

Supplement 2

Statistical analysis plan

Running title

Determinants of physical activity among individuals with diabetes: a cross-sectional study

Authors

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Contributors and roles in the SAP

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Brief background

Engagement in regular physical activity is a cornerstone of type 2 diabetes management to prevent long-term diabetes complications and premature mortality. Morbidity, obesity, stress, and health-related quality of life are all factors that may determine decreased habitual physical activity in general population. Given that individuals with diabetes are at high risk of suffering from these factors, it is likely that individuals with diabetes have different physical activity patterns. No previous large-scale studies have provided a detailed description of habitual physical activity among individuals with diabetes. Availability of such information would be an important resource for planning future treatment courses taking individual characteristics, needs and preferences into account when designing and promoting a physical activity intervention.

Primary aim

To provide descriptive data on habitual physical activity and investigate the association of morbidity, obesity, stress, and health-related quality of life with physical activity among individuals with diabetes based on data from The Danish National Health Survey from 2017.

Secondary aim

To investigate the association of morbidity, obesity, stress, and health-related quality of life with sedentary behavior among individuals with diabetes based on data from The Danish National Health Survey from 2017.

Methods

Study design

The study design is cross-sectional. Reporting of the study will be followed by the STROBE checklist (1).

Data sources

Responders of The Danish National Health Survey (DNHS) in 2017 will be included. The DNHS was based on six mutually exclusive random subsamples; one in each of the five Danish administrative regions, and one national sample. 312,349 individuals were invited via a secure electronical mail service (Digital Post) or regular postal service to participate in the survey. Mandatory questions of the survey for all subsamples will be used in this project (appendix 5).

Variables

Exposures

Comorbidity (excluding diabetes) (categorical)

- Self-reported information on selected long-term conditions (excluding diabetes) and sequela from question 10-11 were used to assess comorbidity. Respondents reported whether they have or have had selected long-term conditions. If respondents reported they have had a long-term condition, they reported whether they were suffering from sequelae due to the specific long-term condition.
- The definition of multimorbidity will be based on diagnoses organized in 10 groups of different body systems according to Willadsen et al. (2). In this study there will only be 7 groups due to lack of information on gastrointestinal and genitourinary diseases from the survey, and the endocrine body system will be excluded since diabetes is not a part of the comorbidity-variable in the present study. The 7 groups will be: 1) Lung (asthma and bronchitis), 2) Musculoskeletal (osteoarthritis, rheumatoid arthritis, osteoporosis, and back diagnoses), 3) Mental (temporary mental disease and long-term mental disease), 4) Cancer, 5) Neurological (stroke and migraine), 6) Cardiovascular (hypertension, angina pectoris, and myocardial infarction), and 7) Sensory organs (tinnitus and cataract).
- The variable will be categorized as follows: 1) Have diabetes and no comorbidities, 2) Have diabetes and one comorbidity from one body system, 3) Have diabetes and two comorbidities from two different body systems, 4) Have diabetes and three or more comorbidities from at least three different body systems. Suffering from several long-term conditions within the same body system, e.g., hypertension and myocardial infarction, will still only count as one comorbidity.
- Studies have found that a decreased mental health status among individuals with comorbidities is associated with lower physical activity (3, 4). Therefore, a variable differentiating between having diabetes and comorbidities with and without a mental disease will be created.

Obesity (categorical)

- Self-reported data on body weight and height were obtained from question 38-39.
- Body mass index (BMI) (kg/m^2) will be calculated and categorized into the following groups: underweight/normal weight ($\text{BMI} < 25.0$), overweight ($\text{BMI} \geq 25.0 - < 30.0$), obese class I ($\text{BMI} \geq 30.0 - < 35.0$), obese class II ($\text{BMI} \geq 35.0 - < 40.0$), and obese class III ($\text{BMI} \geq 40$), as defined by the World Health Organization (5).

Stress (categorical)

- Self-reported psychological stress was obtained with Cohen's 10-item Perceived Stress Scale (PSS) (6) from question 8.
- The PSS will be categorized into three as follows:
 - o Scores ranging from 0-13 will be considered low perceived stress
 - o Scores ranging from 14-26 will be considered moderate perceived stress
 - o Scores ranging from 27-40 will be considered high perceived stress

Health-related quality of life (categorical)

- Self-reported health-related quality of life was obtained with the 12-item Short-Form Health Survey (SF-12) from question 1-7 (7).
- The SF-12 score is divided into a physical and mental score and each variable was dichotomized following the recommendations (8):
 - o Physical: A score of 50 or less determines a physical condition

- Mental: A score of 42 or less may be indicative of clinical depression

Primary outcome

Moderate to vigorous physical activity (MVPA) h/week (continuous)

- Respondents reported hours and minutes spent weekly on moderate and vigorous physical activities in question D-E.
- MVPA in hours and minutes weekly will be calculated into hours.

Secondary outcomes

Adherence to the WHO recommendations of physical activity and sedentary behavior (binary)

- Adherence to the WHO recommendations of physical activity and sedentary behavior was assessed with information regarding hours and minutes spent on weekly MVPA from question D-E.
- Following the WHO recommendations: ≥ 150 mins/week of moderate intensity or ≥ 75 mins/week of vigorous intensity or an appropriate combination hereby.
- Not following the WHO recommendations: < 150 - 300 mins/week of moderate intensity or < 75 mins/week of vigorous intensity (9).

