Experimental study

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Research Question:

Will monitoring and discussing of health-related quality of life to adolescents with Type 1 diabetes improve their psychosocial well-being?

Health Outcome of Interest:

The health outcome of interest is improved psychosocial well-being of adolescent patients with Type 1 diabetes.

Exposure(s) of Interest:

The exposure of interest is monitoring and discussion of health-related quality of life with the diabetes patients.

Types of Experimental Study

Based on the account of Crosby, DiClemente and Salazar (2006), this study falls under a combination of three types of experimental study, a true experimental design, controlled trial and between groups design. This combination of experimental design is referred to as randomized controlled trial.

Inclusion/Exclusion Criteria and Initial Sample Size in Each Arm

Initially, participant clinics, instead of individual participants, were recruited based on the following inclusion criteria: (1) willingness to participate in the study; (2) the number of patients; and (3) similarity of clinical routines. During this stage, there were a total of 179 patients in all the clinics being

considered. The following exclusion criteria were adopted in the selection of individual participants for both groups: (1) duration of diabetes of less than 6 months; (2) mental retardation; (3) lack of fluency in the Dutch language. Only eight patients were excluded, but 80 patients refused to participate. After the baseline data have been obtained, 2 clinics were allocated for monitoring intervention and 2 clinics were allocated to control group. Informed consent was administered among patients willing to participate in the research study. The initial sample size is 46 patients for the intervention group and 45 patients for the control group.

Data Collection at Baseline

Data collection at baseline was not discussed in detail in this study, but in the related study with the same set of authors (De wit, et al., 2007). All patients and their parents were administered a booklet containing questions regarding demographic information and questions to assess their physical and psychosocial well-being which were to be answered at home and returned by mail or submitted to the clinic during one of their routine appointments. Most recent glycosylated hemoglobin (HbA1c) and treatment regimen were recorded form the patients' charts.

Physical and psychosocial well-being of the patients was measured using the 87-item child report version of the Child Health Questionnaire (CHQ-CF87), while their parents completed the CHQ-PF50 equivalent to the CHQ-CF87. Depression, as part of the psychosocial well-being of the patients was assessed using the 20-item Centre for Epidemiological Studies Scale for Depression (CES-D) for both patients and their parents. For diabetes-specific family conflict, the patient and their parents completed the adapted version by Laffel et al. (in De Wit, et al., 2007) of the Diabetes-specific Family

Conflict Scale to assess the degree of family conflict on 19 management tasks. The study participants also completed the Patients' Evaluation of the Quality of Diabetes Care (PEQ-D) for their assessment about the quality of diabetes care they received over the past 12 months

Type, Frequency and Duration of Follow-Up

There were a total of 3 follow-ups during the duration of the study. Follow-ups were in the form of visits where the doctors monitored and assessed the patients health-related quality of life and discussed these with their patients (and their parents if the patient desires). All participants received their allocated intervention (n= 46) and control (n= 45) care during the first visit. Only 43 received intervention during the second visit because one patient transferred to another clinic before the second visit while two other patients did not show up during the second intervention visit. Meanwhile, only 44 received the allocated control care during the second visit because one patient transferred to another clinic. Only 41 received the allocated intervention during the third visit because three other patients failed to show up during the third and last visit. On the other hand, only 40 received their allocated control care because two patients transferred to another clinic while two other did not show up during the scheduled visit. The study and the follow-ups pushed through as scheduled for the intended duration. Compliance among the participating pediatricians may not be an issue because an interim analysis of consultation notes by the physicians confirmed that the assessment of health-related quality of life were administered based on guidelines set for the study. The researchers, however, admitted that since the consultations were not recorded on video, there is no way to verify whether the physicians put on more weight on

glycemic control than psycho-social well-being or vice versa.

Blinding of Subjects and Use of Placebo

Blinding of subjects was not used in this study because the intervention required that the participants are aware that they are receiving the intervention or being provide usual care. There was also no need for the use of placebo because the regimen being experimented on is an intervention in the form of patient (and parent) education and not a type of drug.

Type of Data Analysis

Significant differences between the means of the variables at baseline and after the intervention were compared using the paired t-test for normal samples and the Wilcoxon signed-ranked text when the samples involved are not normally distributed. Analysis of variance (ANOVA) using repeated-measures design and general linear modeling were used to measure the effect of the health-related quality of life between the intervention group and the control group in terms of physical and psychosocial well-being, satisfaction control and glycemic control, controlling for baseline values and characteristics. Multivariate analysis using linear regression was used to investigate interaction and confounding effects of demographic and diabetes-related variables between both groups of participants. Statistical power calculations were also performed to verify if the sample used is sufficient to prevent Type II error.

Results/Main Findings of Study

The mean scores on the CHQ subscales of psychosocial health (p-value < 0. 001), behavior (p-value < 0. 001), mental health (p-value < 0. 001), and family activities (p-value < 0. 001) improved in the health-related quality of life intervention group, with the exception of patients with the highest A1C

values.

Also, patients in the intervention group reported higher self-esteem (CHQ) during follow-up (p-value = 0. 016), regardless of A1C, and were more satisfied with care they are receiving (p-value = 0. 009) than the control group. However, no significant differences in the A1C levels between the two groups over the time they were observed.

In summary, periodic monitoring and discussion of health-related quality of life among the adolescent patients with diabetes was found to be well appreciated and resulted in positive effects on their psychosocial well-being.

Comments (including generalizability of the study)

The study was designed as a randomized controlled trial, which is hailed as the “ gold standard” of experimental designs. This design is believed to be the “ most effective and rigorous design for testing the efficacy of a program or treatment because it allows for causal inference and has the highest level of control possible in a real world setting” (Crosby, et al., 2006, pp. 92, 93). The fact that the study is a true and randomized experimental design, coupled with a statistical power calculation result of 80% power, guarantees generalizability of the findings among adolescents.

References

Crosby, R. A., DiClemente, R. J., Salazar, L. F. (2006). Research methods in health promotion. San Francisco, CA: Josey-Bass.

De Wit, M., Delemarre-Van de Waal, H. A., Bokma, J. A., Haasnoot, K., Houdijk, M. C., Gemke, R. J. et al. (2008). Monitoring and discussing health-related quality of life in adolescents with type 1 diabetes improve psychosocial well-being: A randomized controlled trial. Diabetes Care, 31(8), 1521-1526.

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