average energy intake during pregnancy was 2098 Kcal, with fat accounting for 36.4% (median 37.7%) of the total energy, exceeding the recommended amount of 25%-30% [9]. A 2016 study in Shaanxi, China, categorized foods into five major groups and analyzed the energy
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100 101 102 103 104 105 106 107 108	Several countries have established specific dietary guidelines for pregnant women, including China[8]. However, a dietary survey conducted in 2015 among pregnant women in eight major cities in China showed that the average energy intake during pregnancy was 2098 Kcal, with fat accounting for 36.4% (median 37.7%) of the total energy, exceeding the recommended amount of 25%-30% [9]. A 2016 study in Shaanxi, China, categorized foods into five major groups and analyzed the energy sources for pregnant women from these different food groups. The main sources of energy for pregnant women were snacks (19%), meats (16%), and edible oil (11%), while the main sources of fat were cooking oil (25%), meats (24%) and nuts

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109	(16%)[10]. In a recent 2021 dietary survey of pregnant women in Shanghai, China,
110	the authors found that 66.6% of the participants exceeded the recommended intake
111	levels for poultry and meat, and 46.3% exceeded the recommended oil intake [11].
112	The rapid industrialization of the food system in developing countries like China has
113	led to increased availability of high-energy density and low-nutritional quality
114	foods[12, 13], contributing to excessive dietary fat in pregnant women. Previous
115	studies have suggested that a diet high in fat, particularly saturated fatty acids, and
116	low in polyunsaturated fatty acid in diet may be risk factors for GDM, excessive
117	weight gain, and LGA infants[14-16]. In cases of maternal overnutrition and insulin
118	resistance, high levels of triglyceride are hydrolyzed by placental lipase into free fatty
119	acids, and can enter the fetus[17]. Fetal exposure to excess free fatty acids may result
120	in lipid storage due to limited fatty acid oxidation capacity, leading to a higher risk for
121	adverse pregnancy outcomes, including LGA[15, 18]. Observational study shows that
122	maternal free fatty acid levels in early pregnancy are significantly associated with
123	childhood overweight or obesity[19].
124	Decreasing the risk of LGA through diet intervention
125	Many previous studies have investigated the effect of dietary interventions on health
126	outcomes. A prospective cohort study showed that pregnant women with better
127	dietary fat quality (low saturated fatty acids, high polyunsaturated fatty acids) had a
128	lower incidence of LGA[20]. An intervention aimed at preventing LGA and

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129 controlling birth weight provided guidance on a low-glycemic, low-saturated fat diet

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130	and physical activity for pregnant women who were overweight or obese. The
131	intervention reduced the incidence of GDM and LGA significantly[21]. In another
132	trial, focusing solely on a low glycemic index diet did not reduce the incidence of
133	high birth weight, and fat intake was positively correlated with neonatal central
134	adiposity[22]. This might be due to the fact that when recommending a low-carb diet,
135	there also must be a focus on not exceeding the saturated fat recommendation, as low-
136	carb foods are often replaced with foods high in saturated fat[23]. Moreover, meta-
137	analyses have indicated that controlling saturated fatty acid intake for the general
138	population might improve their metabolic status and reduce the risk of cardiovascular
139	disease[24, 25]. However, a low-fat diet alone did not achieve a better outcome in
140	chronic disease prevention than a Mediterranean diet, which is characterized by a
141	moderate amount of fat intake but mostly monounsaturated fat [26]. This might be
142	due to the complexity of the dietary components of a dietary pattern. Increasing or
143	decreasing a single nutrient without considering the overall macronutrient distribution
144	of foods could have a negative impact on health outcomes, as the health effects of
145	foods cannot be predicted by their content of any single nutrient group[27]. Research
146	shows that from 1991 to 2011, the consumption of meat by Chinese residents
147	continued to increase, but seafood remained relatively low[28]. This may be due to
148	price and dietary habits[28]. Therefore, adopting direct Mediterranean dietary
149	intervention for pregnancy dietary guidance in China may lead to poor compliance. In
150	order to reduce pregnant women's high-fat diet behavior, improve the quality of
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151	dietary fat(increase unsaturated fatty acids, decrease saturated fatty acids, and
152	eliminate trans fatty acids), and promote dietary balance, we development a lipid-
153	focused intervention based on the Dietary Guidelines for Chinese Residents. The
154	main goal is to guide and encourage pregnant women to change unhealthy dietary
155	behaviors characterized by a high-fat intake, which is supplemented by encouraging
156	them to increase the consumption of vegetables and fruits, whole grains, deep-sea fish
157	and shrimp, nuts, etc., and adjusting the frequency of eating. The intervention starts in
158	early pregnancy, as most women only visit the hospitals for dietary guidance when
159	they realize they are already pregnant, and their motivation to change is strong when
160	they become mother-to-be. Also, many pregnancies are unplanned in China, so it is
161	more practical to start the intervention in early pregnancy.
162	Theoretical model for intervention
163	Pregnant women's dietary patterns are influenced by many factors, such as
164	predetermined biological factors, early exposure and experience, psychosocial factors,
165	and environmental factors[29]. Previous studies have shown that lifestyle
166	interventions and nutrition education addressing various determinants based on
167	psychosocial theories could lead to positive changes in pregnant women 's diet and
168	physical activity levels[30]. A healthy lifestyle is beneficial for both pregnant women
169	and their offspring[31]. Pregnant women are at a special life stage with a clear and
170	urgent need for a healthy dietary pattern and a strong motivation to improve their
171	offspring's health[32]. The theory of planned behavior (TPB) shown in Figure 1, was

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172	first proposed as a theory of reasoned action in 1975 to predict an individual's
173	intention to engage in a behavior at a specific place and time[33]. The TPB has been
174	successful in predicting and explaining a wide range of intentions and behaviors,
175	including diet, smoking, drinking, breastfeeding, and substance use[34-37]. It mainly
176	focuses on enhancing the motivation of participants and takes into account the impact
177	of attitudes, perceived norms, and self-efficacy on the formation of behavioral
178	intention. The application of the TPB theory has been on the rise since it was first
179	introduced by Ajzen in 1985. As of 2010, more than 4,000 publications cited the
180	theory[38]. Many intervention studies based on the TPB model have also been
181	effective in leading to positive changes in eating habits and nutrition status, such as
182	increasing fruit and vegetable intake[39], reducing unhealthy snack intake[40], and
183	increasing calcium-rich foods intake[41].
184	For this study, we have developed a multi-component nutrition education intervention
185	based on the extended TPB model[29, 42], as shown in Figure 1, focusing on
186	controlling total fat intake and improving the quality of diet lipids based on a balanced
187	dietary pattern. Outcome expectations, self-efficacy, and action goal setting are the
188	center of our focus. The primary aim is to assess whether the intervention will reduce
189	the risk of the delivery of an LGA infant for pregnant women. Compared to group
190	course education, prenatal dietary guidance provided by obstetricians may be more
191	authoritative, convenient, and therefore more useful for pregnant women. Therefore,
192	while verifying the effectiveness of a lipid-focused dietary group education

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intervention based on TPB theory, this study established another intervention group
that only distributed manuals included intervention content. This low-cost and highly
scalable intervention method provides a scientific basis for integrating intervention
content into routine obstetric examinations in the future.

197 METHODS AND ANALYSIS

198 Study design

199 This is a multicenter, 1:1:1 ratio, parallel, open-blind RCT. The study design strictly 200 adheres to the SPIRIT quality standard criteria for RCTs. The participating centers in 201 this study are Fuxing Hospital affiliated with Capital Medical University; Xuanwu 202 Hospital Affiliated with Capital Medical University; and Beijing Haidian District 203 Maternal and Child Health Care Hospital, all located in Beijing, China. The detailed 204 process is outlined in Figure 2, and the time line is shown in Table 1. The study was 205 initiated in May 2023 and is expected to conclude in August 2024. As of the revision 206 date, the pilot study (2022), formal experimental course design and qualitative 207 research (August 2023), and the cross-sectional survey of questionnaire reliability and 208 validity (September 2023) have been successfully completed.

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Table1. Timeline of intervention and information collection.

Time point	Enrolment and allocation	Post-allocation			Delivery	Postpartum	
	Before 11weeks	11-12 weeks	26-28 weeks	34-36 weeks	, i	42 days postnatal	3 years postnatal
Enrollment Eligibility screen							

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4		consent	N							
5		Allocation								
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7		OFA								
8		NOA		J	J	Ń				
9		RAC		J	J	Ń				
10		Assessments		v	v	v				
11		Reseline data								
12		Demographic		N						
13		Current		v						
14		nregnancy			N					
15		prognancy bealth			N					
16		diet								
17		ulci								
18		(FEO)								
19		(FFO),								
20		Diet checklist		2	2	2		2	2	
21		TDD		N.	N	N		N	v	
22		auestionnaire								
23				N	N	2		2		
24		Child Feeding		v	N	v		v	v	
25		and								
26		Development						,	,	
27		Early Care							\checkmark	
28		Sleen and								
29		Activity								
30		Primary								
31		outcome								
32		LGA GDM								
33		Second								
34		outcome								
35		Mantel								
36		pregnancy								
37		outcome								
38		(Mode of								
39		delivery								
40		Pregnancy								
41		complications.								
42		and								
43		gestational								
44		weight gain								
45		and so on)								
46		Fetal outcome								
47		(birth weight,								
48		placenta								
49		weight, SGA,					\checkmark			
5U F1		preterm,								
51 52		Apgar score,								
52 52		etc.)								
55 E4		Infant length						2	2	
54 55		and weight						N	N	
55 56	210	NOA: Nutrition cl	hecklists and	d "One-1	page flv	er" arm	OEA: Onli	ne educatio	on arm:	
57	211	IPAO-S. Internati	onal Physics	al Activ	ity Ones	tionnaire	- Short Fo	rm PSOI	The	
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8 9 10	215	Ethical approval
11 12 13	216	The study received ethical approval from the Capital Medical University Ethics
14 15 16	217	Committee(Z2022SY077). Additionally, ethical approval was also granted by all
17 18 19	218	centers.
20 21	219	
22 23 24	220	Eligibility criteria
25 26 27	221	Eligible participants will be pregnant women, inclusive of all gender identities.
28 29 30	222	
31 32	223	The inclusion criteria are as follows:
33 34 35	224	Singleton pregnancy, conceived through natural insemination, with a gestational age
36 37 38	225	< 12 weeks, and signed informed consent.
39 40 41	226	
42 43	227	The exclusion criteria are as follows:
44 45 46	228	Gestational age > 12 weeks, pre-existing type 1 or type 2 diabetes, fetal
47 48 49	229	malformations including chromosomal abnormalities or structural malformations
50 51	230	detected by ultrasonography, fetal congenital infections or abnormalities, adherence to
53 54	231	a restricted diet (including vegans), medical conditions that could potentially affect
55 56 57	232	the intervention or follow-up (including severe cardiovascular and kidney diseases
58 59 60		

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233	result in limited physical activity and require diet under professional guidance.), and
234	unwillingness or inability to provide informed consent
235	
236	Intervention
237	Eligible participants will be randomized into one of the three groups: Group 1 Online
238	Nutrition Education; Group 2 Nutrition Checklist and 'One-page Flyer' for self-
239	learning; Group 3 Routine Antenatal Education without any intervention.
240	Group 1: Online nutrition education arm (OEA)
241	The first intervention group will receive 6 sessions of 1-h nutrition education by
242	video-conferencing (Table 2). The course design was based on the TPB model and
243	followed the DESIGN Procedure[29]of Contento and Koch. The DESIGN procedure
244	is a simple, systematic, 6-step process that integrates food and nutrition science,
245	psychological theories, education principles, and communication skills. It provides a
246	framework for planning theory-based, behavior-focused nutrition education that
247	translates theory and evidence into activities, materials, group discussions, and social
248	media. Two graduate students majoring in nutrition will lead the course. The overall
249	goal of the course is to promote a balanced diet with a focus on controlling fat intake.
250	The general goal can be further broken down into three specific behavioral change
251	goals: choosing the right food to eat, cooking healthily, and reading nutrition labels so
252	they can identify healthy packaged food. According to the previous records of the