Total sedentary behavior h/day (continuous)

- In question F, respondents reported hours and minutes spent daily sedentary on the following: work, transport, screen time and other sedentary activities, such as eating, social gatherings etc.
- Total sedentary behavior h/day will be calculated by adding hours and minutes from the abovementioned categories and then calculated into hours.

Covariates

The listed covariates below are suggested to adjust for in the analyses due to possible confounding: Age, sex, ethnicity, marital status, educational level, alcohol consumption, smoking, and diet may be independent risk factors of the four exposures (comorbidity, obesity, stress, and health-related quality of life) and the outcome (physical activity).

Furthermore, the four exposures may be independent risk factors in the individual model, therefore, the variables comorbidity, obesity, stress, and health-related quality of life will be included as potential confounders in each model. Directed Acyclic Graphs (DAGs) of the assumed causal relations between exposures and outcome of the primary analysis have been created (appendix 1-4).

Age (continuous)

- Calculated age at Jan 11th, 2017, from CPR-register

Sex (binary)

- From CPR-register
- Categorizations: Male, Female

Ethnicity (categorical)

- From CPR-register
- Categorizations: Born in Denmark, Western, Non-Western

Marital status (binary)

- Based on question G and CPR-register

- Marital status was categorized into: Married or Living with partner, Living alone

Educational level (categorical)

- Educational level was defined as the highest completed education, and the variable was obtained from question 50-51
- Educational level was categorized into the following: Primary (<10 years), Upper secondary or vocational (10-12 years), Higher education (≥ 13 years)

Alcohol consumption (categorical)

- Respondents were asked about their weekly alcohol consumption in question 24
- Alcohol consumption was categorized in accordance with the national recommendations from the Danish Health Authority and the risk of alcohol-related diseases for men and women:
 - o No alcohol (0 drinks – both men and women)
 - o Below low risk (men >0 & <14 drinks, women >0 & <7 drinks)
 - o Above low risk (men ≥ 14 & ≤ 21 drinks, women ≥ 7 & ≤ 14 drinks)
 - o High risk (men >21 drinks, women >14 drinks)

Smoking (categorical)

- Information regarding respondents smoking habits was obtained from question 13
- Smoking was categorized into the following: Smoker, Ex-smoker, Never smoked

Diet (categorical)

- Frequency and self-rated dietary habits were obtained from question 27-32
- Diet was calculated and categorized in accordance with the Dietary Quality Score: Unhealthy, Medium healthy, Healthy (10)

Statistical methods

Statistical software

STATA/BE 17.0

Sample size

The survey was fully or partially completed by 183,372 respondents (58.7 %). Respondents with diabetes and complete data on outcome, exposures and covariates will be considered as eligible for the analytical sample of the primary aim. Following the categorization of diabetes from DNHS, respondents were defined as “Having diabetes” if they had answered “I have diabetes now” or “I have had diabetes” and “I suffer from sequelae due to the diabetes”. According to this categorization, 10,216 respondents have diabetes. Respondents with complete data on primary outcome, exposures and covariates will be 6,856. The secondary analysis will have a smaller sample size due to fewer complete responses.

Missing data

The percentage of missing data for the primary outcome (MVPA) among individuals with diabetes is 11.8 %. For the secondary outcome (WHO recommendations) the percentage of missing data is 20.5 %, and for the outcome total sedentary behavior the percentage of missing data is 20.0 %. To reduce the possible impact of non-response bias on the estimates, calibration weighting from NATSUP will be applied.

A supplementary table comparing characteristics of responders with non-responders among individuals with diabetes will be conducted.

Primary analyses

Cross-tabulations will be conducted to describe habitual physical activity among individuals with diabetes and to display potential subgroup differences.

Table 1 (participant characteristics) will be standardized on age and sex due to expected large differences between “Individuals with diabetes” and “Individuals with no known diabetes”.

Both crude and multivariable adjusted associations will be estimated.

Four multivariable linear regression analyses will be conducted to investigate the association between selected determinants and MVPA. Adjustments will differentiate from each analysis according to DAGs (appendix 1-4). Model assumptions of linear regressions will be assessed:

- 1) Exposure: Comorbidity with and without mental diseases
Adjustments: Age, alcohol consumption, diet, educational level, ethnicity, sex, marital status, obesity, and smoking
- 2) Exposure: Obesity
Adjustments: **Age, alcohol consumption, diet, educational level, ethnicity, sex, marital status, comorbidity, and smoking**
- 3) Exposure: Stress
Adjustments: Age, educational level, sex, marital status, obesity, comorbidity, and smoking
- 4) Exposure: Health-related quality of life
Adjustments: Age, educational level, sex, marital status, obesity, comorbidity, smoking, and stress

Secondary analyses

Four multivariable logistic regression analyses will be conducted with the same exposures and adjustments as the abovementioned. Using multivariable logistic regression analyses with the WHO guidelines of physical activity as outcome (binary). Model assumptions of logistic regressions will be examined by linearity between independent variables and log odds of outcome.

Furthermore, four multivariable linear regression analyses will be conducted to investigate the secondary aim with sedentary behavior in leisure time as outcome and comorbidity, obesity, stress, and health-related quality of life as exposures. Adjustments in the secondary analyses will be the same as the primary analyses. Model assumptions will be assessed.

At last, cross-tabulations will be conducted to describe proportions of whether inactive participants with diabetes who are motivated for being more physically active. The cross-tabulations will be conducted in subgroups of age and sex due to expected differences in motivation of behavioral changes.

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