Effects of mobile health intervention based on behavioral integrated model on cognitive and behavioral changes in gestational weight management: Randomized controlled trial

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Abstract

Background: The key to gestational weight management intervention involves health-related behaviors, including dietary and exercise management. Behavioral theory-based interventions are effective in improving health-related behaviors. However, evidence for mobile health interventions based on specific behavioral theories is insufficient and their effects have not been fully elucidated.

Objective: To examine the effects of gestational mobile health intervention on psychological cognition and behavior for gestational weight management, using an integrated behavioral model as the theoretical framework.

Methods: This study was conducted in Tertiary maternity hospital and conducted as a single-blind randomized controlled trial (RCT) in Changzhou, Jiangsu Province, China. Using the behavioral model, integrated with the protection motivation theory and information–motivation–behavioral skills model (PMT-IMB model), the intervention group received mobile health intervention using a self-developed app from 14 to 37 gestational weeks, whereas the control group received routine guidance. Psychological cognition and behaviors related to weight management during pregnancy were main outcomes, which measured at baseline, and at second and third trimesters of pregnancy using a self-designed questionnaire. Generalized estimation and regression equations were used to compare the outcome differences between the intervention and control groups.

Results: In total, 302 participants (83.9%) underwent all measurements at three time points (intervention group: 150, control group: 152). Compared with the control group, the intervention group had significantly higher scores for information, perceived vulnerability, response cost, and exercise management in the second trimester, while their scores for perceived vulnerability, response cost, and diet management were significantly higher in the third trimester. Repeated measurement analysis results revealed that the time and group effects on information and response cost were statistically significant for psychological cognition, while only group effects were detected for perceived vulnerability (adjusted B=0.669, 95% CI: 0.050–1.288, p = 0.034). Moreover, the time and group effects on exercise management and total points were statistically significant for weight management behavior.

Conclusions: The intervention program was effective in increasing psychological cognitions and healthy behaviors among Chinese pregnant women. This study provides new evidence supporting the effectiveness of mobile intervention based on behavioral science theory in gestational weight management. Clinical Trial: Chinese Clinical Trial Registration Center (ChiCTR2100043231)

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Results: In total, 302 participants (83.9%) underwent all measurements at three time points (intervention group: 150, control group: 152). Compared with the control group, the intervention group had significantly higher scores for information, perceived vulnerability, response cost, and exercise management in the second trimester, while their scores for perceived vulnerability, response cost, and diet management were significantly higher in the third trimester. Repeated measurement analysis results revealed that the time and group effects on information and response cost were statistically significant for psychological cognition, while only group effects were detected for perceived vulnerability (adjusted B=0.669, 95% CI: 0.050–1.288, p = 0.034). Moreover, the time and group effects on exercise management and total points were statistically significant for weight management behavior.
Conclusions: The intervention program was effective in increasing psychological cognitions and healthy behaviors among Chinese pregnant women. This study provides new evidence supporting the effectiveness of mobile intervention based on behavioral science theory in gestational weight management.
Trial Registration: Chinese Clinical Trial Registration Center (ChiCTR2100043231)

Keywords: Cognition; Health behavior; Information-motivation-behavioral skills model; Mobile health; Psychological models; Pregnant woman; Randomized controlled trial

Introduction

Inappropriate gestational weight gain (GWG) remains a public health problem requiring immediate attention. [1,2] The proportion of inadequate weight gain among pregnant women is approximately 20% in the United States, Canada, and Europe, whereas the proportion of excessive weight gain is approximately 50%. Moreover, in Asia, 31% of pregnant women experience inadequate weight gain, whereas 37% experience excessive weight gain. [3] Currently, the appropriate GWG rate in China is less than 50%. [4,5] Appropriate GWG is essential, as both

excessive and inadequate weight gain pose adverse risks to maternal and child health. [6-9]

Mobile health refers to the use of mobile technologies including mobile phones, personal digital assistants, and even tablet computers to improve patient health.[10] In the current era of rapidly advancing information technology, mobile health is widely used in various medical fields. Despite multiple barriers, including the lack of regulatory oversight, limited evidence-based literature, and concerns of privacy and security, [11] mobile health still has many advantages. It not only overcomes the limitations of time and space but also saves medical and human resources. Notably, mobile health technology has become a popular resource for pregnant women to learn dietary and lifestyle modifications. [12] Mobile health interventions based on gestational diet and physical activity are widely used to promote weight management behavior, [13,14] and several reviews have summarized the effectiveness of this emerging internet intervention approach to promote maternal and infant health. [10,15,16]

Unhealthy behaviors, such as overeating, physical inactivity, and a sedentary lifestyle during pregnancy, are known to be considerably associated with inappropriate GWG. [17] The key to pregnancy weight management intervention is the promotion of health-related behaviors. Interventions based on health behavioral theory are effective in controlling GWG. For instance, the social cognitive theory, [18,19] health belief model, [20] and integrated theory of health behavioral change, [21] have been used to formulate mobile health interventions aimed at gestational weight management. However, the effects of interventions based on behavioral theory are not universal. For example, the behavioral lifestyle intervention based on social cognitive theory had no impact on gestational weight management in African Americans with obesity and the Whites. [22] Hence, the effects of these gestational weight management interventions based on behavioral theory have not been fully elucidated; therefore, it is necessary to empirically test mobile interventions designed on the basis of behavioral theories.

