Impact of *Conversation Map*™ Education Tools Versus Regular Care on Diabetes-Related Knowledge of People With Type 2 Diabetes: A Randomized, Controlled Study

Matthew Reaney, MSc, Esther Gil Zorzo, Alain Golay, MD, Norbert Hermanns, MD, Simon Cleall, MSc, Ute Petzinger, MSc, and Veikko Koivisto, MD, PhD

Abstract

**Objective.** This study compared the effectiveness of *Conversation Map*™ (CM) education tools versus regular care of adults with type 2 diabetes.

**Methods.** Participants from Spain and Germany were randomized to either four CM education sessions or regular care. Data were collected at baseline (visit 1), immediately post-education (visit 2), and 6 months later (visit 3). The primary objective was to compare diabetes knowledge between education groups at visit 3, using the Audit of Diabetes Knowledge (ADKnowl) questionnaire (score range 0–100).

**Results.** Of 681 participants randomized (CM 330, regular care 351), 91.8% completed visit 3. Median ADKnowl scores increased significantly (*P* < 0.001) in both groups (CM visit 1, 60.3; visit 2, 73.5; and visit 3, 72.5; regular care visit 1, 63.3; visit 2, 73.5; and visit 3, 73.6). At visit 3, scores were not ranked significantly differently between education groups (*P* = 0.284). In Spain (n = 310), visit 3 scores were ranked higher for CM than for regular care (*P* < 0.001); in Germany (n = 371), the opposite was true (*P* < 0.001). Of participants receiving regular care, 78.3% of those in Germany and 13.5% of those in Spain had non-CM structured education between visits 1 and 2. In Spain, CM patients had higher satisfaction with care and goal attainment than regular-care patients at visit 2 (visit 2 *P* < 0.001, visit 3 *P* = 0.055). In Germany, CM patients had less emotional distress than regular-care patients (visit 2 *P* = 0.025, visit 3 *P* = 0.003). Median A1C decreased similarly in both groups and countries.

**Conclusion.** Diabetes knowledge and clinical outcomes improved in both education groups. At visit 3, diabetes knowledge in the CM group was not ranked higher than in the regular-care group. In Germany, where regular care frequently involves structured education programs, diabetes knowledge was ranked higher with regular care than with CM. In Spain, where no structured national diabetes education and awareness programs are in place, scores were ranked higher with CM than with regular care.

Diabetes self-management education and ongoing self-management support are crucial components of effective diabetes care and significant contributors to the metabolic and psychological outcomes of people with type 2 diabetes. Approaches vary among countries, care sites, and health care professionals (HCPs), with some routinely offering standardized, structured group education programs and others engaging participants in individual conversations during clinic visits. *Conversation Map*™ (CM) education tools are a series of tools for facilitated group education that were developed by Healthy Interactions in collaboration with the International Diabetes Federation (IDF) and are sponsored by Lilly Diabetes. Different CM versions have been developed for specific regions or countries (United States, Canada, Europe, Asia, Australia, Latin America, and Africa) in cooperation with national and international diabetes associations (IDF and the
Canadian, American, and U.K. diabetes associations) to reflect differences in culture and background.

CM-based education guides people with diabetes through a process with the aim of helping them understand and internalize information about their disease and generate insightful conclusions, which may then result in improved self-management decisions and actions.8

The U.S. CMs were compared to individual education and usual care in 623 patients with type 2 diabetes in the randomized multicenter IDEA study.10,11 Short-term results showed positive effects (P < 0.05) of CM-based and individual education (vs. usual care) on empowerment and understanding endpoints and reductions in negative attitudes to diabetes at 3 months post-randomization.

This study is the first randomized trial of the European CMs to evaluate the medium-term effectiveness of CM-based education compared to regular care. Spain and Germany participated to reflect different approaches to diabetes education. This study was designed to assess whether adults with type 2 diabetes receiving CM-based education acquired a higher level of diabetes-related knowledge than adults receiving regular care, as captured by the Audit of Diabetes Knowledge (ADKnowl) questionnaire12 6 months after completion of the education.

Although knowledge alone is likely insufficient to achieve changes in A1C, it is evident from prior research that behavior and ultimately clinical outcomes are unlikely to change unless there is knowledge together with an understanding of the need to change, what to change, and how to change it.13 Therefore, knowledge was selected as the primary outcome.13 Secondary outcomes included diabetes self-management behavior, physical and psychological well-being, glycemic control (A1C), body weight, patient satisfaction with care, and attainment of personal therapeutic goals.

