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**A THESIS FOR THE DEGREE OF
MASTER OF SCIENCE IN FOOD AND NUTRITION**

**Use of a Mobile Dietary
Self-monitoring Application for
Weight Loss versus a Paper-based
Dietary Diary:
A Randomized Trial**

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Abstract

Use of a Mobile Dietary Self-monitoring Application for Weight Loss versus a Paper-based Dietary Diary: A Randomized Trial

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Effective intervention strategies to maintain a balanced diet and healthy weight are warranted. Mobile health tools may have potential for dietary self-monitoring and assessment. This study aims to evaluate the effectiveness of a mobile dietary self-monitoring application (app) for weight loss compared to a paper-based diary among adults with a body mass index (BMI) of 23 kg/m² or above. A total of 33 men and 17 women aged 18-39 years participated in a six-week randomized trial. This study randomly assigned participants to one of two groups: (A) a smartphone app group (n=25) or (B) a paper-based diary group (n=25). The smartphone app group recorded foods and dietary supplements that they consumed and received immediate dietary feedback using 'Well-D', a dietary self-monitoring app developed by our team. The paper-based diary group was instructed to record foods or supplements that they consumed using the self-recorded diary. The primary outcomes were weight, BMI, waist circumference, body fat mass and skeletal muscle mass. This study also examined changes in nutrient intakes including energy,

carbohydrate, protein, fat, dietary fiber, vitamins, and minerals using 3-day 24-hour recalls across time at pre- and post-intervention. Differences between pre- and post-interventions within each group were compared using a paired t-test or the Wilcoxon signed rank test. Differences in changes between the two groups were analyzed using an independent t-test and the Wilcoxon Mann-Whitney test. The differences in changes of body weight, BMI, waist circumference, body fat mass, and skeletal muscle mass were not significantly different between the app group and the paper-based diary group. For pre-versus post-intervention measures, significant decreases in weight and BMI were observed in the paper-based diary group ($p=0.02$ and 0.01 respectively), but not in the app group ($p=0.25$ and 0.26 respectively). Waist circumference and body fat mass decreased significantly in both groups. The skeletal muscle mass significantly increased only in the app group. The percent changes in nutrient intakes were not statistically significant between the two groups. Energy intake decreased from pre- to post-intervention in the app group and the paper-based diary group. There were significant decreases in the intakes of carbohydrates, cholesterol, calcium, phosphorus, iron, potassium, and thiamin only in the paper-based diary group. In conclusion, there were no differences in changes of anthropometric measures and nutrient intakes between the app group and the paper-based diary group. Both mobile dietary self-monitoring app and paper-based diary may be useful for improving anthropometric measures and dietary intake.

Keywords : Smartphone application, mHealth, weight-loss, randomized trial, mobile dietary self-monitoring application

Student Number: 2017-26422

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List of Abbreviations

NCDs	Noncommunicable diseases
WHO	World Health Organization
ICT	Information and communications technology
mHealth	Mobile health
BMI	Body mass index
AMPM	Automated multiple-pass method
GPAQ	Global physical activity questionnaire
MET	Metabolic equivalent of task
USDA	United States Department of Agriculture
SMS	Short message service

I. Introduction

Noncommunicable diseases (NCDs) were responsible for 71% of all deaths globally in 2016, and obesity is a risk factor of NCDs including diabetes, coronary heart disease, stroke, and cancer (World Health Organization, 2018). The World Health Organization (WHO) has announced that one of the global NCDs targets is to halt the rise of obesity (World Health Organization, 2013). Despite multifaceted efforts to prevent obesity, the prevalence of obesity has nearly tripled between 1975 and 2016 (NCD Risk Factor Collaboration, 2017). Increasing obesity is partly due to the changes in lifestyle factors including eating energy-dense foods and foods high in fat and sugars, and low physical activity (World Health Organization, 2018). Therefore, dietary intervention is the key strategy to reduce the obesity epidemic.

Self-monitoring behavior change may be feasible, sustainable and cost-effective in maintaining a healthy lifestyle. A meta-analysis of behavior change interventions designed to promote physical activity and healthy eating showed that the combination of self-monitoring with at least one other tool was effective (Michie, Abraham, Whittington, McAteer, & Gupta, 2009). Similarly, a systematic review and meta-analysis of intervention studies reported that dietary self-monitoring tools helped individuals lose their weight and improve their diet (Burke, Wang, & Sevick, 2011; Teasdale et al., 2018).

In Korea, smartphone ownership has reached saturation and even the rate of wireless connections (99.4%) was higher than the rate of wired connections (71.3%) (Korea Internet & Security Agency [KISA] and Ministry of Science and ICT, 2018). This means that individuals are adopting a shift toward a more mobile-centric Internet environment, which involves the development of

abundant health related mobile applications (apps). There has been a rise in the number of mobile health (mHealth) solutions because information and communications technology (ICT) has become an integral part of our daily life (World Health Organization, 2017). WHO has announced that a majority (87%, n=109) of countries worldwide have at least one mHealth program in their country (World Health Organization, 2017).

Recently, dietary apps have been developed and tested for estimating their efficacy. Previous studies reported that use of dietary apps was a feasible, effective and useful means of assessing, monitoring, and improving health status (Ashman, Collins, Brown, Rae, & Rollo, 2017; Lee, Song, Ahn, Kim, & Lee, 2017; Mummah, Mathur, King, Gardner, & Sutton, 2016; Tsai et al., 2007). As mobile technologies have a potential to assess dietary intake accurately and provide customized feedback, the online market and prior intervention studies suggested the usefulness of mobile apps to improve individuals' diet (Franco, Fallaize, Lovegrove, & Hwang, 2016; Teasdale et al., 2018)

To the best of our knowledge, no randomized trials examined the effectiveness of a mobile dietary self-monitoring app for weight-loss in Korea. This study aims to evaluate the effectiveness of Well-D, a dietary self-monitoring app, for dietary change and weight loss. We hypothesized that the group that self-monitoring their diet with the app improved diet and weight loss as successfully as the paper-based dietary diary group.

II. Literature Review

1. Mobile health

The mobile health (mHealth) market has been growing steadily, and is expected to continue. The Berlin consulting firm Research2Guidance showed that 325,000 health apps were available as of 2017, and 78,000 new health apps were added to the app stores in 2016 (Research2Guidance, 2017).

mHealth strategies are being implemented in the research and practice of delivering health-related behavior change and managing diseases (Free et al., 2013). Regarding mHealth apps available in mobile app markets, prior studies reported that behavior change techniques were often used in popular physical activity and/or dietary behavior apps and the most frequently used strategies were ‘provide instruction’, ‘set tasks’, and ‘prompt self-monitoring’ (Direito et al., 2014).

A systematic review of 24 intervention studies examining the potential of mobile app for health and fitness addressed high acceptability of smartphone apps for health behavior change (Payne, Lister, West, & Bernhardt, 2015). Apps have been shown to have an effect on the prevention of NCDs. A systematic review analyzed the effectiveness of 12 app-based interventions for diabetes self-management and suggested that those app-based interventions reduced the levels of HbA_{1c} (Wu et al., 2017). A content analysis of hypertension-related smartphone apps available on mobile app markets showed that hypertension apps serve health management functions that track blood pressure, weight, or body mass index (BMI) (Kumar, Khunger, Gupta, & Garg, 2015). Among the hypertension apps available at Google Android, medical device functions, tracking functions, and medication adherence tools

were significantly associated with favorable ratings by consumers after adjusting for price. A systematic review that examined the effectiveness of ICT to reduce NCD risk showed that of 3 mobile interventions for weight loss, 2 studies found a significant reduction in obesity and among 6 mobile interventions designed to improve physical activity, 5 studies reported positive effects (Afshin et al., 2016).

Although there were few mHealth economic evaluations identified, up to now, mHealth has been presumed to be cost effective. A systematic review assessed economic evidence of mHealth based on 39 interventions (Iribarren, Cato, Falzon, & Stone, 2017). Economic evaluations were assessed using the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) checklist. Twenty seven interventions were behavior change communication type interventions, and among them, 74.1% reported positive costing outcomes. Among 7 data collection type interventions and 5 service delivery type interventions, 57.1% and 100% reported positive costing outcomes, respectively (Iribarren et al., 2017). The study which conducted economic analysis of the Lifestyle Education for Activity and Nutrition Study (LEAN) has shown that the Sense Wear Armband, a mobile multisensor armband for tracking energy expenditure, was the most cost-effective tools (\$51/kg lost) compared with standard care, group weight-loss education, and the armband in combination with group weight loss education (Archer et al., 2012). Stumbo SP et al. calculated the cost of implementing a behavioral weight-loss and lifestyle intervention for individuals with serious mental illness in a community setting, and the result showed that the majority of costs were associated with labor (Stumbo et al., 2015). As a new intervention delivery mode, mHealth is promising because of the potential for labor-saving through self-monitoring functionality.

2. Dietary assessment through smartphone apps

Establishing accurate and effective dietary assessment methodologies is fundamental to provide useful dietary feedback and to identify interaction between diet and diseases. However, the dietary assessment methods currently used have inherent challenges including reliance on memory, time-consuming conceptualization of portion sizes, requirements related to literacy or skilled staff, coding burden, knowledge of foods, and time-consuming tasks (Willett, 2012).

In recent years, several studies have explored whether mobile technologies could be used to measure dietary intake or improve the measurement of dietary intake, and thus, whether such technologies could replace traditional dietary assessment methods (Ashman et al., 2017; Boushey, Spoden, Zhu, Delp, & Kerr, 2017; Hutchesson, Rollo, Callister, & Collins, 2015; Laing et al., 2014; Lee et al., 2017). There were implemented in three ways: 1) image-assisted methods to provide dietitians pictures of foods consumed (Ashman et al., 2017; Boushey et al., 2017);, 2) image-based methods to identify foods and estimate portion size automatically from pictures of foods (Boushey et al., 2017);, and 3) text-searching methods to provide user functionalities for input of consumed foods (Hutchesson et al., 2015; Laing et al., 2014; Lee et al., 2017).

The feasibility of mobile apps for dietary monitoring has been reported mainly through user surveys. Participants who used 'Diet-A', which is a mobile app for self-monitoring dietary intake, replied that monitoring their food intake using Diet-A was satisfactory, but some responded that the app was burdensome to record food intakes and that they often forgot to record their diet (Lee et al., 2017). Users' feedback about a modified version of the

'Easy Diet Diary app' has shown that the app was preferred over 24-hour recalls, because it was easy to use and acceptable, but only half of participants responded that estimating portion sizes in the 'Easy Diet Diary App' was easy (Ambrosini, Hurworth, Giglia, Trapp, & Strauss, 2018). Participants who used 'e-CA' responded that it was easier and more practical than a paper-based food record. However, it had several difficulties estimating portion size and recording composite or mixed dishes and had to spend too much time entering food items and paying attention to the process of recording their diet (Bucher Della Torre, Carrard, Farina, Danuser, & Kruseman, 2017). Hutchesson et al. evaluated the acceptability of food record methods via computer, smartphone, and paper food record sheets with three different 7-day food records. 94.4% of participants preferred computer and smartphone recording over paper-based methods (Hutchesson et al., 2015). Although the complete automation of diet analysis has not been achieved yet, mobile technologies have the potential to improve real-time assessment of the diets of individuals and groups and incorporate their daily dietary routines (Cade, 2017)

3. Dietary improvement with smartphone dietary apps

Unhealthy diet is a key behavioral risk factor for NCDs (World Health Organization, 2018). Changing eating habits takes a long time and great effort. Prolonged and repeated stimuli are needed to promote healthy eating. A pilot survey in Australia observed that 96% of female participants aged 15-40 years kept their smartphones on standby during the day (Redmayne, 2017). Because people frequently carry their smartphones with them, mobile apps can engage app users in an efficient way to promote dietary monitoring to motivate and trigger behavioral responses.

