Education in daily routine vs RCT: Healthcare research on the efficacy of an education and treatment program (PRIMAS) for people with type 1 diabetes

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ABSTRACT

A new treatment program has to prove its efficacy in a randomized controlled trial (RCT). However, healthcare research trials (HCRT) show that the effectiveness of education programs is far less convincing in daily routine. We evaluated whether a new education and treatment program for type 1 diabetic patients (PRIMAS) had similar effects in daily routine as in the RCT. 255 people with type 1 diabetes from 42 practices took part in the PRIMAS course and were observed in this HCRT. As in the RCT, PRIMAS consisted of 12 lessons and the outcomes were assessed 6 months after the education course. Primary outcome in both studies was HbA1c assessed in the same central laboratory. Improvement in hypoglycemia awareness, depressive symptoms, diabetes-related distress, self-efficacy, and diabetes empowerment were secondary outcomes. In order to compare the effects of PRIMAS in the RCT with the effects in the HCRT, effect sizes of differences for each study were contrasted. The difference of the two respective effect sizes (RCT – HCRT) along with the 95% confidence interval was analyzed. HbA1c reduction in the RCT was -0.36% (-3.9 mmol/mol) as compared to -0.39% (-4.3 mmol/mol) in the HCRT. The difference of the effect sizes didn't exceed the non-inferiority margin of 0.4 (difference of effect size: Δ -0.03, 95% CI -0.29 to 0.22). Effect sizes in all secondary outcomes were also highly comparable: Improvement of hypoglycemia awareness Δ 0.11, 95% CI -0.15 to 0.38; reduction of depressive symptoms Δ -0.08, 95% CI -0.34 to 0.18; reduction of diabetes distress Δ 0.23, 95% CI -0.04 to 0.49; improvement of self-efficacy Δ 0.05, 95% CI -0.21 to 0.32; improvement of empowerment Δ 0.04, 95% CI -0.23 to 0.36. PRIMAS proofed its effectiveness in daily routine and showed similar effect sizes as in the RCT. PRIMAS can contribute to an improvement of routine health care in people with type 1 diabetes.

INTRODUCTION

The efficacy of education and treatment programs for people with diabetes have been proven in many randomized controlled trials (RCT). However, to fully analyze the goodness of an education program, it has to be evaluated in daily routine and has to prove its effectiveness outside of an artificially controlled trial as well. Healthcare research trials (HCRT) evaluating the effectiveness of interventions often show that a effect in a RCT couldn't withstand the challenges of clinical practice. In this study, we evaluated whether the RCT-proven efficacy of a new education and treatment program for people with type 1 diabetes (PRIMAS) could be replicated in a HCRT.

METHODS

PRIMAS is a structured education and treatment program for people with type 1 diabetes consisting of 12 lessons. PRIMAS was evaluated in a RCT with a 6-month follow-up and demonstrated its efficacy by significantly improving glycemic control. In the HCRT, practices conducted a PRIMAS course according to their clinical routine (no randomization, no control group). As in the RCT, patients completed a baseline measurement prior to the education and 6 months after the end of the education course. Primary outcome in both studies was HbA1c assessed in the same central laboratory. Improvement in hypoglycemia unawareness (Clarke questionnaire), depressive symptoms (CES-D), diabetes-related distress (DDS), self-efficacy (GSE), and diabetes empowerment (DES) were secondary outcomes. In order to compare the effects of PRIMAS in the RCT with the effects in the HCRT, effect sizes of differences in each outcome were analyzed. The difference (baseline – follow-up) of effects (RCT – HCRT) along with the 95% confidence interval was analyzed.

255 people with type 1 diabetes from 42 practices took part in the PRIMAS course and were observed in this HCRT. In the RCT, 75 patients were randomized to PRIMAS and completed the 6-month follow-up. Differences of both samples can be seen in table 1 and table 2.

RESULTS

Primary Outcome:

- In the RCT, PRIMAS lead to reduction in HbA1c of -0.36 ± 1.0% (-3.9 mmol/mol). In the HCRT, HbA1c was significantly reduced by -0.39 ± 1.0% (-4.3 mmol/mol) ($p < .05$).
- The difference between the two effects didn't exceed the non-inferiority margin of 0.4 (difference of effect sizes: Δ -0.03, 95% CI -0.29 to 0.22; figure 1).

