Supplementary Material

Effectiveness of a Lifestyle Improvement Support App in Combination with a Wearable Device in Japanese People with Type 2 Diabetes Mellitus: STEP-DM Study

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Table S1 Eligibility criteria and discontinuation criteria

Eligibility criteria	Inclusion criteria: 1. Patients with T2DM attending the study site as outpatients at the time of SCR. 2. Patients aged ≥20 and <75 years at SCR. 3. Patients with T2DM receiving at least one and no more than four anti-diabetic drugs in addition to diet and exercise therapy at SCR. 4. Patients who had not changed their anti-diabetic drug dosing regimen for ≥12 weeks prior to SCR. 5. Patients whose HbA1c levels were increased or decreased by ≤0.2% at SCR compared with 12 weeks before SCR. 6. Patients with HbA1c ≥7.0% and <8.5% at SCR. For patients aged ≥65 years treated with anti-diabetic agents potentially associated with severe hypoglycemia (e.g., insulin, sulfonylureas, glinides), HbA1c ranges of ≥7.5% and <8.5% were used. 7. Patients with a smartphone device on which apps could be installed, who did not plan to change the device during the research period, and who agreed to the terms and conditions related to the wearable device and the app to be used in this study.* 8. Patients who had not used a wearable device or lifestyle improvement support app for diabetes management within the last 12 weeks prior to SCR. 9. Patients who provided written consent to participate in this study and provided participant information prior to study participation. *Addendum: If a patient owned a smartphone device but the device was not competent to install the application, the patient was deemed able to participate in the study providing they agree to use a device provided at the study site during the study period. Exclusion criteria: 1. Female patients who were pregnant or who wished to become pregnant during the study period. 2. Patients diagnosed with or suspected to have type 1 diabetes mellitus, diabetes mellitus due to some other specific mechanism or disease, or gestational diabetes mellitus. 3. Patients who had difficulty controlling their blood glucose levels because they were in a perioperative period or had infectious diseases. 4. Patients for whom diet or exercise therapy was restricted owing to comorbidities such as cardiovascular or renal disease. 5. Patients who have experienced hypoglycemia requiring assistance from others and who the investigator considered would have difficulty participating in the study. 6. Patients with substantial changes in glycemic control during the last 6 months prior to SCR, as judged by the investigator.

	7. Patients who had difficulty using wearable devices and lifestyle improvement support apps, as judged by the investigator. 8. Patients who were likely to require changes in diet, exercise or drug therapy during the study period, as judged by the investigator. 9. Patients participating in other clinical trials, clinical studies, lifestyle-related improvement programs, etc. (excluding observational studies with no intervention). 10. Patients deemed unsuitable for participation in this study for any other reason (including physical, mental, or social reasons), as judged by the investigator.
Discontinuation criteria	1. The investigator judged it necessary to change diet, exercise therapy or anti-diabetic drugs during the study period. 2. Any deviation from the inclusion/exclusion criteria found after enrollment. 3. The investigator judged it inappropriate to continue participation in the study because of the occurrence of adverse events or disease progression. 4. The participant experienced difficulty continuing participation in the study because of moving or changing hospitals. 5. Participation in other clinical trials, clinical research, lifestyle improvement programs, etc. during the observation period (excluding observational studies with no intervention). 6. The participant started using other wearable devices or lifestyle improvement support apps during the observation period. 7. The investigator judged that any disadvantages to the participant exceeded the expected benefits. 8. The investigator judged that it was too difficult for the participant to continue to participate in the study during the study period. 9. The participant requested to withdraw consent. 10. The entire study was discontinued.

HbAlc glycated hemoglobin, *SCR* screening, *T2DM* type 2 diabetes mellitus.

