

<22nd Century Medical Center FY2024 Activity Report >

Project Title:

Construction of an ICT system to support treatment of diabetes patients and development of a medical device program using the system

Representative (Chairperson):

Kayo Waki, Associate Professor

Member :

Ayaka Seki, Academic Specialist

Kyohei Hasegawa, Academic Specialist

Shuya Iwata, Academic Specialist

Ryohei Nakada, Academic Specialist

Mari Hirato, Academic Specialist

Toshiyuki Shibata, Visiting-Researcher

Katsuaki Morooka, Visiting Researcher

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Teru Okitsu, Visiting- Research Scientist

Sosuke Amano, Visiting- Researcher

Daniel R Lane, Visiting Researcher

Mari Waki, Visiting Researcher

Ji Yuexiang, Visiting Researcher

Naoyuki Kanda, Visiting Researcher

Haruho Sato, Visiting Researcher

Kaori Wakayama, Administrative Staff

Project Summary:

This project aims to understand the various needs of physicians, healthcare workers, and patients, develop smartphone applications with services and functions that satisfy both healthcare professionals and patients through the use of IoT/ICT, and contribute to the broad penetration of DTx (Digital Therapeutics) in the medical industry. We have been constructing and analyzing a system that virtually integrates electronic health records and medical information obtained and managed without temporal and spatial limitations. We are clarifying factors that influence the course and progression of lifestyle-related diseases, and quantitatively verifying the impact of each factor, with the aim of developing new services.

The Department of Ubiquitous Health Informatics was established at the 22nd Century Medical Center in September 2009, and has been working with patients with type 2

diabetes and other high-risk groups with lifestyle-related diseases. The department developed an ICT system (DialBetics, later renamed DialBetes) to support self-management for patients with type 2 diabetes or groups at high risk for lifestyle-related diseases. The Department closed in August 2019. Since September of the same year, the project has been handling ongoing projects and planning and executing new projects, and this year, with the cooperation of several hospitals, we are conducting a multicenter collaborative study on diabetes patients.

In addition, a clinical trial using a smartphone application (an exercise therapy assistance system) developed based on the findings from previous studies and focusing on walking was started a year before last, and recruiting was completed in the first half of this year. Next year, the data acquisition is expected to be completed with the data fixation scheduled for September.

【Research Contents 】

The former Department of Ubiquitous Health Informatics developed a system (renamed from DialBetics to DialBetes) to support self-management in type 2 diabetes patients and conducted randomized controlled trials on a scale of about 50 people. In FY2024, we continued the following activities (1) to (5), including studies using the system developed so far.

(1) Randomized controlled trial on the effectiveness of ICT system to support self-management for diabetic nephropathy

In FY 2018, as the lead institution of the AMED DKD-ICT study, a clinical study using DialBetics was initiated to reduce the progression of diabetic nephropathy in patients with stage 2 diabetic nephropathy. The study was conducted under the "hospital model" in which the DialBetics system is managed and operated by healthcare professionals at medical institutions, and under the "pharmacy model" in which the system is managed and operated by pharmacists at dispensing pharmacies. The system-using group of research participants self-manage using DialBetics and measurement devices (blood glucose meter, blood pressure monitor, body composition monitor, and activity monitor). The system-user group of the "pharmacy model" were surveyed on their medication compliance rate using the ICT Electronic Medication Record Book and received medication guidance. The follow-up period was completed in April 2021 for all patients at all 8 facilities including ours. The results were published in the Digital Medicine journal in April 2024.

(2) Physician-led clinical trials using a smartphone application for diabetes treatment started in the latter half of FY2022

Full-scale recruiting of the target number of 160 patients at 10 institutions participating in the multicenter study was completed in August 2024, and data collection is expected to be completed at the beginning of the next year. The final results are expected to be available at the end of September.

(3) Development of a Diabetes Treatment Smartphone App Focused on Dietary Fiber Intake

A survey of approximately 100 type 2 diabetes patients regarding dietary fiber intake was conducted and found that many patients recognize fiber's importance and wish to know how to increase their fiber consumption. The results were selected for poster presentation at the 2025 American Diabetes Association (ADA) Annual Meeting. In response, we developed an AI-integrated app to support dietary fiber intake and designed an intervention based on this app. We began a proof of concept study of this intervention approach at our institution and Mitsui Memorial Hospital.

As part of this research, a system using generative AI to estimate dietary fiber intake from food images is being developed. The estimation accuracy of the generative AI was improved by means of prompts, and a paper was published. Since then, the accuracy has been further improved through use of fine tuning, and the results have been selected for a poster presentation at the 2025 American Diabetes Association conference.

(4) Clinical research on the correlation between sleep and blood glucose control (STEP1)

A correlation between short sleep duration and glycemic control has been reported, but there is a lack of strong evidence showing a causal relationship that increasing sleep duration improves glycemic control in type 2 diabetes patients with short sleep duration without sleep disorders.