Several studies reported that dietary self-monitoring strategies enabled user to self-monitor and improve their diet (Payne et al., 2015 ; Teasdale et al., 2018). Usually, the apps were implemented in a way that allows users to record foods that they consumed through text-searching and receive immediate dietary feedback (Ipjian & Johnston, 2017; Jimoh et al., 2018; Lee et al., 2017) or target increased vegetable consumption (Mumma et al., 2017). Participants that engaged in mobile intervention studies for dietary self-monitoring responded to the questionnaire related to the feasibility or overall feeling about the app at the post-intervention stage. 65% of users of the smartphone app ‘Diet-A’ reported that the app was helpful for monitoring food consumed and 61.9% of users replied that they were satisfied using the app to monitor their food intake (Lee et al., 2017). An intervention study that compared the effectiveness of the FoodWiz2 app with a paper diary suggested that in relation to enjoyment, convenience, recommendations to friends, overall linking, and reuse in the future, participants prefer the app over the paper diary (Jimoh et al., 2018). A pilot intervention study with MyFitnessPal showed that participants enjoyed using the app to monitor dietary intake

compared with paper-based methods (Ipjian & Johnston, 2017). Mummah et al. conducted a randomized controlled trial with 135 overweight adults and the group using the Vegethon app strongly agreed with the statement that “Vegethon has made me aware of how few vegetables I eat” (mean \pm SD, 4.1 \pm 1.0) (Mummah et al., 2017). Although food recording through the app may be burdensome for some users (Lee et al., 2017), prior research has supported claims related to the acceptance of mobile apps as a tool for dietary self-monitoring.

4. Weight loss studies of smartphone dietary apps

Although obesity rates in Korea are among the lowest in the Organization for Economic Co-operation and Development (OECD) (OECD, 2016), the prevalence of obesity in men aged 19 or more increased from 25.1% in 1998 to 42.3% in 2016 (Korea Centers for Disease Control and Prevention, 2017).

By combining self-monitoring features, mobile apps are expected to be a useful tool for maintaining a healthy weight. Many kinds of mobile apps for weight loss using self-monitoring strategies have been developed and introduced into the market and research (Burke et al., 2011; Chen, Cade, & Allman-Farinelli, 2015). From the perspective of behavior change methodology, physical activity and dietary smartphone apps used behavioral change strategies designed to ‘provide instruction’, ‘set graded tasks’, and ‘prompt self-monitoring’ (Direito et al., 2014). Further weight-loss intervention studies with dietary apps provided diet-related games, text messages, self-reported nutrient features, or automated dietary feedback to promote healthy eating (Carter, Burley, & Cade, 2017; Toro-Ramos et al., 2017; Fukuoka, Gay, Joiner, & Vittinghoff, 2015; Hales et al., 2016; W. Lee, Chae, Kim, Ho, & Choi, 2010).

Specifically, in recent years, several studies have explored the effectiveness of mobile dietary self-monitoring apps as a tool for losing weight (Table 1) (Burke et al., 2017; Carter, Burley, Nykjaer, & Cade, 2013; Chin et al., 2016; Laing et al., 2014; Turner-McGrievy et al., 2017; Toro-Ramos et al., 2017). Among them, several studies recently reported a positive weight loss outcome using dietary self-monitoring apps after 12-week, 15-week and 6-month intervention periods (Burke et al., 2017; Carter et al., 2013; Turner-McGrievy et al., 2017; Toro-Ramos et al., 2017). However, two intervention studies

found no significant changes when comparing the app to conventional methods during a 6-month intervention period (Carter, Burley, Nykjaer, & Cade, 2013; Laing et al., 2014). The effectiveness of the dietary self-monitoring apps as a tool for weight loss compared with traditional methods is still limited.

Table 1. Weight-loss studies using mobile dietary self-monitoring apps among overweight or obese adults

Author, year	Country	Study design	Study groups	App name	Duration	Outcomes
Chin et al., 2016	South Korea	Cohort	1 group 1) Noom Coach users (n=35,921)	Noom Coach	October 2012 - April 2014	Body weight, adherence
Toro-Ramos et al., 2017	South Korea	Intervention	2 groups 1) App +group and private message +offline education (n=104) 2) App (n=55)	Noom Coach	15-week	Body weight, blood pressure, waist circumference, glucose and lipid profiles
Burke et al., 2017	USA	Intervention	3 groups 1) App (n=13) 2) App+real-time feedback (n=13) 3) App + real-time feedback +group sessions (n=13)	Lose it!	12-week	Body weight, adherence, blood pressure, self-efficacy
Carter et al., 2003	UK	Intervention	3 groups 1) App (n=43) 2) Website (n=43) 3) Paper diary (n=42)	My Meal Mate	6-month	Body weight, adherence, anthropometric measures
Laing et al., 2014	USA	Intervention	2 groups 1) Usual care (n=107) 2) App+usual care (n=105)	My FitnessPal	6-month	Body weight
Turner-McGrievy et al., 2017	USA	Intervention	2 groups 1) App (n=42) 2) Bite Counter device (n=39)	Fat Secret	6-month	Body weight, energy intake, adherence

III. Subjects and Methods

1. Participants

For the intervention study, participants were recruited between February 6, 2018 and April 12, 2018 via poster advertisement within Seoul National University and Web-based announcements. The inclusion criteria were as follows: 1) 18 to 40 years of age, 2) BMI of 23 kg/m² or above, 3) willingness for weight loss, and 4) smartphone owner. Pregnant or lactating women were excluded.

2. Screening and Randomization

Potential participants contacted a researcher to show willingness to participate in the intervention study via phone calls. Potential participants were invited to attend a baseline session held at Seoul National University (30 to 45 minutes). Before starting the baseline session, their age was asked and their height and weight were measured using a stadiometer to confirm the eligibility. All of the eligible participants returned a written informed consent prior to enrollment. Participants received 20,000 KRW for attending each three visit, 60,000 KRW in total. This study was approved by the Seoul National University Institutional Review Board (IRB no. 1710/003-007).

A total of 50 participants were randomized with a 1:1 allocation ratio of Well-D app group to the paper-based diary group using a random number table generated by PROC PLAN in SAS version 9.4 (SAS Institute, Cary, NC, USA). Participants were randomly assigned to each group after they completed baseline assessments.

3. Intervention

Both groups were instructed to self-monitor their dietary intakes by recording foods or supplements that they consumed during the 6-week intervention periods.

3.1. Well-D app group

The researcher helped the app group users register to ‘Well-D’, which is a dietary self-monitoring app and provided a Well-D manual to the app group. A multidisciplinary team including dietitians, nutrition professionals, and software engineers worked collaboratively to design and develop a mobile dietary self-monitoring app, Well-D. Therefore, users could access Well-D anytime under network environments. Well-D provides two key functions: (1) recording consumed foods or dietary supplements by text-searching, and (2) real-time dietary feedback. Through administration page, users’ data was accumulated and inserted food and recipe databases can be revised.

The food database of Well-D was sourced from the database of the ‘Diet Evaluation System(DES)’ (Jung et al., 2013) and was comprised of two kinds of databases: a food composition database and a food recipe database. The food composition data were comprised of the list of dietary supplements and foods, which could be ingredients of food recipes. The recipe database had information about food recipes of dishes, ingredients. Per each food recipe, ingredients retrieved from the food composition database and their amounts for a standard serving size (e.g. 1 cup or 1 small bowl) were archived.

Dietitians regularly updated the food composition and recipe databases based on open-source food composition databases from the Ministry of Food and Drug Safety, and the National Institute of Agricultural Sciences and the Korea

Health Industry Development Institute (Lee et al., 2015; Ministry of Food and Drug Safety; National Institute of Agricultural Sciences). A database of dietary supplements, which is part of the Korea National Health and Nutrition Examination Survey (KNHANES V-1,2 and VI-3), 2010, 2011, and 2015 nationwide database was also added (Korea Centers for Disease Control and Prevention, 2011, 2012, 2017a; Yun, Kim, & Oh, 2015). When data on foods or dietary supplements were not available in the aforementioned sources, the dietitians added nutrient amounts manually directly from manufacturer's label or the United States Department of Agriculture (USDA) database (United States Department of Agriculture). The app provided a database of more than 21,000 foods and recipe items.

Well-D provided real-time feedback on daily total energy, carbohydrates, protein, total fat, sodium, saturated fat, fiber, sugar, calcium, vitamin C, riboflavin, and food groups of diabetic exchange list. Whether the users' nutrient intakes were adequate was evaluated based on the Dietary Reference Intakes for Koreans (KDRI) 2015 (Ministry of Health and Welfare and The Korean Nutrition Society, 2015). The Estimated Energy Requirement (EER) was the average energy intake that maintains energy balance in healthy, normal weight individuals (Institute of Medicine, 2005). The EER was calculated using the equation developed by the National Academy of Sciences, Institute of Medicine, and the Food and Nutrition Board, using the user's age, height, current weight, and Physical Activity Level (PAL) (Institute of Medicine, 2005). The researchers implemented a simplified questionnaire to identify the user's PAL based on the Global Physical Activity Questionnaire(GPAQ) devised by the World Health Organization(WHO) (Herrmann, Heumann, Der Ananian, & Ainsworth, 2013). Since each question in the GPAQ was measured by metabolic equivalents (METs), MET values

were converted into PAL (Institute of Medicine, 2005). Sodium intake feedback was set on the basis of the Ministry of Food and Drug Safety's reduction target to lower average daily sodium intake to 3,500 mg by 2020 . For feedback on energy and macronutrient intakes, when the user's intake fell within 10% of the EER and acceptable macronutrient distribution range of KDRI, respectively, they received the comment "adequate". For micronutrients, users received feedback based on the Estimated Average Requirements (EARs), the Reference Nutrient Intake (RNI), the Adequate Intake (AI), and the Tolerable Upper Intake Level (UL) of KDRI. Feedback about the serving sizes of food groups that users need to consume were provided based on the KDRI food group recommendation.

The user interface design of Well-D consisted of the following 13 interface categories: sign up and profile input, login, main page, diet recording, food data creation, recipe data creation, favorite foods, dietary supplement recording, supplement data creation, supplements package data creation, display of foods and supplements consumed, diet feedback, and nutritional report. Users could sign into Well-D after typing the users' profile and e-mail verification. Figure 1 shows a main page. By default, the date of the app was set to 'today', but users could select a date on the top of the main page. Below the date, the app provided information about daily recommended energy intake as well as how much energy needs to be consumed. Tabs for food recording, supplement recording, re-check of foods and supplements consumed, diet feedback and the nutritional report were displayed on the main page.

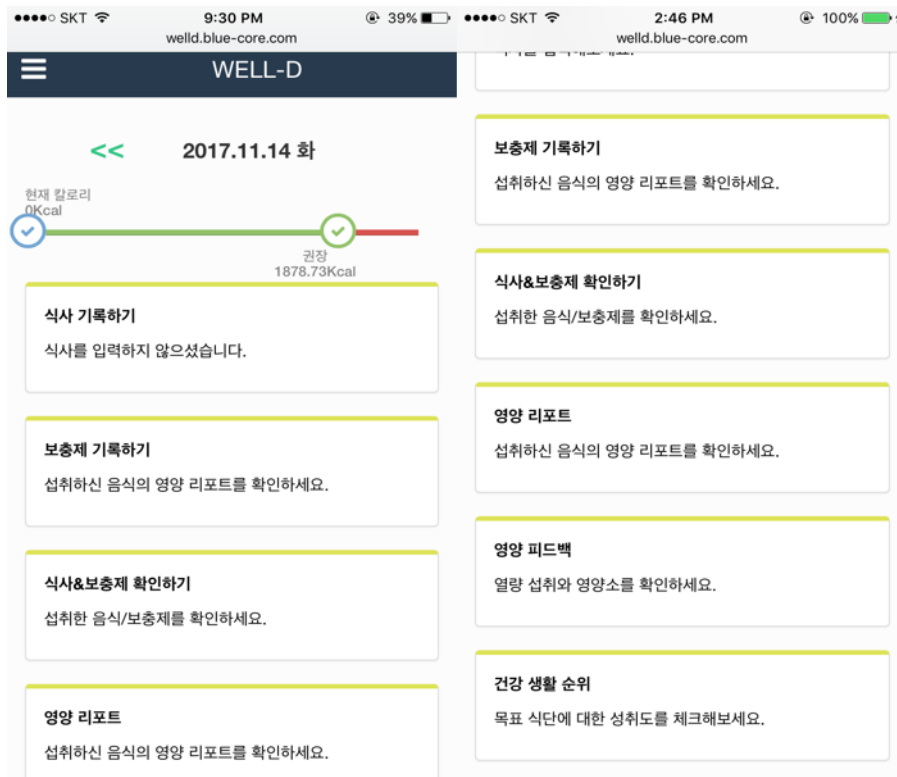


Figure 1. The main page of Well-D after log-in

When users recorded foods or dietary supplements consumed, they could use text-search functions after they chose the type of meal. A search-as-you-type function was designed to make searching easier and faster. Meal occasion was grouped into snack before breakfast, breakfast, snack before noon, lunch, afternoon snack, dinner, snack after dinner, and midnight snack. After choosing the meal occasion, users were directed to choose foods consumed from the list by text-searching or typing in if it was not available in the list. Users had to select or type in serving amounts. Several options for serving sizes were available to choose. After users entered all foods in a meal, users had to click the “save” button to save information that they typed in. The intake data from the meals were automatically sent to the server and were

analyzed to provide dietary feedback.

