Change Request
October 30, 2017

"Balance After Baby Intervention"
OMB no. 0920-1115, exp. date 6/30/2019

Background and Justification

CDC is approved to collect information needed to evaluate the web-based Balance After Baby Intervention. This information includes access to an interactive version of the Balance After Baby Intervention (BABI) website for the intervention group and a "control version" for the control group, and five clinical assessment visits for both groups which include visit-specific surveys and laboratory tests.

CDC obtained approval for information collection in June 2016 and is requesting four changes, as outlined below.

Change #1.
We propose adding an approved question to two of the survey tools. Under the current approval, we have a question asking about participation in other lifestyle programs at the end of the 12-month and 24-month surveys. We would like to add this question to the 6-month survey (Attachment 4 [all versions] – page 22 in English version) and 18-month survey (Attachment 6 [all versions] – page 21 in English version). The purpose of this change is to better keep track of participation in other programs, and to understand and control for effects of other programs on the Balance After Baby Intervention. The proposed data element will allow for the most efficient capture of other tools used during the intervention at all data collection time periods.

The question is:

Since you had your baby, did you participate in a weight loss or lifestyle program or use any other tools to help you get healthy other than the Balance After Baby program?
(select all that apply)

☐ No

☐ Joined a commercial program (i.e., Jenny Craig, Weight Watchers, etc.)

☐ Met with a nutritionist

☐ Met with a lifestyle coach (Control Version Only)

☐ Joined a gym

☐ Used a fitness tracking program or app (such as Fitbit or other apps)

☐ Used a pedometer (Control Version Only)

☐ Other fitness tools: _____

Change #1 will have minimal impact on the time burden in that it adds just 1 question to surveys with 102 and 100 questions:

Attachment	Instrument	Number of Questions under Current Approval
4 (all versions)	6-Month Questionnaire Screenshots	102
6 (all versions)	18-Month Questionnaire Screenshots	100

Change #2.

We would like to reword the first question of the 6-week questionnaire to make the question clearer (Attachment 3 [all versions] – page 2 in English version). The proposed edit is illustrated below:

~~1- Do you have a prior history of gestational diabetes? ☐ Yes ☐ No~~

~~a. If yes, how many times were you diagnosed with gestational diabetes?~~

~~_____~~

1- Before this most recent pregnancy, did you have gestational diabetes in any pregnancy?

☐ Yes ☐ No

a. If yes, in how many pregnancies were you diagnosed with gestational diabetes, not including this most recent one? _____

Change #2 will affect BABI information collection instruments as follows and will have no impact on the time burden:

Attachment	Instrument	Status of Change #2
3 (all versions)	6-Week Questionnaire Screenshots	Requesting approval to modify, no impact on burden

Change #3.

We would like to revise the explanatory text immediately preceding the Burden Statement on the Welcome Page for the 6-week, 6-month, 12-month, 18-month, and 24-month questionnaires. The purpose of this change is to clarify the overall estimated burden time to participants at each visit. Specifically, in the explanatory text, we would like to specify that two questionnaires will be administered (the visit-specific questionnaire and the Food Frequency Questionnaire, which is completed at each visit) and we would like to indicate the estimated burden time for each questionnaire. We are not requesting any edits to the Burden Statement on the visit specific questionnaires or on the food frequency questionnaire. The proposed edit to the explanatory texts on the visit specific questionnaires is illustrated below (new text is highlighted in yellow):

Current Wording:

THANK YOU for taking part in this important project to help us test whether a lifestyle program, designed specifically for women like you with a recent history of gestational diabetes mellitus (GDM), will help women lose weight gained during pregnancy and reduce risk factors for developing type 2 diabetes. The questionnaire will tell us about your medical history, physical activity levels, current diet, mood, and perceived stress. You can skip any questions you choose not to answer. Your answers to this questionnaire will not be shared with anyone outside of the study staff.

Public reporting of this collection of information is estimated to average [customized for length of study-specific survey] minutes/hours per response, including the time for reviewing instructions and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a current valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-1115). Exp. Date 6/31/2019

Revised Wording:

THANK YOU for taking part in this important project to help us test whether a lifestyle program, designed specifically for women like you with a recent history of gestational diabetes mellitus (GDM), will help women lose weight gained during pregnancy and reduce risk factors for developing type 2 diabetes. We will be asking you to complete two questionnaires. The first questionnaire will take about [customized for length of study-specific survey] minutes. It will tell us about your medical history, physical activity levels, mood, and perceived stress. The second questionnaire will take about 18 minutes. It will tell us about the foods you usually eat. You can skip any questions you choose not to answer. Your answers will not be shared with anyone outside of the study staff.

