Progress report 2022

A novel ICT-based patient-centered service at pharmacies

Associate Professor	Kayo Waki, M.D., M.P.H., Ph.D
Project Researcher	Shunpei Enomoto., MAS
Project Researcher	Tomomi Shibuta, RN, PHN, PhD

■ ***Overview***

This project aims to understand the needs of patients and develop services using IoT/ICT that increase the satisfaction of patients and healthcare professionals. We have developed an information network to build a system that virtually collects daily health data, obtained and managed in separate places and times, and virtually integrates them to support self-management of lifestyle-related diseases. Our ultimate goal is to provide digital therapeutics that prevent progression of these diseases by promoting behavior changes and healthier lifestyles.

In fiscal year 2022, we used the knowledge obtained to-date to develop a smartphone application using a new concept that focuses on support of exercise therapy, especially increasing the number of steps per day, by incorporating social cognitive theory in the app. We then started a clinical trial of this new approach.

■ **Research projects**

DialBetics: A novel smartphone-based self-management support system for type 2 diabetes patients

Patients with diabetes are expected to have access to the integral components of diabetes care. Self-management is the core of diabetes treatment because it ties the components of diabetes therapy together, enabling patients to assess and affect the critical elements of nutrition, physical activity, emotional/physical stress, and medications. There is a longstanding need for an effective self-management tool that could automate and standardize much of the counseling process, facilitating self-monitoring of blood glucose, blood pressure, body weight and lifestyle (particularly diet and exercise). Accordingly, we developed just such a real-time, partially-automated interactive system to interpret patients' data—biological information, exercise, and diet content calculated from a message sent by patients—and respond with appropriate actionable findings, helping the patients achieve diabetes self-management.

1. DialBeticsPlus: A smartphone-based self-management support system for patients with diabetic kidney disease who need to slow down the progression of diabetic complications

In 2018, we started a prospective, randomized, controlled, open-label, multi-institutional clinical trial to evaluate the impact of DialBeticsPlus on Diabetic Kidney Disease (DKD). The study was completed in 2021, and the first results are expected to be available in 2023. The intervention produced significant improvements in exercise, with patients averaging 7552 steps per day. The primary outcome, change in urinary albumin-to-creatinine ratio (UACR) after 12 months, was 28.8% better than the control group's change ($p = 0.029$). Secondary outcomes also improved in the intervention group, including a 0.32-point better change in hemoglobin HbA1c percentage ($p = 0.041$). This study is supported by the Japan Agency for Medical Research and Development, AMED.

2. DialBetics Step: A smartphone-based self-management support system focusing on the number of steps

Employing Social Cognitive Theory (SCT) to

promote physical activity, we produced DialBetics Step by adding enhanced goal setting and automated feedback functions to DialBetics. We conducted a pilot study in 2018 and 2019 using DialBetics Step with 34 subjects with hypertension, all employees of private companies. Participants significantly increased their number of daily steps and their daily energy consumption. The results were accepted for publication in JMIR Cardio.

3. DialBeticsLite: A smartphone-based self-management support system for people with abdominal obesity focusing on metabolic syndrome, a risk factor for developing diabetes.

In 2017, we conducted a pilot study of DialBeticsLite among 48 Japanese office workers. In total, 85% (41/48) of the participants reported that their participation in the study helped them improve their lifestyle. BMI, waist circumference, and visceral fat area decreased significantly after the intervention ($p < 0.001$). In addition, daily calorie intake reduced significantly ($p = 0.02$). There was a significant improvement in self-care behavior in terms of exercise and diet ($p = 0.001$). The results were published in JMIR Diabetes (https://diabetes.jmir.org/2022/4/e40366/). Based on these results, in 2017 we used DialBeticsLite in a prospective, randomized, controlled, open-label trial employing among 122 Japanese office workers. The average change of visceral fat area was −23.5 (SD 20.6) cm^2 in the intervention group and +1.9 (SD 16.2) cm^2 in the control group ($p < 0.001$). Statistically significant differences were also found for change of body weight, BMI, and waist circumference. The results were published in JMIR Formative Research (https://formative.jmir.org/2022/3/e33852/).

4. Smart-H: A tablet-based self-management support system for type 2 diabetes patients

The Smart-H version of DialBetics uses a tablet for all communications, including data input and telemedicine, rather than a smartphone.
In 2020, we conducted a pilot study of Smart-H among 20 subjects, all employees of one private company, with a primary focus on usability.

5. Personalized Life-Data Storage (PLS): A personal health record system

We conducted a pilot study and a prospective trial of a personal health record system, PLS. The key characteristic of PLS is use of two access routes for registered data, one from the patient and the other from the physician. The pilot study was completed in July 2021, and the prospective trial, with more than 120 participants, completed in in January 2023. The primary focus of the trials was usability.