When foods that users consume were not available in the database, Well-D automatically asked whether users want to create new food data by text, photo, or combining foods from the existing food database. For foods or dietary supplements that were not listed in the database, the user could add new data in two ways: 1) typing a food name and describing it by text and/or photo; or 2) typing a food name and creating recipe data by putting ingredients from the list of food composition database. Likewise, users could generate recipe data. Dietitians checked the user's new recipe with the aid of a text description or photo and finally updated the recipe database. Figure 2 shows how users can create food data by text or photos. Figure 3 shows how users generate food items by choosing ingredients and typing the amount of each ingredient. Supplemental data could also be created by text or photo.

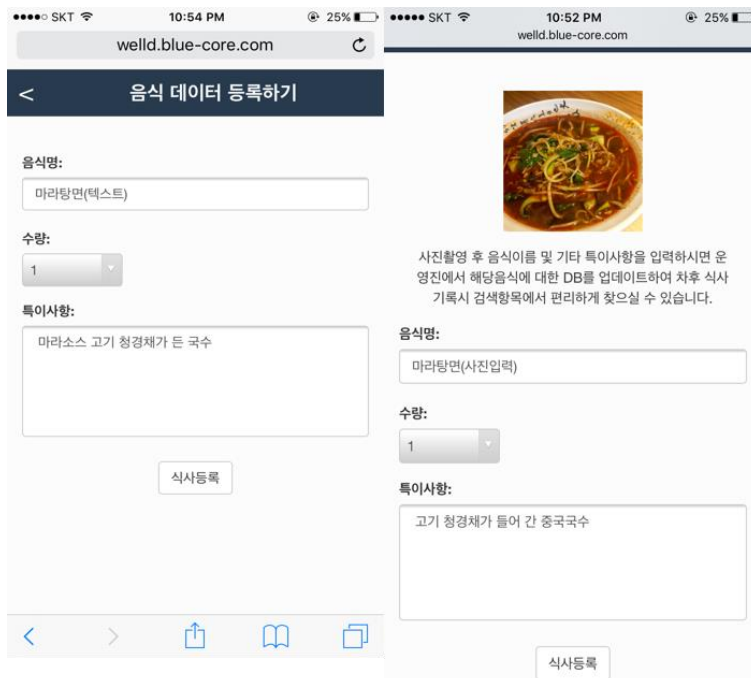


Figure 2. Screenshots of food data creation

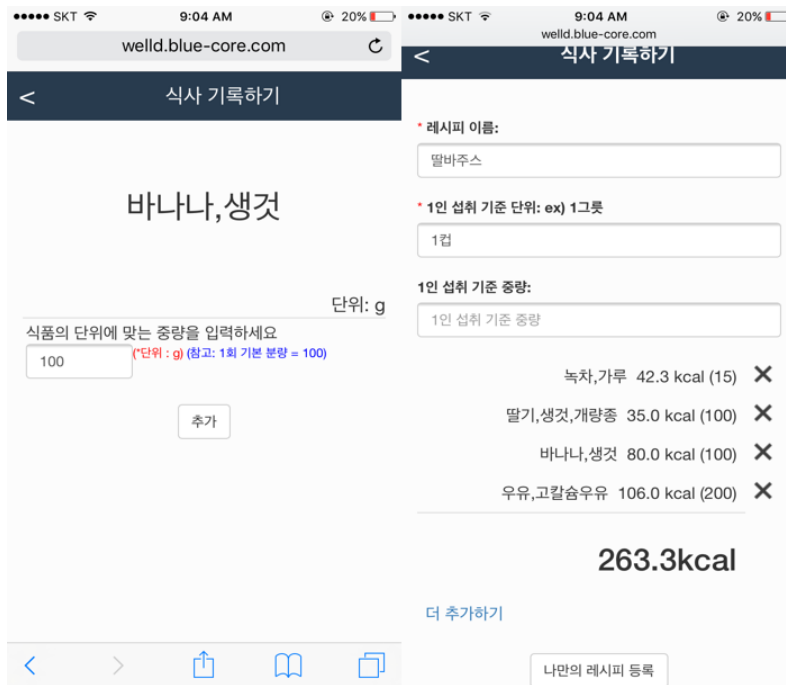


Figure 3. Screenshots of recipe creation

After users recorded all foods and supplements, they could re-check the recorded diet by clicking the ‘display of foods and supplements consumed’ tab. Users could check a list of foods and supplements consumed on a specific date and meal time by clicking the date from the calendar and scrolling down to meal time (Figure 4). Users could delete foods or supplements if they want. Tailored diet feedback on daily nutrients and food group intake was also provided in ‘nutritional feedback’ tab. Users could figure out which nutrients users consume above or below the recommended intake via scale and pie graphs (Figure 5). As daily meal data were accumulated, Well-D could display weekly or monthly dietary intake. On the ‘nutritional report’ tab, weekly or monthly nutrient intake reports were provided as a line chart (Figure 6). To give practical advice on unhealthy food intake, Well-D displayed the top three

contributing foods to the nutrients of which the users consumed too much to give practical advice (Figure 7). For example, when users checked trends of saturated fat intake during a specific period of time (e.g. March 2018), they could see the top three foods that contributed to saturated fat intake in that month.

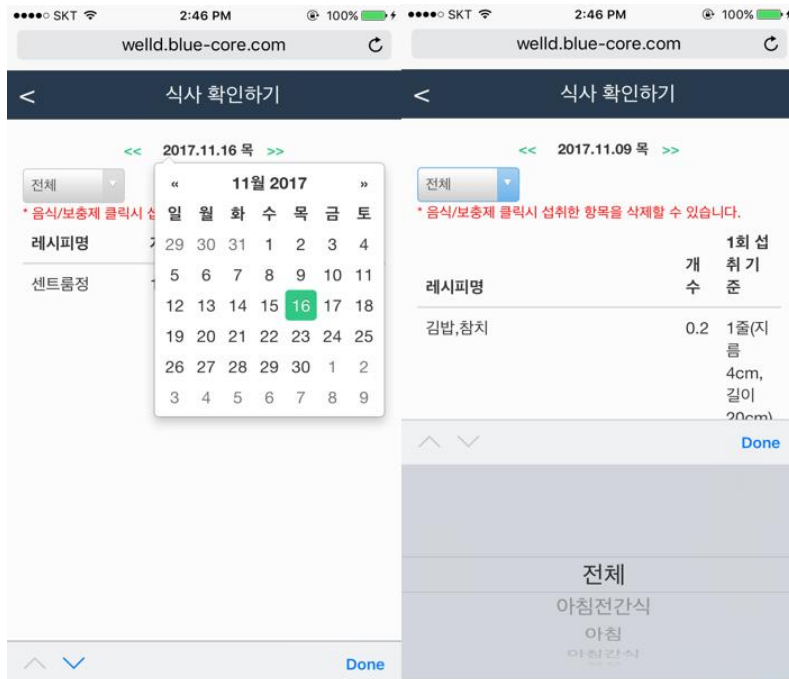


Figure 4. Screenshots of a check-up of foods and supplements recorded

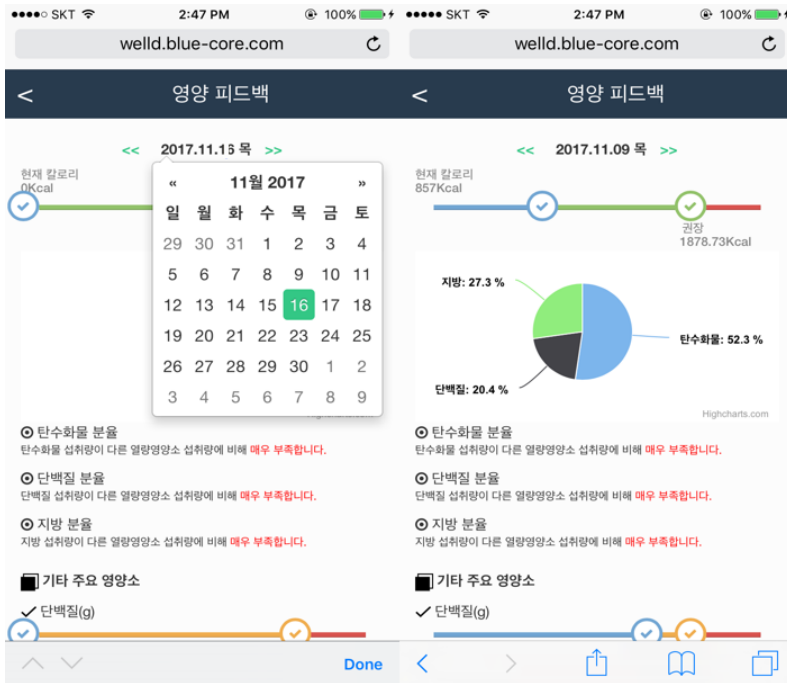


Figure 5. Screenshots of diet feedback

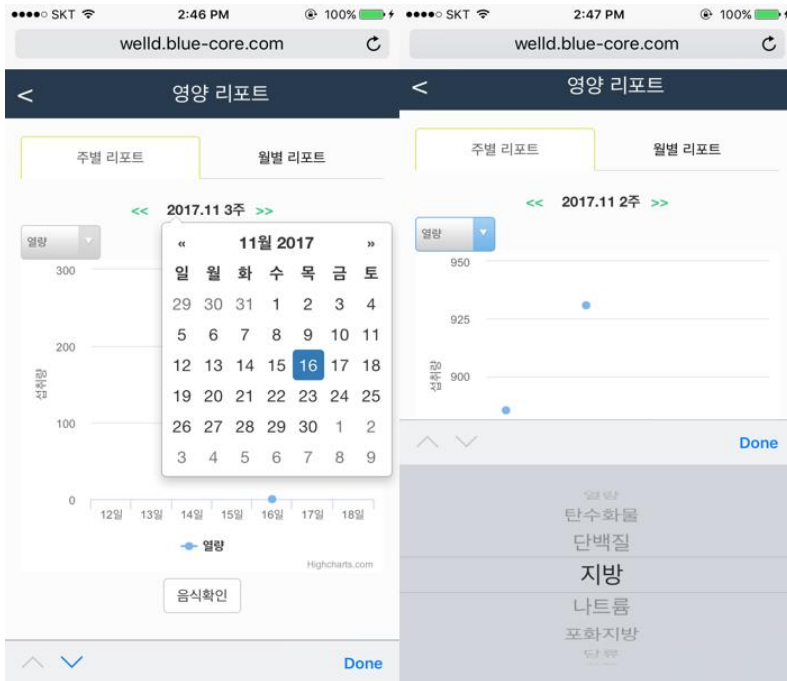


Figure 6. Screenshots of the nutritional report

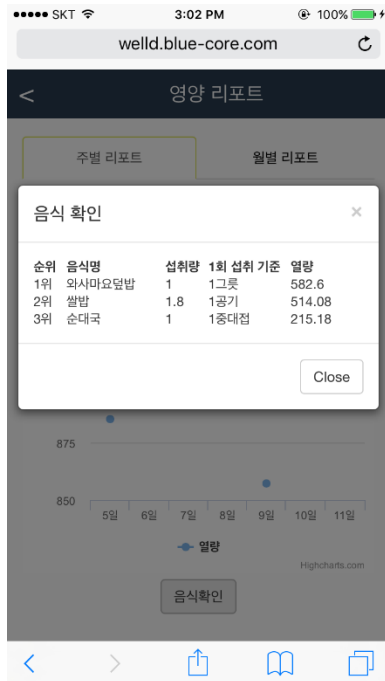


Figure 7. Screenshot of the top three contributing foods to the user’s nutrient intake

3.2. Paper-based diary group

In the paper-based diary group, participants were provided paper-based diaries and pamphlets. The paper-based diary was designed to record the date, time, name and amount of foods and ingredients consumed, and energy intake that participants roughly calculated. The pamphlet provided tips about the proper energy intake goal and weight loss strategies. The researcher also provided instructions on how participants can set a proper energy intake goal on the paper-based diary and pamphlet, and participants wrote their energy intake goal for weight loss on the paper-based diary.

