The effect of mobile application Euglyca on glycemic control of Children and Adolescents with Diabetes Mellitus Type 1

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Protocol

Children and adolescents with T1DM who visited consecutively our clinic were asked to participate in the study provided they owned an Android smartphone and were familiar with its use. Patients were included after one of their parents or their legal guardian signed an informed consent. Inclusion criteria were: 1. Treatment with multiple daily injections (MDI) or continuous subcutaneous insulin infusion (CSII); 2. satisfactory knowledge of the concept of carbohydrates and lipids counting acquired following previous training by the physicians and nutritionist of the department at initial diagnosis and thereafter during follow-up visits. Exclusion criteria were: 1. Use of another medical application for diabetes in the previous 3 months; 2. lack of capacity of reading greek. Eighty patients were finally eligible to participate in the study. 80 patients met the inclusion criteria and agreed to participate in the study. Subsequently they were randomized to two equally numbered groups by drawing one of two nontransparent envelopes which contained one ticket inscribed with either a E (for Euglyca group) or a C (for Control group). To ensure equal allocation rates within the 2 groups, block randomization was employed.

At the initial visit, patients randomized to the E group were advised to download the Euglyca application on their smartphones and they were asked to use the application for the calculation of the bolus insulin dose. Patients randomized to the C group were advised to calculate bolus insulin dose, the way they used to do. Patients repeated their visit to the endocrine pediatric clinic at 3, 6 and 12 months, the latter set as the terminal time-point of this study following the initial visit. At all 4 visits, anthropometrics (weight, height, BMI), blood pressure measurement and heart rate were noted down, while a peripheral blood sample was drawn from all patients in the morning of each visit after an overnight fast for measurement of glycemia and glycosylated hemoglobin (HbA1c) levels. Glucose measurements between 70 and 180 mg/dl were categorized as normoglycemia; any glucose measurement below 70mg/dl was categorized as hypoglycemia; glucose measurements at two hours postprandial measurement found above 180mg/dl were categorized as hyperglycemia. At baseline (first visit), at 6 months (third visit) and at terminal time-point (12 months) all patients filled the World Health Organization-Standard DTSQ. Patients' logbooks and readings from their glucose meters were reviewed by the physicians and nutritionist of the department at each of the four visits and the percentage of normoglycemic, hypoglycemic and hyperglycemic episodes during the preceding trimester was calculated for each patient.

The change of HbA1c values from baseline to the terminal time-point for each group was set as primary outcome, while the percentage of normoglycemic, hypoglycemic and hyperglycemic events over the total number of glucose measurements during the preceding trimester of each visit was set as secondary outcome.

Statistics

Sample size was determined by estimating the change in HbA1c values (primary outcome) based on previous studies (7, 8), assuming 0.5% reduction in HbA1c in the intervention group with 80% power and 5% significance level. Power calculation resulted in 14 patients per group, while the target of the study had been set at recruitment of 80 patients altogether. Results are reported as mean ± standard deviation (SD) for quantitative variables. The absolute difference in a quantitative variable between two different time points was defined as Δ. All quantitative variables (HbA1c; ΔHbA1c; percentages of normoglycemic, hypoglycemic and hyperglycemic events over a total number of glucose measurements; DTSQ's scores) were normally distributed and they were compared between the two studied groups of patients at the different time-points by employing General Linear Models ANOVA and Bonferroni post-hoc test. Repeated measures ANOVA involved one factor between patients (factor "Group" with two levels) and one factor for the repeated measures within patients (factor "time" with 4 or 3 levels depending on the compared variable). Qualitative variables (gender and type of therapy) were compared by employing x^2 (chi square) test after having computed absolute and relative frequencies (percentages %), Statistical significance was set at $P<0,05$. An intention to treat analysis was followed. IBM SPSS V23 Chicago, USA software was used for the statistical analysis.