Association of usual sleep quality and glycemic control in type 2 diabetes in Japanese: a cross sectional study SLEEP AND FOOD REGISTRY IN KANAGAWA

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Abstract

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Protocol

Step 1.

Purpose To investigate the relationship between sleeping time or sleep quality and blood glucose, other metabolic markers, blood pressure, and QOL in patients with diabetes or metabolic/endocrine diseases. To investigate the relationship between diet and blood glucose, other metabolic markers, blood pressure, and QOL in patients with diabetes.Endpoints:Primary endpoints:Sleeping time, sleep quality, and dietary intake (nutrients and food groups).Secondary endpoints:HbA1c, lipids, BMI, age, sex, diabetic microvascular disease, diabetic macrovascular disease, and the DTR-QOL score.

Step 2.

Inclusion Criteria Patients with diabetes or metabolic/endocrine diseases (Diabetes is defined according to the 2013 Treatment Guideline for Diabetes). Patients who give written informed consent to participation. Patients aged 20 years or older and younger than 85 years.

Step 3.

Exclusion Criteria Patients with drug-induced diabetes or patients on steroid therapy. Patients with a history of diabetic ketoacidosis or diabetic coma within 6 months prior to enrollment in the study. Patients receiving renal replacement therapy. Patients in the perioperative period. Female patients who are pregnant or breastfeeding. Patients with other serious diseases in addition to diabetes, such as advanced malignancy, severe infection, severe trauma, or decompensated liver cirrhosis. Other patients who are judged to be inappropriate for the study by the attending physician.

Step 4.

Sample Size and Enrollment PeriodPlanned sample size: 4,000 patients with type 2 diabetesEnrollment period: July 2014 (after ethics committee approval) – March 31, 2016

Step 5.

Study DesignCross-sectional study.

Step 6.

Study Participation and Patient Registration / Allocation Procedures Prior to enrollment of the first patient, this study will be registered with the UMIN Clinical Trials Registry (UMIN-CTR; http://www.umin.ac.jp/ctr/index-j.htm). Approval of the study will be obtained from the ethics committee at each clinical site. Written and oral consent will be obtained from patients who satisfy all of the inclusion criteria and do not meet any of the exclusion criteria. The 4 surveys/questionnaires

mentioned below will be distributed and collected (must be collected within 1 month). The Patient Registration Form will be filled in and sent to the Registration Center to complete enrollment. Allocation of patients will not be conducted. An identification code will be assigned to each registered patient for linkable anonymization. The Confirmation of Registration Notification received from the Registration Center shall be stored with the Informed Consent Form.

Step 7.

Observations, Examinations, and Reported ItemsThe following items will be investigated at the time of enrollment. Data obtained on the day of subject registration or within 1 month prior to registration can be used.Patient characteristics.Sex, age, height, body weight, smoking/drinking history, medical history, diabetes history, diabetic complications, diabetes medications, and other medications for lifestyle-related diseasesLaboratory tests. WBC count, RBC count, platelet count, hemoglobin, hematocrit, TC, TG, HDL-C, LDL-C (calculated), AST, ALT, γGTP, BUN, uric acid, serum creatinine, Na, Cl, K, HbA1c, fasting blood glucose, fasting insulin, glyco-albumin, fasting C-peptide, postprandial C-peptide Urinary albumin, urinary protein, urinary glucose Lipid markers: RLP-C, non-HDL-C, lipoprotein fractions, free fatty acids, small dense-LDL, apoproteins, Apo A / Apo B ratio

Step 8.

Surveys / QuestionnairesThe following 4 surveys/questionnaires will be distributed and collected. Problem Areas in Diabetes Survey (PAID) Pittsburgh Sleep Quality Index / Japanese Edition (PSQI) Diabetes Therapy Related QOL (DTR-QOL) Brief Self-administered Diet History Questionnaire (BDHQ)

Step 9.

Data EntryAmong the 4 surveys/questionnaires collected, the PAID, PSQI and DTR-QOL will be scored according to specified methods. The scores together with data on patient characteristics and laboratory findings will be submitted to the Registration Center and entered into Excel files. BDHQ forms will be sent to the DHQ Support Center for calculation of nutritional values (data will be returned in Excel format).10. AnalysisAfter entry of all data, the database will be locked. Data analysis will be performed by the Department of Biostatistics at Yokohama City University Medical School under the supervision of a statistician.