4. Outcome assessments

4.1. Primary outcomes

Weight, waist circumference, body fat mass, and skeletal muscle mass were measured as primary outcomes at the baseline and after six weeks of intervention. Height was measured only at the baseline. On the day before measurements, the researcher sent text messages to inform participants to avoid large meals before the visit and to wear light clothes for the measurements. Height was measured twice to the nearest 0.1cm without shoes using a digital stadiometer (Biospace, Korea). Body weight was measured to the nearest 0.1 kg on the Inbody 720 (Biospace, Korea) with participants wearing light clothing. BMI was calculated from weight (kg) divided by the squared height (m²). Waist circumference was measured 1 inch above the umbilicus to the nearest 0.1 cm with a tape measure. For the body composition, body fat mass, and skeletal muscle mass were assessed using Inbody 720.

4.2. Secondary outcomes

The participants' diet was assessed using 24-hour recalls (24HR) for three days including one weekend day. A dietitian conducted the 24HR by using the automated multiple-pass method (AMPM). AMPM uses five steps including listing foods consumed the previous day, probing for forgotten foods, collecting the time of consumption, collecting descriptions about and amounts of each food, and final probing (Conway, Ingwersen, Vinyard, & Moshfegh, 2003). On the first day of the three-day 24HR, participants visited the researcher's office and completed 24HRs. They completed the other 2-day 24HRs by phone calls. They were also provided a booklet for a sample

serving size of foods to help assume the amount of foods that they consumed. The amount of nutrients were calculated using the databases sourced from the 'Diet Evaluation System' (Jung et al., 2013) by SAS 9.4 and Microsoft Excel 2013 software. If the foods and dietary supplements were not available in the Diet Evaluation System database, the dietitians updated the additional food composition databases based on the open-source food composition databases from the Ministry of Food and Drug Safety and the National Institute of Agricultural Sciences (Ministry of Food and Drug Safety; National Institute of Agricultural Sciences).

4.3. Other outcomes

Participants recorded self-reported physical activity by using a South Korean version of the global physical activity questionnaire (GPAQ) (Craig et al., 2003). Metabolic equivalent of task (MET)-hours per week values were calculated by using the GPAQ analysis guideline (World Health Organization, 2012). At post-intervention, users in the app group completed a questionnaire about satisfaction with the app in comparison with past weight loss attempts. Usability and usefulness of Well-D versus other weight loss methods were evaluated using a 5-item questionnaire. all

5. Statistical Analysis

The sample size was estimated to detect statistically significant differences in weight loss between the app group and the paper-based diary group using a similar previous 6-week trial (Carter et al., 2013). By assuming a 0.9 kg difference between the two groups and a standard deviation of 1 kg, the calculated sample size with a power of 80% was 21 per group. Considering the loss to follow-up, this study recruited 25 participants for each group.

All of data were analyzed by the intention to treat analysis. This study analyzed baseline characteristics and between the app group and the paper-based diary group by an independent t-test and the Wilcoxon Mann-Whitney test for continuous variables, and a chi-square test and Fisher's exact test for categorical variables. The differences in percent changes of anthropometric measures and nutrient intakes between the app group and the paper-based diary group were analyzed by an independent t-test and the Wilcoxon Mann-Whitney test. The changes of anthropometric measures and nutrient intakes between pre- and post-intervention were calculated after the Box-Cox power transformation (Box & Cox, 1964). The differences between pre and post interventions within each group were compared using a paired t-test or the Wilcoxon signed-rank test. A simple linear regression was used to evaluate the correlation between the number of days of recording foods and weight loss in each group.

The missing data (1 for weight and 2 for other primary outcomes) were carried forward from the baseline assessments. This study also conducted sensitivity analysis with per protocol analysis and multiple imputations to handle missing data. Multivariate imputation that specified the regression method was applied by using SAS PROC MI. A total of 100 imputed datasets

were created using multivariate imputation by chained equations. The imputation procedure for weights, BMI, waist circumferences, body fat mass, and skeletal muscle mass included the following variables: intervention group, gender, weight, waist circumference, and MET hours/week. For imputing missing data on energy, carbohydrate, protein, and fat intake at post intervention, following variables were used: intervention group, gender, age, weight, height, and the intakes of energy, carbohydrate, protein, and fat. A total of 100 estimates from the imputed data sets were averaged and examined if they were similar to the carry-forwarded estimates.

IV. Results

1. Flow diagram of inclusion of study participants

Figure 8 presents the flow diagram of inclusion of participants. After randomization, one lactating participant was excluded. As a result, 33 men and 17 women aged 18-39 years participated in a six-week randomized trial. 32 men and 17 women completed the study. One participant in the paper-based diary group did not respond to the final contact. Another participant responded to our contact, but could not attend a follow-up interview. This participant provided his weight and the number of days that he used a dietary diary. All of the participants completed 3-day 24HR at the baseline. 47 participants completed 3-day 24HR and 1 participant in the app group completed two days of 24HR during a 6-week intervention period.

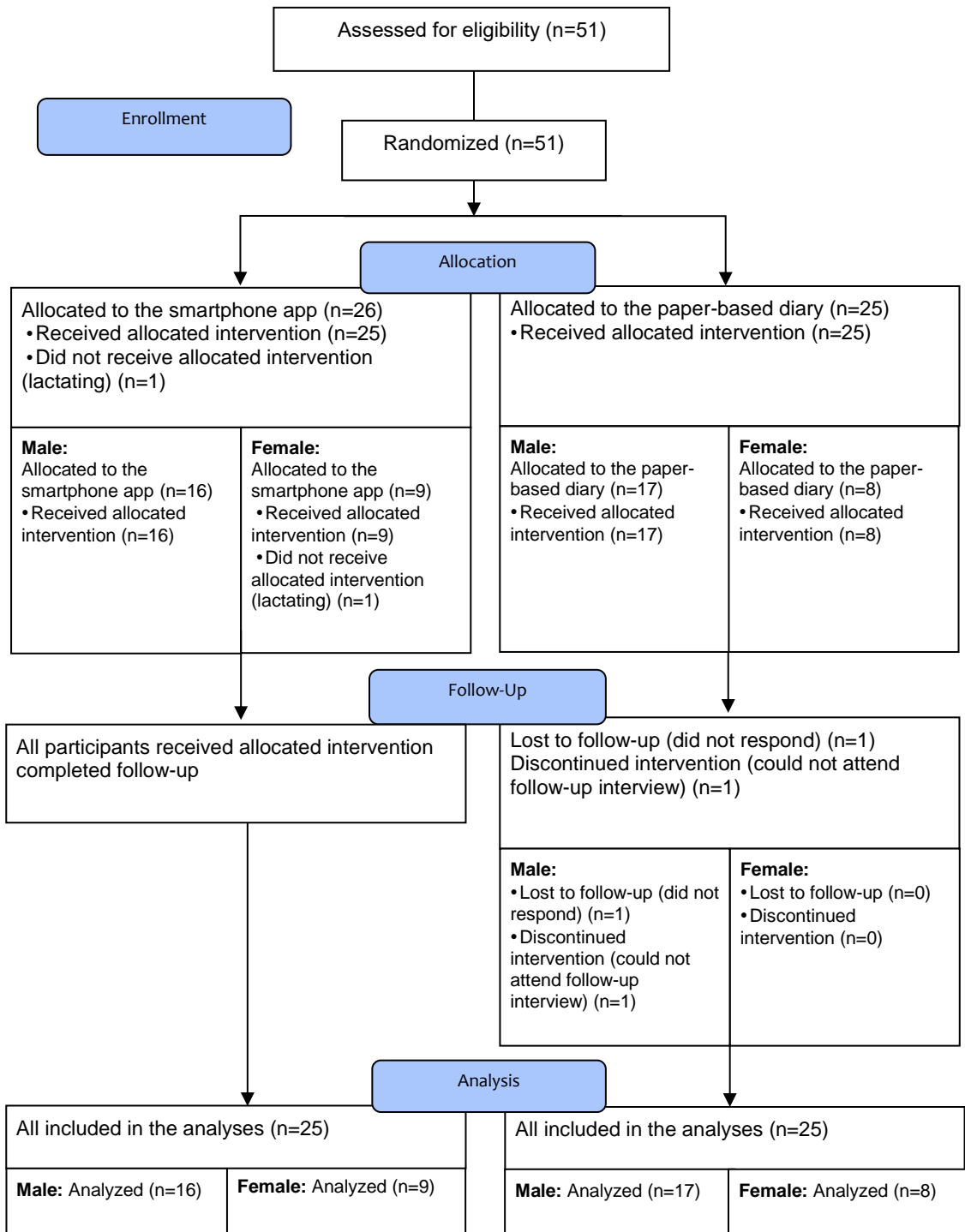


Figure 8. Flow diagram of inclusion of study participants

2. Baseline characteristics of participants

Baseline characteristics were not different between the app and the paper-based diary groups (Table 2). At baseline, there were no significant differences in gender, age, anthropometric measures, and nutrient intakes between the study groups. The mean age of participants was 26.02 years. The mean weight was 77.14kg and mean BMI was 26.72 kg/m². The mean daily intake of energy was 2166.10 kcal/d. On average, intakes of carbohydrate, protein and fat were 263.96g, 95.61g, and 73.46g respectively.

Table 2. Baseline characteristics of participants according to intervention arms

	Total (n=50)	App group (n=25)	Paper-based diary group (n=25)	
Characteristics		n (%)		P-value ^a
Gender				
Male	33 (66%)	16 (64%)	17 (68%)	0.77
Female	17 (34%)	9 (36%)	8 (32%)	
Characteristics		Mean ± standard deviation		P-value ^b
Age (year)	26.02±4.78	26.48±5.28	25.56±4.28	0.50
Weight (kg)	77.14±11.54	77.95±12.89	76.32±10.20	0.62
BMI (kg/m ²)	26.72±2.74	27.07±2.95	26.37±2.53	0.54
Waist circumference (cm)	91.73±9.28	93.13±9.57	90.32±8.95	0.25
Body fat mass (kg)	23.26±6.30	24.20±5.61	22.31±6.91	0.29
Skeletal muscle mass (kg)	30.27±6.07	30.17±6.53	30.36±5.70	0.91
Total physical activity (MET-hour/week)	26.43±25.61	25.28±23.44	27.59±28.05	0.87
Energy (kcal/d)	2166.10±546.46	2270.32±522.08	2061.88±560.80	0.18
Carbohydrate (g/d)	263.96±65.71	259.20±56.32	268.72±74.80	0.61
Protein (g/d)	95.61±27.63	100.83±28.66	90.39±26.07	0.18
Fat (g/d)	73.46±29.34	76.88±30.24	70.03±28.61	0.40
Total dietary fiber (g/d)	17.02±6.11	16.66±5.92	17.37±6.39	0.69
Calcium (mg/d)	530.80±237.89	512.81±185.26	548.80±283.80	>0.99
Sodium (mg/d)	4027.53±1152.40	4122.33±1113.03	3932.72±1205.75	0.74

Abbreviations: BMI, body mass index; MET, metabolic equivalent tasks.

^a Chi-square test was used to assess group differences.

^b Independent t-test and Wilcoxon rank sum test were used to assess group differences.