Public reporting of this collection of information is estimated to average [customized for length of study-specific survey] minutes per response, including the time for reviewing instructions, searching existing data/information sources, gathering and maintaining the data/information needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-1115). Exp. Date 6/31/2019

Change #3 will affect the following BABI information collection instruments and will have no effect on the time burden:

Attachment	Instrument	Status of Change #3
3 (all versions)	6-Week Questionnaire Screenshots	Requesting approval to modify introductory statement, no impact

		on burden
4 (all versions)	6-Month Questionnaire, Screenshots	Requesting approval to modify introductory statement
5 (all versions)	12-Month Questionnaire, Screenshots	Requesting approval to modify introductory statement
6 (all versions)	18-Month Questionnaire, Screenshots	Requesting approval to modify introductory statement
7 (all versions)	24-Month Questionnaire, Screenshots	Requesting approval to modify introductory statement

Change #4.

We propose adding open-ended questions to the end of the 6-month and 12-month questionnaires (Attachments 4 and 6, respectively [all versions]), in order to systematically collect participants' feedback about Balance After Baby. We propose adding 4 open-ended questions for participants in the control group (Attachments 4-C [English version]/4s-C [Spanish version] – page 23 in English version; Attachment 5-C [English version]/5s-C [Spanish version] – page 35 in English version). We propose adding 5 open-ended questions for participants in the intervention group (Attachments 4-I [English version]/4s-I [Spanish version] – page 23 of English version; Attachment 5-I [English version]/5s-I [Spanish version] – page 35 of English version).

Balance After Baby study coordinators have commented that, during routine conversations between coordinators and participants (e.g. upon greeting participants for a study visit), most participants are voluntarily providing feedback and/or wishing to discuss how they engage with different Balance After Baby components; the proposed open-ended questions will systematically capture this information that is already being volunteered. Furthermore, the addition of 4 or 5 questions to the 6-month and 12-month questionnaires, which contain 102 and 152 questions, respectively, will represent minimal extra burden to participants. For these reasons, we estimate that adding these questions will only add 2 minutes of burden time.

Change #4 will affect the following BABI instruments:

Attachment	Instrument	No. of Questions under Current Approval	No. of Proposed Questions to Add
4-I and 4s-I	6-Month Questionnaire, Screenshots, Intervention Group	102	5
4-C and 4s-C	6-Month Questionnaire, Screenshots, Control Group	102	4
5-I and 5s-I	12-Month Questionnaire, Screenshots, Intervention Group	152	5
5-C and 5s-C	12-Month Questionnaire, Screenshots, Control Group	152	4

Timeline and Impact on Burden

CDC plans to begin administering the revised instruments in 2018. OMB approval is requested, effective immediately. The estimated average annualized burden per response will increase from 14.9 minutes to 15.4 minutes, with an estimated increase of 4 total annualized burden hours.

Estimated Annualized Burden Hours Before Proposed Changes

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden Hours per Response	Total Burden Hours
Provider or self-referred postpartum women with recent GDM diagnosis	BABI Screener Questionnaire	98	1	8/60	13
Consented and enrolled postpartum women with recent GDM diagnosis	BABI 6-Week Questionnaire	63	1	17/60	18
	BABI 6-Month Questionnaire	60	1	18/60	18
	BABI 12-Month Questionnaire	57	1	14/60	13
	BABI 18-Month Questionnaire	54	1	14/60	13
	BABI 24-Month Questionnaire	51	1	15/60	13
	Block FFQ (Completed at each visit.)	63	5	18/60	95
				Total	183

Estimated Annualized Burden Hours After Proposed Changes

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden Hours per Response	Total Burden Hours
Provider or self-referred postpartum women with recent GDM diagnosis	BABI Screener Questionnaire	98	1	8/60	13
Consented and enrolled postpartum women with recent GDM diagnosis	BABI 6-Week Questionnaire	63	1	17/60	18
	BABI 6-Month Questionnaire	60	1	20/60	20

	BABI 12-Month Questionnaire	57	1	16/60	15
	BABI 18-Month Questionnaire	54	1	14/60	13
	BABI 24-Month Questionnaire	51	1	15/60	13
	Block FFQ (Completed at each visit.)	63	5	18/60	95
				Total	187