Study Methods

Design, objectives, and outcomes
This was a randomized, controlled, open-label multicenter study. Adults (aged 18–75 years) with type 2 diabetes were eligible if their physician considered them to show poor disease management and to be in need of education or re-education. Participants were recruited at 19 sites in Germany and 14 sites in Spain between September 2009 and November 2010. The sites were asked to screen patients for inclusion and to obtain consent for participation from a minimum number of 12 (maximum 20) patients, to allow for randomization via a computer-generated random sequence at baseline (visit 1) within each site.

Patients were randomized to receive CM-based education sessions or regular care as determined by the usual practice at each site. Inclusion was not restricted by diabetes treatment, time since diagnosis, or A1C level. Rather, patients were eligible for inclusion if their treating HCP considered them as not demonstrating ideal management of the disease (e.g., their A1C was not optimal, they did not adhere to their medication regimen, or they were not empowered to perform self-care) and being in need of education or re-education.

The study was approved by ethical review boards in Spain and Germany. Participants provided informed consent, and the study was conducted in accordance with the Declaration of Helsinki.

Baseline data were collected at visit 1. Participants assigned to the CM group received four CM-based group education sessions (3–10 participants, 2–3 hours each) at 1- to 2-week intervals during a 6-week post-baseline period. There are four individual CM tools, covering the topics of managing diabetes, following a healthy lifestyle, starting insulin, and experiencing life with diabetes. Sessions were facilitated by a trained educator who guided the discussion, and person-to-person interaction was encouraged. This facilitator was the local educator who was responsible for diabetes education at the given site. Facilitators received specific training on how to use the CM tools.

Participants assigned to regular care attended their normal HCP appointments and received instruction or education that would be given as part of regular care during the same 6-week post-baseline period. This included the use of any non-CM-based structured education programs offered at the site, presented by the same local educator.

Data were collected again after completion of the 6-week education period (visit 2). During the 6-month post-education follow-up, both education groups continued to receive regular care, but no additional formal structured education programs were allowed. Final data were collected 6 months post-education (visit 3, month 7.5).

The primary objective was to assess whether participants randomized to CM-based education had greater diabetes-related knowledge at 6 months post-education than participants who received regular care. Diabetes knowledge was measured using the ADKnowl,12 a widely used questionnaire that was developed for use in individual patients and for evaluating the success of educational interventions.14 For 138 statements (33 item sets) on different diabetes-related topics such as A1C, diet, or foot care, respondents were asked whether a given statement is true or false. The ADKnowl total score (0–100) was calculated as a percentage of items answered correctly out of all applicable items answered.

Secondary outcome measures included patient-reported empowerment, self-care, health status, and diabetes-related emotional distress, as well as standard clinical measures. Empowerment was measured using the Michigan Diabetes Empowerment Scale (DES).15 Self-care was evaluated by the Summary of Diabetes Self-Care Activities (SDSCA), measuring the number of days in the past week (0–7) that participants adhered to personalized physician-recommended activities for five different areas (diet, exercise, blood glucose testing, foot care, and smoking). Higher scores reflect better self-care.16 Health status was assessed using the EuroQoL 5 dimension (EQ-5D) instrument.17 Diabetes-related emotional distress was measured using the Problem Areas in Diabetes (PAID) scale.18

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Clinical outcomes included A1C (measured centrally; Interlab GmbH, Munich, Germany; photometric method [Cobas Integra, Roche, Switzerland]), severe hypoglycemia, lipid levels, body weight, BMI, waist circumference, and vital signs. In addition, severe hypoglycemia was defined as symptomatic hypoglycemia requiring assistance by another person (no self-measured blood glucose data collected).

Satisfaction with care and attainment of individual therapeutic goals were assessed using single-item Likert scales developed for this study. Items were rated from 1 to 7, satisfaction with care from “not at all satisfied” to “extremely satisfied” and goal attainment from “I did not achieve what I wanted to at all” to “I achieved everything I wanted to.”

Statistical analyses

Approximately 650 participants were to be enrolled, assuming that 500 participants would complete the 6-month post-education follow-up. This sample size gave 90% power of detecting a significant difference between CM and regular-care groups in the ranks of ADKnowl total score at the two-sided 5% level, assuming that the true probability for scores to be ranked higher in a given group is 58.5%.

