

Filipino women's diet and health study (FiLWHEL): design and methods

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BACKGROUND: Immigration to South Korea from neighboring Asian countries has risen dramatically, primarily due to marriage between Korean men and foreign women. Although Filipino women rank fourth among married immigrant women, little is known about the health condition of this population. This manuscript focuses on the design and methods of Filipino women's diet and health study (FiLWHEL).

SUBJECTS/METHODS: FiLWHEL is a cohort of Filipino women married to Korean men, aged 19 years old or over. The data collection comprised three parts: questionnaire, physical examination, and biospecimen collection. Questionnaires focused on demographic factors, diet, other health-related behaviors, acculturation and immigration-related factors, medical history, quality of life, and children's health information. Participants visited the recruitment site and answered the structured questionnaires through a face-to-face interview. We also measured their anthropometric features and collected fasting blood samples, toenails, and DNA samples. Recruitment started in 2014.

RESULTS/CONCLUSIONS: Collection of data is ongoing, and we plan to prospectively follow our cohort participants. We expect that our study, which is focused on married Filipino women immigrants, can elucidate nutritional/health status and the effects of transitional experiences from several lifestyle factors.

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INTRODUCTION

South Korea first became open to mass immigration from the early 1990's, primarily due to the rapid economic growth. Since 2002, the number of married immigrants has steadily increased with a slight decline in 2006 [1] due to stricter immigration policies [2]. However, the Korean government has provided numerous programs to address the needs of the immigration community, including pregnancy, childbirth, and childcare support since the country is facing a low birth rate problem [3,4]. As of 2014, 8.4% of foreign residents in Korea were married immigrants [5]. They also represented 8.0% of the total marriages [6], reaching a total of 150,994 in 2014 [7]. Furthermore, 4.9% of all live births in 2014 were from this population. These statistics have gained attention since these women and their offspring are becoming an integral part of Korea, and their welfare has become a growing concern.

Filipinos ranked fourth among international married immigrants

in Korea following Chinese, Vietnamese, and Japanese. There was a 47.8% increase in their number from 2010 to 2014. As of 2014, there were 11,052 Filipino married immigrants (men = 316; women = 10,736) [7]. A recent descriptive study reported higher prevalence of obesity in Filipino women in Korea compared to women from China, Vietnam, or other Asian countries, (22%, 16.7%, 7.8%, 19.2%, respectively) [8]. In the United States (US), Filipino immigrants, the second largest Asian-American group after Chinese immigrants, reportedly have higher breast cancer mortality and higher prevalence of diabetes and hypertension compared to other groups of Asian Americans, African-Americans, or Caucasians [9-12]. In the Philippines, cardiovascular disease is the leading cause of death, and this could be attributed to the high prevalence of overweight/obesity. The eighth national nutrition survey conducted in 2013-2014 by the Food and Nutrition Research Institute of the Philippines showed that 31.1% of Filipinos were overweight or obese (body mass index criteria ≥ 25 kg/m²);

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27.6% and 34.4% of men and women, respectively. Moreover, the prevalence of abdominal obesity (waist circumference criteria: women ≥ 88 cm; men ≥ 102 cm) is higher in women than in men (61.5% versus 7.6%) [13].

Due to the rapid economic growth of Korea, the presence of western lifestyles has grown. As a result, fast food and animal food product consumption have greatly increased [14,15]. Diet is one of the major contributing factors that determine chronic diseases, and immigrants are likely to adapt the food habits of their new environment [16-19]. The widely accepted Fetal Origins or Baker Hypothesis proposes that responses to undernutrition during fetal life and infancy permanently alter the body's structure, physiology, and metabolism, resulting in chronic diseases in later life such as cardiovascular diseases and diabetes, and the risk further increases when the body experiences a shift towards an affluent diet [20-22]. In the Philippines, malnutrition continues to persist; prevalence of underweight children aged 0-5 years was 26.2% in 2008, 34.5% in 1990, and 49.9% in all children in 1973 [23,24]. Accordingly, Filipino women in Korea are possibly undergoing an accelerated nutrition transition. In addition, immigrants undergo stressful events of acculturation [25], and stress has been linked to chronic diseases such as mental illness, cardiovascular disease, cancer, and type 2 diabetes [26-30]. Taken all together, we hypothesize that Filipino women in Korea are more susceptible to greater health risks.