Digital Therapeutics (DTx), a treatment utilizing digital technology, is expected to be an alternative to drug therapy in the treatment of diabetes where glycemic control is important. If this study demonstrates the usefulness of a series of interventions, we will continue with STEP2 clinical research to develop a new smartphone application and conduct physician-led clinical trials, with the aim of obtaining regulatory approval and official insurance coverage. The overall results are now under analysis. A part of the results has been selected for a poster presentation at the 2025 American Diabetes Association conference.

(5) • Support for DTx Study Society Activities

Our lab established the DTx Study Society in December 2023 and will hold the first conference in July with invited international lecturers.

The website went live in February.

【Future Prospects 】

Based on the findings from the research to date, we have developed an exercise therapy assistance system, the first of a series of smartphone applications with concepts that differ from previous concepts, and began recruiting in the year before last. The development of an app that focuses on diet is in the stages of proof of concept, and in parallel we have begun initial research into the development of a new app that will contribute to a new digital therapy that takes the concept to the next level by incorporating more advanced concepts. Research activities will be undertaken to realize medical treatment guidance that accompanies patients in their daily lives without time and location restrictions through the use of IoT/ICT. The goal is to realize guidance and medical treatment without restrictions on movement and face-to-face conversation, learning from COVID-19 experiences, with applications for remote areas and urban areas.

【Activities in FY2024 】

<Papers and Publications>

■ Papers in Japanese

None

■ Papers in English

1 • Kayo Waki , Mitsuhiko Nara , Syunpei Enomoto , Makiko Mieno, Eiichiro Kanda Akiko Sankoda, Yuki Kawai, Kana Miyake, Hiromichi Wakui, Yuya Tsurutani, Nobuhito Hirawa Tadashi Yamakawa, Shiro Komiya, Akihiro Isogawa, Shinobu Satoh, Taichi Minami, Tamio Iwamoto, Tatsuro Takano, Yasuo Terauchi, Kouichi Tamura, Toshimasa Yamauchi Masaomi Nangaku, Naoki Kashihara & Kazuhiko Ohe Effectiveness of DialBetesPlus, a self management support system for diabetic kidney disease: Randomized controlled trial NPJ Digit Med. 2024 Apr 27;7(1):104. doi: 10.1038/s41746-024-01114-8.PMID: 38678094

2 • Kerr D, Ahn D, Waki K, Wang J, Breznen B, Klonoff DC. Digital Interventions for Self-Management of Type 2 Diabetes Mellitus: Systematic Literature Review and Meta-Analysis. J Med Internet Res. 2024 Jul 22;26:e55757. doi: 10.2196/55757.

3 • Kurasawa H, Waki K, Seki T, Chiba A, Fujino A, Hayashi K, Nakahara E, Haga T, Noguchi T, Ohe K. Enhancing Type 2 Diabetes Treatment Decisions With Interpretable Machine Learning Models for Predicting Hemoglobin A1c Changes: Machine Learning Model Development. JMIR AI. 2024 Jul 18;3:e56700. doi: 10.2196/56700.

4 • Nicholas Leung, Kayo Waki, Satoshi Nozoe, Shunpei Enomoto, Ryo Saito, Sakurako Hamagami, Toshimasa Yamauchi, Masaomi Nangaku, Kazuhiko Ohe, Yukiko Onishi Efficacy of Save Medical Corporation (SMC)-01, a Smartphone App Designed to Support Type 2 Diabetes Self-Management Based on Established Guidelines: Randomized Controlled Trial. J Med Internet Res. 2024 Sep 10;26:e53740. doi: 10.2196/53740

5 • David C. Klonoff, Guido Freckmann, Stefan Pleus, Boris P. Kovatchev, David Kerr, Chui Tse, Chengdong Li, Michael S.D. Agus, Kathleen Dungan, Barbora Voglová Hagerf, Jan S. Krouwer, Wei An Lee, Shivani Misra, Sang Youl Rhee, Ashutosh Sabharwal, Jane Jeffrie Seley, Viral N. Shah, Nam K. Tran, Kayo Waki, Chris WorthTiffany Tian, Rachel E. Aaron, Keetan Rutledge, Cindy N. Ho, Alessandra T. Ayers, Amanda Adler, David T. Ahn, Halis Kaan Aktürk, Mohammed E. Al-Sofiani, Timothy S. Bailey, Matt Baker, Lia Bally, Raveendhara R. Bannuru, Elizabeth M. Bauer, Yong Mong Bee, Julia E. Blanchette, Eda Cengiz, James Geoffrey Chase, Kong Y. Chen, Daniel Chernavvsky, Mark Clements, Gerard L. Cote, Ketan K. Dhatariya, Andjela Drincic, Niels Ejksjaer, Juan Espinoza, Chiara Fabris, G. Alexander Fleming, Monica A.L. Gabbay, Rodolfo J. Galindo, Ana María Gómez-Medina, Lutz Heinemann, Norbert Hermanns, Thanh Hoang, Sufyan Hussain, Peter G. Jacobs, Johan Jendle, Shashank R. Joshi, Suneil K. Koliwad, Rayhan A. Lal, Lawrence A. Leiter, Marcus Lind, Julia K. Mader, Alberto Maran, Umesh Masharani, Nestoras Mathioudakis, Michael McShane, Chhavi Mehta, Sun Joon Moon, James H. Nichols, David N. O'Neal, Francisco J. Pasquel, Anne L. Peters, Andreas Pfützner, Rodica Pop-Busui, Pratistha Ranjitkar, Connie M. Rhee, David B. Sacks, Signe Schmidt, Simon M. Schwaighofer, Bin Sheng, Gregg D. Simonson, Koji Sode, Elias K. Spanakis, Nicole L. Spartano, Guillermo E. Umpierrez, Maryam Vareth, Hubert W. Vesper, Jing Wang, Eugene Wright, Alan H.B. Wu, Sewagegn Yeshiwas, Mihail Zilbermint, Michael A. Kohn The Diabetes Technology Society Error Grid and Trend Accuracy Matrix for Glucose