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253	participating hospitals, over 95% of the pregnant women have a high-school degree					
254	and all of them are literate, therefore would be able to comprehend the course content.					
255						
256		Table2. Course topics and behavioral strategies.				
	Them	Behavioral strategy	Diet topic			
	Session 1: No more fat 1	 1)Outcome expectations 2)Factual knowledge and skill 3)Self-efficacy/Perceive behavior control 4)Analysis of pros and cons of change(Behavioral Intention) 	Benefits of balance diet Discovering your inadequate of their diet Identifying high-fat foods Use fists and hands to count food servings Overcoming the obstacles of a high-fat diet			
	Session 2: No more fat 2	 Negative outcomes of current behavior Perceived benefits Self-depictions Behavioral intention 	The Dangers of Trans Fatty Acids Knowing that a healthy cooked diet is just as tasty Knowing that the mother's diet affects the child Learn to establish dietary goals			
	Session 3: Eat out smartly	 Negative outcomes of current behavior Knowledge and cognitive skills Perceived norms Self-efficacy 	understand how to choose foods wisely when dining out or ordering delivery online			
	Session 4: Cook healthily	 Perceived benefits Skills and ability Perceived barriers Behavioral intention 	learn the recipes for healthy cooking			
	Session 5: Choose the right snacks	1)Perceived risk 2)Food and nutrition knowledge	understand the definition of ultra-processed foods, learn how to choose healthy snacks			

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	3)Food preferences4)Self-efficacy	
Session 6: Read the label	 Perceived benefits Skills and ability Perceived norms Behavioral intention 	learn how to read nutrition labels and ingredient list

257 Group 2: Nutrition checklist and 'One-page flyer' arm (NOA)

258	A 17-item nutrition checklist and "one-page" flyer are distributed to the participants
259	by physicians at their monthly pregnancy check-ups. Pregnant women can self-
260	identify their nutrition problems through the checklist within 2 minutes and make
261	behavioral changes by following the guidance in the 'one-page flyer'. The 17-item
262	nutrition checklist was adapted from the FIGO checklist[43], which is a very efficient
263	way to assess the nutrition status of pregnant women[44]. This tool helps clinicians
264	and pregnant women quickly identify imbalances in their dietary patterns. The
265	checklist includes four parts. Part 1: self-reported special dietary habits (e.g., vegan,
266	food allergy); Part 2: self-reported height, weight, and BMI; Part 3: 17 questions
267	related to dietary habits with a focus on fat intake (most are yes or no questions); Part
268	4: grading criteria and interpretation of the checklist result. The 'one-page flyer' is an
269	A4 paper-sized dietary instruction flyer. It is based on the theory of planned behavior,
270	including information on the adverse effects of a high-fat diet during pregnancy on
271	mother and baby at the top of the page (outcome expectation), choosing healthy
272	snacks, reading food labels, specific cooking tips using less oil (knowledge and
273	skills), information on diet management aiming to increase confidence (perceived

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274 behavior control and self-efficacy), guidance on establishing specific and feasible 275 behavior change goals (goal-setting using SMART theory). 276 277 Criteria for discontinuing or modifying allocated interventions 278 Not applicable due to the nature of the interventions. 279 280 Strategies to improving and measuring the adherence 281 Adherence to the online education sessions will be assessed by class attendance from 282 sign-ins and visual scans of video conference attendees. We will set up an online 283 group chat for participants to remind them to attend before the start of each class, and 284 we will create a pre-class check-in e-form, post-class Q&A and evaluation e-form to 285 measure participation in the class. For the NOA, after the 17-item nutrition checklist 286 and 'one page flyer' were distributed, pregnant women underwent three dietary 287 screenings in the early, middle, and late stages of pregnancy, and provided one-on-288 one guidance on the main screening issues to improve maternal compliance. 289 The treatment will be considered complete if at least four out of the six sessions are 290 attended for the OEA. For the NOA group, we will count the number of times 291 pregnant women screen for nutritional issues (27 item nutrition checklist) and use a 292 questionnaire to investigate the reading status of 'one page flyer'. Adherence to the 293 nutrition behaviors will be assessed by an improvement of ≥ 3 points of their total 294 scores of the 17-item nutrition checklist compared to their total initial score[45]. The 17

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3 4 5	295	study population will be sorted according to adherence to the dietary guidelines,
6 7 8	296	depending on the score: ≥ 12 high adherence, $6 - 11$ moderate adherence, and < 6 low
9 10	297	adherence[45].
12 13	298	
14 15 16	299	Relevant concomitant care permitted or prohibited during the trial
17 18 19	300	People who participate in this trial cannot participate in another trial.
20 21	301	
22 23 24	302	Provisions for post-trial care
25 26 27	303	No post-trial care is needed since this is an educational intervention.
28 29 30	304	
31 32	305	Outcomes
33 34 35	306	Adverse pregnancy outcomes:
36 37 38	307	Primary outcome:
39 40 41	308	The primary outcome will be the prevalence of LGA at birth, defined as the newborns
42 43	309	with a measured birth weight above the 90th percentile (P_{90}) of the same sex for the
44 45 46	310	same gestational age were evaluated as large for gestational age (Growth standard
47 48 49	311	for newborns by gestation in China, WS/T 800–2022).
50 51 52	312	Secondary outcomes:
52 53 54	313	Neonatal: Birth weight, Macrosomia (birth weight \geq 4000 g), SGA (birth weight
55 56 57	314	below the 10th percentile for gestational age) or low birth weight (birth weight \leq 2500
58 59 60	315	g), preterm birth (< 37 weeks' gestation), low Apgar score (Apgar <7).

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316	Maternal: GDM (GDM is diagnosed when the blood glucose value at any point in
317	time meets or exceeds the above criteria: fasting, 1 hour after oral glucose, and 2
318	hours after glucose thresholds of 5.1, 10.0, and 8.5 mmol/litre, respectively.),
319	gestational hypertension (defined as >20 weeks' gestation, elevated blood pressure
320	[systolic BP \geq 140 mm Hg or diastolic BP \geq 90 mm Hg] in the absence of proteinuria),
321	cesarean section rate, birth canal injury rate, shoulder dystocia rate, maternal insulin
322	treatment rate, maternal weight gain during pregnancy (maternal weight gain
323	generally refers to maternal weight at delivery minus pre-pregnancy weight),
324	preeclampsia (defined as >20 weeks' gestation, new-onset hypertension [systolic
325	blood pressure \geq 140 mm Hg or diastolic blood pressure \geq 90] mm Hg] and new-onset
326	proteinuria [300 mg protein intake within 24 hours or urine protein/creatinine ratio 0.3
327	mg/dL], or in the absence of proteinuria, new-onset hypertension with new-onset
328	thrombocytopenia, renal insufficiency, impaired liver function, pulmonary edema, or
329	cerebral or visual impairment), perinatal mortality (fetuses or neonates death at > 28
330	weeks' gestation - within 7 days of postpartum)
331	
332	Changes in dietary behaviors
333	Changes in dietary behaviors will be assessed by a dietary behavior questionnaire,
334	which was adapted from previous FFQs[46, 47]. The questionnaire includes questions

335 on the intake and frequency of consumption of different categories of foods,

 $\frac{8}{9}$ **336** particularly high-fat foods.

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> We will also assess knowledge and skills related to cooking habits that can reduce fat intake and reading nutrition labels to choose low-fat foods when shopping. Behaviors related to adherence to the dietary guidelines will be assessed by the 17-item nutrition checklist.

A questionnaire was developed to assess the changes in the four components (attitude

Changes in psychosocial determinants based on the TPB model

towards behavior, subjective norm, perceived behavioral control, and behavioral intention) related to diet behaviors (reducing fat intake, cooking healthily, and reading nutrition labels) based on the TPB before and after the intervention. The questionnaire was based on previous studies[39, 48], and content validity has been confirmed by experts in nutrition. Attitudes, perceived norms, self-efficacy, self-depictions, and behavioral intention will be assessed as the mean of the statements under each component measured on 5-point unipolar (+1 to +5) scales. We conducted a questionnaire survey (a cross-sectional survey) on pregnant women at three study sites to test the reliability and validity of The 17-item nutrition checklist, FFQ, and TPB-Q. This helps us to make timely corrections to inappropriate issues before the research begins. This population was randomly distributed between the intervention group and the control group, reducing the bias caused by this confirmatory survey.

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358	Postpartum follow-up
359	The feeding types and complementary foods added will be investigated 42 days after
360	delivery through a questionnaire to be developed. Children are followed again at 3
361	years of age for diet, taste preferences, and physical development. Children's diets
362	will be assessed by a food frequency questionnaire based on a previous study32.
363	Children's physical development will be assessed by their weight, height, sitting
364	height, and body composition, measured by body weight meter, mechanical
365	height/sitting height meter, and body composition analyzer, respectively.
366	
367	Other measures
368	A baseline survey is used to collect information on participants' demography, lifestyle
369	(e.g., sleep, physical activity), and medical and family history. Pregnant women's age,
370	educational background, parity, pre-BMI, height, pre-weight, and other information
371	are sourced from their pregnancy records. This file is established by community
372	doctors after one-on-one questioning and measurement. The weight gain during
373	pregnancy is measured on outpatient scales or home scales and reported to the
374	investigator on their own.
375 376	Sample size
377	The RCT uses the incidence of LGA as the primary outcome. The incidence of LGA
378	in the general population is about 11.0%[49], while the incidence in the intervention
379	group is expected to be 5.0%[50]. Assuming a type 1 error of 5% and a power of
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380 80%, 318 participants will be recruited. Allowing for a 20% dropout, 400 participants 381 will be needed for each of the three arms, with an overall sample size of 1200 382 participants for the study[51]. $n = \frac{(z_{1-\alpha/2} + z_{1-\beta})^2 [p_1(1-p_1)/k + p_2(1-p_2)]}{(p_1 - p_2)^2}$ 383 384 385 Recruitment 386 At the first prenatal check-up, all eligible pregnant women will be introduced of the 387 purpose of the study, the intervention, and the potential benefits and risks. Participants 388 who agree to participate, after obtaining written informed consent, will be randomized 389 into the three different groups. Randomization will be performed by using a computer 390 system that randomly assigns participants into one of the three groups: (1) online nutrition education + nutrition checklist and flyer (2) nutrition checklist and flyer for 391 392 self-learning, and (3) usual care without any intervention. 393 394 **Randomization** 395 396 Allocation 397 The computer system (http://www.jerrydallal.com/random/randomize.htm) generates 398 randomization sequences based on the need of the study. The name of the intervention 399 group, the number of groups, and the sample size for each group is entered into the 400 system to generate the allocation plan. Participants in different groups will receive

- 401 different invitation links for their intervention to have unified management.
 - 403 Concealment mechanism

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3 4 5	404	Allocation concealment is ensured as the randomization code is not released until the
6 7 8	405	participants have met the eligibility and signed informed consent. The allocation is
9 10 11	406	performed automatically by the computer without human control. Participants will
12 13	407	receive a new inclusion number after the groups are formed, and the number is also
14 15 16	408	used as a participant ID for the intervention lessons.
17	409	
18	410	Implementation
19 20 21	411	The enrollment of the participants will be done by doctors who do not have
22 23 24	412	information on group allocation, as the randomization happens after the recruitment.
25 26 27	413	Participants are first divided into different categories according to the plan and then
28 29 30	414	randomized into three groups by research assistants of the study using the computer
31 32	415	program.
33 34 35	416	Doctors will distribute the nutrition checklist and one-page flyer to participants.
36 37 38	417	Research assistants will provide guidance on how to use these materials.
39 40 41	418	Online nutrition education sessions will be delivered by two research assistants who
42 43	419	are Ph.D. students majoring in Nutrition. The course content and study materials have
44 45	420	been reviewed by experts in nutrition.
40	421	
47	400	
49	422	Bunaing
50 51	423	Due to the nature of the study design, it is not possible to blind participants or
52 53 54	424	researchers in the study regarding the intervention type. Therefore, the study is
55 56 57	425	blinded only to the clinical nurses responsible for grouping. Nurses responsible for
58 59	426	enrolment recruitment were unaware of the grouping.
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427 428	Procedure for unblinding if needed
429	Not applicable, and the trial will not be blinded.
430	
121	Statistical analysis
431	Statistical analysis
432	For demographic variables and outcomes, continuous variables will be presented
433	using either the mean or median depending on whether they conform to a normal
434	distribution, and categorical variables will be summarized using frequencies (%). The
435	differences in LGA and GMD incidence among the three groups will be compared
436	using chi- square tests. Analysis of variance will be used to assess differences in birth
437	weight, and the generalized estimating equation will be used for comparing
438	gestational weight gain[52].
439	We will use three analytical methods to analyze our study population[53-55].
440	The Intention-To-Treat Population (ITT), which includes all participants based on
441	their initial random grouping, regardless of whether they completed all interventions;
442	Modified Intention to Treat Population (mITT), which defined by excluding
443	participants when the primary outcome (e.g. stillbirth or intrauterine death of the
444	newborn, congenital malformations) is absent; Population Per Protocol(PP), which
445	includes only those individuals with good adherence to the intervention for the
446	purpose of analysis. For pre-randomization, baseline analysis, and primary and
447	secondary efficacy variable analysis we will use mITT analysis. The primary outcome

