

Impact of Computer-Based Pregnancy-Induced Hypertension and Diabetes Decision Aids on Empowering Pregnant Women

Azam Aslani, PhD¹, Fatemeh Tara, MD^{2,3}, Lila Ghalighi, PhD⁴, Omid Pournik, PhD¹, Sabine Ensing, MD⁵, Ameen Abu-Hanna, PhD⁵, Saeid Eslami, PhD^{1,5,6}

¹Department of Medical Informatics, Mashhad University of Medical Sciences, Mashhad, Iran; ²Research Center for Patient Safety and ³Department of Obstetrics and Gynecology, Mashhad University of Medical Sciences, Mashhad, Iran; ⁴Mental Health Research Center, Iran University of Medical Sciences, Tehran, Iran; ⁵Department of Medical Informatics, Academic Medical Center, University of Amsterdam, Amsterdam, Netherlands; ⁶Pharmaceutical Research Center, School of Pharmacy, Mashhad University of Medical Sciences, Mashhad, Iran

Objectives: We designed a computer-based decision aid (CDA) for use by pregnant women at home to investigate and participate in solving their pregnancy problems related to pregnancy-induced hypertension (PIH) and gestational diabetes (GD). The system cannot and is not intended to replace visits to physicians; rather it can help women focus on the most important symptoms and provides guidance on when to see a doctor. **Methods:** The study is a randomized controlled trial, which is performed among Iranian pregnant women. For subjects, 420 healthy pregnant women have been recruited from two private and two public prenatal centers. The intervention group will receive the CDA for use at home, and the control group will receive care as usual. The CDA relies on knowledge extracted from the national guidelines on PIH and GD. **Results:** The two primary outcomes for the study are self-efficacy and knowledge. Self-efficacy will be measured by the Stanford self-efficacy scale and knowledge will be evaluated by 15 binary (true/false) questions provided by the researchers. Secondary outcomes include type and frequency of doctor and/or medical center visits; blood pressure and blood sugar changes based on the national guidelines and according to pregnancy records, and anxiety will be assessed by the state component of the short Spielberger anxiety scale. **Conclusions:** This paper describes the design of a CDA and a protocol for a randomized controlled trial to study the effects of the CDA on self-efficacy and knowledge of pregnant women pertaining to PIH and GD. Differences in the primary outcomes will be analyzed using 'intention-to-treat' principles.

Keywords: Decision Support Technique, Decision Aid, Pregnancy-Induced Hypertension, Gestational Diabetes, Prenatal Education

Submitted: January 13, 2014

Revised: 1st, March 25, 2014; 2nd, August 29, 2014

Accepted: September 10, 2014

Corresponding Author

Saeid Eslami, PhD

Pharmaceutical Research Center, Mashhad University of Medical Sciences, P.O. Box 91875-1365, Mashhad, Iran. Tel: +98-5138002429, Fax: +98-5138828560, E-mail: EslamiS@mums.ac.ir; S.Eslami@amc.uva.nl

*This trial is registered with the Iran Trial Register under registration number IRCT2013103010777N2.

This is an Open Access article distributed under the terms of the Creative Commons Attribution Non-Commercial License (<http://creativecommons.org/licenses/by-nc/3.0/>) which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.

© 2014 The Korean Society of Medical Informatics

I. Introduction

Every two minutes a woman loses her life because of pregnancy complication. This occurs in 99% of the cases in developing countries. The World Health Organization estimates the maternal mortality rate in Iran at 30 in 100,000 live births [1]. Pregnancy-induced hypertension (PIH) is the cause of death in 17% of these cases, and it is followed by signs and symptoms of preeclampsia in almost half the cases. In fact, hypertensive disorders remain among the most significant and unsolved problems in obstetrics [2].

Gestational diabetes (GD) is another pregnancy complica-

tion that can affect the developing baby throughout the pregnancy. In early pregnancy, a mother's diabetes can result in birth defects that affect major organs, such as the brain and heart. During the second and third trimesters, a mother's diabetes can lead to over-nutrition and excessive growth of the baby. The large babies often require caesarean deliveries, and if delivered vaginally, they are at increased risk of trauma to their shoulders [2,3].

Most cases of pregnancy complications (bleeding, high blood pressure, infections) are predictable, and better health follow-up, especially during pregnancy, would be the key to prevention [1,4]. The reported main causes of maternal death are lack of awareness of dangerous symptoms during pregnancy and ignoring advice from physicians and health-care providers [5].