Our objective for this article is to present a comprehensive description of the study design and methods used in the Filipino women's diet and health study (FILWHEL) study. We address how we calculated the sample size and recruited and collected data from each participant. We emphasize the importance of maintaining the quality of our data and specify the types of data obtained, and discuss the importance of this study.

SUBJECTS AND METHODS

Project organization

The group of FILWHEL study investigators is composed of

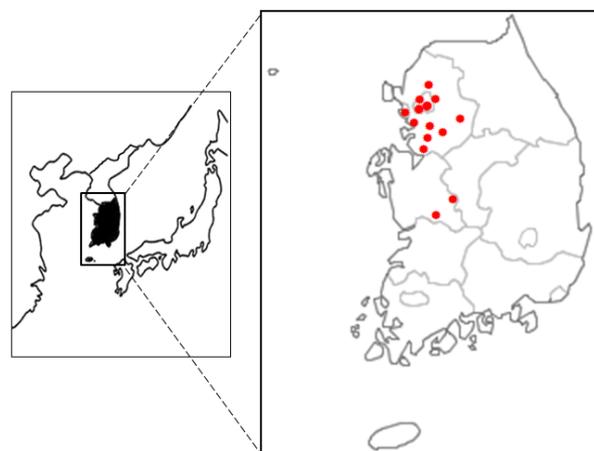


Fig. 1. Survey sites of the Filipino Women's Diet and Health Study (FILWHEL)

professionals in the fields of medicine, nutrition, and epidemiology. In addition, the study has Filipino assistant researchers and volunteer interviewers acquainted with the ways and common lifestyle practices of the Filipinos and who could communicate with the participants without any language barrier.

Aims

The first aim of our study is to explore how health-related behaviors, including diet, metabolic factors, quality of life factors such as physical, mental, and social domains, and acculturation influence the progression of cardiovascular disease and diabetes among Filipino women in Korea. Secondly, we examine how lifestyle, environment, and genetic factors play a role in the health of Filipino women.

Study design

FILWHEL is a cohort of Filipino women married to Korean men in Korea.

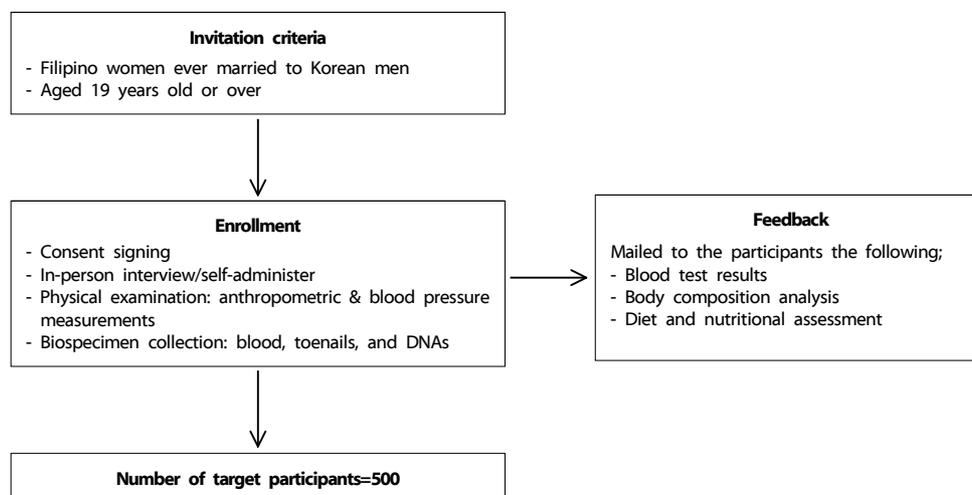


Fig. 2. Cohort enrollment of the Filipino Women's Diet and Health Study (FILWHEL)