In this study, the behavioral model integrated with the protection motivation theory and information–motivation–behavioral skills model (PMT-IBM model) was used to guide the mobile health intervention for gestational weight management. The integrated model involves eight dimensions: information, behavioral skill, motivation, perceived severity, perceived vulnerability, response efficacy, self-efficacy, and response cost. **(Supplementary File 1)** In a previous independent study, we have already extensively validated the integrated model's fitness and ability to interpret gestational weight management behavior in a cross-sectional survey of 525 pregnant women. The study explains the influencing mechanisms underlying gestational weight management behavior at the individual psychological level. [23]Nevertheless, this initially proven interpretive integrated model has not yet been verified for its effectiveness in guiding interventions in practice.

Therefore, this trial aimed to determine whether a mobile health intervention applying the PMT-IBM model as the framework could enhance psychological cognitions and behaviors towards gestational weight management.

Methods

Study design

This was a single-blind randomized controlled trial (RCT). Eligible participants were randomly assigned by computer to (1) intervention (mobile health based on the integrated model) and (2) control (usual guidance) groups. The study was prospectively registered with the Chinese Clinical Trial Registration Center (ChiCTR2100043231) and approved by the Ethics Committee of Nanjing Medical University (no. NMU 2020-63). All participants were comprehensively informed of the voluntary nature of their participation and their right to withdraw from the study at any time. The investigation was performed only after written informed consent had been obtained from the participants.

Study setting and participants

Between August and December 2021, participants were recruited from Changzhou, one of the central cities in China's Yangtze River Delta region and a developed city in southern Jiangsu Province. The city occupies an area of approximately 4,372.15 km^2, with a per capita gross domestic product of more than 25,000 dollars in 2021. (Changzhou Municipal People's Government, 2022) The study site was a tertiary maternity hospital where approximately 40% of the deliveries in this city are performed. The inclusion criteria were as follows: (1) singleton pregnancy, (2) pregnancy confirmed by a pregnancy test (gestational age ≤ 14 weeks), (3) intention to live in the region until delivery, (4) ability to complete the questionnaire, and (5) agreement to participate and provide written informed consent. The exclusion criteria were as follows: (1) age < 18 years; (2) history of neurological, cardiovascular, hepatic, and/or renal medical complications; (3) essential hypertension and diabetes mellitus; and (4) other complications, such as deafness and dumbness.

Sample size

As a phased effect evaluation of a gestational weight management project, this study calculated the sample size based on the behavioral indicator (behavioral scale score) of weight management. The formula was based on a two-sample mean comparison: $n1=n2=2[(Z_\alpha+ Z_\beta)s/d]^2$. [24]The pre-survey results were used to obtain the s=11.8 and d=5.25. [23]Therefore, the estimated sample size was as follows: n1=n2=108. A 20% attrition rate was considered for this study; therefore, the required sample size was increased to 270 participants, including 135 participants in each group.

Randomization and blinding

In this single-blind RCT, the participants were blinded. The randomization sequence was generated using SPSS software (version 25.0) by a research assistant who did not participate in the recruitment process. Random numbers were matched to the intervention app. When participants completed the baseline questionnaire, they were assigned a unique registration number. Thereafter, the backend of the app consolidated the participants' information to screen those who met the inclusion criteria. The registration number was then matched against the groups' random sequence, to categorize the participants into intervention or control groups.

Data collection

Our research team comprehensively studied the operational definitions of each dimension of the PMT-IBM model, as well as designed the questionnaires to strictly comply with the questionnaire design process. [23]Three trained outcome assessors performed face-to-face baseline data collection during the first trimester (T1: gestational age ≤ 14 weeks) at the maternity clinic. The follow-up data were collected using a questionnaire link provided on the mobile health app in the second (T2: 27 weeks ≤ gestational age ≤ 28 weeks) and third (T3: gestational age ≥ 37 weeks) trimesters. During questionnaire completion, the assessors reminded the participants to self-report their actual preceding month circumstances.

Outcome Measures

A detailed baseline evaluation was performed for all participants before initiating the study. The evaluation included the following three parameters: (1) Main demographic characteristics: including maternal age, education level, parity, height, and pre-pregnancy weight. (2) Gestational psychological cognition scales: included seven dimensions (information, behavioral skills, perceived severity, perceived vulnerability, response efficacy, self-efficacy, and response costs), which designed by PMT-IMB model. Each dimension was measured on a five-point Likert scale (from 1 = absolutely disagree to 5 = absolutely agree) and included five items each, with a total score of 5–25. A higher total score indicated better psychological cognition among pregnant women. The total Cronbach's alpha for the cognition scale of 0.860, ranged from 0.822 to 0.938. (3) Gestational weight management behavioral scales included four dimensions: exercise management (nine items), dietary management (four items), self-monitoring and regulation (four items), and management objectives (three items). Each item was rated on a five-point Likert scale ranging from 1 (never) to 5 (always). Scores were analyzed using the gross for each dimension, with higher scores indicating superior

behavioral management in each respective dimension. The total Cronbach's alpha for the behavioral scale of 0.844, ranged from 0.653 to 0.866. The validity test of the scale has been reported in the previous explanatory study. [23] The detailed information for the scales is shown in Supplementary File 2 and the operational definition of gestational weight management behaviors is shown in Supplementary File 3.