6. DKD-ET (StepAdd): A clinical trial of an intervention using a smartphone application focusing on increasing physical activity

In 2021 we produced a new application, StepAdd, and conducted a pilot study of StepAdd at Mitsui Memorial Hospital. StepAdd is an SCT-based digital intervention; it assists patients to set step goals, define the actions needed to achieve the goals, and identify barriers to behavioral change. Daily step counts increased dramatically with high statistical significance ($p < 0.0001$), an 86.7% increase. HbA1c ($p = 0.0001$) and BMI ($p = 0.0038$) also improved. Diabetes self-care in diet, exercise, and foot care as well as self-management behavior, self-regulation, and self-efficacy in achieving daily step goals showed significant improvements. The retention rate of the study was very high, at 97.0%. The results were submitted for publication in 2022. Based on the promising results of the StepAdd pilot study, in 2023 we started a randomized controlled trial to test StepAdd's effectiveness, with the goal of obtaining PMDA approval of the software as a medical device. The study is registered at jRCT (https://jrct.niph.go.jp/en-latest-detail/jRCT2032220603.) Collaborating among five facilities, we are targeting 160 patients. We expect the trial to conclude in 2025.

■ Future directions

We are continuing our clinical trial of StepAdd. We are also proceeding with the development of other applications that incorporate different concepts and contribute to new interventions. We are working on research to develop treatment guidance that is close to the daily life of patients, without restrictions on place and time, by utilizing IoT / ICT. The goal is to enable guidance and medical care that are not restricted by where you are and the date or time, and do not require face-to-face conversations. We are trying to provide access to medical service beyond space and time.

■ Publications in English

1. Klonoff DC, Wang J, Rodbard D, Kohn MA, Li C, Liepmann D, Kerr D, Ahn D, Peters AL, Umpierrez GE, Seley JJ, Xu NY, Nguyen KT, Simonson G, Agus MSD, Al-Sofiani ME, Armaiz-Pena G, Bailey TS, Basu A, Battelino T, Bekele SY, Benhamou PY, Bequette BW, Blevins T, Breton MD, Castle JR, Chase JG, Chen KY, Choudhary P, Clements MA, Close KL, Cook CB, Danne T, Doyle FJ 3rd, Drincic A, Dungan KM, Edelman SV, Ejskjaer N, Espinoza JC, Fleming GA, Forlenza GP, Freckmann G, Galindo RJ, Gomez AM, Gutow HA, Heinemann L, Hirsch IB, Hoang TD, Hovorka R, Jendle JH, Ji L, Joshi SR, Joubert M, Koliwad SK, Lal RA, Lansang MC, Lee WA, Leelarathna L, Leiter LA, Lind M, Litchman ML, Mader JK, Mahoney KM, Mankovsky B, Masharani U, Mathioudakis NN, Mayorov A, Messler J, Miller JD, Mohan V, Nichols JH, Nørgaard K, O'Neal DN, Pasquel FJ, Philis-Tsimikas A, Pieber T, Phillip M, Polonsky WH, Pop-Busui R, Rayman G, Rhee EJ, Russell SJ, Shah VN, Sherr JL, Sode K, Spanakis EK, Wake DJ, Waki K, Wallia A, Weinberg ME, Wolpert H, Wright EE, Zilbermint M, Kovatchev B. A Glycemia Risk Index (GRI) of Hypoglycemia and Hyperglycemia for Continuous Glucose Monitoring Validated by Clinician Ratings. J Diabetes Sci Technol. 2022 Mar 29:19322968221085273. doi: 10.1177/19322968221085273. Epub ahead of print. PMID: 35348391.
2. Kurasawa H, Waki K, Chiba A, Seki T, Hayashi K, Fujino A, Haga T, Noguchi A, Ohe K. Treatment Discontinuation Prediction in Patients With Diabetes Using a Ranking Model: Machine Learning Model Development. JMIR Bioinform Biotech 2022;3(1):e37951. doi:10.2196/37951
3. Hartz L, Waki K. Chapter 19 - An Asian perspective on digital health for diabetes Author links open overlay panel. Diabetes Digital Health and Telehealth.2022:243-254. doi: 10.1016/B978-0-323-90557-2.00010-8
4. Kawai Y, Waki K, Yamaguchi S, Shibuta T, Miyake K, Kimura S, Toyooka T, Nakajima R, Uneda K, Wakui H, Tamura K, Nangaku M, Ohe K. The Use of Information and Communication Technology-Based Self-management System DialBeticsLite in Treating Abdominal Obesity in Japanese Office Workers: Prospective Single-Arm Pilot Intervention Study. JMIR Diabetes. 2022 Nov 28;7(4):e40366. doi: 10.2196/40366. PMID: 36441577.