Study sites and recruitment of participants

Study locations included Seoul, Incheon, Daejeon and Nonsan, and parts of Gyeonggi Province (Fig. 1). We administered surveys at universities, university hospitals, community centers, and churches. Study enrollment started in March 2014, and it is ongoing. Our target number of participants is 500 Filipino women. A Filipino woman is eligible to join if she has ever been married to a Korean man. Active Filipino community leaders played a key role in the recruitment of participants. They disseminated information at their respective areas, encouraged their members to participate, and arranged the venue for the study. In addition, participants were also recruited through personal contacts and social media. To gather more participants, the survey team, including physicians, phlebotomist, interviewers, and other staff, visited several coordinated locations. Prior to the on-site visit, interested participants were contacted and given specific instructions so they could prepare themselves and bring things needed for the interview (e.g. medicine or/and supplement bottles). Detailed instructions about fasting were also given. Those who agreed to participate in our study signed the informed consent and were enrolled. This study was approved by the Institutional Review Board of Sookmyung Women's University (reference number SMWU-1311-BR-012). The data collection had three parts: answering of the questionnaire, physical examination, and biospecimen collection (Fig. 2). Total time spent in all procedures was around 3 hours.

Questionnaire

We asked questions on demographic, socioeconomic, acculturation, quality of life, mental health, and other health-related factors (Table 1). The health-related questions included weight and body size history, nutritional behavior and dietary intake, smoking, physical activity, sleeping pattern, cellular phone and social networking use, medical history comprising gynecologic and obstetrical history as well as past or present medication use, family medical history, and sun exposure. Furthermore, our questionnaire used validated instruments: short format of the International Physical Activity Questionnaire (IPAQ) [31], World Health Organization Quality of Life-BREF (WHOQOL-BREF) [32], and EQ-5D-3L health questionnaire [33]. We assessed mental health by using the DSM-5 self-rated level 1 cross-cutting symptom measure [34]. Additionally, we asked questions regarding the participants' children's medical history and health behavior,

including birth history (birth weight and length as well as presence of infections, anomalies, or abnormalities), after birth medical history, vaccination record, dietary habits and supplement use, use of video games and/or television, and physical activity.

All parts of the questionnaire were written in English. Due to its length, we gave participants several options so they could answer the questionnaire at their convenience. Prior to visiting the site, they can opt to answer the questionnaire online, receive a printed form, phone interview, or just answer it on site. Those who answered on site were interviewed, and some parts were self-administered and if needed, assistance was given. Most participants answered questions through on site face-to-face interviews. Answers were double-checked and if there were any discrepancies, we asked it on site or over the phone.

Dietary assessment

Dietary assessment was conducted through an in-person interview using the 24-hour recall method. The participants provided a detailed description of what they ate and drank on the last full day (midnight to midnight) before the interview. Information gathered included place and time a particular meal was eaten, types and amounts of all foods and beverages, meal composition and, if obtainable, its recipe. Further, information on nutritional supplements or medicine was obtained. The amount consumed was quantified by means of food miniatures, photographs, household measures, weight/volume, and standard units and portions. Each participant was interviewed for approximately 30 minutes. Participants were encouraged to provide the correct estimation of all consumed foods or beverages, if possible. Collected data were edited for completeness, coded, and entered using the CAN-pro 4.0 (Computer Aided Analysis Program 4.0 for professionals, Korean Society of Nutrition, Seoul, Korea). If the food item, in particular Filipino food item, was not included or the nutrient content was different in the existing software, new food codes were generated. The nutrient information of the new food codes were taken directly from the manufacturer's nutritional information.

Anthropometric measurements

Using a non-stretchable tape measure, height and circumferences of waist and hip were measured to the nearest 0.1