All analyses were prespecified. All statistical tests were performed at the two-sided 5% level. Confidence intervals (CIs) were calculated at the 95% level. All efficacy analyses were performed on the full analysis set, including data from all randomized participants using the intention-to-treat principle.19 For clinical outcomes, no imputation of missing values was performed.

All patient-reported outcome tools were scored using their published scoring algorithms and summarized using nonparametric measures (i.e., medians and quartiles). For the primary analysis, ranks of ADKnowl total scores at visit 3 were compared between CM and regular-care education groups using the Wilcoxon rank sum test. A1C levels were additionally compared by mixed-model repeated measures (MMRM) analysis using an unstructured covariance matrix with the following factors and interaction terms: treatment, country, baseline A1C, visit, visit window deviation, baseline PAID score, baseline ADKnowl score, antidiabetic medication class, time since diagnosis, and interactions between visit and antidiabetic medication class, treatment and country, and treatment and visit. Patient nested within an antidiabetic medication class was considered a random effect.

BMI at visit 3 was analyzed using a parametric ANCOVA adjusting for treatment; country; baseline measures of BMI, A1C, waist circumference, and ADKnowl and PAID scores; antidiabetic medication class at visit 3; and time since diagnosis. The proportion of participants reporting severe hypoglycemia, the proportion of participants highly satisfied with care (ratings 6 or 7), and the proportion of participants with high goal attainment (ratings of 6 or 7) were compared using Pearson’s χ² or Fisher’s exact test as appropriate. Factors potentially associated with an increased risk for severe hypoglycemia were explored using logistic regression analysis.

Study Results

Patient disposition

Of 713 individuals screened, 681 were randomized to the CM or regular-care education groups (CM total 330, of which 182 were from Germany and 148 were from Spain; regular care 351, of which 189 were from Germany and 162 were from Spain). In the CM group, 279 individuals (84.5%) attended all four CM sessions. Overall, 625 individuals (91.8%) completed the post-education follow-up at visit 3 (CM 303, regular care 322; Figure 1). Most frequent reasons for discontinuation were participant decision (CM 4.2%, regular care 5.1%) and loss to follow-up (CM 2.7%, regular care 2.3%).

Baseline characteristics

CM and regular-care education groups had similar baseline characteristics (Table 1). However, country-level differences were noted. Median diabetes duration (CM/regular care) was 10/7...
years for participants in Germany and 8/8 years for participants in Spain. The proportion of participants taking insulin was 54/47% for Germany and 39/36% for Spain. Median baseline A1C values in the CM group were 7.2% for both Germany and Spain. Median baseline A1C values in the regular-care groups were 7.3% for Spain and 6.8% for Germany.

During the 6-week education period (visit 1 to visit 2), 98.8% of participants in the CM group received structured diabetes education (CM). In the regular-care group, 78.3% of participants in Germany and 13.5% of participants in Spain received structured education in the same period (according to the protocol, this could not include CM; Table 2). No structured education was allowed in either group during the 6-month post-education follow-up (visit 2 to visit 3).

**Diabetes knowledge**

At baseline, the median ADKnowl score was higher for participants in Germany than for participants in Spain in both education groups (Table 1). At 6 months post-education (visit 3), diabetes knowledge had increased in both education groups in both countries (Figure 2A–C). For the overall population (Figure 2A), median ADKnowl scores at visit 3 were 72.5 (interquartile range [IQR] 65.0–78.6) in the CM and 73.6 (IQR 65.1–80.6) in the regular-care group. At visit 3, the ADKnowl scores of participants in the CM group were not ranked statistically significantly differently from those in the regular-care group ($P = 0.284$). In Germany, ADKnowl scores from participants in the regular-care group were ranked significantly higher than those from participants in the CM group. In contrast, in Spain, ADKnowl scores from participants in the CM group were ranked significantly higher than those from participants in the regular-care group ($P < 0.001$ for all, by Wilcoxon rank sum test).

A nonparametric ANCOVA was performed to assess the impact of baseline patient and disease characteristics on ADKnowl scores at visit 3. Covariates included baseline ADKnowl score, country, baseline A1C, time since diagnosis, practice level of care (general practitioner/specialist), baseline PAID scores, and timing of visit 3. The relative effects controlling for these covariates were as follows, where effects $< 0.5$ indicate higher rankings for regular care, and effects $> 0.5$ indicate higher rankings for CM: overall population 0.51 (95% CI 0.48–0.55), Germany 0.42 (0.38–0.46), and Spain 0.63 (0.57–0.69).