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448	analysis will initially use ITT for preliminary analysis and then use PP for the
449	comparison of robustness.
450	The missing value treatment program follows the guidelines outlined in
451	CPMP/EWP/1776/99. Missing values are filled in for the main variables only,
452	applying the following principles[56]: Primary missing value imputation strategy: we
453	will use Imputed case analysis for the primary outcome (i.e., the occurrence of LGA,
454	which was defined as a birth weight greater than the 90th percentile of the mean
455	weight of children of the same gestational age and sex);Secondary missing value
456	imputation strategy: we will use multiple imputations using the control group
457	observations to fill missing data. The primary analyses are based on worst-case
458	imputation scenario, while sensitivity analyses are conducted using the results of
459	multiple imputations.
460	To identify susceptible subpopulations, we will conduct subgroup analysis by
461	defending subgroups by research centers, corresponding obstetricians, or nutrition
462	physicians. Demographic variables such as age, pre-BMI, parity, level of education,
463	and place of residence will be used for sensitivity analyses.
464	
465	Patient and public involvement
466	Before the formal commencement of the study, we will conduct a pilot study which
467	includes a process evaluation and interviews with obstetricians, dietitians, and
468	pregnant women. The comments and recommendations gathered from these

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469	participants regarding the intervention will guide the revision and improvement of the
470	final intervention. Throughout the intervention phase, we will document the intensity
471	and completeness of the intervention, along with the acceptability and satisfaction
472	levels among pregnant women. In this process, pregnant women, obstetricians, and
473	nutritionists will contribute their opinions and feedback on the study design,
474	implementation, frequency, and other aspects of the course content.
475	
476	Data Availability Statement
477	Not applicable for a protocol as no data has been generated.
478	
479	FIGURE LEGENDS
480	Figure 1. Extended Theory of Planned Behavior /Reasoned Action Approach
481	Figure 2. Study design including the screening, recruitment, randomization process,
482	and the conduct flow.
483	Note : IPAQ-S: International Physical Activity Questionnaire - Short Form; PSQI:
484	The Pittsburgh Sleep Quality Index; TPB-Q: Theory of planned behavior
485	questionnaire; NOA: Nutrition checklists and "One-page flyer" arm; OEA: Online
486	education arm.
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51		
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54		
55	507	foodback on the scheme. Vadi Thene and Viesce Good wated and wrote the wrote cal
56	507	recuback on the scheme. I all Zhang and Alaoge Gao drafted and wrote the protocol,
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517	
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12 13	532		during pregnancy on the risk of macrosomia and large-for-gestational-age
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Figure 1. Extended Theory of Planned Behavior /Reasoned Action Approach

230x113mm (150 x 150 DPI)
DECLINED

Routine antenatal care

BMI, age and pregnancy outcomes

recorded (if agreed)

Session 1: No more fat 1

Session 2: No more fat 2

Session 3: Eat out smartly

Session 4: Cook healthily

Session 6: Read the label

3 year Follow-Up:

Mother: Questionnaire: diet

PSQI, TPB-Q.

Anthropometry Samples: blood

Child: medications and supplements

Questionnaire: feeding and growth,

early care/education; sleep and activity

Session 5: Choose the

right snacks





Standard Protocol Items: Recommendations for Interventional Trials

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Check	Section/item	Item No
Page 1	Title	1
Page 4	Trial registration	2a
Page 4	Protocol version	3
Page 24	Funding	4
Page 23	Roles and responsibilities	5a
Page 5	Introduction	
Page 5	Background and rationale	6а
Page 9	Objectives	7
Page 9	Trial design	8
Page 9	Study setting	9
Page 11	Eligibility criteria	10
Page 12	Interventions	11a
Page 16	Outcomes	12
Page 10	Participant timeline	13
Page 19	Sample size	14
Page 19	Recruitment	15
Page 19	Allocation:	
Page 19	Sequence generation	16a
Page 20	Allocation concealment mechanism	16b
Page 20	Implementation	16c
Page 21	Blinding (masking)	17a
Page 16	Data collection methods	18a
Page 21	Data management	19

Page 21	Statistical methods	20a
NA	Data monitoring	21a
Page 16	Harms	22
Page 15	Auditing	23
Page 3	Research ethics approval	24
NA	Protocol amendments	25
Page 19	Consent or assent	26a
		26b
Page 24	Confidentiality	27
Page 24	Declaration of interests	28
Page 23	Access to data	29
Page 16	Ancillary and post-trial care	30
Page 24	Dissemination policy	31a
		31b
		31c
NA	Appendices	
	Informed consent materials	32
	Biological specimens	33

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

A lipid-focused dietary education intervention in pregnant women: study protocol for an open-label, parallel, randomized, intervention study addressing adverse pregnancy outcomes in China.

Journal:	BMJ Open
Manuscript ID	bmjopen-2023-076911.R3
Article Type:	Protocol
Date Submitted by the Author:	05-Nov-2023
Complete List of Authors:	Zhang, Yadi; Capital Medical University, Department of Epidemiology and Health Statistics Gao, Xiaoge; Teachers College of Columbia University, Department of Health and Behavior Studies Zhu, Haiyan; Capital Medical University, Department of Obstetrics and Gynecology Sun, Shengzhi; Capital Medical University, Department of Epidemiology and Health Statistics Contento, I; Teachers College of Columbia University, Department of Health and Behavior Studies Koch, Pamela Ann; Teachers College of Columbia University, Department of Health and Behavior Studies Yu, Huanling; Capital Medical University, Department of Nutrition and Food Hygiene
Primary Subject Heading :	Public health
Secondary Subject Heading:	Nutrition and metabolism, Epidemiology, Research methods
Keywords:	EPIDEMIOLOGIC STUDIES, Health Education, Primary Prevention, PUBLIC HEALTH, Obesity

SCHOLARONE[™] Manuscripts

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4	1	A lipid-focused dietary education intervention in pregnant women: study
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7 8	2	protocorior an open label, paranel, randomized, intervention study addressing
9	-	
10	3	adverse pregnancy outcomes in China
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Word count: 4,777
8

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3 4 5	34	Abstract (273 words)
6 7 8	35	Introduction: The incidence of infants who are large-for-gestational-age (LGA) is
9 10	36	on the rise in China, and its detrimental effects on health has received increasing
12 13	37	attention. Diet-based interventions have the potential to reduce adverse birth
14 15 16	38	outcomes, particularly in decreasing the occurrence of LGA infants. We aim to
17 18	39	evaluate the effect of lipid-focused diet education based on the theories of behavior
20 21	40	change in pregnant women on maternal and offspring outcomes through a
22 23 24	41	randomized control trial.
25 26 27	42	Methods and analysis: We have designed an open-label, parallel, multicenter
28 29	43	randomized controlled trial in collaboration with three hospitals in Beijing, China.
30 31 32	44	Pregnant women will be recruited before reaching 12 weeks of gestation, and will
33 34 35	45	be randomized in a 1:1:1 ratio into three arms: 1) Online education arm, 2) Diet
36 37 28	46	checklist and 'one-page flyer' arm, and 3) Routine antenatal education. The
38 39 40	47	primary outcome LGA will be recorded at birth. Demographic information,
41 42 43	48	physical activity, sleep, and medical history will be collected through
44 45 46	49	questionnaires and case cards prior to enrolment. Questionnaires will also be used
47 48	50	to collected dietary behaviors and psychosocial factors of pregnant women at
49 50 51	51	enrolment, at 24-28 weeks and 34-36 weeks of gestation. Additionally, information
52 53 54	52	on breastfeeding and complementary food supplementation for infants and young
55 56	53	children will be obtained through questionnaires. Physical development indicators
57 58 59 60	54	of children and taste tests will be assessed three years after delivery.

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55	Ethics and dissemination: The study has received ethical approval from the Capital
56	Medical University Ethics Committee and other collaborating study centers. Informed
57	consent will be introduced to pregnant women and their consent obtained. The
58	findings will be reported in relevant national and international academic conferences
59	and peer-reviewed publications.
60	Trial registration: The trail is registered ChiCTR2300071126
61	
62	Keywords: Study protocol, Pregnancy, Diet lipid, Large for gestational age, Theories
63	of behavior change
64	
65	Protocol version: V4.
66	

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3 4 5	67	
6 7 8	68	Article Summary
9 10	69	Strengths and limitations of this study
12 13	70	 (Strengths) This study is a rigorous cause-and-effect randomized controlled
14 15 16	71	study.
17 18 19	72	➤ (Strengths) This study includes a large sample size that will be able to detect
20 21	73	small differences.
22 23 24	74	(Strengths) The pilot study have already proven that prenatal nutrition
25 26 27	75	education activities based on behavioral change theory have beneficial effects on
28 29 20	76	participants.
31 32	77	(Limitations) Due to the characteristics of the study design, participants are
33 34 35	78	aware of the intervention they receive.
36 37 38	79	(Limitations) People to be included in the study are being recruited from
39 40	80	different research centers and will receive different levels of routine maternal
41 42 43	81	education.
44 45 46	82	
47 48 40	83	INTRODUCTION (1,360 words)
50 51	84	Large for gestational age (LGA) baby is defined as a newborn weighing above the
52 53 54	85	90th percentile of newborns for the same gestational age. In China, approximately
55 56 57	86	10.1% of infants are classified as LGA[1], and the incidence is higher among
58 59	87	pregnant women with high gestational weight gain[2]. Studies have shown that LGA
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88	can have adverse effects on both pregnant women and infants. Maternal outcomes for
89	those giving birth to an LGA infant are more likely to have a higher risk of cesarean
90	delivery, birth canal injury, and postpartum hemorrhage[3]. Infants who are LGA
91	have an increased risk of shoulder dystocia, clavicle fractures, brachial plexus injury,
92	and increased admissions to the neonatal intensive care unit[3]. Follow-up studies
93	have also shown that LGA infants face an increased risk of early obesity, metabolic
94	disease, and giving birth to LGA offspring[4-6]. Individuals giving birth to LGA
95	infants or experiencing excessive weight gain during pregnancy are associated with
96	several risk factors in adulthood, including overweight and obesity, gestational
97	diabetes mellitus (GDM), lack of physical activity during pregnancy, and a high
98	consumption of sugar and fat[2, 7].
99	The role of diet in gestational weight gain and the incidence of LGA
100	Several countries have established specific dietary guidelines for pregnant women,
101	including China[8]. However, a dietary survey conducted in 2015 among pregnant
102	women in eight major cities in China showed that the average energy intake during
103	pregnancy was 2098 Kcal, with fat accounting for 36.4% (median 37.7%) of the total
104	energy, exceeding the recommended amount of 25%-30% [9]. A 2016 study in
105	Shaanxi, China, categorized foods into five major groups and analyzed the energy
106	sources for pregnant women from these different food groups. The main sources of
107	energy for pregnant women were snacks (19%), meats (16%), and edible oil (11%),
108	while the main sources of fat were cooking oil (25%), meats (24%) and nuts

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109	(16%)[10]. In a recent 2021 dietary survey of pregnant women in Shanghai, China,
110	the authors found that 66.6% of the participants exceeded the recommended intake
111	levels for poultry and meat, and 46.3% exceeded the recommended oil intake [11].
112	The rapid industrialization of the food system in developing countries like China has
113	led to increased availability of high-energy density and low-nutritional quality
114	foods[12, 13], contributing to excessive dietary fat in pregnant women. Previous
115	studies have suggested that a diet high in fat, particularly saturated fatty acids, and
116	low in polyunsaturated fatty acid in diet may be risk factors for GDM, excessive
117	weight gain, and LGA infants[14-16]. In cases of maternal overnutrition and insulin
118	resistance, high levels of triglyceride are hydrolyzed by placental lipase into free fatty
119	acids, and can enter the fetus[17]. Fetal exposure to excess free fatty acids may result
120	in lipid storage due to limited fatty acid oxidation capacity, leading to a higher risk for
121	adverse pregnancy outcomes, including LGA[15, 18]. Observational study shows that
122	maternal free fatty acid levels in early pregnancy are significantly associated with
123	childhood overweight or obesity[19].
124	Decreasing the risk of LGA through diet intervention
125	Many previous studies have investigated the effect of dietary interventions on health
126	outcomes. A prospective cohort study showed that pregnant women with better
127	dietary fat quality (low saturated fatty acids, high polyunsaturated fatty acids) had a
128	lower incidence of LGA[20]. An intervention aimed at preventing LGA and