Control group

Participants in the intervention and control groups received the usual guidance provided by the hospital. Regular prenatal examinations were provided at the obstetrics clinic, and obstetricians routinely offered health interventions for pregnancy weight management. These include the provision of pregnancy-related healthcare knowledge and precautions to pregnant women, distribution of manuals on healthy diet and exercise management during pregnancy, articulation of the GWG standards, and recommendation of half an hour of daily exercise. Nutritional clinic doctors provided nutritional guidance based on the body composition analysis, developed personalized diet plans and exercise programs, and guided pregnant women in weight control and self-care.

Intervention group

The mobile health intervention was implemented using a self-developed app, "Pregnancy Assistant". The app was divided into different sections for pregnant women, other hospital clients, and a system database. The module for pregnant women included gestational age, a questionnaire, science popularization, notification, and weight records. The hospital client could upload health education-related materials. All survey data were downloaded and stored in the database.

The forms of educational intervention included image texts, videos, expert lectures, and peer communication. First, according to the research results on the model construction, [23]the main contents of the interventions were determined based on the information, motivation, and behavioral skills dimensions. We developed various health intervention materials under the seven psychological cognition dimensions by referring to studies on gestational weight management [25] and gestational guidelines on nutrition [26-28]and exercise, [26,29]combined with the recommendations from clinical nutrition experts, obstetricians, and nurses. The intervention period ranged from 14 to 37 gestational weeks. The health education-related materials (i.e., image, text, and video) were updated through "Pregnancy Assistant" app, (24 items in total, once a week). The researchers also regularly reminded pregnant women via the Wechat to use the health education materials to improve intervention compliance. Second, every two weeks, a 45-min online expert lecture was held to introduce information regarding the risks and severity of inappropriate GWG, its epidemiological knowledge such as risk factors, susceptible populations, and suitable preventive dietary and exercise methods. Following the expert lecture, a 15-min question-and-answer session was offered to participants to address existing obstacles against weight management. Moreover, to boost confidence and stimulate healthy behavioral changes, experienced participants were encouraged to share their thoughts and experiences via a WeChat communication group. The detailed intervention content is shown in Supplementary File 4.

Statistical analysis

In the descriptive statistical analysis, continuous variables are expressed as mean values and standard deviations (SDs). A two-sample independent t-test was used to compare the two groups, while analysis of variance (ANOVA) was used to compare multiple groups. Categorical variables, presented as frequencies (%), are compared between groups using Pearson chi-square test. In a general linear model, the cognition dimensions in the PMT-IMB model and weight management behavioral dimensions were considered as the dependent variables. Intervention or not was considered the primary independent variable (0 for the control group and 1 for the intervention group). Covariates included age, education level, parity, and pre-pregnancy body mass index (BMI). Each participant completed the same questionnaire thrice, providing repeatable and dependable measurement data. Therefore, the differential changes in psychological cognitions and behaviors at T2 and T3 with respect to T1 between the two groups were assessed using generalized estimating

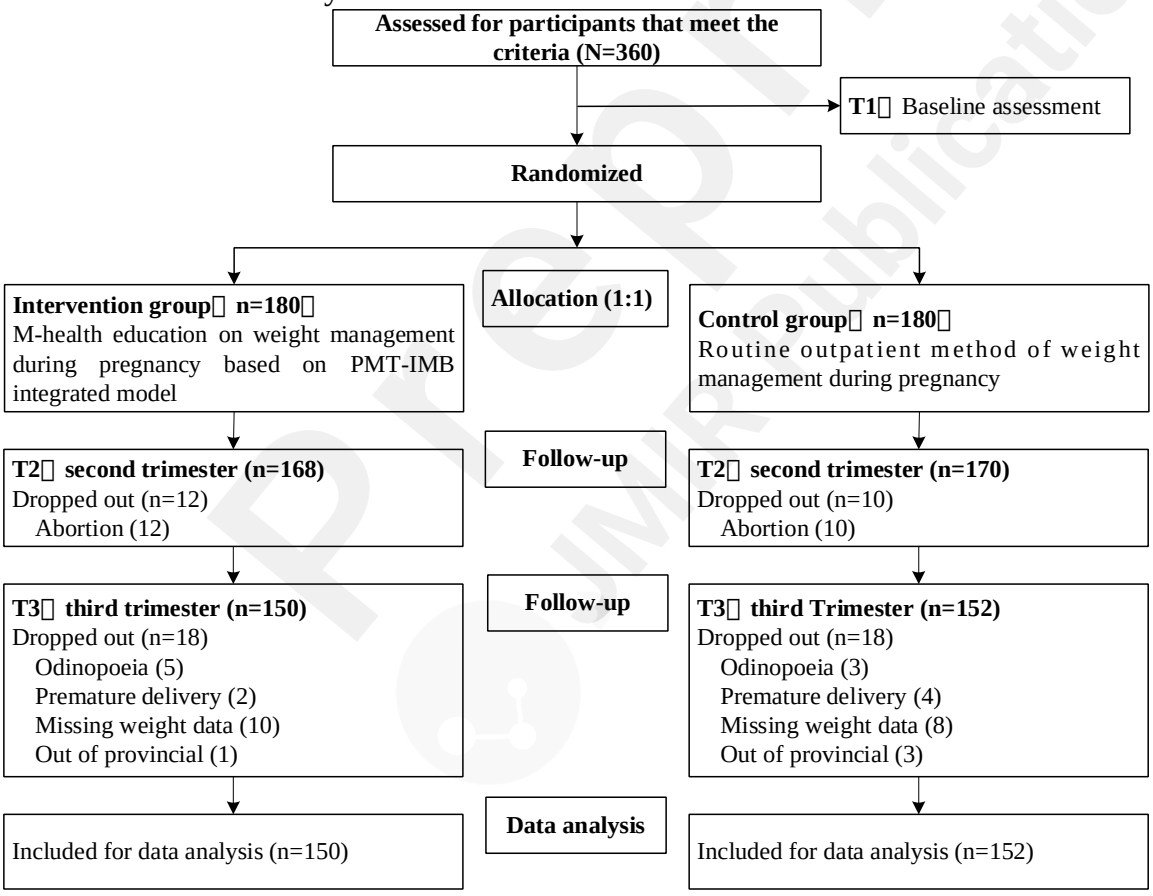
equations. When no statistical interaction between time and group was present, we only included the group's main effect and time terms to demonstrate the intervention's effect. Those who had a miscarriage or premature birth during follow-up were excluded from the final data analysis. Therefore, intention-to-treat analysis was not used in the analysis of this study. All data analyses were performed using IBM SPSS Statistics for Windows, version 25.0 (IBM Corp., Armonk, NY, USA), and statistical significance was set at $p < 0.05$ (two-sided).