Supplementary Table S2 Questionnaire

Questionnaire at baseline (Response options are in parentheses):

Q1: Do you think diabetes has a negative effect on your mind or body? (Yes; Somewhat; Not so much; No)

Q2: Do you think diet therapy is important in diabetes treatment? (Important; Somewhat important; Not very important; Not important)

Q3: Have you been able to implement diet therapy to treat your diabetes? (Yes; Somewhat; Not much; Not at all)

Q4: Do you think exercise therapy is important in diabetes treatment? (Important; Somewhat important; Not very important; Not important)

Q5: Have you been able to implement exercise therapy to treat your diabetes? (Yes; Somewhat; Not much; Not at all)

Q6: Do you feel supported by your family and others in your diabetes treatment? (Yes; Somewhat supported; Not very supported; Not supported at all)

Q7: Are you interested in diabetes therapy that uses devices/apps (Fitbit and TOMOCO™)? (Interested; Somewhat interested; Not very interested; Not interested)

Q8: Do you think diabetes therapy using the device/apps (Fitbit and TOMOCO™) will improve your diabetes? (I have high expectations; Somewhat promising; Not very promising; I have low expectations)

Q9: Years of experience using smartphones (<1 year; ≥1 to <4 years; ≥4 to <7 years; ≥7 to <10 years; ≥10 years)

Q10: Experience with wristband and wristwatch wearable devices (Experience in using them; No experience in use/not sure)

Q11: Usual smartphone usage (Message exchanges; Online shopping; SNS; Viewing videos; Online games; Not listed above)

Questionnaire at 12 weeks (Response options are in parentheses):

Q1: Do you think TOMOCO™ has been helpful in your diabetes self-management? (Helpful; Somewhat helpful; Not very helpful; Not helpful)

Q2: Has the use of TOMOCO™ increased your motivation to follow the diet therapy? (Motivated; Slightly more motivated; Not very motivated; Not motivated)

Q3: Has the use of TOMOCO™ increased your motivation to engage in exercise therapy? (Motivated; Slightly more motivated; Not very motivated; Not motivated)

Q4: Would you like to continue to use TOMOCO™ for diabetes self-management purposes? (Yes; A little; Not much; No)

Q5: How much of a burden was it for you to use TOMOCO™? (No burden; Not much of a burden; Somewhat burdensome; It was a burden)

Q6: Do you think Fitbit has been helpful for diabetes self-management? (Helpful; Somewhat helpful; Not very helpful; Not helpful)

Q7: Has Fitbit increased your motivation to follow the diet therapy? (Motivated; Slightly more motivated; Not very motivated; Not motivated)

Q8: Has the use of Fitbit increased your motivation to engage in exercise therapy? (Motivated; Slightly more motivated; Not very motivated; Not motivated)

Q9: Would you like to continue to use Fitbit for diabetes self-management purposes? (I want to use it; Slightly want to use it; Not very much; Don’t want to use it)
Q10: How much of a burden did you find it to use Fitbit? (Did not feel it was a burden; Did not feel much of a burden; Somewhat burdensome; Felt it was a burden)

SNS social networking service.

Supplementary Table S3 Transtheoretical model score at baseline

	TTM score	*n* (%)
Behavior change stage	1	0 (0.0%)
	2	4 (6.8%)
	3	28 (47.5%)
	4	17 (28.8%)
	5	10 (16.9%)

Values are *n* (%) of participants.

TTM transtheoretical model.

1 = precontemplation; 2 = contemplation; 3 = preparation; 4 = action; and 5 = maintenance.

