

# Integrated personalized diabetes management (iPDM) improves satisfaction of patients with insulin-treated diabetes and their physicians: Results from the PDM-ProValue study program

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## Objectives

- Integrated Personalized Diabetes Management (iPDM) is supposed to support improvement of glyemic control by facilitating the therapeutic decision-making process.
- The iterative 6-step, structured iPDM intervention program starts with 1) an initial assessment of the patient status and a demand-oriented education/training. Subsequently, 2) blood glucose (BG) data are collected according to a structured, therapy-adapted regimen, followed by 3) electronic documentation and 4) systematic data analysis. In step 5), current treatment is reviewed and adapted individually when indicated and finally 6) the treatment effectiveness is assessed at the patient's next visit. The process is then run through again.
- Bringing together the health care physician (HCP) and the patient in the therapeutic decision-making process, and integrating digital tools for data analysis and visualization are two major elements of the iPDM process.
- A structured and somewhat tightly organized process as iPDM may improve therapy outcomes especially if the participating patients and physicians readily experience its beneficial effects.
- Therefore, the PDM-ProValue study program was not only designed to determine if implementation of iPDM in daily practice improves glyemic control (primary endpoint); in addition, we investigated a set of additional clinical parameters and patient reported outcomes (PROs).
- Here we report the results of patient and physician treatment satisfaction assessments as well as patient adherence.

## Methods

- The 12-month, prospective, controlled, cluster-randomized study program enrolled 907 eligible people with type 2 diabetes at 101 study sites (general practitioner and diabetes specialist practices) throughout Germany (1).
- Study sites were randomized in the PDM arm (n=53) and in the control (CNL) arm (n=48).
- Patients with BOT, SIT, CT or ICT therapy regimen were treated in the CNL arm with usual care; the respective treatment for patients in the iPDM arm was organized according to the iPDM process.
- The study visits were conducted at baseline (visit 1), week 3 (visit 2), and months 3 (visit 3), 6 (visit 4), 9 (visit 5) and 12 (visit 6).
- Patient reported outcome (PRO) questionnaires were administered at visits 1, 4, and 6. Physician questionnaires were administered at visits 1 and 6 to assess physician perceptions of the integrated PDM process.
- Patients' treatment satisfaction was assessed with the Diabetes Treatment Satisfaction Questionnaire (DTSQc and DTSQs). Change in patient adherence over time vs. baseline was evaluated by the physicians using a Likert scale.
- Physician satisfaction was assessed with the newly developed Diabetes Treatment - Physician Satisfaction Questionnaire (DT-PSQ, Figure 1).

## Results

- Patients were highly comparable at baseline (e.g., socio-demography, diabetes history and treatment satisfaction). The same is true for the characteristics of randomized study sites and physicians (Table 1).
- After 12 months, the iPDM group showed a greater improvement in treatment satisfaction (DTSQc: 12.2 vs. 10.4, delta=1.78, p=0.0035) and, the mean DTSQs was higher in the iPDM (31.1) group compared to the control (CNL) group (30.0, delta=0.924, p=0.02) (Figure 2A).
- Percentage of patients for which the physicians stated an enhanced therapy adherence was greater in the iPDM group than in the CNL group, both compared to before study enrollment and compared to the first three months of study participation (Figure 2B).
- Physician treatment satisfaction was markedly higher in the iPDM group compared to the CNL group. All scores of the DT-PSQ questionnaire showed a highly significant between-group difference at month 12 (Figure 3).
- Physicians indicated that the iPDM process has beneficial effects with regard to both the overall assessment and the effects of the diabetes therapy. In addition, they rated the ratio between efforts and benefits as good.
- Physicians indicated that the iPDM process enabled them to gain an overview of BG values more quickly and that discussing BG values with the patient makes appropriate adjustments easier. This led to the overall assessment that physicians rated the discussion of BG values as more effective in the iPDM vs. CNL group.