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129 controlling birth weight provided guidance on a low-glycemic, low-saturated fat diet

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130	and physical activity for pregnant women who were overweight or obese. The
131	intervention reduced the incidence of GDM and LGA significantly[21]. In another
132	trial, focusing solely on a low glycemic index diet did not reduce the incidence of
133	high birth weight, and fat intake was positively correlated with neonatal central
134	adiposity[22]. This might be due to the fact that when recommending a low-carb diet,
135	there also must be a focus on not exceeding the saturated fat recommendation, as low-
136	carb foods are often replaced with foods high in saturated fat[23]. Moreover, meta-
137	analyses have indicated that controlling saturated fatty acid intake for the general
138	population might improve their metabolic status and reduce the risk of cardiovascular
139	disease[24, 25]. However, a low-fat diet alone did not achieve a better outcome in
140	chronic disease prevention than a Mediterranean diet, which is characterized by a
141	moderate amount of fat intake but mostly monounsaturated fat [26]. This might be
142	due to the complexity of the dietary components of a dietary pattern. Increasing or
143	decreasing a single nutrient without considering the overall macronutrient distribution
144	of foods could have a negative impact on health outcomes, as the health effects of
145	foods cannot be predicted by their content of any single nutrient group[27]. Research
146	shows that from 1991 to 2011, the consumption of meat by Chinese residents
147	continued to increase, but seafood remained relatively low[28]. This may be due to
148	price and dietary habits[28]. Therefore, adopting direct Mediterranean dietary
149	intervention for pregnancy dietary guidance in China may lead to poor compliance. In
150	order to reduce pregnant women's high-fat diet behavior, improve the quality of
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151	dietary fat(increase unsaturated fatty acids, decrease saturated fatty acids, and
152	eliminate trans fatty acids), and promote dietary balance, we development a lipid-
153	focused intervention based on the Dietary Guidelines for Chinese Residents. The
154	main goal is to guide and encourage pregnant women to change unhealthy dietary
155	behaviors characterized by a high-fat intake, which is supplemented by encouraging
156	them to increase the consumption of vegetables and fruits, whole grains, deep-sea fish
157	and shrimp, nuts, etc., and adjusting the frequency of eating. The intervention starts in
158	early pregnancy, as most women only visit the hospitals for dietary guidance when
159	they realize they are already pregnant, and their motivation to change is strong when
160	they become mother-to-be. Also, many pregnancies are unplanned in China, so it is
161	more practical to start the intervention in early pregnancy.
162	Theoretical model for intervention
163	Pregnant women's dietary patterns are influenced by many factors, such as
164	predetermined biological factors, early exposure and experience, psychosocial factors,
165	and environmental factors[29]. Previous studies have shown that lifestyle
166	interventions and nutrition education addressing various determinants based on
167	psychosocial theories could lead to positive changes in pregnant women 's diet and
168	physical activity levels[30]. A healthy lifestyle is beneficial for both pregnant women
169	and their offspring[31]. Pregnant women are at a special life stage with a clear and
170	urgent need for a healthy dietary pattern and a strong motivation to improve their
171	offspring's health[32]. The theory of planned behavior (TPB) shown in Figure 1, was

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172	first proposed as a theory of reasoned action in 1975 to predict an individual's
173	intention to engage in a behavior at a specific place and time[33]. The TPB has been
174	successful in predicting and explaining a wide range of intentions and behaviors,
175	including diet, smoking, drinking, breastfeeding, and substance use[34-37]. It mainly
176	focuses on enhancing the motivation of participants and takes into account the impact
177	of attitudes, perceived norms, and self-efficacy on the formation of behavioral
178	intention. The application of the TPB theory has been on the rise since it was first
179	introduced by Ajzen in 1985. As of 2010, more than 4,000 publications cited the
180	theory[38]. Many intervention studies based on the TPB model have also been
181	effective in leading to positive changes in eating habits and nutrition status, such as
182	increasing fruit and vegetable intake[39], reducing unhealthy snack intake[40], and
183	increasing calcium-rich foods intake[41].
184	For this study, we have developed a multi-component nutrition education intervention
185	based on the extended TPB model[29, 42], as shown in Figure 1, focusing on
186	controlling total fat intake and improving the quality of diet lipids based on a balanced
187	dietary pattern. Outcome expectations, self-efficacy, and action goal setting are the
188	center of our focus. The primary aim is to assess whether the intervention will reduce
189	the risk of the delivery of an LGA infant for pregnant women. Compared to group
190	course education, prenatal dietary guidance provided by obstetricians may be more
191	authoritative, convenient, and therefore more useful for pregnant women. Therefore,
192	while verifying the effectiveness of a lipid-focused dietary group education

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intervention based on TPB theory, this study established another intervention group
that only distributed manuals included intervention content. This low-cost and highly
scalable intervention method provides a scientific basis for integrating intervention
content into routine obstetric examinations in the future.

197 METHODS AND ANALYSIS

198 Study design

199 This is a multicenter, 1:1:1 ratio, parallel, open-blind RCT. The study design strictly 200 adheres to the SPIRIT quality standard criteria for RCTs. The participating centers in 201 this study are Fuxing Hospital affiliated with Capital Medical University; Xuanwu 202 Hospital Affiliated with Capital Medical University; and Beijing Haidian District 203 Maternal and Child Health Care Hospital, all located in Beijing, China. The detailed 204 process is outlined in Figure 2, and the time line is shown in Table 1. The study was 205 initiated in May 2023 and is expected to conclude in August 2024. As of the revision 206 date, the pilot study (2022), formal experimental course design and qualitative 207 research (August 2023), and the cross-sectional survey of questionnaire reliability and 208 validity (September 2023) have been successfully completed.

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Table1. Timeline of intervention and information collection.

Time point	Enrolment and allocation	Post-allocation		Delivery	Postpartum		
	Before 11weeks	11-12 weeks	26-28 weeks	34-36 weeks	·	42 days postnatal	3 years postnatal
Enrollment Eligibility screen							

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3		Informed	1						
4		consent	N						
5		Allocation							
6		Interventions							
7		OEA							
8		NOA		Ń	Ń	Ń			
9		RAC		Ň	Ň	Ń			
10		Assessments							
11		Baseline data							
12		Demographic		\checkmark					
13		Current							
14		pregnancy			\checkmark				
15		health							
16		diet							
1/		assessment		2	2	2		2	2
18		(FFO),		N	N	N		N	N
19		questionnaire							
20		Diet checklist						\checkmark	\checkmark
21		TPB		N	N	2		$\overline{\mathbf{v}}$	N
22		questionnaire		N,	N,	N		N,	N,
23		IPAQ, PSQI		\checkmark	\checkmark			\checkmark	\checkmark
24		Child Feeding							
25		and							
20		Development,						\checkmark	\checkmark
28		Early Care,						•	·
20		Sleep and							
30		Activity							
31		Primary							
32		outcome					1		
33		LGA, GDM					N		
34		Second							
35		outcome							
36		Mantel							
37		pregnancy							
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42		and							
43		gestational							
44		weight gain							
45		and so on)							
46		Fetal outcome							
47		(birth weight.							
48		placenta							
49		weight, SGA,					\checkmark		
50		preterm,							
51		Apgar score,							
52		etc.)							
ン ご ころ		Infant length						2	2
54 55		and weight						N	N
55 56	210	NOA: Nutrition cl	necklists and	1 "One-r	bage flve	r" arm [.] (DEA: Onlin	e education	arm:
50 57	211	IPAO-S. Internation	onal Physics	al Activi	ty Quest	ionnaire	- Short For	m· PSOI· T	he
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3 4 5	213	
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9 10	215	Ethical approval
11 12 13	216	The study received ethical approval from the Capital Medical University Ethics
14 15 16	217	Committee(Z2022SY077). Additionally, ethical approval was also granted by all
17 18	218	centers.
19 20 21	219	
22 23 24	220	Eligibility criteria
25 26	221	Eligible participants will be pregnant women, inclusive of all gender identities.
27 28 29	222	
30 31 32	223	The inclusion criteria are as follows:
33 34 35	224	Singleton pregnancy, conceived through natural insemination, with a gestational age
36 37	225	< 12 weeks, and signed informed consent.
38 39 40	226	
41 42 43	227	The exclusion criteria are as follows:
44 45	228	Gestational age > 12 weeks, pre-existing type 1 or type 2 diabetes, fetal
46 47 48	229	malformations including chromosomal abnormalities or structural malformations
49 50 51	230	detected by ultrasonography, fetal congenital infections or abnormalities, adherence to
52 53	231	a restricted diet (including vegans), medical conditions that could potentially affect
55 56	232	the intervention or follow-up (including severe cardiovascular and kidney diseases
57 58 59		
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2	233	result in limited physical activity and require diet under professional guidance.), and
:	234	unwillingness or inability to provide informed consent
:	235	
:	236	Intervention
:	237	Eligible participants will be randomized into one of the three groups: Group 1 Online
:	238	Nutrition Education; Group 2 Nutrition Checklist and 'One-page Flyer' for self-
:	239	learning; Group 3 Routine Antenatal Education without any intervention.
:	240	Group 1: Online nutrition education arm (OEA)
:	241	The first intervention group will receive 6 sessions of 1-h nutrition education by
2	242	video-conferencing (Table 2). The course design was based on the TPB model and
:	243	followed the DESIGN Procedure[29]of Contento and Koch. The DESIGN procedure
:	244	is a simple, systematic, 6-step process that integrates food and nutrition science,
:	245	psychological theories, education principles, and communication skills. It provides a
2	246	framework for planning theory-based, behavior-focused nutrition education that
2	247	translates theory and evidence into activities, materials, group discussions, and social
:	248	media. Two graduate students majoring in nutrition will lead the course. The overall
2	249	goal of the course is to promote a balanced diet with a focus on controlling fat intake.
2	250	The general goal can be further broken down into three specific behavioral change
:	251	goals: choosing the right food to eat, cooking healthily, and reading nutrition labels so
:	252	they can identify healthy packaged food. According to the previous records of the

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253	participating hospitals, over 95% of the pregnant women have a high-school degree						
254	and all of them are literate, therefore would be able to comprehend the course content.						
255							
256		Table2. Course topics and behavio	ral strategies.				
	Them	Behavioral strategy	Diet topic				
	Session 1: No more fat 1	 1)Outcome expectations 2)Factual knowledge and skill 3)Self-efficacy/Perceive behavior control 4)Analysis of pros and cons of change(Behavioral Intention) 	Benefits of balance diet Discovering your inadequate of their diet Identifying high-fat foods Use fists and hands to count food servings Overcoming the obstacles of a high-fat diet				
	Session 2: No more fat 2	 Negative outcomes of current behavior Perceived benefits Self-depictions Behavioral intention 	The Dangers of Trans Fatty Acids Knowing that a healthy cooked diet is just as tasty Knowing that the mother's diet affects the child Learn to establish dietary goals				
	Session 3: Eat out smartly	 Negative outcomes of current behavior Knowledge and cognitive skills Perceived norms Self-efficacy 	understand how to choose foods wisely when dining out or ordering delivery online				
	Session 4: Cook healthily	 Perceived benefits Skills and ability Perceived barriers Behavioral intention 	learn the recipes for healthy cooking				
	Session 5: Choose the right snacks	1)Perceived risk 2)Food and nutrition knowledge	understand the definition of ultra-processed foods, learn how to choose healthy snacks				

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	3)Food preferences4)Self-efficacy	
Session 6: Read the label	 Perceived benefits Skills and ability Perceived norms Behavioral intention 	learn how to read nutrition labels and ingredient list

257 *Group 2: Nutrition checklist and 'One-page flyer' arm (NOA)*

258 A 17-item nutrition checklist and "one-page" flyer are distributed to the participants 259 by physicians at their monthly pregnancy check-ups. Pregnant women can self-260 identify their nutrition problems through the checklist within 2 minutes and make 261 behavioral changes by following the guidance in the 'one-page flyer'. The 17-item 262 nutrition checklist was adapted from the FIGO checklist[43], which is a very efficient 263 way to assess the nutrition status of pregnant women[44]. This tool helps clinicians 264 and pregnant women quickly identify imbalances in their dietary patterns. The 265 checklist includes four parts. Part 1: self-reported special dietary habits (e.g., vegan, 266 food allergy); Part 2: self-reported height, weight, and BMI; Part 3: 17 questions 267 related to dietary habits with a focus on fat intake (most are yes or no questions); Part 268 4: grading criteria and interpretation of the checklist result. The 'one-page flyer' is an 269 A4 paper-sized dietary instruction flyer. It is based on the theory of planned behavior, 270 including information on the adverse effects of a high-fat diet during pregnancy on 271 mother and baby at the top of the page (outcome expectation), choosing healthy 272 snacks, reading food labels, specific cooking tips using less oil (knowledge and 273 skills), information on diet management aiming to increase confidence (perceived

