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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-15-15BEB]

[Docket No. CDC-2015-0071]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS)

ACTION: Notice with comment period

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collect

project entitled *Balance After Baby Intervention: Phase 2 (BABI2.)* A three-year clearance is requested to conduct a randomized controlled trial of a website-based lifestyle program with a racially diverse population of postpartum women who had recent Gestational diabetes mellitus (GDM).

DATES: Written comments must be received on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2015-0071 by any of the following methods:
Federal eRulemaking Portal: Regulation.gov. Follow the instructions for submitting comments.
Mail: Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

Please note: All public comment should be submitted through the Federal eRulemaking portal (Regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Balance After Baby Intervention: Phase 2 (BABI2) – 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 BABI2 data collection request aims to address 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 will meet eligibility requirements and attend the first study visit, approximately half will be assigned to the control group and will receive standard postpartum follow-up, while those assigned to the intervention group will have access to the BAB informational website and a lifestyle coach. For all participants, the BABI2 study visits will involve the completion of visit-specific questionnaires, laboratory testing, and the collection of physical measurements such as height and weight. Collected data will be used by CDC and BABI2 investigators to assess the impact and effectiveness of the BABI2 intervention as a potential public health weight loss tool 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, annualized over a 3-year collection 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 BABI2 Screener Questionnaire up to 36 minutes for the BABI2 6-month Questionnaire.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)
Women with a recent history GDM	BABI2 Screener Questionnaire	98	1	8/60	13
Women with a recent history GDM	BABI2 6-Week Questionnaire	63	1	35/60	37
Women with a recent history GDM	BABI2 6-Month Questionnaire	60	1	36/60	36

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)
Women with a recent history GDM	BABI2 12-Month Questionnaire	57	1	32/60	31
Women with a recent history GDM	BABI2 18-Month Questionnaire	54	1	32/60	29
Women with a recent history GDM	BABI2 24-Month Questionnaire	51	1	33/60	28
Total					174

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Leroy A. Richardson
Chief, Information Collection Review Office
Office of Scientific Integrity
Office of the Associate Director for Science
Office of the Director
Centers for Disease Control and Prevention

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