28-10-2024

Statistical analysis plan

Title:

Does deciding not to participate in a lifestyle intervention affect the long-term change in psychosocial well-being for children with obesity?

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Purpose:

In this plan for statistical analysis, we provide an overview of the study's context and objectives, as well as general aspects of data management and data analysis. The statistical analysis plan will be attached as a supplementary document upon submission.

Introduction

Childhood obesity is associated with an increased risk of developing non-communicable lifestyle diseases later in life(1-4), while reduced psychological well-being often occurs during childhood. Children living with obesity suffer from lower self-esteem, which have been associated with increased level of sadness and loneliness(5). They also experience higher degree of bullying/teasing(6, 7), have lower quality of life (8, 9) and increasing risk of depression (10) as compared to their peers living without obesity.

Family-centered lifestyle interventions including a multifactorial approach are still considered the first line of treatment when handling childhood obesity(11, 12). The literature suggest that this type of intervention can stabilize or to some extent reduce weight when treating children with obesity(12-14).

Previous studies have reported life stressors, societal norms of weight and body size, as well as earlier experiences with the health care system to be the primary determinants for caregivers not letting their children with obesity participate in lifestyle interventions(15-17).

However, no studies have been able to describe if deciding not to participate in a lifestyle intervention potentially affect the psychosocial well-being in children with obesity.

Objective

To investigate the impact in psychosocial well-being for children with obesity deciding not to participate in a family-centered lifestyle intervention (deciding not to participate group) compared to children who attended the intervention (intervention group), and to children never invited into the intervention (non-intervention group). As a secondary objective, we aim to investigate the effect that is not caused by the weight change by adjusting for this.

Material and methods

Design

This is an observational cohort study investigating the impact in psychosocial well-being for children with obesity deciding not to participate in a lifestyle intervention. Data will be obtained from mandatory health check-ups at school, Danish national registries, and Danish National Well-being Questionnaire (DNWQ).

Participants

Children were screened by a community health nurse during school time. If the child's BMI (age- and sex-adjusted) was above 30 kg/m^2, the parents would be informed and invited to participate in the local lifestyle intervention. If the parents accepted, they would be referred to the intervention. The intervention had a maximum duration of one year and typical consisted of 3-4 consultations with a specialized community health care nurse.

This study will include children with obesity with an inclusion visit between August 1st, 2014, and June 30th, 2020, from the city of Aarhus. February 1st, 2023, will be the last day of follow-up (figure 1). The inclusion visit will be defined as the day of deciding not to participate in the intervention (decided not to participate group), the first day of attending the intervention (intervention group), or the first observation with obesity (non-intervention group).

The groups

- Decided not to participate group: Children with obesity declining to participate in a lifestyle intervention.
- Intervention group: Children with obesity who attended the lifestyle intervention.
- Non-intervention group: Children with obesity never invited into the intervention.

Inclusion criteria

1. An inclusion visit between August 1st, 2014, and June 30th, 2020 (figure 1).
2. Obesity at time of referral as defined by the International Obesity Task Force (IOTF) guideline(18).
3. A measure of weight and height within 6 months before or after time of inclusion
4. Age at inclusion between 5 to 10 years of age.
5. A completed DNWQ at inclusion:
    - The deciding not to participate / non-intervention group - with a timeframe between 6 months prior to and 6 months after inclusion.
    - The intervention group - with a timeframe between 10 months prior to and 2 months after inclusion.
6. A completed DNWQ at follow-up (1 to 3 years after inclusion).

Exclusion criteria

1. Children first decided not to participate, but subsequently accepting the intervention.

Outcome

The outcome of this study will be the dichotomized responses at follow-up to specific items obtained from the DNWQ. The DNWQ is used to examine how primary school children perceive their psychosocial well-being and learning environment in school. The DNWQ has been a mandatory assignment for the public schools in Denmark and was introduced in 2015. DNWQ consist of 20 items for children in 0th to 3rd grade assessed using a three-point Likert scale ranging from 1 to 3. For children in 4th to 9th grade the DNWQ consist of 40 items assessed on a five-point Likert scale ranging from 1 to 5.