Results

Participant recruitment and retention

After evaluation, 360 participants satisfied the eligibility criteria at baseline and were randomly assigned to intervention and control groups (n=180 per group). After their inclusion in the study, pregnant women registered themselves on the app using their mobile phones and completed the baseline questionnaire. The second-trimester follow-up involved 338 participants (intervention group: 168; control group: 170; retention rate: 88.9%). By the third trimester, 302 participants with complete follow-up data were included in the final data analysis (intervention group: 150, control group: 152). The overall retention rate was 83.9%. Participants who dropped out at each stage of the study are shown in **Figure 1**.

Figure 1 Flow chart of the assessment, allocation, reasons for withdrawal, and number of participants included in the data analysis



Main demographic characteristics

The participants' demographic characteristics are presented in **Table 1.** Among the 302 participants, the mean ages of the intervention and control groups were 29.31 (SD=3.38) and 29.16 (SD=3.49) years, respectively. In both groups, more than half of the participants had at least a college education (59.3% *vs.* 54.6%, $p = 0.407$). Most participants were primipara, and the proportion of participants with an appropriate pre-pregnancy BMI also exceeded 70%. No statistically significant

between-group differences were observed in the main demographic characteristics ($p > 0.05$).

Table 1 Main demographic characteristics between the intervention group and control group (N=302)

Characteristics	Intervention group (N=150)		Control group (N=152)		t/χ^2	*p*
	Mean/N	SD/%	Mean/N	SD/%		
Age (years)	29.31	3.38	29.16	3.49	0.376	0.707
Education level [a]						
College education and above	89	59.3%	83	54.6%	0.688	0.407
Junior college and below	61	40.7%	69	45.4%		
Parity						
Multiparity	39	26.0%	38	25.0%	0.040	0.842
Primiparity	111	74.0%	114	75.0%		
Pre-pregnancy BMI (kg/m^2)	21.16	2.62	21.25	2.57	-0.324	0.746
underweight	19	12.7%	17	11.2%	0.744	0.874
normal weight	110	73.3%	116	76.3%		
overweight	18	12.0%	15	9.9%		
obese	3	2.0%	4	2.6%		

Note

N=frequency; SD=Standard deviation; t=t-test; χ^2=chi-squared test.

[a] Junior college degree is the median level of education.

Intervention effect on psychological cognitions and weight management behaviors

As shown in **Table 2**, at baseline, only the management objective dimension (adjusted B = 0.686, p = 0.042) was significant, whereas all dimensions of psychological cognition and weight management behavior were not significantly different between the two groups. Adjusted general linear models demonstrated that participants in the intervention group had noticeably higher scores for information (adjusted B = 0.174, p = 0.019), perceived vulnerability (adjusted B = 0.894, p = 0.025), response cost (adjusted B = 1.101, p = 0.006), and exercise management (adjusted B = 2.089, p = 0.011) at T2 than their counterparts in the control group. Furthermore, their scores for perceived vulnerability (adjusted B = 1.078, p = 0.013), response cost (adjusted B = 1.538, p =0.001), and dietary management (adjusted B = 0.959, p = 0.007) were statistically significantly higher at T3. Although behavioral skills, perceived severity, response efficacy, self-efficacy, self-monitoring and regulation, and management objectives yielded generally better scores in the intervention group than in the control group at T2 and T3, statistical significance was not achieved.

