According to Michael Berger, diabetes education is a complex intervention. This implies that after proving the efficacy of a diabetes self-management education programme in a randomised controlled trial (RCT), healthcare research should establish its effectiveness under routine care conditions (RCC). In this comparative effectiveness research analysis, we compared the effectiveness of a newly developed education programme for insulin pump users (called “INPUT”) in an RCC trial with its efficacy in an RCT.

In this analysis, we included 191 people with CSII who participated in the INPUT programme under RCC and 135 people with CSII who received the INPUT education programme in a randomised controlled trial (RCT), healthcare research should establish its effectiveness under routine care conditions (RCC). In this comparative effectiveness research analysis, we compared the effectiveness of a newly developed education programme for insulin pump users (called “INPUT”) in an RCC trial with its efficacy in an RCT.

**Materials and Methods**

Differences in study population: RCC vs. RCT

- At baseline, participants under RCC were older, had lower HbA1c values, and reported less diabetes distress compared to the RCT setting (Table 1).
- Also, demographic characteristics were not associated with clinical improvement indicating that INPUT was effective across different age ranges, gender, BMI, diabetes duration, duration of pump therapy, years of education, or whether or not participants used continuous glucose monitoring systems or had late complications.
- The only significant predictors of clinical improvement were poor glycaemic control at baseline, hypoglycaemia problems at baseline, and elevated diabetes distress at baseline (Figure 5).

**Results**

- The only significant predictors of clinical improvement were poor glycaemic control at baseline, hypoglycaemia problems at baseline, and elevated diabetes distress at baseline (Figure 5).
- Results indicated that the different trial settings (RCC vs. RCT) were associated with a different sample composition. This could be mostly due to the differences in inclusion/exclusion criteria between the two settings. Everyone whom the diabetes practice deemed suitable could be included in the RCC trial, whereas rather strict criteria were present in the RCT.
- INPUT demonstrated its effectiveness under conditions of routine care. Furthermore, the effects were comparable to those achieved in the RCT. In summary, this comparative effectiveness analysis showed that the delivery of the structured diabetes education programme INPUT had at least equal effectiveness in a real world setting compared to the RCT setting.

**Conclusion**

- Effect sizes of RCC and RCT were also comparable with the exception of hypoglycaemia unawareness and empowerment (Figure 2).
- Unadjusted analysis revealed that a greater improvement in empowerment was achieved in the RCC. All other between-group differences were non-significant (Figure 3).
- When adjusted for the baseline values, there was a significant effect on HbA1c, indicating that a relatively greater improvement in HbA1c was achieved in the RCT (Figure 4).
- Predicted clinical improvement: reduction in HbA1c, hypoglycaemia problems, and/or diabetes distress.

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