'Information' is the primary element in pregnancy health-care and the key to empowering pregnant women. Without information, people cannot actively participate in the care process and make smart decisions about medical intervention [6,7]. Ideally (as long as they wish), all patients (and consumers) should be able to access valid and relevant information about their health status. It is assumed that informed mothers may feel more in control of their new status, indulge more in self-care during pregnancy, and increase their adherence to treatment recommendations [6,8].

Consumer health informatics is designed to empower consumers by putting health information into their hands. Patient empowerment refers to the enhanced ability of patients to actively understand and influence their own health status. In this sense, empowerment is the means, and quality of life is the end [9]. Self-efficacy is a relevant outcome that is commonly used in studies assessing women's empowerment [10]. Self-efficacy is defined as a dynamic cognitive process that represents a personal conviction to successfully perform a required behavior in a given situation [11].

One challenge to bringing medical knowledge to consumers is to develop computer-based decision support systems for use by consumers [12]. Decision support includes telephone decision coaching services, decision aids, one-on-one counseling, group information or support sessions, and decision protocols or algorithms [13]. The main challenge in developing comprehensive systems for consumers is that little is known about how patients interact with computer-based tools and how they digest and act on information [12].

The project aims to empower women by the use of a computer-based decision aid (CDA) on PIH and GD based on the Iranian national guidelines (provided by international evidence). The system generates recommendations based on the user's symptoms and medical history, allows a personal

medical history to be noted, and offers easy to read information. Pregnant women can use this decision support tool at home to investigate health issues and participate in solving their pregnancy problems concerning PIH and GD. This system does not and cannot replace visits to clinicians. In particular, the aim of such support is not to make definitive diagnoses or to propose treatment but to answer simple questions, such as "Do I need to see a doctor?" or "Which symptoms are urgent and need more attention?"

II. Methods

1. Design of the Intervention

The decision aid for PIH and GD has been developed using the three steps of the Ottawa Decision Support framework: identifying needs, providing decision support, and evaluating decision support. A cross-sectional study was done to reveal pregnant women's awareness of dangerous signs in pregnancy and the information seeking patterns of our study target population (under publication). The need for a decision aid was identified following a literature search and by consulting focus groups with experts.

Because of the interactive nature of decision aids, computer-based solutions have clear advantages over traditional media. This computer-based decision system is a self-triage application. The program can be installed on the personal computers or laptops of patients recruited to the intervention group. Services under this system include the following:

1) **Information Retrieval:** provides information on PHI and GD. The content is based on guidelines and research findings. The information that women retrieve is based on a list of topics, and hyperlinks to educational content are placed in the decision support section (more information about symptoms). Feedback is provided based on user responses to multiple choice questions.

2) **Clinical Data Entry:** The following two categories of information are entered into the computer system by pregnant women: (1) general information (e.g., age, gestational age, weight, height) and health history (e.g., history of confirmed preeclampsia, renal disease, smoking, drug abuse), (2) symptoms (having yes or no answers) of PIH and GD for two types of questions: emergency symptoms and flexible symptoms. Pregnant women answer five questions on emergency symptoms ('persistent headache', 'vigorous nausea and vomiting', 'vision changes', 'decreased fetal movements', and 'sever epigastric pain') and on ten flexible symptoms ('weight gain of more than one kg per week', 'weakness', 'hand and face edema', 'hand tremor', 'incontinency', 'constant or decreased weight during past weeks', 'increased thirst', 'increased urina-

tion, ‘infections of bladder and vagina’). The answers to all these questions form the basis for the decision aid’s suggestions. If participants are aware of lab test results, they can also answer nine related questions which will be considered by the system to provide suggestions.

3) **Decision Support Tool:** this is a decision aid in the form of a self-directed, interactive computerized decision aid for PIH and GD (CDA-PIHGD). We use the two types of entered data (the general and symptom information) to create relevant combinations of variables (e.g., gestational age >20 and severe epigastric pain with history of preeclampsia). Based on (inter) national guidelines and other published evidence, we created and classified ten rules based on these variable combinations. The system will advise pregnant women based on these rules. Three types of recommendations are provided: A ‘go to a clinician (or an emergency center) without delay’, B ‘visit a clinician within 24 hours’, and C ‘notify your symptoms to a doctor via telephone call within 24 hours’ (see Figure 1).

4) **Record Notes and Actions:** a history of symptoms that pregnant women enter when they log into the system, and the system’s recommendation, which will be stored in a data-

base residing on the participants’ PC (or laptop).

5) **Reminder:** When a pregnant woman rejects the system’s advice, this is recorded in the system. It is assumed that she did not visit/call the clinicians and she will be reminded about this rejection when she logs into the system again.

In addition to usual care, the intervention group will receive the CDA-PIHGD. The control group will receive usual care. The duration of the intervention is considered from recruitment to the time of delivery. The evaluation of the intervention will be assessed at one week before delivery.