3. Changes in anthropometric measures

This study found no statistically significant difference in percent change of body weight between the app group and the paper-based diary group (mean \pm SD, -0.12 ± 0.52 % vs. -0.39 ± 0.73 %; p for group difference = 0.24) (Figure 9, Table 3). Likewise, differences in the percent change of BMI, waist circumference, body fat mass and skeletal muscle mass were not statistically significant between two groups (p for group difference = 0.25, 0.86, 0.54 and 0.07 respectively).

When the pre-intervention anthropometric measures was compared with the post-intervention measures, significant decreases in body weight and BMI was observed in the paper-based diary group (mean \pm SD, -1.36 ± 2.74 and -0.47 ± 0.91 respectively; p-value=0.02 and 0.01 respectively), but not in the app group (mean \pm SD, -0.38 ± 1.61 and -0.14 ± 0.56 respectively; p-value=0.25 and 0.26 respectively) (Table 4). Waist circumference and body fat mass decreased significantly in both groups. The skeletal muscle mass significantly increased in the app group, but not in the paper-based diary group (mean \pm SD, 0.42 ± 1.02 in the app group and -0.01 ± 0.77 in the paper-based diary group; p-value=0.05 and 0.48 respectively).

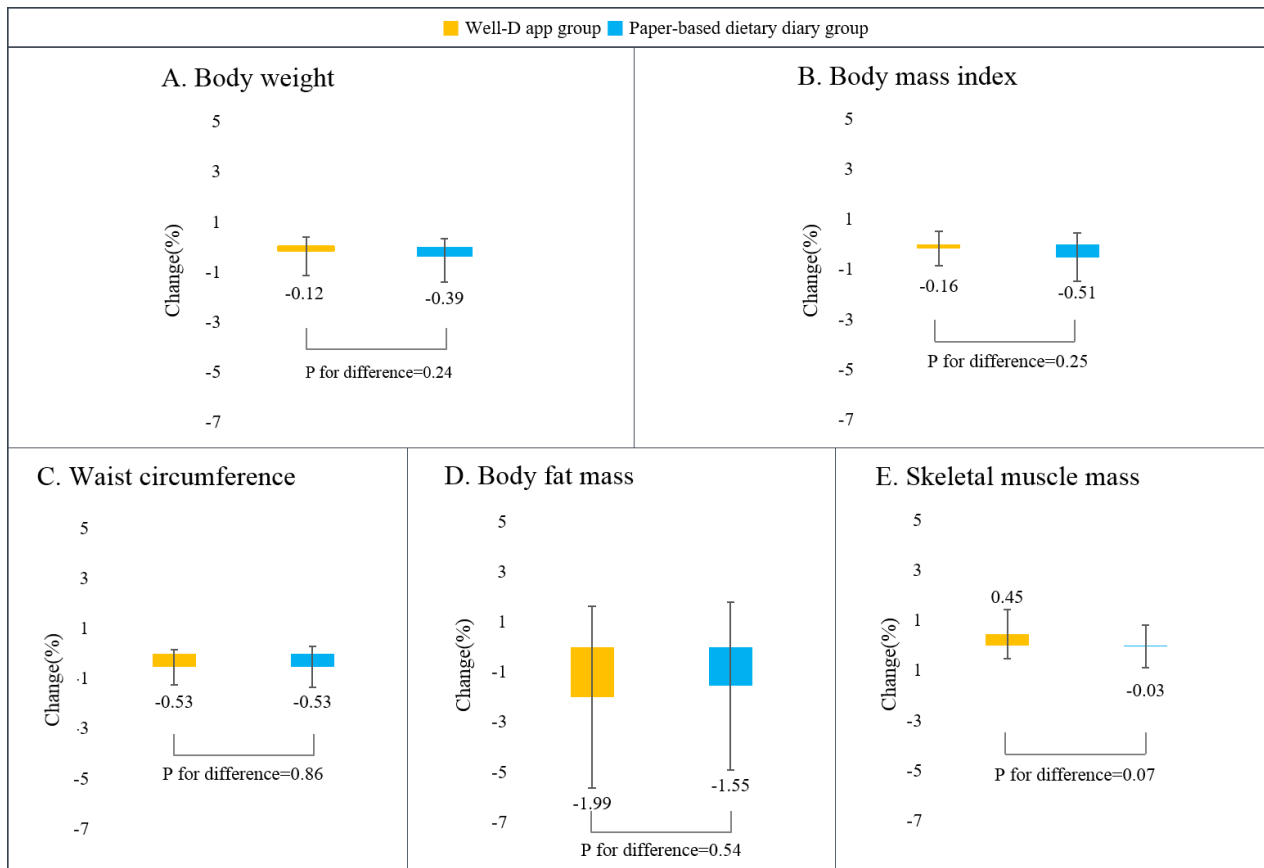


Figure 9. Differences in changes of anthropometric measures between the app group and the paper-based diary group

Table 3. Differences in changes of anthropometric measures between the app group and the paper-based diary group

Characteristics	App group (n=25)			Paper-based diary group (n=25)			P-value ^b
	Baseline	6 wk	Change (%) ^a	Baseline	6 wk	Change (%) ^a	
Weight (kg)	77.95±12.89	77.6±13.00	-0.12±0.52	76.32±10.20	75.00±9.30	-0.39±0.73	0.24
BMI (kg/m ²)	27.07±2.95	26.94±2.97	-0.16±0.69	26.37±2.53	25.90±2.20	-0.51±0.96	0.25
Waist circumference (cm)	93.13±9.57	90.89±9.20	-0.53±0.70	90.32±8.95	88.05±7.08	-0.53±0.82	0.86
Body fat mass (kg)	24.20±5.61	23.04±6.07	-1.99±3.63	22.31±6.91	21.03±5.87	-1.55±3.35	0.54
Skeletal muscle mass (kg)	30.17±6.53	30.59±6.56	0.45±0.98	30.36±5.70	30.35±5.81	-0.03±0.84	0.07

^a Percentage of change is calculated after transformed to natural logarithms

^b Independent t-test and Wilcoxon rank sum test were used to assess group differences

Table 4. Changes in anthropometric measures from the baseline to 6 weeks

Characteristics	App group (n=25)				Paper-based diary group (n=25)			
	Baseline	6 wk	Change	P-value ^a	Baseline	6 wk	Change	P-value ^a
Weight (kg)	77.95±12.89	77.57±13.02	-0.38±1.61	0.25	76.32±10.2	74.96±9.30	-1.36±2.74	0.02
BMI (kg/m ²)	27.07±2.95	26.94±2.97	-0.14±0.56	0.26	26.37±2.53	25.90±2.20	-0.47±0.91	0.01
Waist (cm)	93.13±9.57	90.89±9.20	-2.24±2.80	<0.01	90.32±8.95	88.05±7.08	-2.27±3.81	<0.01
Body fat mass (kg)	24.20±5.61	23.04±6.07	-1.17±1.86	<0.01	22.31±6.91	21.03±5.87	-1.28±2.40	0.01
Skeletal muscle mass (kg)	30.17±6.53	30.59±6.56	0.42±1.02	0.05	30.36±5.70	30.35±5.81	-0.01±0.77	0.94

^a Paired t-test or Wilcoxon signed rank test were used to assess differences in nutrient intake from the baseline to 6 weeks within each group.

4. Changes in nutrient intakes

Differences in percent changes of energy intakes between the app group and the paper-based diary group were not statistically significant (mean \pm SD, -1.54 \pm 3.59 % vs. -2.05 \pm 5.39 %; p for group difference = 0.70) (Table 5).

Likewise, differences in the percent changes of carbohydrate, protein, fat, saturated fat, total dietary fiber, cholesterol, calcium, phosphorus, iron, sodium, potassium. Vitamin A, thiamine, riboflavin, niacin and vitamin C were not statistically significant between two groups.

When differences in nutrient intakes between pre- and post- intervention in each intervention arm were examined, energy intake decreased significantly or marginally significantly from pre- to post-intervention in both groups (app group: p-value=0.04; and the paper-based diary group: p-value=0.06) (Table 6). There were no significant decreases from pre- to post-intervention for the intakes of nutrients in the app group except energy intake. There were significant decreases for the intakes of carbohydrate, cholesterol, calcium, phosphorus, iron, potassium, and thiamin in the paper-based diary group (p-values were <0.01, 0.04, 0.01, 0.01, 0.04, 0.01 and 0.01 respectively)

Table 5. Differences in changes of nutrient intakes between the app group and the paper-based diary group

Characteristics	App group (n=25)			Paper-based diary group (n=25)			P-value ^b
	Mean ± standard deviation						
	Baseline	6 wk	Change (%) ^a	Baseline	6 wk	Change (%) ^a	
Energy (kcal/d)	2270.32±522.08	1984.41±365.32	-1.54±3.59	2061.88±560.80	1780.62±571.00	-2.05±5.39	0.70
Carbohydrate (g/d)	259.20±56.32	239.38±73.95	-1.68±5.34	268.72±74.80	217.74±60.88	-3.62±8.01	0.59
Protein (g/d)	100.83±28.66	91.86±20.51	-1.33±6.69	90.39±26.07	78.27±30.61	-3.89±10.21	0.30
Fat (g/d)	76.88±30.24	66.20±21.45	-2.10±12.96	70.03±28.61	65.70±29.89	-1.66±10.87	0.90
Saturated fat (g/d)	26.81±10.66	24.17±12.85	-2.18±19.42	24.09±10.67	19.86±7.50	-5.19±17.46	0.57
Total dietary fiber (g/d)	16.66±5.92	15.30±5.06	-1.29±16.31	17.37±6.39	15.00±5.67	-4.00±16.64	0.70
Cholesterol (mg/d)	368.41±121.56	359.11±148.06	-0.31±8.10	362.99±146.24	289.02±100.67	-3.26±8.41	0.33
Calcium (mg/d)	512.81±185.26	525.19±312.42	-0.38±7.47	548.80±283.80	438.86±241.87	-3.98±6.96	0.08
Phosphorus (mg/d)	1076.47±300.19	1041.92±297.08	-0.38±5.00	1067.55±281.07	878.06±268.59	-2.89±5.21	0.09
Iron (mg/d)	16.83±12.30	14.50±7.90	-1.35±21.09	19.68±32.32	17.91±32.40	-6.66±19.11	0.30
Sodium (mg/d)	4122.33±1113.03	3849.21±1198.38	-0.92±3.99	3932.72±1205.75	3531.87±1596.02	-2.43±7.60	0.89
Potassium (mg/d)	2254.36±562.28	2318.08±743.53	0.25±4.28	2325.87±658.33	2015.71±587.76	-1.93±3.80	0.06
Vitamin A (µg RE/d)	741.99±937.11	785.19±1087.62	1.20±11.60	588.38±716.89	574.15±580.02	1.26±19.91	0.71
Thiamine (mg/d)	2.68±5.14	2.89±5.94	226.32±1323.37	6.35±21.46	1.57±1.81	-14.59±596.32	0.44
Riboflavin (mg/d)	2.90±5.34	2.94±5.84	-119.57±581.86	5.86±21.10	1.48±1.30	-1.14±388.82	0.95
Niacin (mg/d)	25.66±28.68	24.25±30.84	-2.07±16.13	25.19±28.65	17.97±10.22	-4.31±19.43	0.66
Vitamin C (mg/d)	276.37±337.99	201.70±314.24	-6.49±21.14	127.28±119.96	154.73±281.76	-2.45±31.78	0.60

^a Percentage of change is calculated after transformed to natural logarithms

^b Independent t-test and Wilcoxon rank sum test were used to assess group differences