Table 2 The intervention effect of psychological cognitions and weight management behaviors based on unadjusted and adjusted general linear models (N=302)

Outcomes	Time	Intervention group (N=150)		Control group (N=152)		Model 1 [a]			Model 2 [b]		
		Mean	SD	Mean	SD	B	95%CI	*p*	adjusted B	adjusted 95%CI	*p*
Psychological cognitions											
Information	T1	13.77	3.10	13.55	2.90	0.221	-0.459,0.901	0.524	0.174	-0.500,0.849	0.611
	T2	16.54	2.96	15.69	3.23	0.849	0.148,1.551	**0.018**	0.836	0.139,1.534	**0.019**
	T3	17.25	3.02	16.53	3.28	0.720	0.007,1.434	**0.048**	0.678	-0.031,1.387	0.061

Behavioral Skills	T1	17.11	3.76	16.36	3.97	0.751	-0.124,1.627	0.092	0.731	-0.144,1.606	0.101
	T2	17.30	3.61	16.71	3.93	0.589	-0.265,1.444	0.176	0.615	-0.234,1.465	0.155
	T3	18.31	4.14	17.81	4.04	0.497	-0.429,1.424	0.291	0.483	-0.434,1.401	0.301
Perceived Severity	T1	21.24	4.60	21.36	4.45	-0.122	-1.147,0.903	0.815	-0.175	-1.184,0.834	0.733
	T2	21.95	3.82	21.90	3.60	0.045	-0.795,0.885	0.915	0.035	-0.807,0.877	0.934
	T3	21.72	3.83	21.55	3.61	0.174	-0.669,1.017	0.685	0.109	-0.722,0.939	0.797
Perceived Vulnerability	T1	19.32	3.50	19.31	3.63	0.011	-0.796,0.818	0.979	0.009	-0.803,0.821	0.982
	T2	19.54	3.23	18.63	3.65	0.915	0.134,1.696	**0.022**	0.894	0.113,1.675	**0.025**
	T3	19.66	3.56	18.58	3.89	1.081	0.237,1.926	**0.012**	1.078	0.231,1.924	**0.013**
Response Efficacy	T1	21.81	3.68	22.28	3.72	-0.463	-1.302,0.376	0.278	-0.523	-1.351,0.305	0.215
	T2	21.93	3.54	21.61	4.09	0.321	-0.545,1.188	0.466	0.313	-0.553,1.178	0.478
	T3	21.85	3.65	21.47	3.77	0.386	-0.454,1.227	0.367	0.347	-0.493,1.187	0.417
Self-efficacy	T1	19.94	3.88	20.14	3.94	-0.205	-1.090,0.681	0.649	-0.233	-1.120,0.655	0.606
	T2	18.89	3.94	18.64	4.08	0.249	-0.660,1.157	0.591	0.326	-0.575,1.227	0.477
	T3	19.01	4.57	18.70	4.18	0.316	-0.676,1.308	0.531	0.342	-0.649,1.334	0.497
Response Cost	T1	17.13	4.09	16.65	4.55	0.482	-0.498,1.462	0.334	0.492	-0.483,1.467	0.322
	T2	18.15	3.33	17.05	3.51	1.101	0.326,1.875	**0.005**	1.101	0.325,1.876	**0.006**
	T3	18.40	3.58	16.88	4.13	1.518	0.643,2.394	**0.001**	1.538	0.663,2.414	**0.001**
Weight Management Behaviors											
Exercise Management	T1	22.81	5.71	21.87	6.22	0.945	-0.407,2.297	0.170	0.849	-1.489,2.187	0.213
	T2	25.66	6.75	23.55	7.50	2.107	0.491,3.724	**0.011**	2.089	-0.477,3.702	**0.011**
	T3	26.86	7.47	25.41	7.13	1.452	-0.202,3.106	0.085	1.420	-0.238,3.078	0.093

Diet Management	T1	13.33	3.59	13.10	3.32	0.228	-0.554,1.010	0.567	0.166	-0.602,0.935	0.670
	T2	12.67	3.42	12.59	3.18	0.081	-0.666,0.828	0.831	-0.003	-0.729,0.724	0.995
	T3	13.68	2.79	12.64	3.41	1.035	0.329,1.741	**0.004**	0.959	0.269,1.648	**0.007**
Self-monitoring and Regulation	T1	10.91	3.44	10.60	3.52	0.308	-0.480,1.096	0.443	0.235	-0.540,1.009	0.551
	T2	11.08	3.26	10.89	3.20	0.185	-0.547,0.917	0.619	0.119	-0.588,0.826	0.741
	T3	12.31	3.32	11.87	3.21	0.445	-0.295,1.185	0.238	0.394	-0.333,1.120	0.287
Management Objectives	T1	6.65	2.97	5.94	2.86	0.713	0.052,1.373	**0.035**	0.686	0.024,1.349	**0.042**
	T2	6.40	2.89	6.14	2.82	0.262	-0.384,0.908	0.426	0.229	-0.416,0.875	0.485
	T3	7.37	3.30	7.07	2.77	0.294	-0.395,0.984	0.401	0.272	-0.415,0.958	0.436
Total Scores	T1	53.70	11.07	51.51	11.52	2.193	-0.366,4.753	0.093	1.936	-0.571,4.444	0.130
	T2	55.81	12.32	53.18	12.83	2.636	-0.214,5.485	0.070	2.435	-0.368,5.239	0.088
	T3	60.22	13.57	56.99	13.46	3.227	0.167,6.287	0.039	3.044	0.006,6.081	0.050

Note:
SD=Standard deviation; B=regression coefficient; CI=Confidence Interval; T1=first trimester; T2=second trimester; T3=third trimester.
a Model 1 was not adjusted for covariables.
b Model 2 was adjusted for covariables, including age, education level, parity, and pre-pregnancy body mass index. The reference group comprised the control group.