Table 1. Summary of primary variables collected in the Filipino Women's Diet and Health Study (FILWHEL)

| Primary variable | Summary |
|-----------------------------------|---|
| Demographic | Age, insurance, marital status, education, citizenship, socioeconomic status, religion, and husband's education and age |
| Acculturation/immigration related | Korean language skills, length of stay in Korea, and manner of meeting husband |
| Health-related behaviors | Dietary habits and intake (24-hour recall), smoking, physical activity, sleeping pattern, cellular phone and social networking use, and sun exposure |
| Medical history | Gynecologic and obstetrical history, medication/supplement use, and family disease history |
| Quality of life | Physical and mental health, social relationships, and environment |
| Children's health information | Birth history (birth weight and length, infections, anomalies, or abnormalities), after birth medical history, vaccination record, dietary habits and supplement use, use of video games and television, and physical activity |
| Anthropometric | Current height, weight, waist and hip circumferences, and other body composition, weight history 2 years ago, at age 20, 35, and before coming to Korea, and body size history at different life stages: elementary, high school, university, and prior to marriage |
| Biospecimen | Toenails, blood, and DNA |

cm with the participant standing. Waist circumference was measured at the midpoint, between the lower border of the rib cage and the iliac crest, and hip circumference was measured at the largest circumference. Body composition was measured by the bioelectric impedance analysis machine (InBody 620, Biospace Co. Ltd, Seoul, Korea). The participants were barefoot, wore light clothing, and accessories were removed. The machine measured body fat mass, soft lean mass, fat free mass, skeletal muscle mass, and percent body fat.

Blood pressure measurements

Blood pressure (BP) was measured using a sphygmomanometer in accordance with the standard BP measurement principles while the participant was seated calmly at least after a 5-minute rest. Two BP readings were obtained using the same arm with a 5-minute interval after the first measurement.

Biospecimen collection

Collected biospecimens included toenail clippings and fasting blood samples. We asked the participants to clip their toenails using stainless steel clippers and place them in small envelopes. However, if toenails were polished, we instructed them, if possible, to remove the polish at home and save their toenail clippings every time they clip and send them to us within 3 months (from the study entry) by using our prepared envelopes that had return stamps and our office address. We stored their toenails at room temperature for future mineral analysis. For the blood sample, we asked them to fast for more than 8 hours, and fasting was carefully defined as not including food and beverages such as coffee or tea. In addition, we instructed them to refrain from smoking within the fasting period as well as alcohol intake 2 days before the blood sample collection. Blood samples were drawn through a venipuncture procedure, and a maximum amount of 19 ml was taken from each participant. Whole blood samples together with the centrifuged blood serum were stored at 2-8°C until they were transferred to the laboratory for analysis and aliquoting (Seegene Medical Foundation, Korea). All procedures were conducted within 24 hours from blood collection. Aliquots of serum and plasma and DNAs were stored at -86°C. The analyzed serum biomarkers include creatinine, fasting blood glucose (FBS), aspartate transaminase/serum glutamic oxaloacetic transaminase (AST /SGOT), alanine transaminase/serum glutamic-pyruvic transaminase (ALT /SGPT), total cholesterol, triglyceride, high-density lipoprotein (HDL) cholesterol, 25-OH-Vitamin D, insulin, high-sensitivity C-reactive protein (hs-CRP), glycated haemoglobin (HbA1c), and complete blood count with differential (CBC+Diff.).

Participant referral and feedback

We mailed the blood test results, body composition analysis, and dietary assessments to each participant. In this way, they were encouraged to improve or maintain a healthy lifestyle. Participants with concerns regarding their blood test results were advised to see their personal physicians or make appointments with the FiLWHEL physician.

Quality control of data

Personal interviews were conducted by the Filipinos who

could speak the Filipino language, thereby reducing the chance of interviewer-interviewee misunderstandings, and answers for sensitive questions were easily obtained. Detailed instructions and guidelines were given to the interviewers prior to conducting the interview. In cases wherein the participants preferred to self-administer the questionnaire, except for the 24-hour recall that required interviewers, assistance was offered to the participants whenever they had any difficulties.

Physical examination procedures and biospecimen collection were carried out by trained professionals. BP measurements were repeated two times. Quality control measures for blood samples include repeated emphasis of the importance of fasting and the choice of laboratory for analysis. Interested participants were carefully instructed and reminded several times about the fasting procedures before the actual blood collection. On site, each participant was asked about the details of their last food or beverage intake. Moreover, blood samples were analyzed and aliquoted by the Seegene laboratory, an international company that is compliant with high quality control procedures. The coefficients of variation (CV %) of duplicate analysis was also obtained.