Table 6. Changes in nutrient intakes from the baseline to 6 weeks

Characteristics	App group (n=25)				Paper-based diary group (n=25)			
	Mean ± standard deviation			P-value ^a	Mean ± standard deviation			P-value ^a
	Baseline	6 wk	Change		Baseline	6 wk	Change	
Energy (kcal/d)	2270.32±522.08	1984.41±365.32	-285.91±636.22	0.04	2061.88±560.80	1780.62±571.00	-281.27±708.79	0.06
Carbohydrate (g/d)	259.2±56.32	239.38±73.95	-19.82±81.39	0.11	268.72±74.8	217.74±60.88	-50.98±85.43	<0.01
Protein (g/d)	100.83±28.66	91.86±20.51	-8.96±34.06	0.25	90.39±26.07	78.27±30.61	-12.12±34.1	0.09
Fat (g/d)	76.88±30.24	66.20±21.45	-10.69±40.7	0.20	70.03±28.61	65.70±29.89	-4.32±25.87	0.60
Saturated fat (g/d)	26.81±10.66	24.17±12.85	-2.64±17.75	0.17	24.09±10.67	19.86±7.50	-4.23±11.82	0.08
Total dietary fiber (g/d)	16.66±5.92	15.30±5.06	-1.36±7.98	0.42	17.37±6.39	15.00±5.67	-2.37±6.97	0.10
Cholesterol (mg/d)	368.41±121.56	359.11±148.06	-9.31±196.3	0.11	362.99±146.24	289.02±100.67	-73.97±166.7	0.04
Calcium (mg/d)	512.81±185.26	525.19±312.42	12.38±298.07	0.72	548.80±283.80	438.86±241.87	-109.94±219.49	0.01
Phosphorus (mg/d)	1076.47±300.19	1041.92±297.08	-34.55±409.44	0.63	1067.55±281.07	878.06±268.59	-189.49±311.96	0.01
Iron (mg/d)	16.83±12.30	14.50±7.90	-2.34±13.83	0.56	19.68±32.32	17.91±32.40	-1.77±6.70	0.04
Sodium (mg/d)	4122.33±1113.03	3849.21±1198.38	-273.12±1458.73	0.23	3932.72±1205.75	3531.87±1596.02	-400.85±1558.34	0.21
Potassium (mg/d)	2254.36±562.28	2318.08±743.53	63.72±850.83	0.83	2325.87±658.33	2015.71±587.76	-310.16±545.14	0.01
Vitamin A (µg RE/d)	741.99±937.11	785.19±1087.62	43.19±548.75	0.50	588.38±716.89	574.15±580.02	-14.23±575.34	0.84
Thiamine (mg/d)	2.68±5.14	2.89±5.94	0.20±1.88	0.49	6.35±21.46	1.57±1.81	-4.78±21.73	0.05
Riboflavin (mg/d)	2.90±5.34	2.94±5.84	0.04±2.08	0.70	5.86±21.10	1.48±1.30	-4.38±21.21	0.09
Niacin (mg/d)	25.66±28.68	24.25±30.84	-1.41±11.05	0.84	25.19±28.65	17.97±10.22	-7.22±28.82	0.26
Vitamin C (mg/d)	276.37±337.99	201.70±314.24	-74.67±213.90	0.11	127.28±119.96	154.73±281.76	27.45±291.77	0.42

^a Paired t-test or Wilcoxon signed rank test were used to assess differences in nutrient intake from the baseline to 6 weeks within each group.

5. Change in body weight according to the number of days of recording

Over a 6-week intervention period, the mean total number of days recorded was 18.52 days in the app group and 15.50 days in the paper-based diary group. This study examined whether the degree of weight loss was associated with the number of days of dietary recording in the app group and the paper-based diary group (Figure 10). The change in body weight from pre- to post-intervention tended to increase according to the increasing number of days recorded. However, the coefficient of slope was not statistically significant (p-value of the slope was 0.25 in the app group and 0.07 in the paper-based diary group). The R-squares were 0.0575 in the app group and 0.1431 in the paper-based diary group.

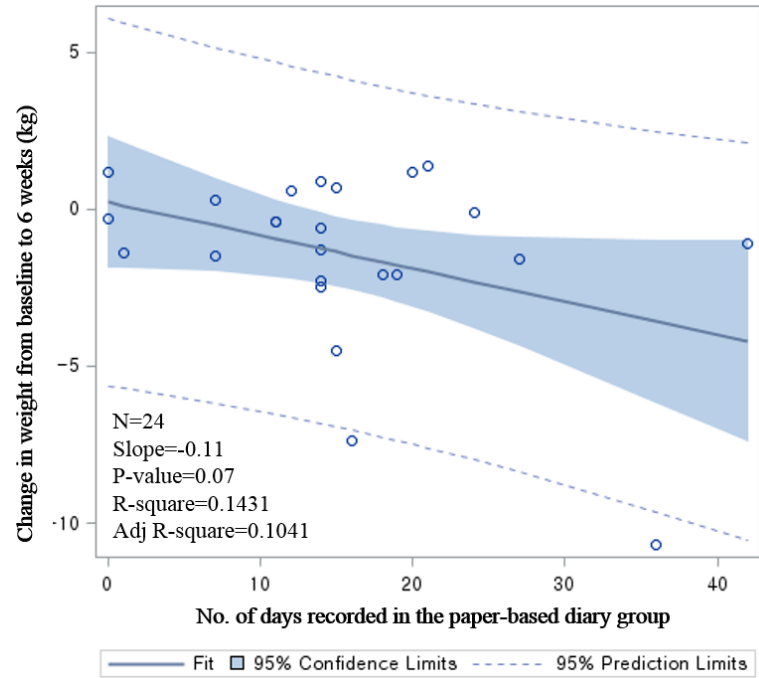
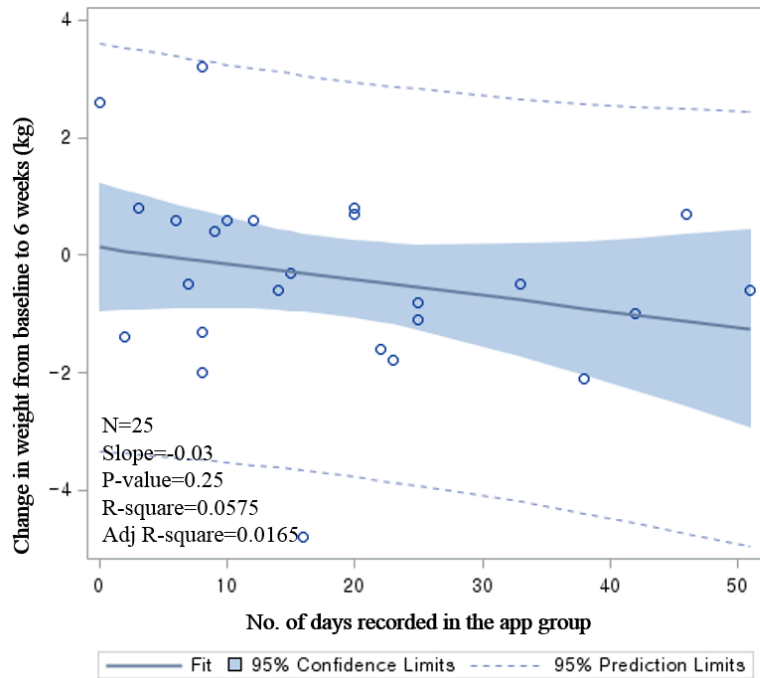


Figure 10. Weight loss according to the number of days of dietary recording in the app group and the paper-based diary group

6. Results of sensitivity analysis

The results presented in Table 3-6 were similar in the sensitivity analysis of per protocol set and a multiple imputation method for missing anthropometric measures and intakes of energy, carbohydrate, protein, and fat (Table 7-10).

For the per protocol analysis, there were no statistically significant differences in percent change of anthropometric measures and intakes of energy, carbohydrate, protein and fat between the app group and the paper-based diary group (Table 7). Compared pre-intervention measures to the post-intervention measures, there were significant decreases in body weight and BMI in the paper-based diary group (mean \pm SD, -1.42 ± 2.79 and -0.49 ± 0.92 respectively; p-value=0.02 and 0.01 respectively), but not in the app group (mean \pm SD, -0.38 ± 1.61 and -0.14 ± 0.56 respectively; p-value=0.25 and 0.26 respectively) (Table 8). Waist circumference and body fat mass decreased significantly in both groups, but the skeletal muscle mass significantly increased only in the app group (mean \pm SD, 0.42 ± 1.02 ; p-value=0.05). Energy intake decreased significantly in both groups (app group: p-value=0.04; and the paper-based diary group: p-value=0.05).

When the multiple imputation method was used, significant differences between the app group and the paper-based diary group were not found for percent change of anthropometric measures and intakes of energy, carbohydrate, protein and fat (Table 9). There were significant decreases from pre- to post-intervention in body weight and BMI in the paper-based diary group (mean \pm SD, -1.37 ± 2.74 and -0.47 ± 0.91 respectively; p-value=0.02 and 0.01 respectively), but not in the app group (mean \pm SD, -0.38 ± 1.61 and -0.14 ± 0.56 respectively; p-value=0.25 and 0.26 respectively) (Table 10). Waist circumference and body fat mass decreased significantly in both groups, but

the skeletal muscle mass significantly increased only in the app group (mean \pm SD, 0.42 ± 1.02 ; p-value=0.05). Energy intake decreased significantly in both groups (app group: p-value=0.04; and the paper-based diary group: p-value=0.04).

Table 7. Differences in changes of anthropometric measures and nutrient intakes between the app group and the paper-based diary group (by per protocol analysis)

Characteristics	App group (n=25)			Paper-based diary group (n=23)			P-value ^b
	Mean ± standard deviation						
	Baseline	6 wk	Change(%) ^a	Baseline	6 wk	Change(%) ^a	
Weight (kg)	77.95±12.89	77.6±13.00	-0.12±0.52	76.32±10.2	75.07±9.48	-0.41±0.74	0.21
BMI (kg/m ²)	27.07±2.95	26.94±2.97	-0.16±0.69	26.37±2.53	25.97±2.22	-0.54±0.98	0.22
Waist (cm)	93.13±9.57	90.89±9.20	-0.53±0.70	90.32±8.95	87.7±6.86	-0.57±0.84	0.90
Body fat mass (kg)	24.20±5.61	23.04±6.07	-1.99±3.63	22.31±6.91	20.94±5.71	-1.69±3.47	0.84
Skeletal muscle mass (kg)	30.17±6.53	30.59±6.56	0.45±0.98	30.36±5.70	30.13±6.01	-0.04±0.88	0.08
Energy (kcal/d)	2272.40±547.30	1974.60±365.01	-297.8±655.8	2013.48±566.80	1704.87±574.43	-308.6±725.8	0.96
Carbohydrate (g/d)	264.90±58.15	245.48±80.35	-19.46±88.15	262.76±74.65	205.73±54.54	-57.04±89.33	0.40
Protein (g/d)	105.60±33.97	98.41±41.11	-7.19±52.59	89.72±26.74	75.57±31.53	-14.16±35.37	0.60
Fat (g/d)	80.18±35.62	71.42±33.69	-8.76±49.18	64.14±20.74	59.64±21.38	-4.50±25.93	0.71
Saturated fat (g/d)	29.27±28.39	29.10±36.18	-0.18±46.07	19.50±10.11	17.00±6.71	-2.51±11.37	0.86
Total dietary fiber (g/d)	16.63±5.97	15.29±5.06	-1.34±8.00	17.09±6.54	14.37±5.68	-2.72±7.17	0.53
Cholesterol (mg/d)	371.30±122.50	362.79±160.24	-19.46±88.15	367.14±146.84	282.21±93.89	-84.92±168.83	0.24
Calcium (mg/d)	512.18±185.63	523.73±312.15	11.55±297.78	552.01±295.1	425.13±245.18	-126.88±224.90	0.11
Phosphorus (mg/d)	1075.56±300.61	1041.57±296.66	-33.99±409.70	1054.49±289.59	842.19±267.70	-212.30±331.60	0.11

(continued)

Table 7. Differences in changes of anthropometric measures and nutrient intakes between the app group and the paper-based diary group (by per protocol analysis) (continued)