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274	behavior control and self-efficacy), guidance on establishing specific and feasible
275	behavior change goals (goal-setting using SMART theory).
276	
277	Criteria for discontinuing or modifying allocated interventions
278	Not applicable due to the nature of the interventions.
279	
280	Strategies to improving and measuring the adherence
281	Adherence to the online education sessions will be assessed by class attendance from
282	sign-ins and visual scans of video conference attendees. We will set up an online
283	group chat for participants to remind them to attend before the start of each class, and
284	we will create a pre-class check-in e-form, post-class Q&A and evaluation e-form to
285	measure participation in the class. For the NOA, after the 17-item nutrition checklist
286	and 'one page flyer' were distributed, pregnant women underwent three dietary
287	screenings in the early, middle, and late stages of pregnancy, and provided one-on-
288	one guidance on the main screening issues to improve maternal compliance.
289	The treatment will be considered complete if at least four out of the six sessions are
290	attended for the OEA. For the NOA group, we will count the number of times
291	pregnant women screen for nutritional issues (27 item nutrition checklist) and use a
292	questionnaire to investigate the reading status of 'one page flyer'. Adherence to the
293	nutrition behaviors will be assessed by an improvement of ≥ 3 points of their total
294	scores of the 17-item nutrition checklist compared to their total initial score[45]. The
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3 4 295	study population will be sorted according to adherence to the dietary guidelines,
6 7 296	depending on the score: ≥ 12 high adherence, $6 - 11$ moderate adherence, and < 6 low
8 9 10 297	adherence[45].
11 12 298	
13 14 15 299	Relevant concomitant care permitted or prohibited during the trial
16 17 18 300	People who participate in this trial cannot participate in another trial.
19 20 31 301	
21 22 23 302	Provisions for post-trial care
24 25 26 303	No post-trial care is needed since this is an educational intervention.
27 28 30 304	
30 31 305	Outcomes
32 33 34 3 06	Adverse pregnancy outcomes:
35 36 307	Primary outcome:
37 507 38 39 209	The primary outcome, will be the providence of LCA at kinth, defined as the powhere.
40 41 42	id a blind a b
42 309 43 44	with a measured birth weight above the 90th percentile (P_{90}) of the same sex for the
45 310 46 47 5 4 4	same gestational age were evaluated as large for gestational age (Growth standard
48 311 49	for newborns by gestation in China, WS/T 800—2022).
50 312 51 52	Secondary outcomes:
53 313 54 55 0.14	Neonatal: Birth weight, Macrosomia (birth weight \geq 4000 g), SGA (birth weight
56 314 57	below the 10th percentile for gestational age) or low birth weight (birth weight ≤ 2500
59 315 60	g), preterm birth (< 37 weeks gestation), low Apgar score (Apgar), low birth</td

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316	weight infant (birth weight ≤ 2500 g), preterm birth (gestational age <37 weeks),
317	Apgar score.
318	Maternal: GDM (GDM is diagnosed when the blood glucose value at any point in
319	time meets or exceeds the above criteria: fasting, 1 hour after oral glucose, and 2
320	hours after glucose thresholds of 5.1, 10.0, and 8.5 mmol/litre, respectively.),
321	gestational hypertension (defined as >20 weeks' gestation, elevated blood pressure
322	[systolic BP \geq 140 mm Hg or diastolic BP \geq 90 mm Hg] in the absence of proteinuria),
323	cesarean section rate, birth canal injury rate, shoulder dystocia rate, maternal insulin
324	treatment rate, maternal weight gain during pregnancy (maternal weight gain
325	generally refers to maternal weight at delivery minus pre-pregnancy weight),
326	preeclampsia (defined as >20 weeks' gestation, new-onset hypertension [systolic
327	blood pressure \geq 140 mm Hg or diastolic blood pressure \geq 90] mm Hg] and new-onset
328	proteinuria [300 mg protein intake within 24 hours or urine protein/creatinine ratio 0.3
329	mg/dL], or in the absence of proteinuria, new-onset hypertension with new-onset
330	thrombocytopenia, renal insufficiency, impaired liver function, pulmonary edema, or
331	cerebral or visual impairment), perinatal mortality (fetuses or neonates death at > 28
332	weeks' gestation - within 7 days of postpartum)
333	
334	Changes in dietary behaviors
335	Changes in dietary behaviors will be assessed by a dietary behavior questionnaire,
336	which was adapted from previous FFQs[46, 47]. The questionnaire includes questions

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on the intake and frequency of consumption of different categories of foods,

particularly high-fat foods.

We will also assess knowledge and skills related to cooking habits that can reduce fat
intake and reading nutrition labels to choose low-fat foods when shopping. Behaviors
related to adherence to the dietary guidelines will be assessed by the 17-item nutrition

- 342 checklist.

344 Changes in psychosocial determinants based on the TPB model

A questionnaire was developed to assess the changes in the four components (attitude towards behavior, subjective norm, perceived behavioral control, and behavioral intention) related to diet behaviors (reducing fat intake, cooking healthily, and reading nutrition labels) based on the TPB before and after the intervention. The questionnaire was based on previous studies[39, 48], and content validity has been confirmed by experts in nutrition. Attitudes, perceived norms, self-efficacy, self-depictions, and behavioral intention will be assessed as the mean of the statements under each component measured on 5-point unipolar (+1 to +5) scales. We conducted a questionnaire survey (a cross-sectional survey) on pregnant women at three study sites to test the reliability and validity of The 17-item nutrition checklist, FFQ, and TPB-Q. This helps us to make timely corrections to inappropriate issues before the research begins. This population was randomly distributed between

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3 4	357	the intervention group and the control group, reducing the bias caused by this
5		
7 8	358	confirmatory survey.
9 10 11	359	
12 13	360	Postpartum follow-up
15 16	361	The feeding types and complementary foods added will be investigated 42 days after
17 18 19	362	delivery through a questionnaire to be developed. Children are followed again at 3
20 21	363	years of age for diet, taste preferences, and physical development. Children's diets
22 23 24	364	will be assessed by a food frequency questionnaire based on a previous study32.
25 26 27	365	Children's physical development will be assessed by their weight, height, sitting
28 29	366	height, and body composition, measured by body weight meter, mechanical
31 32	367	height/sitting height meter, and body composition analyzer, respectively.
33 34 35	368	
36 37	369	Other measures
38 39 40	370	A baseline survey is used to collect information on participants' demography, lifestyle
41 42 43	371	(e.g., sleep, physical activity), and medical and family history. Pregnant women's age,
44 45 46	372	educational background, parity, pre-BMI, height, pre-weight, and other information
47 48	373	are sourced from their pregnancy records. This file is established by community
49 50 51	374	doctors after one-on-one questioning and measurement. The weight gain during
52 53 54	375	pregnancy is measured on outpatient scales or home scales and reported to the
55 56	376	investigator on their own.
57 58	377	
59 60	378	Sample size

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The RCT uses the incidence of LGA as the primary outcome. The incidence of LGA in the general population is about 11.0%[49], while the incidence in the intervention group is expected to be 5.0%[50]. Assuming a type 1 error of 5% and a power of 80%, 318 participants will be recruited. Allowing for a 20% dropout, 400 participants will be needed for each of the three arms, with an overall sample size of 1200 participants for the study [51]. $n = \frac{(z_{1-\alpha/2} + z_{1-\beta})^{2} [p_{1}(1-p_{1})/k + p_{2}(1-p_{2})]}{(p_{1}-p_{2})^{2}}$ Recruitment At the first prenatal check-up, all eligible pregnant women will be introduced of the purpose of the study, the intervention, and the potential benefits and risks. Participants who agree to participate, after obtaining written informed consent, will be randomized into the three different groups. Randomization will be performed by using a computer system that randomly assigns participants into one of the three groups: (1) online nutrition education + nutrition checklist and flyer (2) nutrition checklist and flyer for self-learning, and (3) usual care without any intervention. **Randomization** Allocation The computer system (http://www.jerrydallal.com/random/randomize.htm) generates randomization sequences based on the need of the study. The name of the intervention group, the number of groups, and the sample size for each group is entered into the

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4 5	402	system to generate the allocation plan. Participants in different groups will receive
6 7 8	403	different invitation links for their intervention to have unified management.
9	404	
10 11	405	Concealment mechanism
12 13	406	Allocation concealment is ensured as the randomization code is not released until the
14 15 16	407	participants have met the eligibility and signed informed consent. The allocation is
17 18 19	408	performed automatically by the computer without human control. Participants will
20 21	409	receive a new inclusion number after the groups are formed, and the number is also
22 23 24	410	used as a participant ID for the intervention lessons.
25	411	
26 27	412	Implementation
28 29 30	413	The enrollment of the participants will be done by doctors who do not have
31 32	414	information on group allocation, as the randomization happens after the recruitment.
34 35	415	Participants are first divided into different categories according to the plan and then
36 37 38	416	randomized into three groups by research assistants of the study using the computer
39 40	417	program.
41 42 43	418	Doctors will distribute the nutrition checklist and one-page flyer to participants.
44 45 46	419	Research assistants will provide guidance on how to use these materials.
47 48 49	420	Online nutrition education sessions will be delivered by two research assistants who
50 51	421	are Ph.D. students majoring in Nutrition. The course content and study materials have
52 53 54	422	been reviewed by experts in nutrition.
55	423	
56 57 58	424	Blinding
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425	Due to the nature of the study design, it is not possible to blind participants or
426	researchers in the study regarding the intervention type. Therefore, the study is
427	blinded only to the clinical nurses responsible for grouping. Nurses responsible for
428	enrolment recruitment were unaware of the grouping.
429 430	Procedure for unblinding if needed
431	Not applicable, and the trial will not be blinded.
432	
433	Statistical analysis
434	For demographic variables and outcomes, continuous variables will be presented
435	using either the mean or median depending on whether they conform to a normal
436	distribution, and categorical variables will be summarized using frequencies (%). The
437	differences in LGA and GMD incidence among the three groups will be compared
438	using chi- square tests. Analysis of variance will be used to assess differences in birth
439	weight, and the generalized estimating equation will be used for comparing
440	gestational weight gain[52].
441	We will use three analytical methods to analyze our study population[53-55].
442	The Intention-To-Treat Population (ITT), which includes all participants based on
443	their initial random grouping, regardless of whether they completed all interventions;
444	Modified Intention to Treat Population (mITT), which defined by excluding
445	participants when the primary outcome (e.g. stillbirth or intrauterine death of the
446	newborn, congenital malformations) is absent; Population Per Protocol(PP), which

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447	includes only those individuals with good adherence to the intervention for the
448	purpose of analysis. For pre-randomization, baseline analysis, and primary and
449	secondary efficacy variable analysis we will use mITT analysis. The primary outcome
450	analysis will initially use ITT for preliminary analysis and then use PP for the
451	comparison of robustness.
452	The missing value treatment program follows the guidelines outlined in
453	CPMP/EWP/1776/99. Missing values are filled in for the main variables only,
454	applying the following principles[56]: Primary missing value imputation strategy: we
455	will use Imputed case analysis for the primary outcome (i.e., the occurrence of LGA,
456	which was defined as a birth weight greater than the 90th percentile of the mean
457	weight of children of the same gestational age and sex);Secondary missing value
458	imputation strategy: we will use multiple imputations using the control group
459	observations to fill missing data. The primary analyses are based on worst-case
460	imputation scenario, while sensitivity analyses are conducted using the results of
461	multiple imputations.
462	To identify susceptible subpopulations, we will conduct subgroup analysis by
463	defending subgroups by research centers, corresponding obstetricians, or nutrition
464	physicians. Demographic variables such as age, pre-BMI (According to standard of
465	recommendation for weight gain during pregnancy period, the pre pregnancy BMI of
466	pregnant women is divided into four categories: <18.5 kg/m ² , 18.5 kg/m ² \leq BMI <24.0

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467	kg/m ² , 24.0 kg/m ² \leq BMI<28.0 kg/, and BMI \geq 28.0 kg/m ² .), parity, level of
468	education, and place of residence will be used for sensitivity analyses.
469	
470	Patient and public involvement
471	Before the formal commencement of the study, we will conduct a pilot study which
472	includes a process evaluation and interviews with obstetricians, dietitians, and
473	pregnant women. The comments and recommendations gathered from these
474	participants regarding the intervention will guide the revision and improvement of the
475	final intervention. Throughout the intervention phase, we will document the intensity
476	and completeness of the intervention, along with the acceptability and satisfaction
477	levels among pregnant women. In this process, pregnant women, obstetricians, and
478	nutritionists will contribute their opinions and feedback on the study design,
479	implementation, frequency, and other aspects of the course content.
480	
481	Data Availability Statement
482	Not applicable for a protocol as no data has been generated.
483	
484	FIGURE LEGENDS
485	Figure 1. Extended Theory of Planned Behavior /Reasoned Action Approach
486	Figure 2. Study design including the screening, recruitment, randomization process,
487	and the conduct flow.