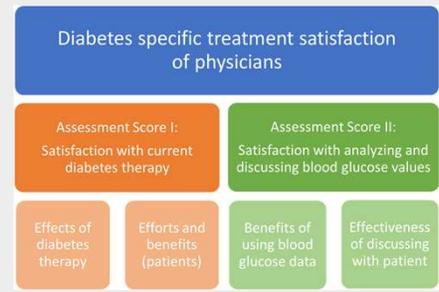


Figure 1: Structure of the Diabetes Treatment Physician Satisfaction Questionnaire (DT-PSQ). The validated tool can be used to investigate the influence of physicians' satisfaction on diabetes therapy as well as how physicians' satisfaction can be altered

	CNL (n=47)	iPDM (n=53)
Physician gender, male (%)	76.6	76.9
Physician age (years; mean±SD)	50.6±6.8	51.4±7.6
Professional experience as physician (years; mean±SD)	23.0±6.8	22.9±8.0
Percentage of study sites with ≤500 diabetes patients per quarter (%)	66.6	56.6
Percentage of type 2 diabetes per study site (%; mean±SD)	84.4±12.4	86.5±14.5

Table 1: Study site characteristics

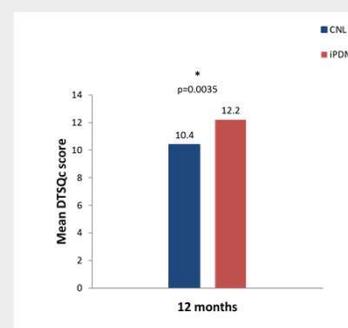


Figure 2A: Change of patient diabetes treatment satisfaction (DTSQc); p-value refers to adjusted LSM values

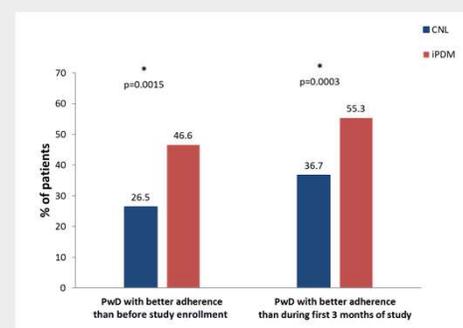


Figure 2B: Change of patient adherence. PwD: people with diabetes. P-values refer to adjusted odds ratios.

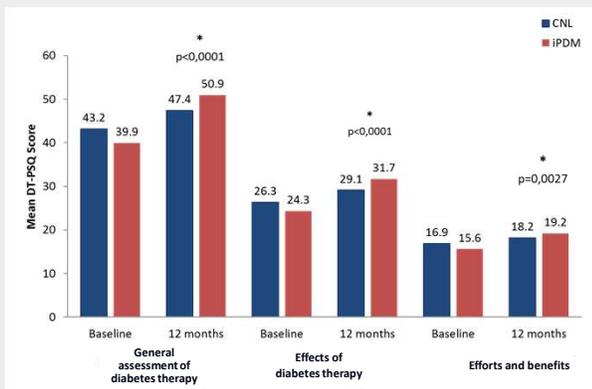
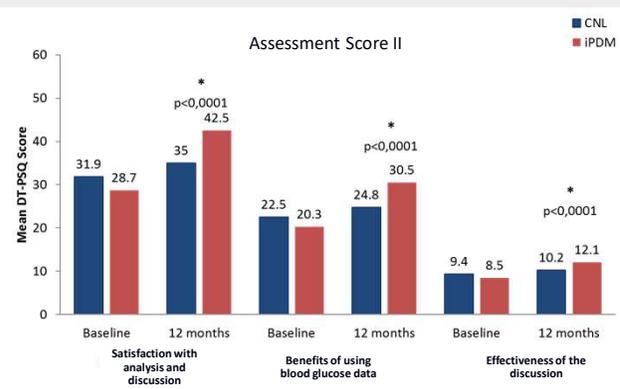


Figure 3: Diabetes Treatment - Physician Satisfaction Questionnaire results. 6 sub-scores were assessed at baseline and again at month 12. P-values refer to adjusted LSM values (LSM: least squares mean)



## Conclusion and outlook

- These results document the considerable benefit of an iPDM approach. Providing structured guidance together with a low-threshold digital solution resulted in significant improvements in patient and physician treatment satisfaction and better patient adherence. Its implementation may help to overcome unsatisfactory glyemic control and clinical inertia.
- The iPDM approach is an effective, practical procedure to provide a framework for identifying deficits regarding glyemic self-management and patient knowledge/training, guiding diabetes therapy by collecting and analyzing BG data and encouraging patient adherence due to patient-physician collaboration.
- Expanding the process with adequate digital tools and opening it up for additional, sophisticated solutions for coaching or education can be key to addressing the needs of people with diabetes.