Secondary Outcome:

The effects of PRIMAS in the HCRT were similar to those achieved in the RCT (figure 3). Thus, effect sizes in all secondary outcomes were highly comparable (figure 4):

- Reduction of hypoglycemia unawareness:
  - RCT: -0.5 vs. HCRT: -0.4
  - Effect size of difference: Δ 0.11, 95% CI -0.15 to 0.38
- Reduction of depressive symptoms
  - RCT: -1.2 vs. HCRT: -1.8
  - Effect size of difference: Δ -0.08, 95% CI -0.34 to 0.18
- Reduction of diabetes-related distress
  - RCT: -0.3 vs. HCRT: -0.2
  - Effect size of difference: Δ 0.23, 95% CI -0.04 to 0.49
- Improvement of self-efficacy
  - RCT: 1.4 vs. HCRT: 1.1
  - Effect size of difference: Δ 0.05, 95% CI -0.21 to 0.32
- Improvement of empowerment
  - RCT: 2.4 vs. HCRT: 2.3
  - Effect size of difference: Δ 0.04, 95% CI -0.23 to 0.36

CONCLUSION

This healthcare research trial demonstrated the effectiveness of PRIMAS. Under routine care conditions, PRIMAS was able to improve glycemic control in a 6-month follow-up. This effect was equivalent to the effect demonstrated in the RCT. Furthermore, the effects on secondary outcomes PRIMAS achieved in the RCT could be replicated in the HCRT. PRIMAS proved to be a potent tool for clinical practice to educate patients with type 1 diabetes. Therefore, PRIMAS can contribute to an improvement of routine healthcare in people with type 1 diabetes.

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Table 1: Sample Characteristics

	RCT PRIMAS	HCRT	p
N	75	255	
Mean age ± SD (years)	45.1 ± 13.6	42.8 ± 14.1	.216
Mean diabetes duration ± SD (years)	18.6 ± 12.2	13.3 ± 11.7	.001
Mean BMI ± SD (kg/m²)	26.6 ± 4.7	26.1 ± 5.7	.478
% female	37.8	45.6	.217
Mean HbA1c ± SD (%)	8.2 ± 1.1	8.3 ± 1.8	.521
Mean HbA1c ± SD (mmol/mol)	66.4 ± 11.9	67.5 ± 20.0	.521
% with CSII	24.7	14.8	.071
% with complications	40.3	28.7	.055

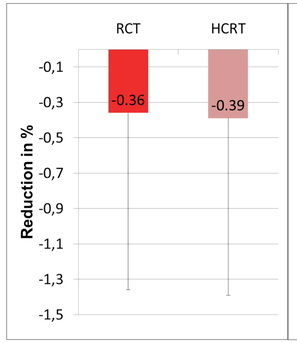

Figure 1: Reduction in HbA1c

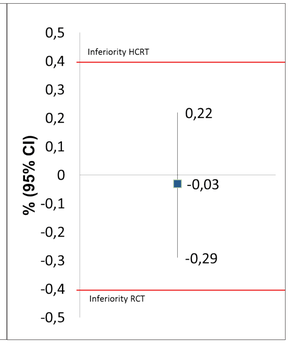

Figure 2: Difference of effect sizes regarding HbA1c reduction of the RCT and HCRT

Table 2: Comparison of psychosocial variables

M ± SD	RCT PRIMAS	HCRT	p
Hypoglycaemia unawareness	1.8 ± 1.7	1.5 ± 1.5	.237
Depression	14.2 ± 9.0	14.6 ± 9.5	.694
Diabetes distress	1.3 ± 1.0	1.0 ± 0.8	.024
Self-efficacy	21.9 ± 4.7	21.4 ± 5.3	.412
Empowerment	24.6 ± 6.0	24.3 ± 5.9	.550

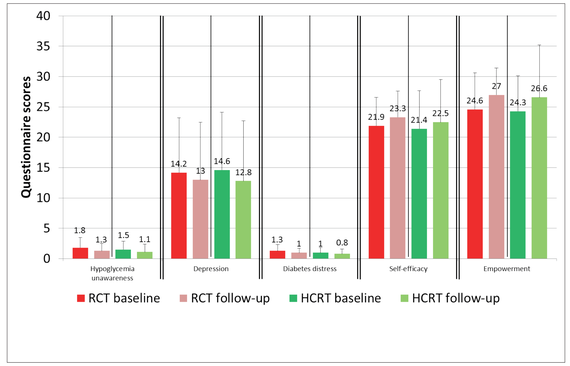

Figure 3: Comparison of improvements in secondary outcomes

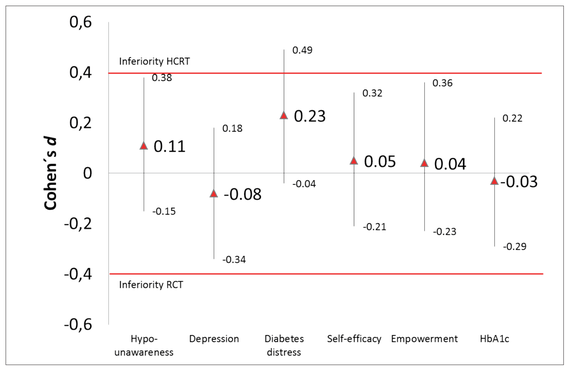

Figure 4: Effect sizes of differences in primary and secondary outcomes (RCT - HCRT)