Generalized estimating equations for psychological cognition and weight management behaviors

Psychological cognitions and weight management behaviors were used as dependent variables, while time and group were used as independent variables in the generalized estimating equation analysis **(Table 3).** Regarding psychological cognitions, a statistically significant group effect on information (B = 0.597, 95% CI: 0.035–1.158, p = 0.037), perceived vulnerability (B = 0.669, 95% CI: 0.050–1.288, p = 0.034), and response cost (B = 1.034, 95% CI: 0.367–1.700, p = 0.002) were observed. Moreover, time had a statistically significant effect on information (T2: B = 2.457, 95% CI = 2.866–2.832, p < 0.001; T3: B = 3.235, 95% CI: 2.859–3.611, p < 0.001) and response cost (T2: B = 0.702, 95% CI: 0.203–1.201, p = 0.006; T3: B = 0.745, 95% CI: 0.199–1.291, p = 0.008). However, no significant differences were noted in the perceived severity and response efficacy dimensions among the groups and times.

Regarding weight management behaviors, the two groups had a statistically significant effect on

exercise management (B = 1.501, 95% CI: 0.232–2.771, p = 0.020). Furthermore, time had a statistically significant effect on exercise management (T2: B = 2.262, 95% CI: 1.489–3.034, p < 0.001; T3: B = 3.791, 95% CI: 2.999–4.584, p < 0.001) and dietary management (T2: B = –0.579, 95% CI: 0.818–1.824, p = 0.007). Regarding total weight management behavioral scores, the group (B = 2.685, 95% CI: 0.323–5.047, p = 0.026) and time (T2: B = 1.891, 95% CI: 0.524–3.258, p =0.007; T3: B = 6.000, 95% CI: 4.527–7.473, p < 0.001) effects were all statistically significant.

Table 3 Changes in psychological cognitions and weight management behaviors at T2 and T3 in control and intervention group compared to baseline (T1) based on generalized estimating equation models

Outcomes	Independent Variables [a]	Category	B	95% CI	Wald χ^2	*p*
Psychological cognition						
Information	Group	Intervention	0.597	0.035□1.158	4.341	**0.037**
	Time	T2	2.457	2.086□2.832	164.991	**□0.001**
		T3	3.235	2.859□3.611	284.399	**□0.001**
Behavioral Skills	Group	Intervention	0.613	-0.091□1.317	2.912	0.088
	Time	T2	0.268	-0.179□0.715	1.381	0.240
		T3	1.321	0.818□1.824	26.525	**□0.001**
Perceived Severity	Group	Intervention	0.032	-0.686□0.751	0.008	0.929
	Time	T2	0.632	0.121□1.124	5.919	0.015
		T3	0.331	-0.181□0.843	1.609	0.205
Perceived Vulnerability	Group	Intervention	0.669	0.050□1.288	4.485	**0.034**
	Time	T2	-0.235	-0.675□0.204	1.099	0.294
		T3	-0.199	-0.690□0.293	0.628	0.428
Response Efficacy	Group	Intervention	0.082	-0.602□0.765	0.055	0.815
	Time	T2	-0.275	-0.726□0.176	1.424	0.233
		T3	-0.387	-0.803□0.029	3.333	0.068
Self-efficacy	Group	Intervention	0.120	-0.607□0.847	0.104	0.747
	Time	T2	-1.275	-1.798□-0.751	22.775	**□0.001**
		T3	-1.189	-1.687□-0.690	21.858	**□0.001**
Response Cost	Group	Intervention	1.034	0.367□1.700	9.244	**0.002**
	Time	T2	0.702	0.203□1.201	7.611	**0.006**
		T3	0.745	0.199□1.291	7.147	**0.008**
Weight Management Behavior						
Exercise Management	Group	Intervention	1.501	0.232□2.771	5.373	**0.020**
	Time	T2	2.262	1.489□3.034	32.902	**□0.001**
		T3	3.791	2.999□4.584	87.977	**□0.001**
Diet Management	Group	Intervention	0.448	-0.121□1.017	2.384	0.123

	Time	T2	-0.579	-1.003□-0.156	7.200	**0.007**
		T3	-0.053	-0.506□0.400	0.053	0.819
Self-monitoring and Regulation	Group	Intervention	0.313	-0.275□0.900	1.088	0.297
	Time	T2	0.235	-0.192□0.663	1.162	0.281
		T3	1.338	0.891□1.784	34.495	□**0.001**
Management Objectives	Group	Intervention	0.423	-0.091□0.937	2.603	0.107
	Time	T2	-0.026	-0.415□0.362	0.018	0.894
		T3	0.924	0.546□1.302	22.967	□**0.001**
Total Points	Group	Intervention	2.685	0.323□5.047	4.964	**0.026**
	Time	T2	1.891	0.524□3.258	7.347	**0.007**
		T3	6.000	4.527□7.473	67.720	□**0.001**

Note:

GEE=generalized estimating equation; B=coefficient; T2=second trimester; T3=third trimester.
[a] For the group, the control group was the reference; for time, the first trimester (T1) was the reference.