For this study we have selected 7 items to best describe the psychosocial well-being in our cohort. We will include completed questionnaires at time of inclusion and at follow-up. At follow-up, we will prioritize completed questionnaires closest to two years from time of inclusion visit.
All answers will be dichotomized into: Good well-being / Poor well-being, depending on the item. Responses 1 and 2 for grades 0-3 and response 1-3 for grades 4-9 will be characterized as poor well-being.

The psychosocial well-being items:

Question 1:
Are you happy with your school? (0^{th} to 9^{th} grade)

Question 2:
Do you feel lonely at school? (0^{th} to 3^{rd} grade)
Do you feel lonely? (4^{th} to 9^{th} grade)

Question 3:
Is anyone teasing you so that you feel sad? (0^{th} to 3^{rd} grade)
Have you been bullied this school year? (4^{th} to 9^{th} grade)

Question 4:
Does your stomach ache when you are at school? (0^{th} to 3^{rd} grade)
How often does your stomach ache? (4^{th} to 9^{th} grade)

Question 5:
Are you good at solving your problems? (0^{th} to 3^{rd} grade)
How often can you find a solution to problems, just by trying hard enough? (4^{th} to 9^{th} grade)

Question 6:
Can you concentrate during class? (0^{th} to 9^{th} grade)

Question 7:

Are you good at helping each other in class? (0th to 3rd grade)
Most students in my class are friendly and helpful. (4th to 9th grade)

Data sources and study variables

Data sources

TM-Sund: TM-Sund is a data capturing tool used by community health nurses and has been used to record data on height and weight obtained from health check-ups at the school and data on children attending or deciding not to participate in the intervention.
The National Registers at Statistic Denmark (DST): DST will be used to identify relevant co-variables such as proxies for Socioeconomic status, immigration background, family structure and psychiatric diagnoses of the child or parents.
The Department of IT and Learning (STIL): The DNWQ will be obtained from STIL, Ministry of Children and Youth.

Study variables:

We wish to include the following co-variates at inclusion:

- BMI z-score (e.g. 3.0 SD) (19)
- Sex (girl/boy)
- Highest completed Household Education (HHE)
    - "Short": Primary school (UNESCO's International Standard Classification of Education (ISCED) level 1-2).
    - "Middle": Highschool, vocational education, and similar shorter education (ISCED level 3-5).
    - "Long": Tertiary education at bachelor level or higher (ISCED level 6-8)
- Immigration status (Danish origin / immigrants 1. or 2. generation)
- Disposition for mental illness (lifetime) (yes / no)
- Mental illness, child (lifetime) (yes / no)
- Family structure (two caretakers / not-two caretakers)

Statistical methods:

All statistical analyses will be performed using Stata/SE 15 (StataCorp LP, College Station, Texas, USA). All statistical tests will be two-sided with a significance level at 0.05.

For the characteristics at inclusion

- Normally distributed data will be analyzed using a one-way ANOVA (several means) and a t-test (two means).
- Non-normally distributed data will be analyzed using a Wilcoxon ranksum test (2 groups) and Kruskal-Wallis test (> 2 groups).
- Categorical variables will be analyzed using a Fisher's exact test.

For missing data (education, immigration status, and family-type), a multiple imputation (MI) with chained equations will be utilized to replace missing values with imputed values. Rubin's rule will be applied to obtain overall estimates of 100 imputed datasets.

We will perform the analyses in several steps:
Firstly, the McNemar's test will be used to investigate potential change in psychosocial well-being from time of inclusion to follow-up for each of the dichotomized items (Q1-Q7) in all three groups. All items will be dichotomized into: Good well-being/Poor well-being.

Secondly, the impact in psychosocial well-being for children declining participation will be compared to the intervention group and to the non-intervention group by a logistic regression.
The logistic regression analysis will be reported as both a crude (only including the outcome and the groups) and a multivariable model. The psychosocial well-being at inclusion will act as an explanatory variable in the models.
The multivariable model will be adjusted for no more than 1 co-variate per 10 observations of the least common outcome. The co-variates are listed in prioritized order: 1) BMI z-score 2) sex, 3) highest completed household education, 4) immigration status, 5) disposition for mental illness, 6) mental illness and 7) family structure.

