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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-16-15BEB]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of

the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Balance After Baby Intervention – New – National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The CDC Division of Reproductive Health (DRH) is focused on understanding and preventing complications due to pregnancy and the development of chronic diseases in reproductive age women.

Similarly, the CDC established the National Diabetes Prevention Program (NDPP), administered through the Division of Diabetes Translation (DDT), to make strategies for preventing type 2 diabetes broadly available to individuals at high risk of developing diabetes. Gestational diabetes mellitus (GDM) is one of the most common pregnancy complications in the US, affecting approximately 3-13% of pregnancies, or approximately 200,000 cases annually. As defined by the American Diabetes Association (2003), GDM is glucose intolerance that first presents during pregnancy after the first trimester. Women with a history of GDM have a substantially increased risk of developing type 2 diabetes mellitus (T2DM) within 5 to 16 years after their index pregnancy. It has also been shown that many women with a history of GDM gain weight after pregnancy, increasing their risk for obesity, which itself is a strong risk factor for repeat GDM and T2DM. Because of this, as US obesity prevalence continues to increase, there is a concurrent rise in the incidence and prevalence of GDM and T2DM, resulting in a large disease burden on individuals, families, and society. To assist in reducing this national disease burden, it is critical to develop and implement successful interventions that reduce the annual number of newly diagnosed T2DM cases, especially in increased risk populations, such as women with a history of GDM. As part of this Healthy People 2020 objective, the Diabetes Prevention

Program (DPP) demonstrated that an intensive lifestyle intervention (16 face-to-face sessions over a 24-week period) promoting physical activity, healthy eating, and weight reduction significantly decreased T2DM incidence by 58% in high risk patients. However, the DPP included predominantly older individuals whose ability to attend group meetings and adopt healthy lifestyle changes is different than younger postpartum women. For this reason, successful adaptations of the DPP that address barriers in postpartum women with recent GDM, such as limited time and resources, fatigue, and childcare demands, must be identified and tested.

This Balance After Baby Intervention (BABI) data collection request aims to collect information that can be used to evaluate an intervention that addresses these barriers through the conduct of a randomized, controlled intervention trial of a website-based lifestyle program, Balance after Baby (BAB), that is adapted from the DPP and tailored specifically for postpartum women with recent GDM.

The project aims to screen 293 (98 annualized over 3 years) women with a recent GDM pregnancy for enrollment into the study, followed by assessments at the following five post-partum time points: 6-weeks, 6-months, 12-months, 18-months, and 24-months. Of the estimated 190 (63 annualized) women who are anticipated to meet eligibility requirements and attend the

first study visit, approximately half will be assigned to the control group and the other half will be assigned to the intervention group. Women in the control group will have access to a "control version" of the BABI website, containing post-partum information such as the "It's Never too Early to Prevent Diabetes" tip sheet and links to other related public websites. Those assigned to the intervention group will have access to the full, interactive version of the BABI website and will be instructed to log-on once a week to view educational modules regarding healthy lifestyle options and to enter and track their weight and physical activity against their self-appointed goals. They will also have access to a web-based Lifestyle Coach who will communicate with them throughout the first year of their participation.

All participants will be required to complete clinical assessment visits involving the completion of visit-specific questionnaires with integrated food frequency questionnaires, laboratory testing, and the collection of physical measurements such as height and weight. The results of the two study arms, intervention and control, will be compared to assess whether the intervention significantly increased postpartum weight loss and decreased glucose tolerance for women at increased T2DM risk.

For the calculation of the estimated burden hours per study

visit detailed in the table below, a constant 5% rate of exclusion and attrition was applied between visits. The burden table provides a participant estimate, which will be evenly distributed across control and intervention groups for each information collection step (both groups complete the same questionnaires), annualized over a 3-year clearance period. Therefore, of the 190 women (63 annualized) who attend the 6-week visit, the estimated number of participants returning for the 6-month visit is reduced to 180 (60 annualized), followed by 172 (57 annualized), 162 (54 annualized), and 154 (51 annualized) for the 12-, 18-, and 24-month visits respectively. The average burden per questionnaire ranges from 8 minutes for the BABI Screener Questionnaire up to 18 minutes for the BABI 6-Month Questionnaire. The average burden hours per response for the 6-Week, 6-, 12-, 18-, 24-Month Questionnaires, and Block© Food Frequency Questionnaire (FFQ) are shown in the table below. Participation is voluntary and there are no costs to respondents other than their time.

The total estimated annualized burden hours are 183.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)
Women with a recent history GDM	BABI Screener Questionnaire	98	1	8/60
	BABI 6-Week Questionnaire	63	1	17/60
	BABI 6-Month Questionnaire	60	1	18/60
	BABI 12-Month Questionnaire	57	1	14/60
	BABI 18-Month Questionnaire	54	1	14/60
	BABI 24-Month Questionnaire	51	1	15/60
	Block FFQ	63	5	18/60

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