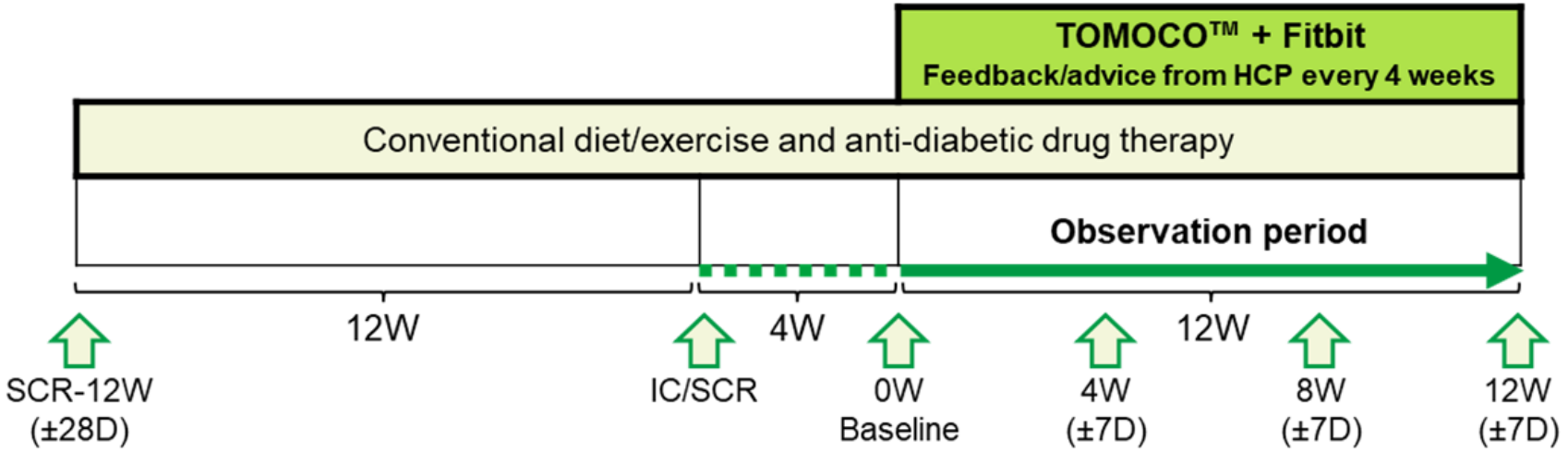

Fig. S1. Study design

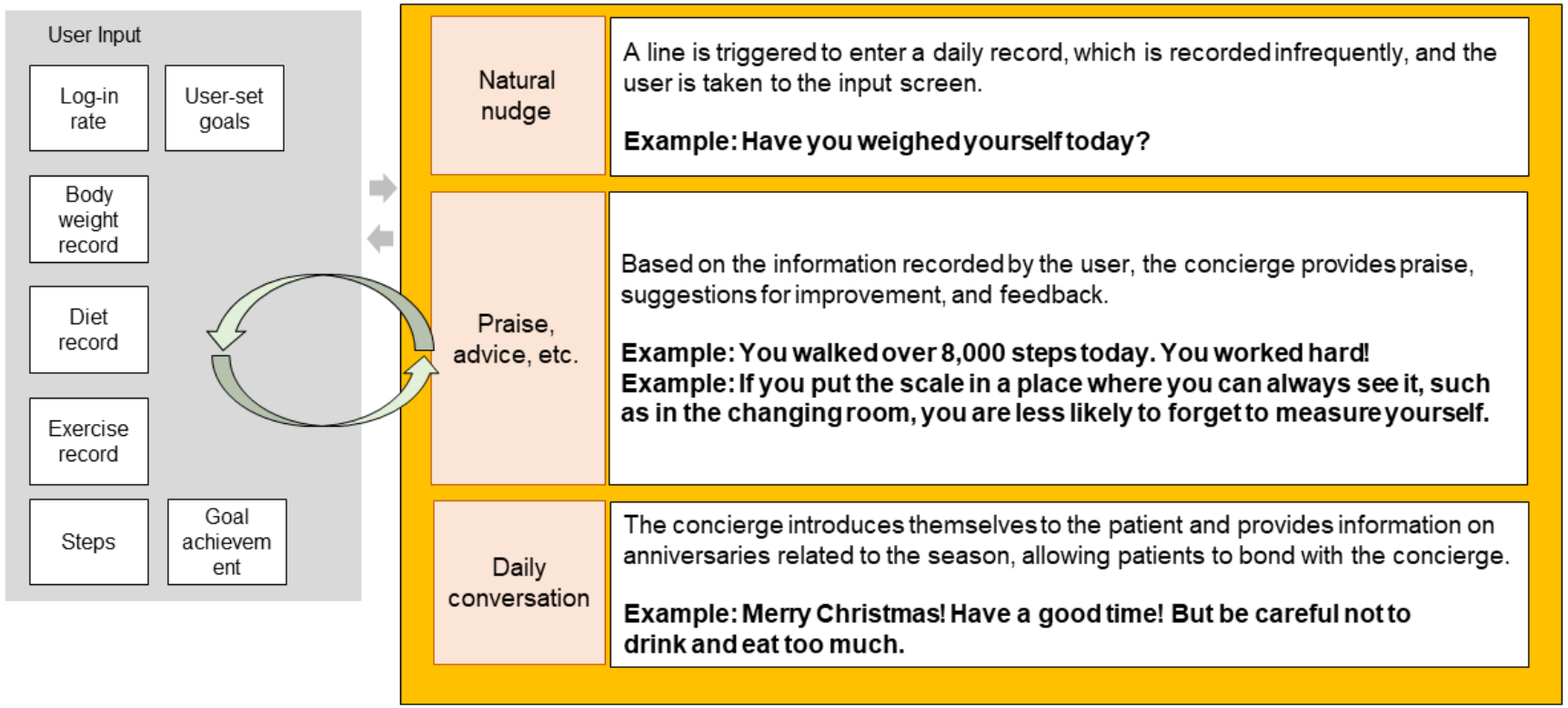

Fig. S2. Algorithm for triggering TOMOCO™ concierge conversations

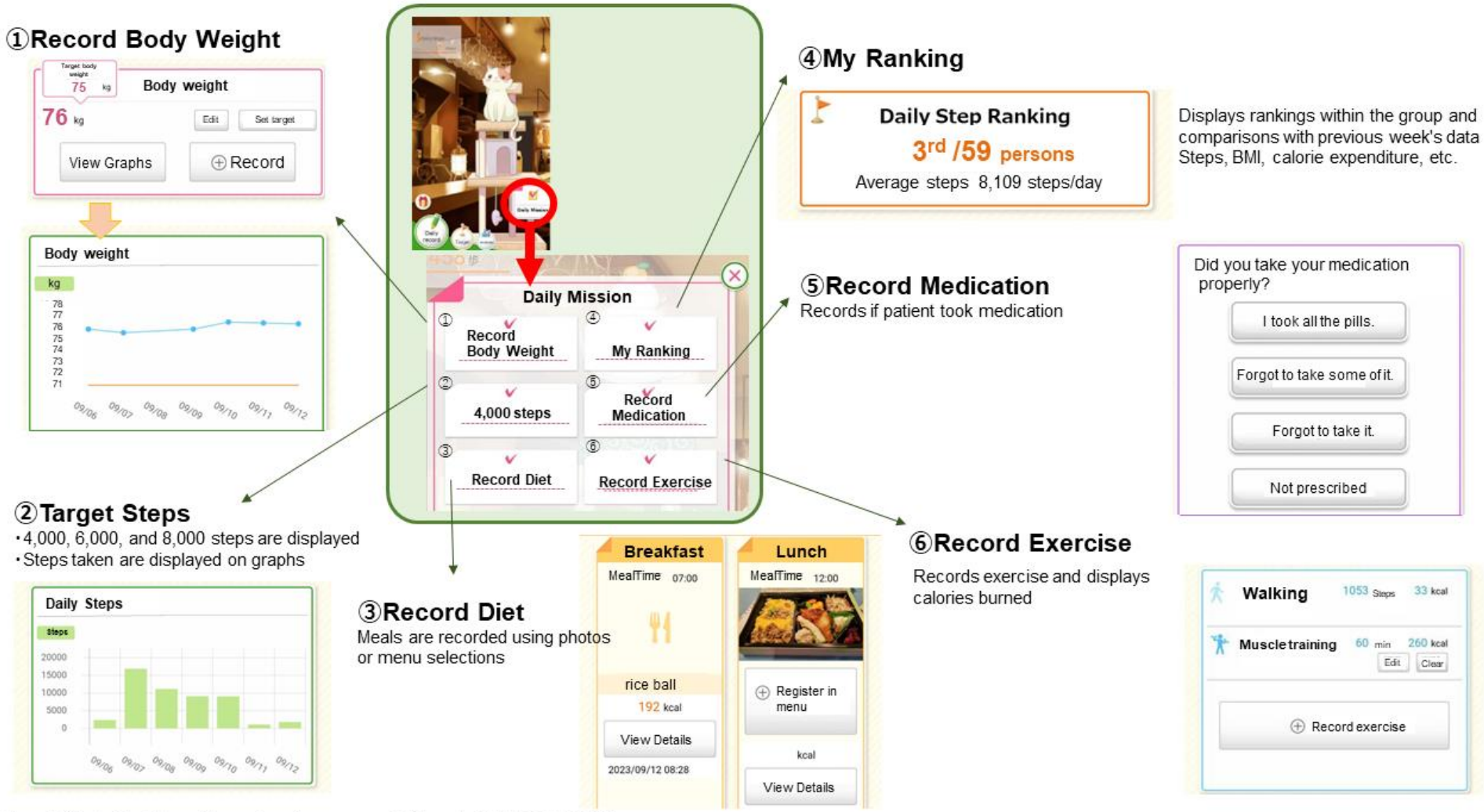