489

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492

education arm.

Note: IPAQ-S: International Physical Activity Questionnaire - Short Form; PSQI:

questionnaire; NOA: Nutrition checklists and "One-page flyer" arm; OEA: Online

to be the work

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The Pittsburgh Sleep Quality Index; TPB-Q: Theory of planned behavior

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509	
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17 18 19	518	colonization through modulation of offspring intestinal immune cell composition,
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Figure 1. Extended Theory of Planned Behavior /Reasoned Action Approach

230x113mm (150 x 150 DPI)

BMJ Open: first published as 10.1136/bmjopen-2023-076911 on 4 January 2024. Downloaded from http://bmjopen.bmj.com/ on June 7, 2025 at Department GEZ-LTA Erasmushogeschool . Protected by copyright, including for uses related to text and data mining, Al training, and similar technologies.







Figure 2. Study design including the screening, recruitment, randomization process, and the conduct flow.

Note: IPAQ-S: International Physical Activity Questionnaire - Short Form; PSQI: The Pittsburgh Sleep Quality Index; TPB-Q: Theory of planned behavior questionnaire; NOA: Nutrition checklists and "One-page flyer" arm; OEA: Online education arm.

Figure 2. Study design including the screening, recruitment, randomization process, and the conduct flow.

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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Check	Section/item	Item No
Page 1	Title	1
Page 4	Trial registration	2a
Page 4	Protocol version	3
Page 24	Funding	4
Page 23	Roles and responsibilities	5a
Page 5	Introduction	
Page 5	Background and rationale	6a
Page 9	Objectives	7
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Page 12	Interventions	11a
Page 16	Outcomes	12
Page 10	Participant timeline	13
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Page 19	Recruitment	15
Page 19	Allocation:	
Page 19	Sequence generation	16a
Page 20	Allocation concealment mechanis	m 16b
Page 20	Implementation	16c
Page 21	Blinding (masking)	17a
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Page 21	Statistical methods	20a
NA	Data monitoring	21a
Page 16	Harms	22
Page 15	Auditing	23
Page 3	Research ethics approval	24
NA	Protocol amendments	25
Page 19	Consent or assent	26a
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A lipid-focused dietary education intervention in pregnant women: study protocol for an open-label, parallel, randomized, intervention study addressing adverse pregnancy outcomes in China.

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3	~ ~ ~	
4	34	Abstract (273 words)
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7	35	Introduction: The incidence of infants who are large-for-gestational-age (LGA) is
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9	36	on the rise in China, and its detrimental effects on health has received increasing
10	50	on the rise in China, and its detrimental creets on nearth has received increasing
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12	37	attention. Diet-based interventions have the potential to reduce adverse birth
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15	38	outcomes, particularly in decreasing the occurrence of LGA infants. We aim to
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18	39	evaluate the effect of lipid-focused diet education based on the theories of benavior
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20	40	change in pregnant women on maternal and offspring outcomes through a
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23	41	randomized control trial
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26	42	Methods and analysis: We have designed an open-label, parallel, multicenter
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28	43	randomized controlled trial in collaboration with three hospitals in Beijing, China.
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31	11	Dragnant woman will be rearrited before reaching 12 weeks of gostation and will
32	44	Pregnant women win be recruited before reaching 12 weeks of gestation, and win
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34	45	be randomized in a 1:1:1 ratio into three arms: 1) Online education arm, 2) Diet
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36 27	46	checklist and 'one-page flyer' arm and 3) Routine antenatal education. The
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40	4/	primary outcome LGA will be recorded at birth. Demographic information,
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42	48	physical activity, sleep, and medical history will be collected through
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44 45	49	questionnaires and case cards prior to enrolment. Questionnaires will also be used
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48	50	to collected dietary behaviors and psychosocial factors of pregnant women at
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3	67	
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6 7 8	68	Article Summary
9 10	69	Strengths and limitations of this study
12 13	70	(Strengths) This study is a rigorous cause-and-effect randomized controlled
14 15 16	71	study.
17 18 19	72	(Strengths) This study includes a large sample size that will be able to detect
20 21	73	small differences.
22 23 24	74	(Strengths) The pilot study have already proven that prenatal nutrition
25 26 27	75	education activities based on behavioral change theory have beneficial effects on
28 29	76	participants.
30 31 32	77	(Limitations) Due to the characteristics of the study design, participants are
33 34 35	78	aware of the intervention they receive.
36 37 29	79	(Limitations) People to be included in the study are being recruited from
39 40	80	different research centers and will receive different levels of routine maternal
41 42 43	81	education.
44 45 46	82	
47 48	83	INTRODUCTION (1,360 words)
49 50 51	84	Large for gestational age (LGA) baby is defined as a newborn weighing above the
52 53 54	85	90th percentile of newborns for the same gestational age. In China, approximately
55 56 57	86	10.1% of infants are classified as LGA[1], and the incidence is higher among
58 59 60	87	pregnant women with high gestational weight gain[2]. Studies have shown that LGA

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88	can have adverse effects on both pregnant women and infants. Maternal outcomes for
89	those giving birth to an LGA infant are more likely to have a higher risk of cesarean
90	delivery, birth canal injury, and postpartum hemorrhage[3]. Infants who are LGA
91	have an increased risk of shoulder dystocia, clavicle fractures, brachial plexus injury,
92	and increased admissions to the neonatal intensive care unit[3]. Follow-up studies
93	have also shown that LGA infants face an increased risk of early obesity, metabolic
94	disease, and giving birth to LGA offspring[4-6]. Individuals giving birth to LGA
95	infants or experiencing excessive weight gain during pregnancy are associated with
96	several risk factors in adulthood, including overweight and obesity, gestational
97	diabetes mellitus (GDM), lack of physical activity during pregnancy, and a high
98	consumption of sugar and fat[2, 7].
99	The role of diet in gestational weight gain and the incidence of LGA
100	Several countries have established specific dietary guidelines for pregnant women,
101	including China[8]. However, a dietary survey conducted in 2015 among pregnant
102	women in eight major cities in China showed that the average energy intake during
103	pregnancy was 2098 Kcal, with fat accounting for 36.4% (median 37.7%) of the total
104	energy, exceeding the recommended amount of 25%-30% [9]. A 2016 study in
105	Shaanxi, China, categorized foods into five major groups and analyzed the energy
106	sources for pregnant women from these different food groups. The main sources of
107	energy for pregnant women were snacks (19%), meats (16%), and edible oil (11%),
108	while the main sources of fat were cooking oil (25%), meats (24%) and nuts

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109	(16%)[10]. In a recent 2021 dietary survey of pregnant women in Shanghai, China,
110	the authors found that 66.6% of the participants exceeded the recommended intake
111	levels for poultry and meat, and 46.3% exceeded the recommended oil intake [11].
112	The rapid industrialization of the food system in developing countries like China has
113	led to increased availability of high-energy density and low-nutritional quality
114	foods[12, 13], contributing to excessive dietary fat in pregnant women. Previous
115	studies have suggested that a diet high in fat, particularly saturated fatty acids, and
116	low in polyunsaturated fatty acid in diet may be risk factors for GDM, excessive
117	weight gain, and LGA infants[14-16]. In cases of maternal overnutrition and insulin
118	resistance, high levels of triglyceride are hydrolyzed by placental lipase into free fatty
119	acids, and can enter the fetus[17]. Fetal exposure to excess free fatty acids may result
120	in lipid storage due to limited fatty acid oxidation capacity, leading to a higher risk for
121	adverse pregnancy outcomes, including LGA[15, 18]. Observational study shows that
122	maternal free fatty acid levels in early pregnancy are significantly associated with
123	childhood overweight or obesity[19].
124	Decreasing the risk of LGA through diet intervention
125	Many previous studies have investigated the effect of dietary interventions on health
126	outcomes. A prospective cohort study showed that pregnant women with better
127	dietary fat quality (low saturated fatty acids, high polyunsaturated fatty acids) had a

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128 lower incidence of LGA[20]. An intervention aimed at preventing LGA and

129 controlling birth weight provided guidance on a low-glycemic, low-saturated fat diet

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130	and physical activity for pregnant women who were overweight or obese. The
131	intervention reduced the incidence of GDM and LGA significantly[21]. In another
132	trial, focusing solely on a low glycemic index diet did not reduce the incidence of
133	high birth weight, and fat intake was positively correlated with neonatal central
134	adiposity[22]. This might be due to the fact that when recommending a low-carb diet,
135	there also must be a focus on not exceeding the saturated fat recommendation, as low-
136	carb foods are often replaced with foods high in saturated fat[23]. Moreover, meta-
137	analyses have indicated that controlling saturated fatty acid intake for the general
138	population might improve their metabolic status and reduce the risk of cardiovascular
139	disease[24, 25]. However, a low-fat diet alone did not achieve a better outcome in
140	chronic disease prevention than a Mediterranean diet, which is characterized by a
141	moderate amount of fat intake but mostly monounsaturated fat [26]. This might be
142	due to the complexity of the dietary components of a dietary pattern. Increasing or
143	decreasing a single nutrient without considering the overall macronutrient distribution
144	of foods could have a negative impact on health outcomes, as the health effects of
145	foods cannot be predicted by their content of any single nutrient group[27]. Research
146	shows that from 1991 to 2011, the consumption of meat by Chinese residents
147	continued to increase, but seafood remained relatively low[28]. This may be due to
148	price and dietary habits[28]. Therefore, adopting direct Mediterranean dietary
149	intervention for pregnancy dietary guidance in China may lead to poor compliance. In
150	order to reduce pregnant women's high-fat diet behavior, improve the quality of

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151	dietary fat(increase unsaturated fatty acids, decrease saturated fatty acids, and
152	eliminate trans fatty acids), and promote dietary balance, we development a lipid-
153	focused intervention based on the Dietary Guidelines for Chinese Residents. The
154	main goal is to guide and encourage pregnant women to change unhealthy dietary
155	behaviors characterized by a high-fat intake, which is supplemented by encouraging
156	them to increase the consumption of vegetables and fruits, whole grains, deep-sea fish
157	and shrimp, nuts, etc., and adjusting the frequency of eating. The intervention starts in
158	early pregnancy, as most women only visit the hospitals for dietary guidance when
159	they realize they are already pregnant, and their motivation to change is strong when
160	they become mother-to-be. Also, many pregnancies are unplanned in China, so it is
161	more practical to start the intervention in early pregnancy.
162	Theoretical model for intervention
163	Pregnant women's dietary patterns are influenced by many factors, such as
164	predetermined biological factors, early exposure and experience, psychosocial factors,
165	and environmental factors[29]. Previous studies have shown that lifestyle
166	interventions and nutrition education addressing various determinants based on
167	psychosocial theories could lead to positive changes in pregnant women 's diet and
168	physical activity levels[30]. A healthy lifestyle is beneficial for both pregnant women
169	and their offspring[31]. Pregnant women are at a special life stage with a clear and
170	urgent need for a healthy dietary pattern and a strong motivation to improve their
171	offspring's health[32]. The theory of planned behavior (TPB) shown in Figure 1, was

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172	first proposed as a theory of reasoned action in 1975 to predict an individual's
173	intention to engage in a behavior at a specific place and time[33]. The TPB has been
174	successful in predicting and explaining a wide range of intentions and behaviors,
175	including diet, smoking, drinking, breastfeeding, and substance use[34-37]. It mainly
176	focuses on enhancing the motivation of participants and takes into account the impact
177	of attitudes, perceived norms, and self-efficacy on the formation of behavioral
178	intention. The application of the TPB theory has been on the rise since it was first
179	introduced by Ajzen in 1985. As of 2010, more than 4,000 publications cited the
180	theory[38]. Many intervention studies based on the TPB model have also been
181	effective in leading to positive changes in eating habits and nutrition status, such as
182	increasing fruit and vegetable intake[39], reducing unhealthy snack intake[40], and
183	increasing calcium-rich foods intake[41].
184	For this study, we have developed a multi-component nutrition education intervention
185	based on the extended TPB model[29, 42], as shown in Figure 1, focusing on
186	controlling total fat intake and improving the quality of diet lipids based on a balanced
187	dietary pattern. Outcome expectations, self-efficacy, and action goal setting are the
188	center of our focus. The primary aim is to assess whether the intervention will reduce
189	the risk of the delivery of an LGA infant for pregnant women. Compared to group
190	course education, prenatal dietary guidance provided by obstetricians may be more
191	authoritative, convenient, and therefore more useful for pregnant women. Therefore,
192	while verifying the effectiveness of a lipid-focused dietary group education

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intervention based on TPB theory, this study established another intervention group
that only distributed manuals included intervention content. This low-cost and highly
scalable intervention method provides a scientific basis for integrating intervention
content into routine obstetric examinations in the future.

