

Statistical Analysis Plan (SAP)

Study Title:	OBdIPHY (OBesity DIgital-PHYsical care study) Effects of digital-physical care for families with children and adolescents living with obesity
Study Registration Number:	276515 (Clinicaltrials.gov)
Sponsor:	Research council, Region Halland, Sweden The Sparbanken Foundation, Varberg, Sweden VINNOVA Winter project, Sweden Southern healthcare region project support, Sweden The Jerring foundation, Sweden Grants from the Swedish state under the agreement between the Swedish government and the county councils, the ALF-agreement (ALFGBG-984419)
Intervention:	Semi-digital care for childhood obesity with digital treatment meetings and an app as support for lifestyle treatment.
Protocol Number:	ClinicalTrials no 276515
Statistical Analysis Plan Version:	Version 1.0
Statistical Analysis Plan Date:	2025-04-17
Author:	Terese Torstensson, Region Halland, Träslövsvägen 68, 43237 Varberg, SWEDEN

SAP Primary Author: Terese Torstensson

Senior Statistician: Jari Martikainen

SAP Contributor (Primary Investigation): Lovisa Sjogren

SAP Contributor (Co-supervisor): Jenny Kindblom

Abbreviations

BMiz Body Mass Index z-score

OBDIPHY Obesity digital-physical care study

SAP Statistical Analysis Plan

1. Introduction

The aim of this project is to study the safety and effectiveness of semi-digital lifestyle treatment for childhood obesity. This statistical analysis plan (SAP) defines the statistical methods that will be used for the final analyses of the data collected in the trial OBDIPHY (Obesity digital-physical care study). The SAP was created based on the project plan registered at ClinicalTrial.gov, id no 276515 registered 12/07/2021.

2. Overview and objectives for study design

This is a prospective randomized controlled multicentre non-inferiority trial, conducted in three different councils in southwest of Sweden. The aim of this study was to evaluate semi-digital care compared to regular physical/in person care and evaluate if semi-digital care is non-inferior to standard care among families with children or adolescents aged 10-16 year living with obesity in Sweden. The study participants either received treatment as usual or treatment as usual combined with a semi-digital solution. The semi-digital solution includes that half of the sessions are digital and an app where the participants could self-monitor health data, have an overview over they treatment plan and easy communication with their caregivers.

The null hypothesis is that semi-digital care will have an effect and decrease body mass index z-score (BMI_z), however inferior to treatment as usual. In addition to evaluating the new treatment alternative, BMI_z, weight development and metabolic risk factors and food habits during the study will also be evaluated. See figure 1 for study design.

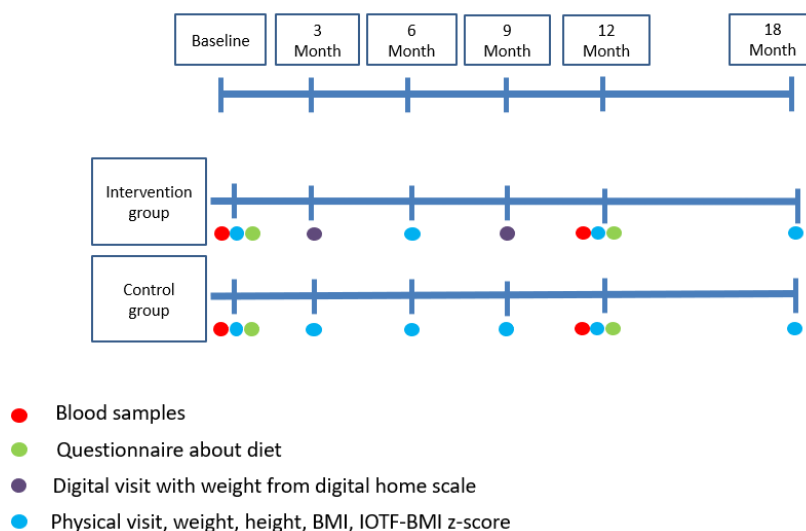


Figure 1. Study design.

The inclusion of participants started in March 2022 and was planned to end in December 2022, but was extended to the end of May 2023. The last participants had their one-year visit in May 2024. Unfortunately, due to organisational and structural challenges the Skåne site had difficulties to provide both the digital and the standard care. Participants from the Skåne site therefore did not receive care in accordance with the study protocol. Due to severe protocol violation, the participants from the Skåne site were excluded as per decision by the study steering committee on the 5th of December 2024, prior to any data analyses.

3. Outcomes and analyses

Descriptive data will be presented using mean and standard deviation (SD) if the data is normally distributed, otherwise median and interquartile range (IQR) will be presented. Binary and categorical variables will be presented using number and percentage.

3.1 Primary outcome

The primary outcome of this clinical trial is the change in BMI_z from baseline to 12 months. The hypothesis of the study is that the change in BMI_z in the intervention group is non-inferior to the control group. This will be analysed using a non-inferiority approach.

3.2 Secondary outcomes

The effect of semi-digital care on change in BMI_z, weight, metabolic markers and dietary habits after one year (for BMI_z and weight also at 3, 6 and 9 months) will be investigated.

Analyses: For continuous variables regarding change in BMI_z, weight and blood markers the means between the groups will be compared. A non-parametric test to compare frequencies for categorical variables will be used. We will also use logistic regression models to evaluate the odds for change in zBMI larger than 0.25 sd.

3.3 Exploratory analyses

Exploratory analyses guided by the findings will be performed.

4. Population

A power calculation was performed, based on a change of 0.21 BMI_z at 12 months with a standard deviation of 0.24 in the standard care group, and with a non-inferiority limit of 0.12 BMI_z between the groups. To reach 80 % power with a significant level of 0.05, a study population of 100 participants, 50 in each group was needed.

5. Missing data

In the case of missing data, the last observation carried forward approach will be used when data is available from 6- or 9-month follow up. Values that are outside the time-range for the visits will be included in the analysis when needed.