2. Ethics

The ethical committee of Mashhad University of Medical Sciences granted ethics approval to conduct this trial (511/4404). A signed consent form is obtained from all participants at the time of recruitment.

3. Setting for the Trial

The CDA-PIHGD study is being conducted in the primary healthcare setting of Mashhad (second Iranian city with about three million inhabitants). All women planning to give birth

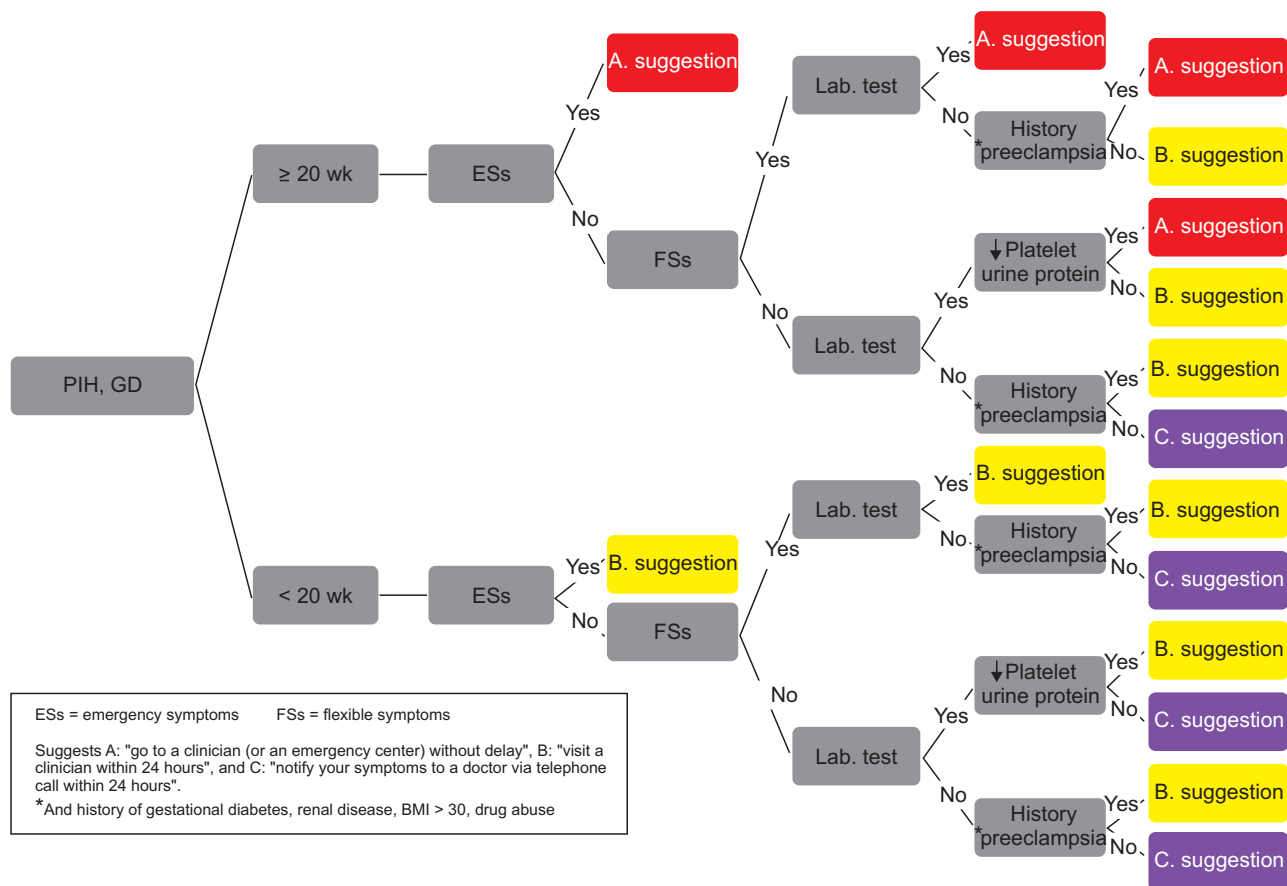


Figure 1. The process of recommendations' suggestion in the computerized decision aid for PIH and GD (CDA-PIHGD). PIH: pregnancy-induced hypertension, GD: gestational diabetes, BMI: body mass index.

at the publicly funded maternity health services (two public health offices) and the private health services (two gynecologists' offices) can participate in this study. Six gynecologists are active at the two public health offices, and they see about 1,700 (250–300 repeated visits) pregnant women per month. The two gynecologists in the private offices see about 700 (100–150 repeated visits) pregnant women per month.