Fig. S3. Distinctive features of the TOMOCO™

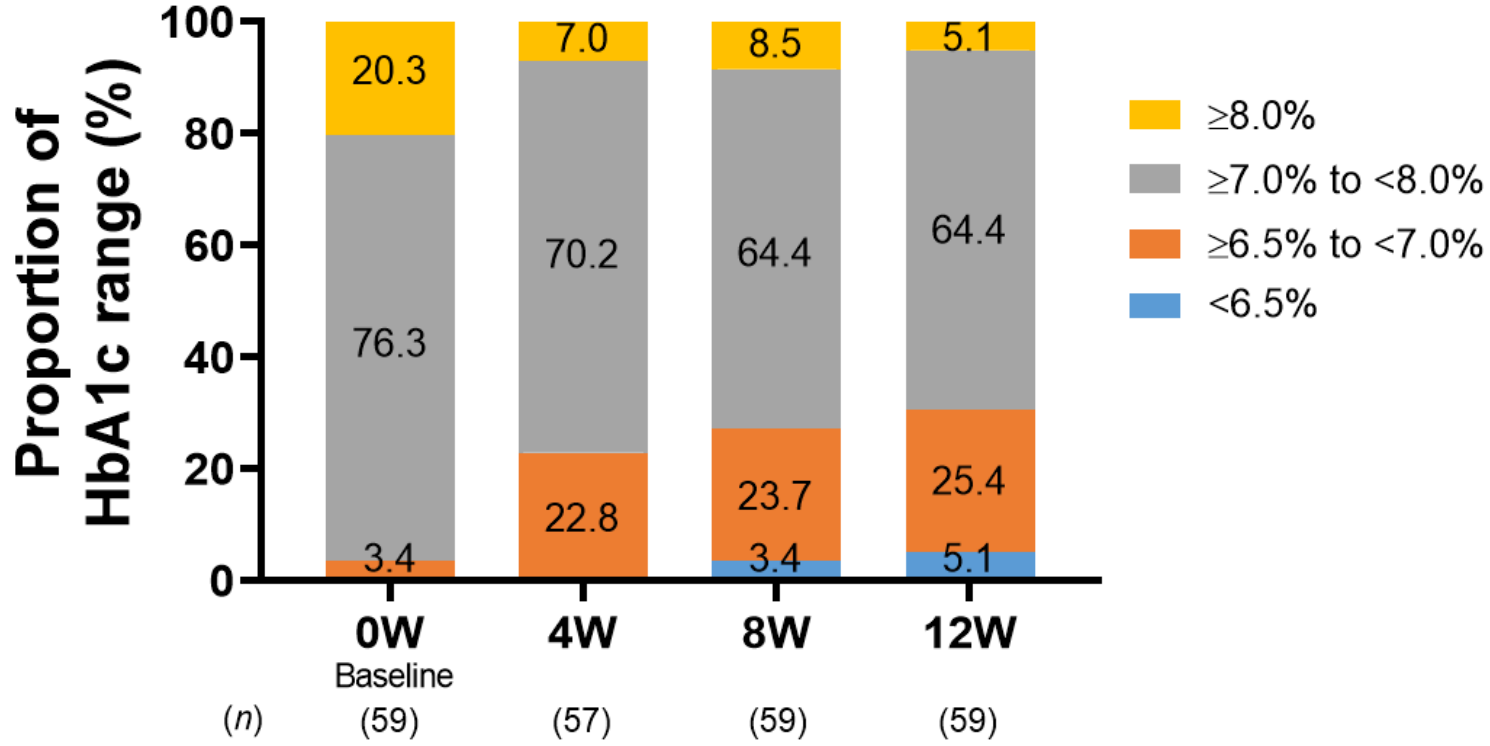

Fig. S4. Categorical distribution of HbA1c levels

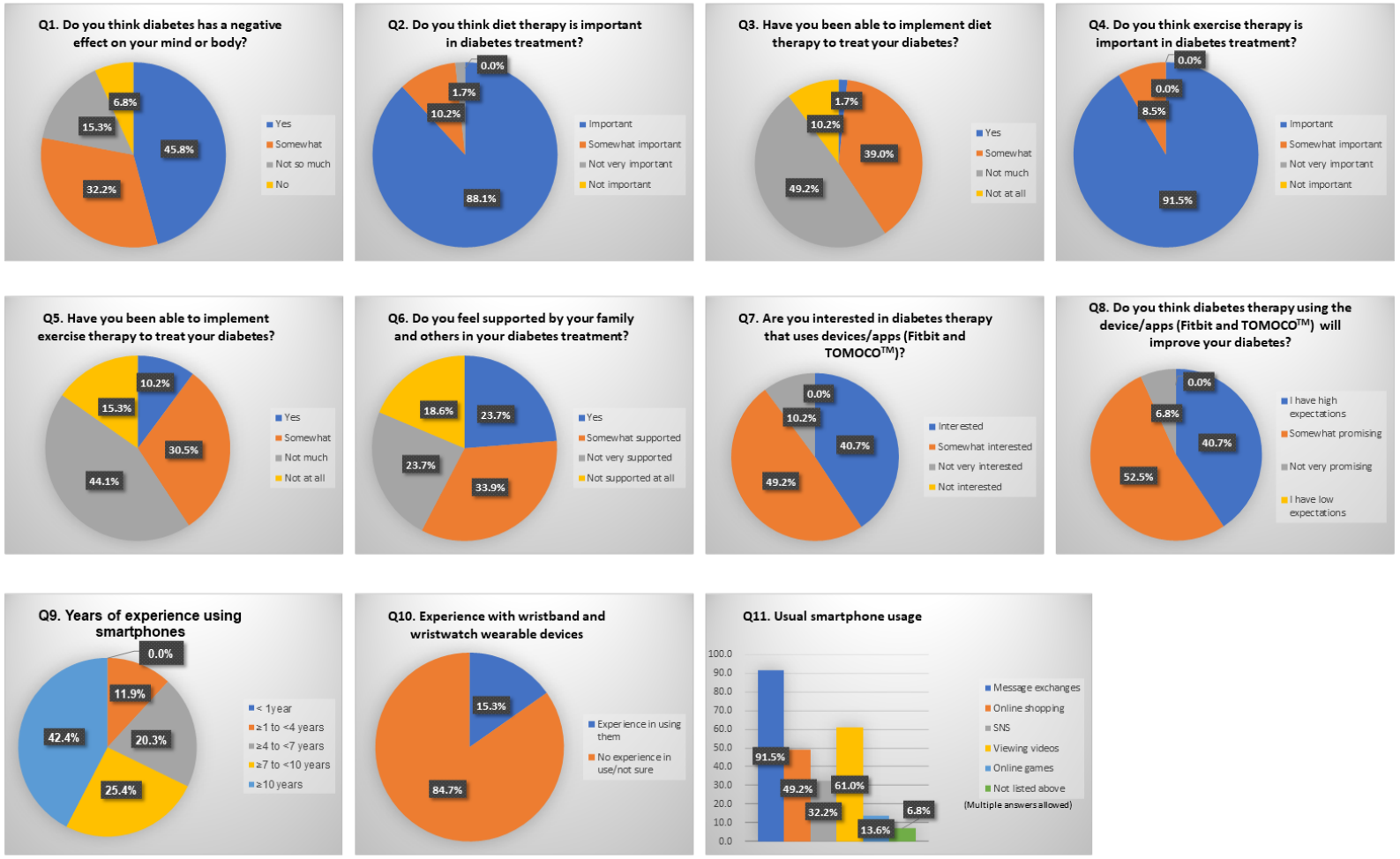