**Diabetes empowerment**

Empowerment was measured by DES scores (range 1–5, with higher values reflecting greater self-perceived empowerment). In the CM education group, median DES scores increased from 3.7 (IQR 3.4–4.0) at baseline to 4.0 (IQR 3.7–4.2) at visit 3; in the regular-care edueca-

### Table 1. Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Overall (CM: $n = 330$)</th>
<th>Regular Care (CM: $n = 351$)</th>
<th>Germany (CM: $n = 182$)</th>
<th>Regular Care (CM: $n = 189$)</th>
<th>Spain (CM: $n = 148$)</th>
<th>Regular Care (CM: $n = 162$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (years [SD])</td>
<td>62.0 (9.59)</td>
<td>61.9 (8.72)</td>
<td>61.7 (10.64)</td>
<td>61.8 (8.82)</td>
<td>62.3 (8.13)</td>
<td>62.1 (8.63)</td>
</tr>
<tr>
<td>Sex ($n$ [%])</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>179 (54.2)</td>
<td>184 (52.4)</td>
<td>86 (47.3)</td>
<td>90 (47.6)</td>
<td>93 (62.8)</td>
<td>94 (58.0)</td>
</tr>
<tr>
<td>Female</td>
<td>151 (45.8)</td>
<td>167 (47.6)</td>
<td>96 (52.7)</td>
<td>99 (52.4)</td>
<td>55 (37.2)</td>
<td>68 (42.0)</td>
</tr>
<tr>
<td>Median A1C (% [IQR])</td>
<td>7.2 (6.5–8.0)</td>
<td>7.0 (6.4–7.8)</td>
<td>7.2 (6.4–7.9)</td>
<td>6.8 (6.3–7.4)</td>
<td>7.2 (6.6–8.0)</td>
<td>7.3 (6.7–8.0)</td>
</tr>
<tr>
<td>Mean BMI (kg/m² [SD])</td>
<td>31.22 (5.435)</td>
<td>31.74 (5.857)</td>
<td>31.98 (5.926)</td>
<td>32.13 (5.761)</td>
<td>30.29 (4.614)</td>
<td>31.28 (5.953)</td>
</tr>
<tr>
<td>Median diabetes duration (years [IQR])</td>
<td>9 (4–15)</td>
<td>7 (2–13)</td>
<td>10 (3–15)</td>
<td>7 (1–12)</td>
<td>8 (8–13)</td>
<td>8 (3–14)</td>
</tr>
<tr>
<td>Taking insulin ($n$ [%])</td>
<td>155 (47.0)</td>
<td>147 (41.9)</td>
<td>98 (53.9)</td>
<td>88 (46.6)</td>
<td>57 (38.5)</td>
<td>59 (36.4)</td>
</tr>
<tr>
<td>Median ADKnowl score (score [IQR])</td>
<td>60.3 (50.5–71.3)</td>
<td>63.3 (51.4–73.5)</td>
<td>67.0 (53.1–75.5)</td>
<td>69.4 (58.2–76.4)</td>
<td>56.8 (47.0–64.0)</td>
<td>56.3 (46.4–65.8)</td>
</tr>
</tbody>
</table>

SD, standard deviation.
tion group, median DES scores increased from 3.7 (IQR 3.4–4.0) at baseline to 3.9 (IQR 3.6–4.1) at visit 3 (P = 0.075 for group difference at visit 3). Country-level analyses revealed no clinically relevant differences between the two education groups. Similar changes were observed for DES subscale scores, with the exception of “setting goals,” for which little change was observed.

Self-care for diabetes
Self-care in relation to diet, exercise, blood glucose testing, foot care, and smoking status was evaluated using the SDSCA questionnaire. In both groups of the overall population, mean and median SDSCA scores showed no clinically relevant changes at visit 2 and visit 3 for any domains other than foot care. In the CM group, the median number of days engaging in foot care (in the past 7 days) increased from 2.0 at baseline to 3.5 at visit 2 and 3.5 at visit 3; in the regular-care group, this measure increased from 2.5 at baseline to 3.5 at visit 2 and 3.5 at visit 3 (no statistical tests performed). The country-level analyses showed similar patterns for Germany and Spain.