In Mashhad, the provision of information on prenatal caring is not uniform. Some women receive information that is verbal and/or written by participating in a prenatal training, while some women receive information during monthly visits to their gynecologists.

4. Design

Cluster randomization has been chosen to avoid contamination from the intervention to the control group. Gynecologists were randomized either to the intervention arm, providing women with the decision aid, or to the control arm, providing usual care. Gynecologists were used as the unit of randomization.

5. Sample Size

The required sample size has been set at a 0.05 level of significance and 80% power to detect a difference of 15% (40%–55%) in the rate of self-efficacy between women in the intervention and control groups. The anticipated difference in outcome measure was based on a study assessing self-efficacy of women with gestational diabetes according to the Stanford self-efficacy scale [14] and the evaluation of an educational program on the self-efficacy of diabetic patients [15]. Using an intraclass correlation coefficient of 0.05, we have a sample size estimate of 170 women per arm of the trial. The sample size was further adjusted for a 20% attrition rate due to cluster randomization. Finally, we have a sample size estimate of 210 women per arm of the trial.

For the study, inclusion criteria for women were characteristics that healthy pregnant women attending participating gynecologists were eligible to participate provided they were aged 16 years or older with a singleton pregnancy, and had 18 or more weeks of gestation; while women were excluded if they were non-Persian speaking, were unable to give written informed consent, or were unable to read and write or work with a computer. In addition, pregnant women with any complications of pregnancy, such as hypertension and diabetes, at the time of the study were excluded.

6. Data Collection

The women are asked to complete two questionnaires, the first upon entering the study and the second during the last

Pregnancy-Induced Hypertension and Diabetes Decision Aids

week before delivery. Women with unexpected delivery will fill the questionnaires after delivery. Other information (such as, blood pressure and blood sugar of women, baby weight) will be collected from the pregnant women's medical records in hospital and office.

Blinding of the researchers and women subjects was not practical in this study. The gynecologists and participating women in intervention group will experience a new prenatal care service that is different from usual care.

As in a similar study [16] prior to analysis, a random sample of 10% of the entered records will be audited. A person independent of the study will conduct the sampling and audit, and the rate of accuracy will be reported.

III. Results

The two primary outcomes for the study are self-efficacy and knowledge. Self-efficacy will be measured according to the Stanford self-efficacy scale [17]; the difference between the mean self-efficacy scores of women in each arm will be compared. Knowledge will be evaluated by 15 true/false questions which are provided by the researchers.

Secondary outcomes include type and frequency of visiting their doctor and/or a medical center, blood pressure and blood sugar changes according to the national guidelines, which will be measured during the intervention by data available in the pregnancy records. Anxiety will be assessed by state component of the short Spielberger anxiety scale in both arms of the trial [18]. In addition, neonatal mortality, birth weight, and gestational age will be assessed and compared in the two arms.

The acceptability of the CDA to the women subjects and gynecologists will be assessed by interviewing them in both arms of the trial and comparing open-ended comments using content analysis.

IV. Discussion

This study will investigate the effectiveness of the CDA in enhancing the empowerment and self-efficacy of pregnant women. This system advises pregnant women on dealing with PHI and diabetes. We hypothesize that the CDA can improve pregnant women's self-efficacy and confidence in their ability to deal with pregnancy problems. We expect a 15% effect size due to the intervention.

As more health care activities migrate from hospitals to community care, the informatics tools and functionalities also migrate [19]. The CDA-PIHGD is going to transfer triage to pregnant women's homes, and the impact of this

migration of care on the early prevention of gestational hypertension and diabetes progression will be discussed.

Developing countries are faced with some difficulties in implementing IT applications, such as poor economics, political uncertainty, and the lack of cutting edge infrastructure [20]. The CDS implementation will consider these difficulties and provide appropriate solutions. We will explain how we addressed them.

The standard guidelines for statistical reporting of clinical trials will be followed. Differences in the primary outcomes will be analyzed using 'intention-to-treat' principles. The primary outcomes and secondary outcomes will be compared between groups with the *t*-test for knowledge scores and self-efficacy scores. Anxiety will be reported using a Likert scale, and the responses of the two groups will be compared. Confidence intervals and *p*-values will be adjusted for the effect of clustering and loss to follow-up within clusters will be reported.

Randomization at the gynecologists' level is the most appropriate choice in terms of power and also practicality in this study. However, some level of contamination could occur at the level of the participants by women in the intervention group sharing the decision aid with women in the control group within a variety of maternity care environments, as well as through social settings. We will tolerate this level of contamination in public centers; this confounding variable is not present in the private offices. Another limitation of our study is that it includes only pregnant women who are able to work with computers. We will interpret the study results in light of this limitation.