Discussion

To the best of our knowledge, this RCT is the first to use mobile health intervention guided by the novel PMT-IBM behavioral theory and test its effectiveness on gestational weight management. Although the mechanism underlying this phenomenon requires further research, statistically significant results suggest that the intervention potentially plays positive roles in raising psychological cognitions in weight management including information, perceived vulnerability, and response cost, as well as promoting dietary and exercise management during pregnancy.

Effect on psychological cognitions

Most pregnant women lack awareness and hold misguided beliefs regarding weight gain and management. Moreover, a general lack of awareness regarding the specific risks of being overweight or obese during pregnancy is also an important barrier to appropriate GWG. [30] Based on our findings, promoting healthy behaviors in terms of information, perceived vulnerability, and response cost, via mobile health, are of practical relevance. Mobile health technologies such as apps can be applied to the design of the content of online interventions for these important psychological cognition dimensions. The intervention content should focus on increasing awareness regarding GWG and control, and perceived vulnerability to adverse outcomes and risks, while decreasing perceptions of difficult decision-making and personal insecurities. However, no statistically significant between-group differences were noted in the behavioral skills, perceived severity, self-efficacy, and response efficacy dimensions. This may be because most pregnant women lack persistence in long-term dietary management and physical exercise and have limited ability to control weight and achieve exercise compliance based on healthy behaviors in reality. [31,32] Furthermore, some pregnant women insufficiently recognize the seriousness of inappropriate GWG, mistakenly believing that pregnancy is perilous by nature and that the occurrence of complications is random. [33]In addition, due to the free availability of extensive information on the Internet, the control group also had extra opportunities to access health information or learn them on their own from other sources, which may have affected the accurate evaluation of the intervention. The effectiveness of interventions informed by the theory may be affected by how successfully the theory is applied to the intervention. Although theories are ideal for explaining and validating behavior, they may not be excellent for guiding interventions because of several complicated variables, including

time of exposure and environment (i.e., exposure to advertisements promoting fast food and sugary beverages). Therefore, this potentially leads to deviations from the theoretical to the actual effects. [34] Furthermore, in the process of developing the intervention, attention should be paid to the environment and intensity of intervention; moreover, differences in social, economic, cultural, and other factors should be considered. [35]

Effect on weight management behaviors

Our findings indicate that the intervention group's exercise management significantly improved at T2. Evidence from a previous meta-analysis also suggests that prenatal exercise may be an effective method to promote appropriate birth weight of newborns and GWG.[36] In this study, exercise behavior was measured only by the gestational weight management behavioral scales, and future studies should include objective measures of physical activity (i.e., step number or physical activity measuring tools) at different stages of pregnancy to evaluate the potential of mobile health intervention in improving gestational exercise. At T3, statistically significant improvements were noted in the intervention group's dietary management but not in exercise management. A possible explanation could be that pregnant women may experience obvious weight gain in the third trimester compared with that at pre-pregnancy. The altered body shape potentially results in physical activity restriction, leading pregnant women to prefer weight management through a healthy diet. [37] Therefore, in the third trimester, physical activity should be emphasized and health education related to suitable exercise should be reinforced. Previous studies have found smartphone applications and other digital interventions to promote a healthy diet among pregnant women with obesity and overweight. [38,39]However, altering the long-term dietary patterns in this intervention study, which focused on psychological cognition, proved difficult, and this might have been influenced by deeply rooted Chinese concepts (i.e., "the better the eating during pregnancy, the better the growth of the fetus"). Furthermore, dietary behavioral modification is influenced by external conditions (i.e., the convenience of accessing healthy foods), which is beyond the current intervention. Therefore, the ideal dietary intervention should be considered from multiple perspectives, including some external reinforcing factors.

Strengths and limitations

This study has several strengths. First, compared with previous similar studies, [39-41]the population in this study not only included women who were overweight or obese prior to pregnancy but also included women of all BMI categories. Second, the behavioral intervention used two classical behavioral theoretical models so that intervention framework was multi-dimensional, providing a multi-pronged approach to gestational weight management.

However, this study has several limitations that warrant consideration. First, participants were recruited from a single hospital in Jiangsu Province, which may not adequately represent the entire target population globally. Multi-regional, multi-center RCT should be conducted in the future. Second, the outcomes were self-reported by participants, thus potentially leading to reporting and recall bias. Third, the nonrandom sampling method could result in some selection bias. Fourth, the mean and SD values of psychological and behavioral scales were similar across the groups; therefore, the significance of the findings needs to be further examined and the results need to be carefully interpreted.