Characteristics	App group (n=25)			Paper-based diary group (n=23)			P-value ^b
	Mean ± standard deviation						
	Baseline	6 wk	Change(%) ^a	Baseline	6 wk	Change(%) ^a	
Iron (mg/d)	16.82±12.30	14.49±7.90	-2.33±13.83	20.27±33.69	18.17±33.83	-2.09±6.80	0.21
Sodium (mg/d)	4092.57±1126.24	3830.41±1178.22	-262.2±1464.6	3808.2±1137.88	3332.03±1542.03	-476.2±1621.1	0.63
Potassium (mg/d)	2249±569.7	2315.52±741.64	66.53±846.7	2299.72±680.21	1947.52±602.81	-352.2±587.1	0.05
Vitamin A (µg RE/d)	725.93±941.87	785.16±1087.64	59.24±552.61	554.92±557.09	531.32±446.06	-23.61±598.2	0.62
Thiamine (mg/d)	2.68±5.15	2.89±5.94	0.2±1.88	6.77±22.36	1.58±1.89	-5.19±22.65	0.36
Riboflavin (mg/d)	2.9±5.34	2.94±5.84	0.05±2.08	6.26±21.99	1.49±1.35	-4.77±22.11	0.27
Niacin (mg/d)	25.65±28.69	24.25±30.84	-1.4±11.05	25.82±29.84	17.89±10.79	-7.94±29.99	0.50
Vitamin C (mg/d)	248.44±321.57	201.66±314.24	-46.78±201.07	131.41±124.47	153.17±290.06	21.76±298.76	0.78

Table 8. Changes in anthropometric measures and nutrient intakes from the baseline to 6 weeks (by per protocol analysis)

Characteristics	App group (n=25)				Paper-based diary group (n=23)			
	Mean ± standard deviation			P-value ^a	Mean ± standard deviation			P value ^a
	Baseline	6 wk	Change		Baseline	6 wk	Change	
Weight (kg)	77.95±12.89	77.57±13.02	-0.38±1.61	0.25	76.32±10.20	75.07±9.48	-1.42±2.79	0.02
BMI (kg/m ²)	27.07±2.95	26.94±2.97	-0.14±0.56	0.26	26.37±2.53	25.97±2.22	-0.49±0.92	0.01
Waist (cm)	93.13±9.57	90.89±9.20	-2.24±2.80	<0.01	90.32±8.95	87.70±6.86	-2.47±3.92	<0.01
Body fat mass (kg)	24.20±5.61	23.04±6.07	-1.17±1.86	<0.01	22.31±6.91	20.94±5.71	-8.97±4.64	0.01
Skeletal muscle mass (kg)	30.17±6.53	30.59±6.56	0.42±1.02	0.05	30.36±5.70	30.13±6.01	-0.01±0.80	0.94
Energy (kcal/d)	2272.40±547.30	1974.6±365.01	-297.8±655.8	0.04	2013.48±566.8	1704.87±574.43	-308.60±725.80	0.05
Carbohydrate (g/d)	264.90±58.15	245.48±80.35	-19.46±88.15	0.12	262.76±74.65	205.73±54.54	-57.04±89.33	<0.01
Protein (g/d)	105.60±33.97	98.41±41.11	-7.19±52.59	0.45	89.72±26.74	75.57±31.53	-14.16±35.37	0.07
Fat (g/d)	80.18±35.62	71.42±33.69	-8.76±49.18	0.35	64.14±20.74	59.64±21.38	-4.50±25.93	0.41
Saturated fat (g/d)	29.27±28.39	29.10±36.18	-0.18±46.07	0.31	19.50±10.11	17.00±6.71	-2.51±11.37	0.33
Total dietary fiber (g/d)	16.63±5.97	15.29±5.06	-1.34±8.00	0.44	17.09±6.54	14.37±5.68	-2.72±7.17	0.08
Cholesterol (mg/d)	371.30±122.50	362.79±160.24	-19.46±88.15	0.41	367.14±146.84	282.21±93.89	-84.92±168.83	0.03
Calcium (mg/d)	512.18±185.63	523.73±312.15	11.55±297.78	0.71	552.01±295.10	425.13±245.18	-126.88±224.90	0.02
Phosphorus (mg/d)	1075.56±300.61	1041.57±296.66	-33.99±409.70	0.63	1054.49±289.59	842.19±267.70	-212.30±331.60	<0.01
Iron (mg/d)	16.82±12.30	14.49±7.90	-2.33±13.83	0.56	20.27±33.69	18.17±33.83	-2.09±6.80	0.03
Sodium (mg/d)	4092.57±1126.24	3830.41±1178.22	-262.20±1464.60	0.27	3808.20±1137.88	3332.03±1542.03	-476.20±1621.10	0.17
Potassium (mg/d)	2249±569.70	2315.52±741.64	66.53±846.70	0.80	2299.72±680.21	1947.52±602.81	-352.20±587.10	<0.01

(continued)

Table 8. Changes in anthropometric measures and nutrient intakes from the baseline to 6 weeks (by per protocol analysis) (continued)

Characteristics	App group (n=25)				Paper-based diary group (n=23)			
	Mean ± standard deviation			P-value ^a	Mean ± standard deviation			P value ^a
	Baseline	6 wk	Change		Baseline	6 wk	Change	
Vitamin A (µg RE/d)	725.93±941.87	785.16±1087.64	59.24±552.61	0.38	554.92±557.09	531.32±446.06	-23.61±598.20	0.86
Thiamine (mg/d)	2.68±5.15	2.89±5.94	0.2±1.88	0.49	6.77±22.36	1.58±1.89	-5.19±22.65	0.10
Riboflavin (mg/d)	2.90±5.34	2.94±5.84	0.05±2.08	0.76	6.26±21.99	1.49±1.35	-4.77±22.11	0.09
Niacin (mg/d)	25.65±28.69	24.25±30.84	-1.4±11.05	0.84	25.82±29.84	17.89±10.79	-7.94±29.99	0.19
Vitamin C (mg/d)	248.44±321.57	201.66±314.24	-46.78±201.07	0.32	131.41±124.47	153.17±290.06	21.76±298.76	0.34

Table 9. Differences in changes of anthropometric measures and nutrient intakes between the app group and the paper-based diary group (missing data were imputed by multiple imputation method)

Characteristics	App group (n=25)			Paper-based diary group (n=25)			P-value ^b
	Mean ± standard deviation						
	Baseline	6 wk	Change(%) ^a	Baseline	6 wk	Change(%) ^a	
Weight (kg)	77.95±12.89	77.60±13.00	-0.12±0.52	76.32±10.20	74.96±9.30	-0.38±0.74	0.24
BMI (kg/m ²)	27.07±2.95	26.94±2.97	-0.16±0.69	26.37±2.53	25.90±2.20	-0.49±0.98	0.25
Waist (cm)	93.13±9.57	90.89±9.20	-0.53±0.70	90.32±8.95	87.97±6.86	-0.53±0.83	>0.99
Body fat mass (kg)	31.22±5.90	29.79±6.43	-1.99±3.63	29.69±8.01	20.95±5.81	-1.66±3.32	0.85
Skeletal muscle mass (kg)	30.17±6.53	30.59±6.56	0.45±0.98	30.36±5.70	30.34±5.80	-0.04±0.84	0.07
Energy (kcal/d)	2270.32±522.08	1984.41±365.32	-1.54±3.59	2061.88±560.80	1726.06±541.53	-2.39±5.39	0.51
Carbohydrate (g/d)	259.20±56.32	239.38±73.95	-1.68±5.34	268.72±74.80	208.04±52.49	-4.27±8.02	0.28
Protein (g/d)	100.83±28.66	91.86±20.51	-1.33±6.69	90.39±26.07	78.38±30.97	-3.89±10.21	0.30
Fat (g/d)	76.88±30.24	66.20±21.45	-2.10±12.96	70.03±28.61	60.42±20.44	-2.78±11.54	0.84

^a Percentage of change is calculated after transformed to natural logarithms

^b Independent t-test and Wilcoxon rank sum test were used to assess group differences

Table 10. Changes in anthropometric measures and nutrient intakes from the baseline to 6 weeks (missing data were imputed by multiple imputation method)

Characteristics	App group (n=25)				Paper-based diary group (n=25)			
	Mean ± standard deviation							
	Baseline	6 wk	Change	P-value ^a	Baseline	6 wk	Change	P value ^a
Weight (kg)	77.95±12.89	77.57±13.02	-0.38±1.61	0.25	76.32±10.20	74.96±9.30	-1.37±2.74	0.02
BMI (kg/m ²)	27.07±2.95	26.94±2.97	-0.14±0.56	0.26	26.37±2.53	25.90±2.20	-0.47±0.91	0.01
Waist (cm)	93.13±9.57	90.89±9.20	-2.24±2.80	<0.01	90.32±8.95	87.97±6.86	-2.36±3.82	<0.01
Body fat mass (kg)	24.20±5.61	23.04±6.07	-1.17±1.86	<0.01	22.31±6.91	20.95±5.81	-1.36±2.38	0.01
Skeletal muscle mass (kg)	30.17±6.53	30.59±6.56	0.42±1.02	0.05	30.36±5.70	30.34±5.80	-0.02±0.77	0.88
Energy (kcal/d)	2270.32±522.08	1984.41±365.32	-285.91±636.22	0.04	2061.88±560.8	1726.06±541.53	-335.82±712.93	0.04
Carbohydrate (g/d)	259.20±56.32	239.38±73.95	-19.82±81.39	0.11	268.72±74.80	208.04±52.49	-60.68±86.01	<0.01
Protein (g/d)	100.83±28.66	91.86±20.51	-8.96±34.06	0.25	90.39±26.07	78.38±30.97	-12.01±34.18	0.09
Fat (g/d)	76.88±30.24	66.20±21.45	-10.69±40.70	0.20	70.03±28.61	60.42±20.44	-9.61±33.51	0.31

^a Paired t-test or Wilcoxon signed-rank test were used to assess differences in nutrient intake from the baseline to 6 weeks within each group.

7. Feasibility of the app

Participants' responses in the app group to the questions regarding usability and usefulness of Well-D versus other diet methods are presented in Table 11. Of the 25 users in the app group, 84% of the users agreed to the statement 'Do you agree that the app you used for this research provides newer information than other weight loss methods you have tried in the past?' More than half of the users answered that the app was more motivating than other weight loss methods that users have used in the past (52%). However, 56% of the users disagreed with the statement 'Do you agree that Well-D is more convenient than other weight loss methods you have used in the past?'

Table 11. Responses to questions about usability and usefulness of the Well-D versus other diet methods (n=25)

Items	Absolutely disagree	Mostly disagree	Neutral	Mostly agree	Strongly agree
1. Do you agree that Well-D is easier than other weight loss methods you have used in the past?	3 (12%)	5 (20%)	12 (48%)	5 (20%)	0 (0%)
2. Do you agree that Well-D is more convenient than other weight loss methods you have used in the past?	1 (4%)	13 (52%)	7 (28%)	4 (16%)	0 (0%)
3. Do you agree that Well-D provides newer information than other weight loss methods you have used in the past?	0 (0%)	2 (8%)	2 (8%)	15 (60%)	6 (24%)
4. Do you agree that Well-D is more motivating than other weight loss methods you have used in the past?	1 (4%)	4 (16%)	7 (28%)	11 (44%)	2 (8%)
5. Do you agree that Well-D changes eating habits more than other weight loss methods you have used in the past?	0 (0%)	8 (32%)	6 (24%)	10 (40%)	1 (4%)

V. Discussion

This study conducted a weight loss randomized trial of young adults with 23 kg/m² or more of BMI in order to compare the effectiveness of the mobile dietary self-monitoring app versus the paper-based diary. There were no significant differences in changes of body weight, BMI, waist circumference, body fat mass and skeletal muscle mass between the app group and the paper-based diary group. Waist circumference and body fat mass significantly decreased in both groups and skeletal muscle mass significantly increased in the app group. In addition, the changes of nutrient intake were not different between the two groups. When nutrient intakes from the baseline to the 6-week intervention period were compared, energy intakes decreased in both groups and the intakes of carbohydrates, cholesterol, calcium, phosphorus, iron, potassium, and thiamin significantly decreased in the paper-based diary group only.