197 METHODS AND ANALYSIS

198 Study design

199 This is a multicenter, 1:1:1 ratio, parallel, open-blind RCT. The study design strictly 200 adheres to the SPIRIT quality standard criteria for RCTs. The participating centers in 201 this study are Fuxing Hospital affiliated with Capital Medical University; Xuanwu 202 Hospital Affiliated with Capital Medical University; and Beijing Haidian District 203 Maternal and Child Health Care Hospital, all located in Beijing, China. The detailed 204 process is outlined in Figure 2, and the time line is shown in Table 1. The study was 205 initiated in May 2023 and is expected to conclude in August 2024. As of the revision 206 date, the pilot study (2022), formal experimental course design and qualitative research (August 2023), and the cross-sectional survey of questionnaire reliability and 207 208 validity (September 2023) have been successfully completed.

209

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Table1. Timeline of intervention and information collection.

Time point	Enrolment and allocation	Post-allocation			Delivery	Postpartum		
	Before 11weeks	11-12 weeks	24-26 weeks	34-36 weeks	-	42 days postnatal	3 years postnatal	
Enrollment								
Eligibility screen	\checkmark							
Informed consent	\checkmark							

Allocation Interventions	N					
OEA	\checkmark	\checkmark				
NOA						
RAC		\checkmark	\checkmark			
Assessments						
Baseline data	1					
Demographic						
Current		.1				
pregnancy		γ				
diat						
assessment	,				,	
(FFO)						٦
questionnaire						
Diet checklist	\checkmark				\checkmark	٦
TPB	,		,		.1	
questionnaire	\mathcal{N}	\mathcal{N}	N		\mathcal{N}	٦
ÎPAQ, PSQI	\checkmark	\checkmark	\checkmark			١
Child Feeding						
and						
Development,						٦
Early Care,					,	
Sleep and						
Activity						
Primary						
LGA GDM				N		
Second				v		
outcome						
Mantel						
pregnancv						
outcome						
(Mode of						
delivery,						
Pregnancy				\checkmark		
complications,						
and						
gestational						
weight gain						
and so on)						
retai outcome						
oni weight,						
weight SGA						
preterm				1		
Apgar score.						
etc.)						
Infant length					2	
and weight					N	``
NOA: Nutrition check	dists and "One	-page fly	ver" arm	: OEA: On	line educat	ion ar
IPAO-S. International	Physical Acti	vity One	stionnai	e - Short F	Form PSOI	: The
Pittsburgh Sleen Qual	ity Index: TPF	3-0. The	ory of nl	anned heh	avior questi	onnai
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3	214	
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6 7 8	215	
9 10	216	Eligibility criteria
11 12 13	217	Eligible participants will be pregnant women, inclusive of all gender identities.
14 15 16	218	
17 18	219	The inclusion criteria are as follows:
20 21	220	Singleton pregnancy, conceived through natural insemination, with a gestational age
22 23 24	221	< 12 weeks, and signed informed consent.
25 26 27	222	
28 29 30	223	The exclusion criteria are as follows:
31 32	224	Multifetal pregnancy, IVF, pre-existing type 1 or type 2 diabetes, fetal malformations
33 34 35	225	including chromosomal abnormalities or structural malformations detected by
36 37 38	226	ultrasonography, fetal congenital infections or abnormalities, adherence to a restricted
39 40	227	diet (including vegans), medical conditions that could potentially affect the
41 42 43	228	intervention or follow-up (including severe cardiovascular and kidney diseases result
44 45 46	229	in limited physical activity and require diet under professional guidance.), and
47 48 49	230	unwillingness or inability to provide informed consent
50 51	231	
52 53 54 55 56	232	Intervention

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233	Eligible participants will be randomized into one of the three groups: Group 1 Online		
234	Nutrition Education; Group 2 Nutrition Checklist and 'One-page Flyer' for self-		
235	learning; Group 3 Routine Antenatal Education without any intervention.		
236	Group 1: Online n	utrition education arm (OEA)	
237	The first interventi	on group will receive 6 sessions of	1-h nutrition education by
238	video-conferencing	g (Table 2). The course design was	based on the TPB model and
239	followed the DESI	GN Procedure[29]of Contento and	Koch. The DESIGN procedure
240	is a simple, system	atic, 6-step process that integrates f	ood and nutrition science,
241	psychological theories, education principles, and communication skills. It provides a		
242	framework for planning theory-based, behavior-focused nutrition education that		
243	translates theory and evidence into activities, materials, group discussions, and social		
244	media. Two graduate students majoring in nutrition will lead the course. The overall		
245	goal of the course is to promote a balanced diet with a focus on controlling fat intake.		
246	The general goal can be further broken down into three specific behavioral change		
247	goals: choosing the	e right food to eat, cooking healthily	v, and reading nutrition labels so
248	they can identify healthy packaged food. According to the previous records of the		
249	participating hospitals, over 95% of the pregnant women have a high-school degree		
250	and all of them are	literate, therefore would be able to	comprehend the course content.
251			
252		Table2. Course topics and behavior	ral strategies.
	Them	Behavioral strategy	Diet topic

Session 1: No more fat 1	 1)Outcome expectations 2)Factual knowledge and skill 3)Self-efficacy/Perceive behavior control 4)Analysis of pros and cons of change(Behavioral Intention) 	Benefits of balance diet Discovering your inadequate of their diet Identifying high-fat foods Use fists and hands to count food servings Overcoming the obstacles of a high-fat diet
Session 2: No more fat 2	 Negative outcomes of current behavior Perceived benefits Self-depictions Behavioral intention 	The Dangers of Trans Fatty Acids Knowing that a healthy cooked diet is just as tasty Knowing that the mother's diet affects the child Learn to establish dietary goals
Session 3: Eat out smartly	 Negative outcomes of current behavior Knowledge and cognitive skills Perceived norms Self-efficacy 	understand how to choose foods wisely when dining out or ordering delivery online
Session 4: Cook healthily	 Perceived benefits Skills and ability Perceived barriers Behavioral intention 	learn the recipes for healthy cooking
Session 5: Choose the right snacks	 Perceived risk Food and nutrition knowledge Food preferences Self-efficacy 	understand the definition of ultra-processed foods, learn how to choose healthy snacks
Session 6: Read the label	 Perceived benefits Skills and ability Perceived norms Behavioral intention 	learn how to read nutrition labels and ingredient list

253 Group 2: Nutrition checklist and 'One-page flyer' arm (NOA)

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254	A 17-item nutrition checklist and "one-page" flyer are distributed to the participants
255	by physicians at their monthly pregnancy check-ups. Pregnant women can self-
256	identify their nutrition problems through the checklist within 2 minutes and make
257	behavioral changes by following the guidance in the 'one-page flyer'. The 17-item
258	nutrition checklist was adapted from the FIGO checklist[43], which is a very efficient
259	way to assess the nutrition status of pregnant women[44]. This tool helps clinicians
260	and pregnant women quickly identify imbalances in their dietary patterns. The
261	checklist includes four parts. Part 1: self-reported special dietary habits (e.g., vegan,
262	food allergy); Part 2: self-reported height, weight, and BMI; Part 3: 17 questions
263	related to dietary habits with a focus on fat intake (most are yes or no questions); Part
264	4: grading criteria and interpretation of the checklist result. The 'one-page flyer' is an
265	A4 paper-sized dietary instruction flyer. It is based on the theory of planned behavior,
266	including information on the adverse effects of a high-fat diet during pregnancy on
267	mother and baby at the top of the page (outcome expectation), choosing healthy
268	snacks, reading food labels, specific cooking tips using less oil (knowledge and
269	skills), information on diet management aiming to increase confidence (perceived
270	behavior control and self-efficacy), guidance on establishing specific and feasible
271	behavior change goals (goal-setting using SMART theory).
272	
273	Criteria for discontinuing or modifying allocated interventions

Criteria for discontinuing or modifying allocated interventions

Not applicable due to the nature of the interventions.

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3 4 5	275	
6 7 8	276	Strategies to improving and measuring the adherence
9 10	277	Adherence to the online education sessions will be assessed by class attendance from
12 13	278	sign-ins and visual scans of video conference attendees. We will set up an online
14 15 16	279	group chat for participants to remind them to attend before the start of each class, and
17 18 19	280	we will create a pre-class check-in e-form, post-class Q&A and evaluation e-form to
20 21 22	281	measure participation in the class. For the NOA, after the 17-item nutrition checklist
22 23 24	282	and 'one page flyer' were distributed, pregnant women underwent three dietary
25 26 27	283	screenings in the early, middle, and late stages of pregnancy, and provided one-on-
28 29 30	284	one guidance on the main screening issues to improve maternal compliance.
31 32	285	The treatment will be considered complete if at least four out of the six sessions are
33 34 35	286	attended for the OEA. For the NOA group, we will count the number of times
36 37 38	287	pregnant women screen for nutritional issues (27 item nutrition checklist) and use a
39 40 41	288	questionnaire to investigate the reading status of 'one page flyer'. Adherence to the
42 43	289	nutrition behaviors will be assessed by an improvement of \geq 3 points of their total
44 45 46	290	scores of the 17-item nutrition checklist compared to their total initial score[45]. The
47 48 49	291	study population will be sorted according to adherence to the dietary guidelines,
50 51 52	292	depending on the score: ≥ 12 high adherence, $6 - 11$ moderate adherence, and < 6 low
52 53 54	293	adherence[45].
55 56 57	294	
58 59 60	295	Relevant concomitant care permitted or prohibited during the trial

eople who participate in this trial cannot participate in another trial.
rovisions for post-trial care
o post-trial care is needed since this is an educational intervention.
utcomes
dverse pregnancy outcomes:
rimary outcome:
he primary outcome will be the prevalence of LGA at birth, defined as the newborns
ith a measured birth weight above the 90th percentile (P_{90}) of the same sex for the
me gestational age were evaluated as large for gestational age (Growth standard
r newborns by gestation in China, WS/T 800–2022).
econdary outcomes:
eonatal: Birth weight, Macrosomia (birth weight \geq 4000 g), SGA (birth weight
elow the 10th percentile for gestational age) or low birth weight (birth weight \leq 2500
, preterm birth (< 37 weeks' gestation), low Apgar score (Apgar <7), low birth
eight infant (birth weight ≤ 2500 g), preterm birth (gestational age <37 weeks),
pgar score.
aternal: GDM (GDM is diagnosed when the blood glucose value at any point in
me meets or exceeds the above criteria: fasting, 1 hour after oral glucose, and 2

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1 2		
3 4 5	296	People who participate in this trial cannot participate in another trial.
6 7 8	297	
9 10	298	Provisions for post-trial care
11 12 13	299	No post-trial care is needed since this is an educational intervention.
14 15 16	300	
17 18 19	301	Outcomes
20 21 22	302	Adverse pregnancy outcomes:
23 24	303	Primary outcome:
25 26 27	304	The primary outcome will be the prevalence of LGA at birth, defined as the n
28 29 30	305	with a measured birth weight above the 90th percentile (P_{90}) of the same sex f
31 32	306	same gestational age were evaluated as large for gestational age (Growth sta
33 34 35	307	for newborns by gestation in China, WS/T 800–2022).
36 37 38	308	Secondary outcomes:
39 40 41	309	Neonatal: Birth weight, Macrosomia (birth weight \geq 4000 g), SGA (birth weight)
41 42 43	310	below the 10th percentile for gestational age) or low birth weight (birth weigh
44 45 46	311	g), preterm birth (< 37 weeks' gestation), low Apgar score (Apgar <7), low bi
47 48 49	312	weight infant (birth weight ≤ 2500 g), preterm birth (gestational age <37 we
50 51	313	Apgar score.
52 53 54	314	Maternal: GDM (GDM is diagnosed when the blood glucose value at any point
55 56 57	315	time meets or exceeds the above criteria: fasting, 1 hour after oral glucose, an
58 59 60	316	hours after glucose thresholds of 5.1, 10.0, and 8.5 mmol/litre, respectively.),