Conflict of Interest

No potential conflict of interest relevant to this article was reported.

Acknowledgments

This work is supported by the Research Council of Mashhad University of Medical Sciences by grants for this study and related PhD project (No. 910525). We sincerely thank the gynecologists involved in the study.

References

1. Iran at a glance [Internet]. Tehran: United Nations Population Fund (UNFPA); c2012 [cited at 2014 Sep 15]. Available from: <http://iran.unfpa.org/Country%20Profile.asp>.
2. Cunningham FG, Leveno KJ, Bloom SL, Hauth JC, Rouse DJ, Spong CY. Williams Obstetrics. 24th ed. New York (NY): McGraw-Hill Education; 2014.
3. Hicks R. Managing gestational diabetes in pregnancy [Internet]. London: WebMD; c2014 [cited at 2014 Sep 15]. Available from: <http://www.webmd.boots.com/diabetes/guide/managing-gestational-diabetes-pregnancy>.
4. Unicef. Statistics: Iran, Islamic Republic of [Internet]. New York (NY): Unicef; c2013 [cited at 2014 Sep 15]. Available from: http://www.unicef.org/infobycountry/iran_statistics.html.
5. Beigi M, Javanmardi Z, Shahidi S. Interventions to decrease the mortality rate among pregnant women. Iran J Nurs Midwifery Res 2009;14(3):151-4.
6. Watkins L, Weeks AD. Providing information to pregnant women: how, what and where BJOG 2009;116(7):877-9.
7. Angelmar R, Berman PC. Patient empowerment and efficient health outcomes. In: Financing sustainable healthcare in Europe: new approaches for new outcomes. Luxembourg: Ministry of Health; 2007. p. 139-60.
8. Vlemmix F, Warendorf JK, Rosman AN, Kok M, Mol BW, Morris JM, et al. Decision aids to improve informed decision-making in pregnancy care: a systematic review. BJOG 2013;120(3):257-66.
9. Kar SB, Pascual CA, Chickering KL. Empowerment of women for health promotion: a meta-analysis. Soc Sci Med 1999;49(11):1431-60.
10. Samoocha D, Bruinvels DJ, Elbers NA, Anema JR, van der Beek AJ. Effectiveness of web-based interventions on patient empowerment: a systematic review and meta-analysis. J Med Internet Res 2010;12(2):e23.
11. Vasegh Rahimparvar SF, Hamzehkhani M, Geranmayeh M, Rahimi R. Effect of educational software on self-efficacy of pregnant women to cope with labor: a randomized controlled trial. Arch Gynecol Obstet 2012;286(1):63-70.
12. Eysenbach G. Consumer health informatics. BMJ 2000;320(7251):1713-6.
13. Horey D, Kealy M, Davey MA, Small R, Crowther CA. Interventions for supporting pregnant women's decision-making about mode of birth after a caesarean. Cochrane Database Syst Rev 2013;7:CD010041.
14. Bastani F, Zarabi R. Correlations of self-efficacy among women with gestational diabetes. HAYAT 2011;16(3-4):56-65.
15. Shojaezadeh D, Tol A, Sharifirad GR, Mohajeri Tehrani MR. Evaluation of educational program based on empowerment model on promoting self-efficacy and its

- relation with diabetes control among type 2 diabetes. *Iran J Diabetes Metab* 2012;11(5):474-82.
16. Nagle C, Lewis S, Meiser B, Metcalfe S, Carlin JB, Bell R, et al. Evaluation of a decision aid for prenatal testing of fetal abnormalities: a cluster randomised trial [ISRCTN22532458]. *BMC Public Health* 2006;6:96.
 17. Stanford Patient Education Research Center [Internet]. Stanford (CA): Stanford School of Medicine; c2014 [cited at 2014 Sep 15]. Available from: <http://patienteducation.stanford.edu/research/diabscales.htm>.
 18. Marteau TM, Bekker H. The development of a six-item short-form of the state scale of the Spielberger State-Trait Anxiety Inventory (STAI). *Br J Clin Psychol* 1992;31(Pt 3):301-6.
 19. Moen A, Mæland Knudsen LM. Nursing informatics: decades of contribution to health informatics. *Healthc Inform Res* 2013;19(2):86-92.
 20. Luna D, Almerares A, Mayan JC 3rd, González Bernaldo de Quirós F, Otero C. Health informatics in developing countries: going beyond pilot practices to sustainable implementations: a review of the current challenges. *Healthc Inform Res* 2014;20(1):3-10.