In a literature review, the effectiveness of mHealth weight-loss programs that used short message service (SMS), websites, and smartphone apps in intervention studies of US obese adults suggests that mHealth technologies may be more effective than conventional care (Bhardwaj, Wodajo, Gochipathala, Paul, & Coustasse, 2017). Several studies used mobile dietary tracking apps for weight loss (Burke et al., 2017; Carter et al., 2013; Chin et al., 2016; Laing et al., 2014; Turner-McGrievy et al., 2017; Toro-Ramos et al., 2017). A longitudinal study with a median follow-up of 275 days investigated the effectiveness of the Noom Coach app on weight reduction among 35,921 South Korean adults with 23 kg/m² or more of BMI who recorded dietary data two or more times a month for six consecutive months (Chin et al., 2016). The

study found that 22.7% of app users reduced their weight more than 10% in comparison with the baseline. Similarly, an intervention study in Korea showed that using Noom Coach app with daily behavior and nutrition education content and coaching resulted in a significant weight loss effect of -7.5% at the end of the 15 weeks intervention periods, and the effect of -5.2% was maintained at a 52-week follow-up (Toro-Ramos et al., 2017). A US intervention study showed that participants using the smartphone app ‘Lose It!’ lost weight at a significant level after a 12-week intervention period (Burke et al., 2017). Another trial of the ‘My Meal Mate’ app showed a significant weight loss among overweight and obese participants during a 6-month intervention period. However, the weight change over time was not significantly different when the app group was compared to the diary group (Carter et al., 2013). There was no difference in weight change between usual care and care with the MyFitnessPal app in overweight participants during the 6-month intervention period (Laing et al., 2014). App users in the aforementioned studies experienced a significant weight loss in comparison with the baseline (Burke et al., 2017; Carter et al., 2013; Laing et al., 2014; Turner-McGrievy et al., 2017; Toro-Ramos et al., 2017). Two intervention studies compared the app group with the paper-based diary group or the usual care group and found that the magnitude of weight loss was not statistically different (Carter et al., 2013; Laing et al., 2014). One intervention study showed that the group that self-monitored their diet with a mobile app lost significantly more weight than the wearable Bite Counter device group (Turner-McGrievy et al., 2017).

Consistent with previous research, this study found a significant loss of body fat in comparison to the baseline measure in the app group but no differences in changes of anthropometric measures between the app group and

the paper-based diary group. No significant difference between two groups that this study observed could be partly because of a short follow-up. A significant improvement from the baseline in both app and the paper-based diary groups suggests that both tools may be effective in modulating users' diet and losing users' weights. Further larger intervention studies with a longer period are warranted.

Several studies supported the effectiveness of an app to improve users' diet (Ipjian & Johnston, 2017; Jimoh et al., 2018; Lee et al., 2017; Mummah et al., 2016). The feasibility of the smartphone app Diet-A was tested in a three-month intervention study, resulting in significant decreases in sodium and calcium intake among adolescents (Lee et al., 2017). A pilot intervention study with MyFitnessPal showed that change in urinary sodium in the app group was significantly lower than the paper-based journal group during a 4-week intervention period (Ipjian & Johnston, 2017). In another intervention study, 34 adolescents recorded food intake using a paper diary or the FoodWiz2 app during a 4-week intervention period and the app group showed significantly reduced consumption of chocolate snacks and fizzy drinks in comparison to the baseline (Jimoh et al., 2018). A pilot study of 17 overweight adults found that the Vegethon app group consumed vegetables significantly higher than the control group at the end of the 12-week pilot study (Mummah et al., 2016).

In this study, there were significant decreases in the intakes of carbohydrate, cholesterol, calcium, phosphorus, iron, potassium, and thiamin among the paper-based diary group, but not in the app group. It may suggest that participants in the app group tended to keep their nutrient intakes compared to the paper-based diary group, even though energy intake was decreased in the both groups. Although the reason is not clear, real-time feedback on key

nutrients including dietary fiber and calcium may have caused app users to avoid reducing good nutrients. Given that 84% of the users responded that Well-D provides newer information than other weight loss methods, the app may be useful for users who intended to maintain a healthy diet and weight.

Adherence to the intervention is one of the key factors for achieving improved health outcomes (World Health Organization, 2003). When comparing usage frequency of the My Meal Mate app to the pattern of electronic dietary self-monitoring and weight loss, participants in the highest frequency-of-use category lost an average of -6.4kg more than those in the lowest frequency-of-use category during the 6-month intervention period (Carter et al., 2017). A cohort study showed that the greater number of recordings into the smartphone app was associated with higher weight loss (Chin et al., 2016). In our study, this study observed the tendency of greater weight loss as the number of recordings increased, albeit without statistical significance. This may be partly explained by the fact that the intervention period in this study was relatively short and baseline BMIs of participants were lower than BMIs in other weight loss studies (Carter et al., 2017; Chin et al., 2016).

According to the aforementioned previous studies in the literature review, most users who recorded their dietary intakes through mobile dietary self-monitoring apps reported that the apps that they used enable them to monitor their food intake (Ipjian & Johnston, 2017; Lee et al., 2017; Mummah et al., 2017). However, such monitoring could be burdensome for some users (Lee et al., 2017).

In this study, about 84% of users in the app group responded that Well-D provides more new information than other weight loss methods. Additionally, most of the users in the app group responded Well-D was neither easy to use

nor convenient for weight loss compared to other weight loss methods used previously. Even though the dietitians updated the database frequently, the users included in this study consumed diverse types of foods because the majority of the users were young adults. Moreover, Well-D did not support automatic logins which might contribute to inconvenience during use. Improved technical support for the app is required to enhance usability. Because users were satisfied with the information that the app provided, it may be useful for users who have a desire to improve their diets as well as lose weight.

This study is a randomized parallel trial with a high follow-up rate. Because the researchers who conducted this study participated to develop the app, this study had full access to the data. However, this study has several limitations. Because the population was composed of young adults, the results may not be generalizable to children or older people. Because this study included participants with 23 kg/m² or above BMI, the magnitude of weight loss during the 6-week intervention period may not be large enough to see the difference. However, waist circumference and body fat mass significantly decreased in the app group. Well-D needs to be improved in terms of usability and interface based on the users' responses. The study period was relatively short. Further longer and larger intervention studies on the effectiveness of smartphone application-based dietary care are warranted.

This study conducted a randomized trial to evaluate the effectiveness of a mobile dietary self-monitoring app for weight loss versus a paper-based diary. The participants reduced their energy intake, waist circumference, and body fat mass in both groups. However, no difference in changes between the app group and the paper-based diary group suggests the evidence that both smartphone app and hand-writing may be effective in weight loss. There was

no change in the app group but a significant decrease in several vitamins and minerals in the paper-based diary group. Therefore, this study suggests that both the app and the paper-based diary may be useful for improving anthropometric measures and dietary intake.

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국문초록

식습관 관리 어플리케이션과 식사 일지 사용 간 체중 감량 효과 비교 : 무작위 배정 중재 연구

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안정선

비만 유행률은 전 세계적으로 증가하는 추세이며, 이를 예방하기 위한 효과적인 중재 전략이 요구된다. 선행된 중재연구들에서 식습관 관리 어플리케이션이 체중 감량 및 식사 관리 도구로서 효과가 있는지 평가하였으며, 연구의 설계 및 사용된 도구에 따라 그 효과 여부가 다르게 나타났다. 따라서 본 연구에서는 체질량지수 (BMI)가 23 kg/m^2 이상인 젊은 성인들을 대상으로 무작위 배정 중재 연구를 수행하여 6주 동안 스마트폰 어플리케이션 사용군과 식사 일지 사용군 간 체중 감량 효과를 비교하고자 하였다.

대상자 참여 기준은 1) 만 연령 18세 이상 40세 이하의 성인, 2) BMI 23 kg/m^2 이상인 자, 3) 체중 감량 의지가 있는 자, 4) 임신

부 및 수유부가 아닌 자, 5) 스마트폰 사용자로 설정하였다.

연구의 주요 결과 변수로서 체중(kg), BMI(kg/m²), 허리둘레(cm), 체지방량(kg), 골격근량(kg)을 조사하였고 보조 결과 변수로서 영양소 섭취 변화 및 중재 기간 중 연구 참여도를 조사하였다. 중재 기간 동안 어플리케이션군은 본 연구진이 개발한 식품습관 관리 어플리케이션 Well-D를 사용하여 섭취한 음식 및 식이 보충제를 검색하여 기록했고, 참여자의 프로필과 식사섭취 데이터를 기반으로 한 즉각적인 영양소 및 식품 피드백을 제공받았다. 식사 일지군은 식사 일지를 이용해 날짜, 시간 및 섭취한 음식, 재료, 분량, 열량, 식이 보충제를 기록하였고, 체중 감량을 위한 목표 열량을 직접 계산하여 실제 섭취 열량과 비교하였다. 식사 일지와 더불어 체중 감량 전략이 포함된 리플릿을 함께 제공받았다.

군 간 연구대상자의 특성 및 결과변수의 퍼센트 변화 차이(%)는 연속형 변수의 경우 independent t-test 또는 Wilcoxon Mann-Whitney test로 분석하였고, 범주형 변수의 경우 Chi-square test 혹은 Fisher's exact test로 분석하였다. 각 군 내 중재 전후 측정치 변화 차이는 조사된 측정치를 Box-cox analysis로 변환한 뒤 paired t-test 혹은 Wilcoxon rank sum test로 분석하였다. 참여자의 연구 순응도에 따른 체중 변화를 simple linear regression으로 분석하였다. 데이터는 Intention to treat analysis로 분석되었다. 결측값은 이월대체(carried forward method)하였고 민감성 분석으로서 per-protocol analysis와 다중대체법을 이용해(multiple imputation

by chained equations) 중재 후 신체계측치와, 열량, 탄수화물, 단백질, 지방의 결측값을 대체한 뒤 결과를 비교하였다.

어플리케이션군 및 식사일지군으로서 각각 25명의 참여자가 배정되었고 6주 간의 중재연구에 참여하였다. 어플리케이션군의 참여자는 모두 중재를 마친 뒤 방문하여 중재 후 조사에 참여하였고, 식사일지군 중 23명의 참여자가 중재 후 조사를 완료하였다. 최종적으로 각 군별 25명을 분석에 포함하였다.

기저조사에서 연구참여자 간 특성 차이는 유의하지 않았다. 체중을 포함한 모든 측정치의 군 간 퍼센트 변화 차이는 통계적으로 유의하지 않았다 (체중 % 변화의 평균 \pm 표준편차: -0.12 ± 0.52 vs -0.39 ± 0.73 ; p-value=0.24). 중재 전후 식사일지군 내에서 체중과 BMI가 유의하게 감소하였다. 허리둘레, 체지방량은 두 군 내에서 모두 유의하게 감소하였으나, 골격근량은 어플리케이션군 내에서만 유의하게 증가하였다. 두 군 모두 연구 참여 순응도에 따라 체중이 낮아지는 경향이 있었으나 그 변화는 통계적으로 유의하지 않았다.

어플리케이션군과 식사일지군 간 영양소 퍼센트 변화에 유의한 차이가 없었고, 두 군 내에서 모두 중재 전후 에너지 섭취량이 감소했다 (각 p-value=0.04, 0.06). 식사일지군 내에서 중재 전후 탄수화물, 콜레스테롤, 칼슘, 인, 철분, 칼륨, 티아민 섭취량의 유의한 감소가 있었다. 민감성 분석 수행 결과 경향의 변화가 없었다.

본 연구에서는 과체중 및 비만 성인을 대상으로 스마트폰 식

습관 관리 어플리케이션을 이용한 체중 변화 효과를 식사일지 사용과 비교하여 파악하였다. 연구 결과 어플리케이션군과 식사일지군 간 신체계측치 및 영양소 퍼센트 변화에 유의한 차이가 없었다. 그러나 어플리케이션군 내에서 허리둘레, 체지방량 및 열량섭취량의 유의한 감소와 골격근량의 유의한 증가가 있었으며, 식사일지군 내에서 체중, BMI, 허리둘레, 체지방량, 탄수화물, 콜레스테롤, 칼슘, 인, 철분, 칼륨, 티아민 섭취량의 유의한 감소가 있었다. 본 연구 결과 어플리케이션 사용과 식사일지 모두 신체계측치 변화 및 영양소 섭취량 변화 가능성이 제시되었으며, 향후 효과적인 식습관 관리 방법 마련 시 참고자료가 될 수 있을 것이라 사료된다.

주요어 : 스마트폰 어플리케이션, 식습관 관리 어플리케이션, 비만, 무작위 배정 중재연구

학 번 : 2017-26422