As an explorative outcome, a logistic regression model adjusted for change in BMI z-score (from inclusion to follow-up) will be performed to remove the potential effect of weight change on the

association between exposure and psychosocial well-being. The BMI z-score observed closest to the included DNWQ at follow-up will be used.

If possible, we wish to investigate the stratified effect of sex, BMI z-score at inclusion, parental level of education, immigration status, disposition for mental illness and change in BMI z score before we examine their potential for effect modification for the impact in psychosocial well-being for the items Q1-Q4 for the decided not to participate group compared to the non-intervention and intervention groups.

Results:

Figure 1:

Lexi diagram for time of inclusion (x-axis), inclusion age of the participants (y-axis), and time points for the DNWQ.

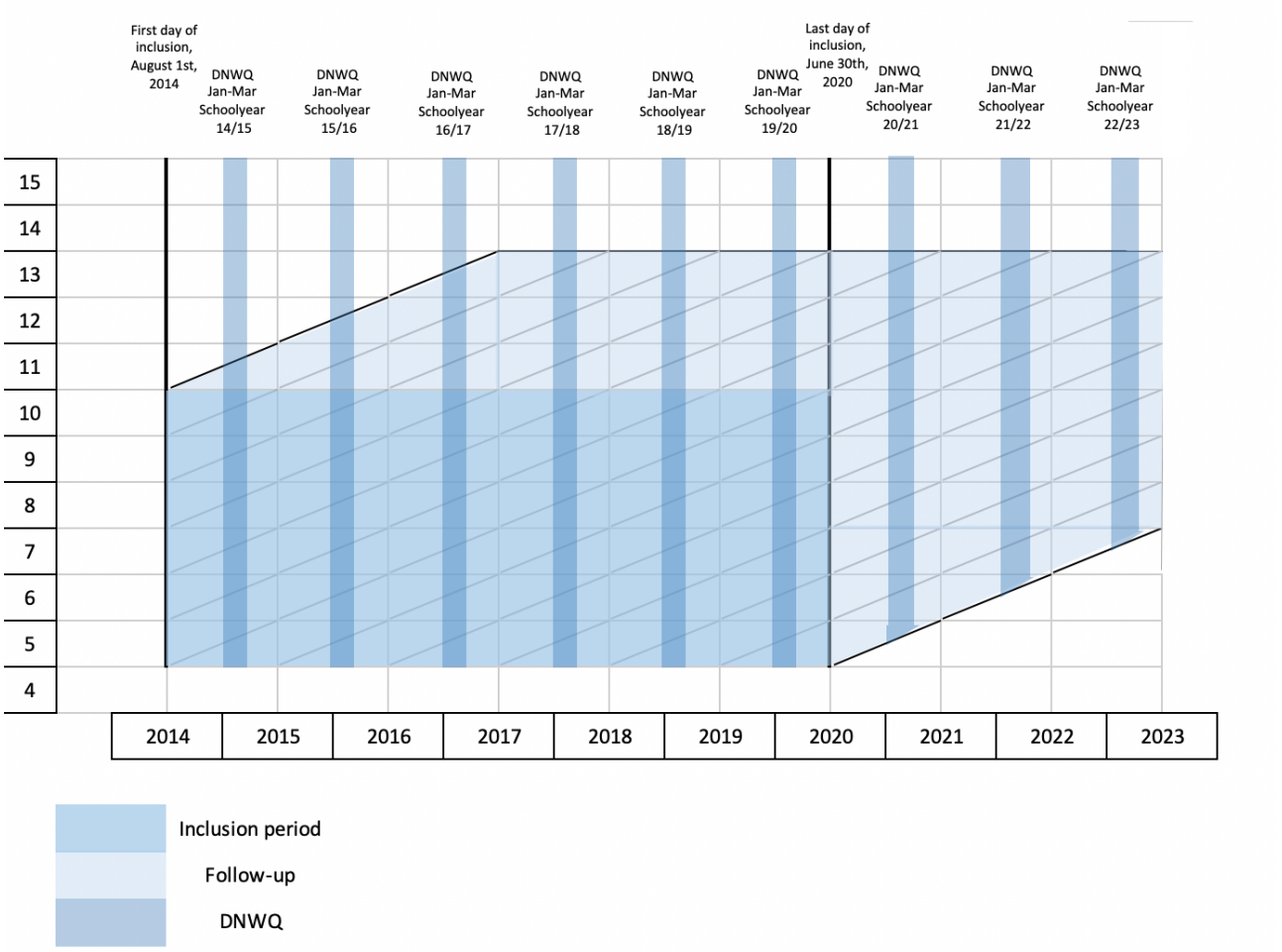

Table 1:

Characteristics at inclusion, divided by groups.