In addition, the study process at all sites followed the same protocol, and all study days were supervised. Lastly, before data entry, all parts of the questionnaires were checked, and seemingly unclear or missing answers and other observed inconsistencies were clarified on site or over the phone. All entries were double-checked.

Statistical analysis

Analysis were performed using SAS version 9.3 software package (SAS Institute Inc., Cary, NC, USA). Estimations based on the incidence of pre-diabetes and diabetes in the Philippines led to the conclusion that enrollment of 500 participants with 100 cases occurred during the follow-up would provide 80% power to detect a relative risk of 0.5 comparing the top quartile with the bottom quartile [35].

DISCUSSION

FiLWHEL is a cohort of Filipino women married to Korean men. This study will provide descriptive statistics of morbidities and lifestyle factors as well as the associations between lifestyle or clinical factors and health outcomes. To our knowledge, there is no cohort yet for Filipino women in Korea, and their health information is scarce. Although they are not as numerous as the Chinese or Vietnamese immigrants, the existing data on Filipino women from other studies showing higher mortality rates and prevalence of chronic diseases compelled us to initiate this cohort. In the US, breast cancer mortality in Filipino women was reportedly higher compared to other Asian-Americans (Chinese, Vietnamese, Korean, and Japanese ethnicities) [9]. Further, Filipino women had higher prevalence of diabetes and hypertension compared to other Asian groups, African-Americans, or Caucasians [10-12]. Among patients with coronary heart disease, compared to Caucasians, Filipinos had higher prevalence of hypertension (both men and women, 79.2% versus 60.8%; for women alone, 87.4% versus 68.0%) and diabetes (both men and women, 34.7% versus 24.1%; for

women alone, 45.1% versus 30.5%) despite obesity being higher among Caucasians (4.2% versus 18.2%) [10]. In another study comparing three populations, the prevalence of age-adjusted type 2 diabetes was significantly higher in Filipinos (32.1%) than in Caucasian (5.8%) or African-American (12.1%) women [12]. Additionally, in the California Health Interview Survey, Filipinos showed higher prevalence of diabetes (8.05%) compared to Japanese (7.07%), Vietnamese (7.03%), and Koreans (6.3%) [11]. Filipino women living in San Diego and Hawaii showed similar high prevalence rates of diabetes (31.6% and 24.9%, $P = 0.79$) [36].

The strengths of this study are as follows: 1) we collected and stored samples of blood, toenails, and DNAs; 2) we obtained extensive data on lifestyle and clinical factors; 3) Filipino staff and volunteers could directly communicate, thus, clear information was obtained, and we can maintain close contact with the participants; 4) FILWHEL is the first comprehensive Filipino immigrant study in Korea; 5) our study will provide a better understanding of their health situation, especially in identifying risks and etiology of diseases; and 6) the results of this study will help healthcare policy makers target specific health problems and could inform prevention initiatives to improve maternal health of married immigrant women.

There are several limitations of our study. Firstly, FILWHEL was not originally designed as a representative sample of the national population but as a longitudinal study based on convenience sampling of interested participants among Filipino women married to Korean men. Thus, this may limit the ability to generalize the results. However, our study may provide information on the biological, mental, and physical health status of this population. Secondly, in cases where participants self-reported specific parts of the questionnaires, misclassification may have been introduced in the exposure status. Nevertheless, we checked all questionnaires thoroughly, and when we observed discrepancies, we asked the participants either on site or through a phone call. Thirdly, we had only one day 24-hour recall that could possibly limit the day to day variation of one's food intake. However, we are currently developing the FILWHEL food frequency questionnaire to reflect one's long-term diet intake. We plan to prospectively follow the cohort participants. During the follow-up, the manner of data collection may include on site visit, online or mailed questionnaire, or phone interview. Results from our study can help our understanding on how lifestyles, genetic background, and immigration play a role in the etiology and development of diseases among Filipino women. Furthermore, our study can help fill in the gap of the immigrant health data to improve immigrant women's health.

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CONFLICT OF INTEREST

The authors declare no potential conflicts of interests.

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