Monitors. J Diabetes Sci Technol. 2024 Nov;18(6):1346-1361. doi: 10.1177/19322968241275701.

6 • Mari Waki, Ryohei Nakada, Kayo Waki, Yuki Ban, Ryo Suzuki, Toshimasa Yamauchi, Masaomi Nangaku, Kazuhiko Ohe Validation of Sleep Measurements of an Actigraphy Watch: Instrument Validation Study. JMIR Form Res. 2025 Jan 6;9:e63529. doi: 10.2196/63529.

<Presentations at Conferences and Conference >

■ Domestic Conferences

- The 67th Annual Scientific Meeting of the Japan Diabetes Society (Tokyo, May 2024)

Kayo Waki: " Consider the practicalities of medical Dx and diabetes treatment. " (Joint Committee on Informatization of Diabetes Care) (Chairperson)

- The 11th Japan Association for Diabetes Education and Care(Kyoto, July 2024)

Kayo Waki:" How PHRs are used for diabetes education and support? /Digital" (in Japanese)

- The 24rd Annual Meeting of the Japanese Society for Diabetes Informatics (Tokyo, August 2024)

Kayo Waki:" Will AI change healthcare?" (Chairperson)

Kayo Waki: "Industry-University Collaboration Overseas - Diabetes Technology Society Activities" (in Japanese)

- The 44th Annual Conference of the Japan Federation of Medical Informatics / 25th Annual Conference of the Japanese Society for Medical Informatics (Fukuoka, November 2024)

Kayo Waki: " The Road to Dx - Digital Health Weaves the Future of Medicine " (Chairperson)

Kayo Waki: " A New Paradigm for UI and UX - Frontiers of Digital Health " (Chairperson)

Kayo Waki:" Paradigm Shift in Renal Disease Management Brought about by Digital Health "(Japanese Society of Nephrology):

Kayo Waki : "The Development of Digital Health and its Challenges for a New Future in Diabetes Care" (The Japan Diabetes Society) (Chairperson)

Kayo Waki : "Challenges and Solutions for Digital Health using Diabetes as a Model disease" (Chairperson)

Ryohei Nakada : "Medical Data Analysis 2: Verification of Sleep Measurement Devices and Correction Methods"

<International Conferences>

Kidney Health In Aging and Aged Societies: JSN/ERA Symposium Collaboration with JSDT
(Kyoto, September 2024)

Kayo Waki : “Effect of Digital Health among the elderly”

<Lectures and Research Meetings>

■ Invited Lectures/Symposiums

The Association of Insurance Medicine of Japan Research Lectures (Tokyo, June 2024)

Kayo Waki:” About Digital Therapeutics for Chronic Diseases“

<Social Activities>

■ AMED

• Development of evidence to contribute to recommendations for health care services and digital technology interventions for the onset and progression of chronic kidney disease (Principal investigator : Yoshitaka Isaka, PI: Kayo Waki)

• Research to establish appropriate evaluation of healthcare services for prevention of onset of type 2 diabetes (Principal investigator: Hirotaka Watada, Research assistant: Kayo Waki)

■ Other research grants

None

<Joint Research>

• Raxi co., ltd. : Establishment of an ICT system to support treatment of diabetes patients and development of a medical device program using the system

• Astellas Pharma Inc. : Research on DTx dissemination and solutions

<Off-Campus Activities >

■ Kayo Waki

• Central Investigation Committee for Pancreas Transplantation:

Medical Officer,

• Japan Association for Medical Informatics (JAMI)

Councilor

Member of the Board of Directors

International Committee Member

Chair, Education Committee

- The Japan Society for Diabetes Informatics

Board of Directors

- DTx Research Group

Founder and Representative Director

■ Toshiyuki Shibata

- DTx Research Group

Secretary General

【Clinical Results, Clinical Trials, Clinical Research 】

- Kayo Waki, Outpatient of Diabetes and Metabolism, J-DOIT3 Follow-up Study

Collaborating Physician

- Kayo Waki, Physician-led Clinical Trials Clinical Trial Coordinating Physician