	Decided not to participate group		Intervention group		Non-intervention group	
	n		n		n	
Age at inclusion, median (IQR)						
Sex (% boys)						
BMI z-score at inclusion mean (SD)						
Highest completed household education, n (%)						
Short						
Medium						
Long						
Family type, n (%)						
Two caretakers						
not-two caretakers						
Immigration status (%)						
Danish						
First or second generation immigrants						
Psychiatric diagnosis, child (% yes)						
Parental mental illness (% yes)						

Table 2:

Descriptive presentation of the distribution of answers to each of the items on psychosocial well-being at inclusion and follow-up, divided by groups.

n (%)	Decided not to participate group		Intervention group		Non-intervention group	
	Inclusion	Follow-up	Inclusion	Follow-up	Inclusion	Follow-up
Question 1: Are you happy with your school?						
Good well-being (yes)						
Poor well-being (no)						
Question 2: Do you feel lonely at school? (0-3 grade) Do you feel lonely? (4-9 grade)						
Good well-being (no)						
Poor well-being (yes)						
Question 3: Is anyone teasing you so that you feel sad? (0-3 grade) Have you been bullied this school year? ? (4-9 grade)						
Good well-being (no)						
Poor well-being (yes)						
Question 4: Does your stomach ache when you are at school? (0-3 grade) How often does your stomach ache? (4-9 grade)						
Good well-being (no/rarely)						
Poor well-being (yes/often)						
Question 5: Are you good at solving your problems? (0-3 grade) How often can you find a solution to problems, just by trying hard enough? (4-9 grade)						
Good well-being (yes/often)						
Poor well-being (no/rarely)						
Question 6: Can you concentrate during class?						
Good well-being (yes)						
Poor well-being (no)						
Question 7: Are you good at helping each other in class? (0-3 grade) Most students in my class are friendly and helpful? (4-9 grade)						
Good well-being (yes)						
Poor well-being (no)						

Table 3:

Logistic regression analyses comparing the decided not to participate group and the intervention group.

The multivariable model will be adjusted for up to 1 co-variable per 10 observations.

Decided not to participate group vs. intervention group	
	OR (95% CI), p-value
Q1 – Enjoyment at school	
Univariable logistic regression	
Multivariable logistic regression	
Q2 – Feelings of loneliness at school	
Univariable logistic regression	
Multivariable logistic regression	
Q3 –Experiences of bullying	
Univariable logistic regression	
Multivariable logistic regression	
Q4 – Experiences of stomach aches	
Univariable logistic regression	
Multivariable logistic regression	
Q5 – Problem-solving	
Univariable logistic regression	
Multivariable logistic regression	
Q6 – Concentration in the classroom	
Univariable logistic regression	
Multivariable logistic regression	
Q7 – Helpfulness in the classroom	
Univariable logistic regression	
Multivariable logistic regression	

Table 4:

Logistic regression analyses comparing the decided not to participate group and the non-intervention group.

The multivariable model will be adjusted for up to 1 co-variable per 10 observations.

Decided not to participate group vs. non-intervention group	
	OR (95% CI), p-value
Q1 – Enjoyment at school	
Univariable logistic regression	
Multivariable logistic regression	
Q2 – Feelings of loneliness at school	
Univariable logistic regression	
Multivariable logistic regression	
Q3 –Experiences of bullying	
Univariable logistic regression	
Multivariable logistic regression	
Q4 – Experiences of stomach aches	
Univariable logistic regression	
Multivariable logistic regression	
Q5 – Problem-solving	
Univariable logistic regression	
Multivariable logistic regression	
Q6 – Concentration in the classroom	
Univariable logistic regression	
Multivariable logistic regression	
Q7 – Helpfulness in the classroom	
Univariable logistic regression	
Multivariable logistic regression	

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