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317	gestational hypertension (defined as >20 weeks' gestation, elevated blood pressure
318	[systolic BP \geq 140 mm Hg or diastolic BP \geq 90 mm Hg] in the absence of proteinuria),
319	cesarean section rate, birth canal injury rate, shoulder dystocia rate, maternal insulin
320	treatment rate, maternal weight gain during pregnancy (maternal weight gain
321	generally refers to maternal weight at delivery minus pre-pregnancy weight),
322	preeclampsia (defined as >20 weeks' gestation, new-onset hypertension [systolic
323	blood pressure \geq 140 mm Hg or diastolic blood pressure \geq 90] mm Hg] and new-onset
324	proteinuria [300 mg protein intake within 24 hours or urine protein/creatinine ratio 0.3
325	mg/dL], or in the absence of proteinuria, new-onset hypertension with new-onset
326	thrombocytopenia, renal insufficiency, impaired liver function, pulmonary edema, or
327	cerebral or visual impairment), perinatal mortality (fetuses or neonates death at > 28
328	weeks' gestation - within 7 days of postpartum)
329	
330	Changes in dietary behaviors
331	Changes in dietary behaviors will be assessed by a dietary behavior questionnaire,
332	which was adapted from previous FFQs[46, 47]. The questionnaire includes questions
333	on the intake and frequency of consumption of different categories of foods,
334	particularly high-fat foods.
335	We will also assess knowledge and skills related to cooking habits that can reduce fat
336	intake and reading nutrition labels to choose low-fat foods when shopping. Behaviors

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related to adherence to the dietary guidelines will be assessed by the 17-item nutrition checklist. Changes in psychosocial determinants based on the TPB model A questionnaire was developed to assess the changes in the four components (attitude towards behavior, subjective norm, perceived behavioral control, and behavioral intention) related to diet behaviors (reducing fat intake, cooking healthily, and reading nutrition labels) based on the TPB before and after the intervention. The questionnaire was based on previous studies [39, 48], and content validity has been confirmed by experts in nutrition. Attitudes, perceived norms, self-efficacy, self-depictions, and behavioral intention will be assessed as the mean of the statements under each component measured on 5-point unipolar (+1 to +5) scales. We conducted a questionnaire survey (a cross-sectional survey) on pregnant women at three study sites to test the reliability and validity of The 17-item nutrition checklist, FFQ, and TPB-Q. This helps us to make timely corrections to inappropriate issues before the research begins. This population was randomly distributed between the intervention group and the control group, reducing the bias caused by this confirmatory survey. Postpartum follow-up

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357	The feeding types and complementary foods added will be investigated 42 days after
358	delivery through a questionnaire to be developed. Children are followed again at 3
359	years of age for diet, taste preferences, and physical development. Children's diets
360	will be assessed by a food frequency questionnaire based on a previous study32.
361	Children's physical development will be assessed by their weight, height, sitting
362	height, and body composition, measured by body weight meter, mechanical
363	height/sitting height meter, and body composition analyzer, respectively.
364	
365	Other measures
366	A baseline survey is used to collect information on participants' demography, lifestyle
367	(e.g., sleep, physical activity), and medical and family history. Pregnant women's age,
368	educational background, parity, pre-BMI, height, pre-weight, and other information
369	are sourced from their pregnancy records. This file is established by community
370	doctors after one-on-one questioning and measurement. The weight gain during
371	pregnancy is measured on outpatient scales or home scales and reported to the
372	investigator on their own.
373	
374	Sample size
375	The RCT uses the incidence of LGA as the primary outcome. The incidence of LGA
376	in the general population is about 11.0%[49], while the incidence in the intervention
377	group is expected to be 5.0%[50]. Assuming a type 1 error of 5% and a power of
378	80%, 318 participants will be recruited. Allowing for a 20% dropout, 400 participants

will be needed for each of the three arms, with an overall sample size of 1200

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380 participants for the study[51]. $n = \frac{(z_{1-\alpha/2} + z_{1-\beta})^2 [p_1(1-p_1)/k + p_2(1-p_2)]}{(p_1 - p_2)^2}$ 381 382 383 Recruitment 384 At the first prenatal check-up, all eligible pregnant women will be introduced of the 385 purpose of the study, the intervention, and the potential benefits and risks. Participants 386 who agree to participate, after obtaining written informed consent, will be randomized 387 into the three different groups. Randomization will be performed by using a computer 388 system that randomly assigns participants into one of the three groups: (1) online 389 nutrition education + nutrition checklist and flyer (2) nutrition checklist and flyer for self-learning, and (3) usual care without any intervention. 390 391 392 **Randomization** 393 394 Allocation 395 The computer system (http://www.jerrydallal.com/random/randomize.htm) generates 396 randomization sequences based on the need of the study. The name of the intervention 397 group, the number of groups, and the sample size for each group is entered into the 398 system to generate the allocation plan. Participants in different groups will receive 399 different invitation links for their intervention to have unified management. 400 Concealment mechanism 401 Allocation concealment is ensured as the randomization code is not released until the 402 403 participants have met the eligibility and signed informed consent. The allocation is 22

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3 4 5	404	performed automatically by the computer without human control. Participants will
6 7 8	405	receive a new inclusion number after the groups are formed, and the number is also
9 10	406	used as a participant ID for the intervention lessons.
11	407	
12	408	Implementation
14 15 16	409	The enrollment of the participants will be done by doctors who do not have
17 18 19	410	information on group allocation, as the randomization happens after the recruitment.
20 21 22	411	Participants are first divided into different categories according to the plan and then
23 24	412	randomized into three groups by research assistants of the study using the computer
25 26 27	413	program.
28 29 30	414	Doctors will distribute the nutrition checklist and one-page flyer to participants.
31 32 33	415	Research assistants will provide guidance on how to use these materials.
34 35	416	Online nutrition education sessions will be delivered by two research assistants who
36 37 38	417	are Ph.D. students majoring in Nutrition. The course content and study materials have
39 40 41	418	been reviewed by experts in nutrition.
42	419	
43 44	420	Blinding
45 46	421	Due to the nature of the study design, it is not possible to blind participants or
47 48 49	422	researchers in the study regarding the intervention type. Therefore, the study is
50 51 52	423	blinded only to the clinical nurses responsible for grouping. Nurses responsible for
53 54	424	enrolment recruitment were unaware of the grouping.
55	425	
56 57	426	Procedure for unblinding if needed
58 59 60	427	Not applicable, and the trial will not be blinded.

428	
429	Statistical analysis
430	For demographic variables and outcomes, continuous variables will be presented
431	using either the mean or median depending on whether they conform to a normal
432	distribution, and categorical variables will be summarized using frequencies (%). The
433	differences in LGA and GMD incidence among the three groups will be compared
434	using chi- square tests. Analysis of variance will be used to assess differences in birth
435	weight, and the generalized estimating equation will be used for comparing
436	gestational weight gain[52].
437	We will use three analytical methods to analyze our study population[53-55].
438	The Intention-To-Treat Population (ITT), which includes all participants based on
439	their initial random grouping, regardless of whether they completed all interventions;
440	Modified Intention to Treat Population (mITT), which defined by excluding
441	participants when the primary outcome (e.g. stillbirth or intrauterine death of the
442	newborn, congenital malformations) is absent; Population Per Protocol(PP), which
443	includes only those individuals with good adherence to the intervention for the
444	purpose of analysis. For pre-randomization, baseline analysis, and primary and
445	secondary efficacy variable analysis we will use mITT analysis. The primary outcome
446	analysis will initially use ITT for preliminary analysis and then use PP for the
447	comparison of robustness.

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448	The missing value treatment program follows the guidelines outlined in
449	CPMP/EWP/1776/99. Missing values are filled in for the main variables only,
450	applying the following principles[56]: Primary missing value imputation strategy: we
451	will use Imputed case analysis for the primary outcome (i.e., the occurrence of LGA,
452	which was defined as a birth weight greater than the 90th percentile of the mean
453	weight of children of the same gestational age and sex);Secondary missing value
454	imputation strategy: we will use multiple imputations using the control group
455	observations to fill missing data. The primary analyses are based on worst-case
456	imputation scenario, while sensitivity analyses are conducted using the results of
457	multiple imputations.
458	To identify susceptible subpopulations, we will conduct subgroup analysis by
459	defending subgroups by research centers, corresponding obstetricians, or nutrition
460	physicians. Demographic variables such as age, pre-BMI (According to standard of
461	recommendation for weight gain during pregnancy period, the pre pregnancy BMI of
462	pregnant women is divided into four categories: <18.5 kg/m ² , 18.5 kg/m ² \leq BMI<24.0
463	kg/m ² , 24.0 kg/m ² \leq BMI<28.0 kg/, and BMI \geq 28.0 kg/m ² .), parity, level of
464	education, and place of residence will be used for sensitivity analyses.
465	
466	PATIENT AND PUBLIC INVOLVEMENT
467	Before the formal commencement of the study, we will conduct a pilot study which

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468 includes a process evaluation and interviews with obstetricians, dietitians, and
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4	69	pregnant women. The comments and recommendations gathered from these
4	70	participants regarding the intervention will guide the revision and improvement of the
4	71	final intervention. Throughout the intervention phase, we will document the intensity
4	72	and completeness of the intervention, along with the acceptability and satisfaction
4	73	levels among pregnant women. In this process, pregnant women, obstetricians, and
4	74	nutritionists will contribute their opinions and feedback on the study design,
4	75	implementation, frequency, and other aspects of the course content.
4	76	
4	77	ETHICS AND DISSEMINATION
4	78	The study received ethical approval from the Capital Medical University Ethics
4	79	Committee(Z2022SY077, Z2023SY137). Additionally, ethical approval was also
4	80	granted by all centers. The research design followed SPIRIT recommendations and
4	81	was registered with the Chinese Clinical Trial Registry (ChiCTR2300071126). The
4	82	findings will be reported in relevant national and international academic conferences
4	83	and peer-reviewed publications.
4	84	
4	85	Data Availability Statement
4	86	Not applicable for a protocol as no data has been generated.
4	87	
4	88	FIGURE LEGENDS
4	89	Figure 1. Extended Theory of Planned Behavior /Reasoned Action Approach
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490	Figure 2. Study design including the screening, recruitment, randomization process,
491	and the conduct flow.
492	Note : IPAQ-S: International Physical Activity Questionnaire - Short Form; PSQI:
493	The Pittsburgh Sleep Quality Index; TPB-Q: Theory of planned behavior
494	questionnaire; NOA: Nutrition checklists and "One-page flyer" arm; OEA: Online
495 496	education arm.

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512	Medical University.
513	
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515	Haiyan, Isobel Contento, Pamela Koch, and Sun Shengzhi gave design comments and
516	feedback on the scheme. Yadi Zhang and Xiaoge Gao drafted and wrote the protocol,

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3	517	
4 5	517	and Huanling Yu, Isobel Contento, and Pamela Koch review edit. All authors
6		
7	518	contributed to the research project.
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9	519	
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 12	500	
12	520	Funding This study is funded by the Beijing Municipal Natural Science Foundation
14		
15	521	(Effects and mechanisms of gestational diabetes mellitus affecting intestinal microbial
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17	522	colonization through modulation of offspring intestinal immune cell composition
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21	523	KZ202210025039).
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25 26	525	Competing interests None declared
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31	527	Patient consent for publication Not required.
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36	520	Drevenance and near review Net commissioned: automally near reviewed
37	329	rrovenance and peer review Not commissioned, externany peer reviewed.
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42	531	Open access This is an open access article distributed in accordance with the Creative
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44 45	532	Commons Attribution Non Commercial (CC BV-NC 4.0) license which permits
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48	533	others to distribute, remix, adapt, build upon this work non-commercially, and license
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50	534	their derivative works on different terms, provided the original work is properly cited,
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52 53	535	appropriate credit is given any changes made indicated, and the use is non-
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56	536	commercial. See: <u>http://creativecommons.org/licenses/by-nc/4.0/</u> .
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Figure 1. Extended Theory of Planned Behavior /Reasoned Action Approach

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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

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*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "<u>Attribution-NonCommercial-NoDerivs 3.0 Unported</u>" license.