Conclusions

This study assessed the applicability and effectiveness of a gestational weight mobile health intervention program based on the behavioral model integrated with PMT-IMB model. This intervention enhanced the psychological cognition among pregnant women in information, perceived vulnerability, and response cost, improved dietary and exercise management. Further research is necessary to confirm the generalizability, operability, and durability of our findings in practice.

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Conflict of interest

None.

Abbreviations

GWG: gestational weight gain

PMT-IMB model: protection motivation theory and information–motivation–behavior skills model

RCT: randomized controlled trial

BMI: body mass index

T1: first trimester

T2: second trimester

T3: third trimester

SD: standard deviation

ORa: adjusted odds ratio

CI: confidence interval

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Author Contributions

H.Y., M.Z. and L.W. designed the study and critically reviewed, commented, and revised the manuscript. M.Z., H.Y., and J.J.G. participated in data analysis, performed the final statistical analyses, and prepared the first version of the manuscript. M.Z., J.J.G., L.W. and. S.Q.Z. collected the data. M.Z., J.J.G., and. S.Q.Z. collected literature materials. All authors have read and agreed to the published version of the manuscript.

Supporting information

Additional supporting information may be obtained by contacting the corresponding author.

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Supplementary Files

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Figures

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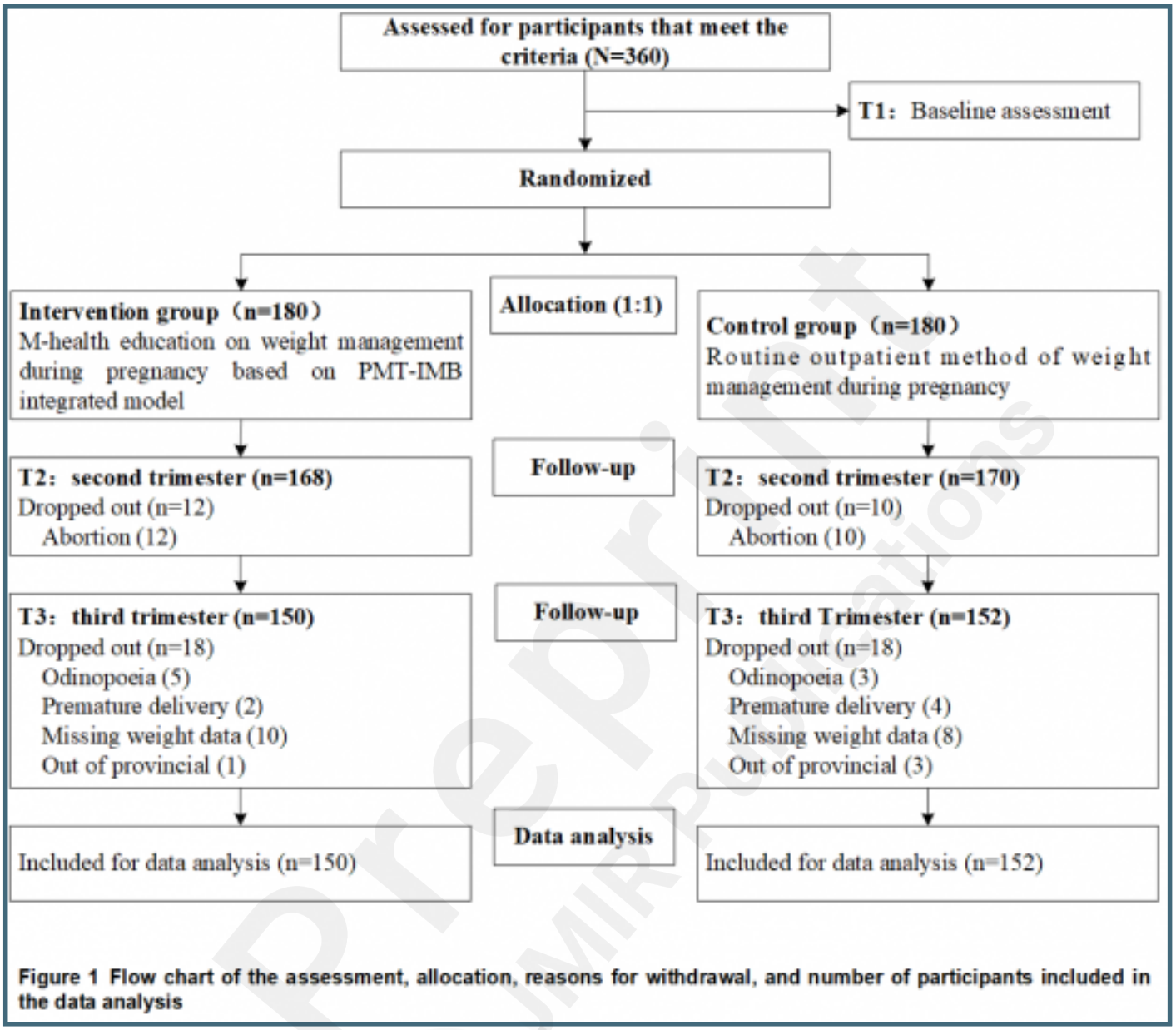

Figure 1 Flow chart of the assessment, allocation, reasons for withdrawal, and number of participants included in the data analysis

CONSORT???????s

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