Fig. S5. Response to the questionnaire survey at baseline

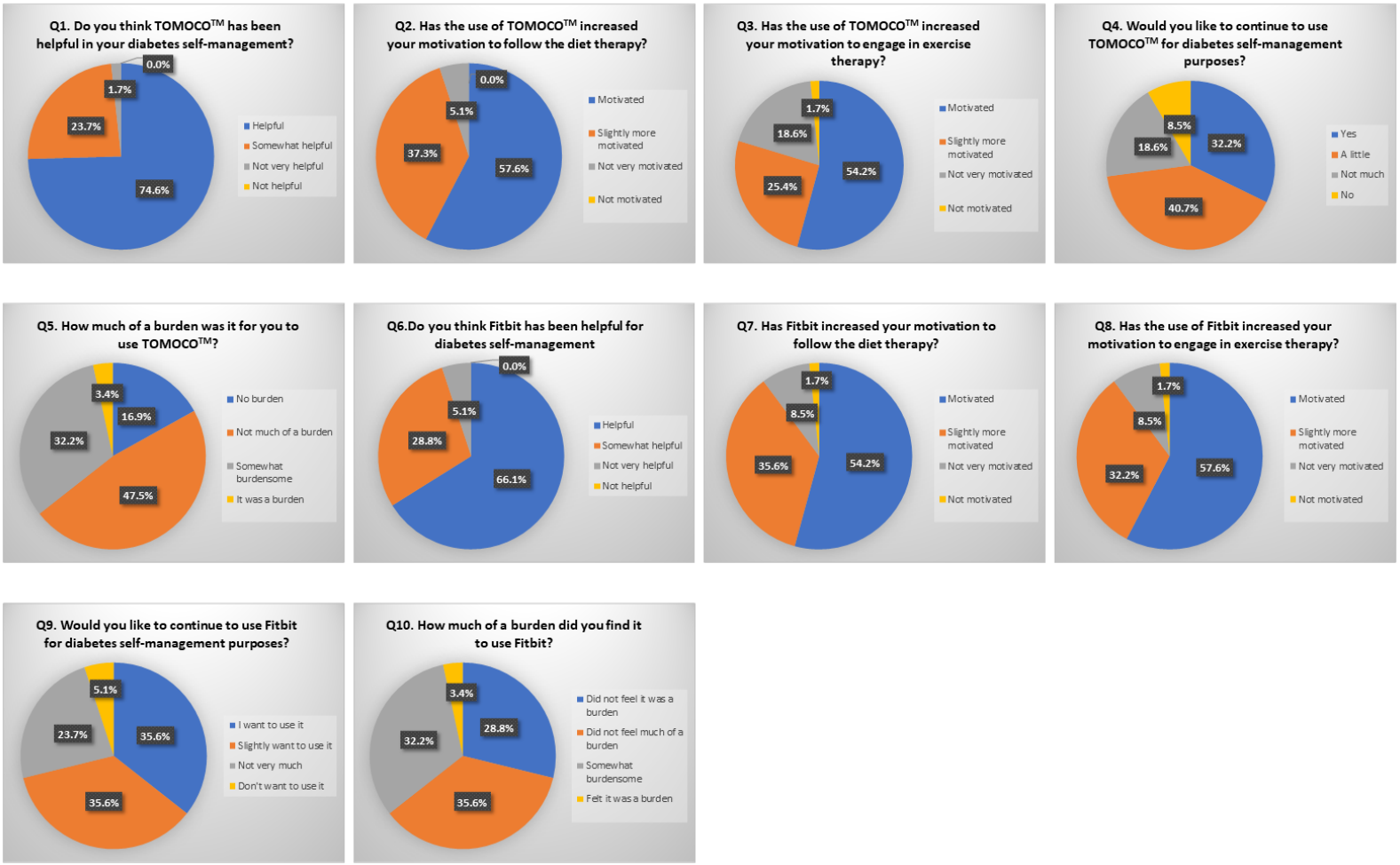

Fig. S6. Response to the questionnaire survey at 12 weeks

Fig. S1. Study Design. *D* days, *HCP* health care provider, *IC* informed consent, *SCR* screening, *W* weeks.

Fig. S2. Algorithm for triggering TOMOCO™ concierge conversation.

Fig. S3. Distinctive features of the TOMOCO™.

Fig. S4. Categorical distribution of HbA1c levels. *HbA1c* glycated hemoglobin, *W* weeks.

Fig. S5. Responses to the questionnaire survey at baseline. *SNS* social networking service.

Fig. S6. Responses to the questionnaire survey at 12 weeks.