Health status
Overall health status was evaluated using the EQ-5D questionnaire. Pain/discomfort was the EQ-5D domain impaired most frequently at each visit, with the proportion of participants reporting pain/discomfort decreasing from baseline to visits 2 and 3 (Figure 3A–C). Median EQ-5D visual analog scale (VAS) scores (range 0–100, higher scores indicate better health status) in the CM group were 70 (IQR 58–80) at baseline and 75 (IQR 60–85) at visit 2. For the regular-care group, VAS scores were 70 (IQR 55–80) at baseline and 75 (IQR 60–85) at visit 2. There were with no statistically significant differences between the CM and regular-care education groups at visit 2 or visit 3 (P = 0.480 and P = 0.810, respectively).

Country-level analyses showed similar patterns. For participants in Germany, mean EQ-5D VAS scores remained below the population-based normative value of 82.2 at all visits.21 For participants in Spain, mean values reached levels of 76.2 for the CM group and 73.1 for the regular-care group at visit 3, which is close to the population-based mean normative value of 76.5.20

Diabetes-related distress
Distress was evaluated using PAID scores. Participants in Germany had low baseline distress levels (median PAID score of 18 points on a 0–100 scale, with higher scores reflecting higher emotional distress). Participants in Spain started at higher distress levels; median scores were 35.0 points for the CM group and 36.3 points for the regular-care group. At visit 2 and visit 3, median PAID scores had decreased in both education groups (Figure 4A–C). No differences were observed between the CM and regular-care education groups for the overall population or for participants in Spain (Figure 4A and C). For participants in Germany, median PAID scores were significantly lower in the CM group than in the regular-care group at both visit 2 and visit 3 (Figure 4B).

Clinical outcomes
A1C. At visit 3, median A1C levels had significantly decreased from baseline in both groups and in both countries. For the overall population, median A1C scores at visit 3 were 6.9 (IQR 6.3–7.7) in the CM group and 6.8 (IQR 6.2–7.6) in the regular-care group. At visit 3, there were no statistically significant differences between groups for the overall population or for participants in either country. The median changes in A1C from baseline were statistically significant for both education groups overall (P < 0.001 for both groups) and for both countries (Germany P < 0.001 for both groups; Spain P = 0.017 for the CM group and P = 0.004 for the regular-care group).

An MMRM analysis adjusting for baseline A1C, anti-diabetic medication, country, baseline PAID scores, and time since diagnosis provided similar results (least squares [LS] mean difference, CM minus regular care, –0.07 [95% CI –0.21 to 0.07], P = 0.315). At baseline, 42.9% of CM and 50.3% of regular-care group participants in the overall population had an A1C ≤ 7%. At visit 3, 55.4% of CM and 57.5% of regular-care group participants had an A1C ≤ 7% (Germany: CM 58.4%, regular care 67.8%; Spain: CM 51.8%, regular care 45.3%).

Hypoglycemia. During the 6-week education period (visit 1 to visit 2), 2.8% of CM and 2.4% of regular-care group participants experienced at least one episode of severe hypoglycemia requiring assistance (P = 0.781). The corresponding rates for the 6-month post-education period (visit 2 to visit 3) were 3.6
Logistic regression analysis over the complete observation period did not indicate any association between education group and incidence of severe hypoglycemia requiring assistance. However, country and baseline ADKnowl scores were both associated with risk of severe hypoglycemia. Participants in Germany were less likely than those in Spain to experience a severe hypoglycemic episode (odds ratio [OR] 0.37, 95% CI 0.16–0.87). Participants with lower baseline ADKnowl scores were more likely to experience a severe hypoglycemic episode (OR 0.97, 95% CI 0.95–1.00).

Cardiovascular risk factors. Median BMI remained unchanged in both education groups and for both countries. In the overall population, the median BMI for the CM group was 30.7 kg/m² (IQR 27.1–34.9) at baseline and 30.4 (IQR 26.9–34.9) at visit 3; the median BMI for the regular-care group was 31.2 kg/m² (IQR 27.7–35.3) at baseline and 30.9 (IQR 27.3–35.1) at visit 3.

A parametric ANCOVA was performed to assess the association of disease characteristics with BMI at visit 3, using the follow-
ing covariates: treatment; country; baseline waist circumference, A1C, ADKnowl scores, and PAID scores; time since diagnosis; and antidiabetic medication at visit 3. The ANCOVA revealed no statistically significant differences between groups (LS mean difference, CM minus regular care, −0.15 [95% CI −0.37 to 0.06], \( P = 0.163 \)). There were no clinically relevant differences between groups in mean body weight, waist circumference, lipid levels (total, HDL, and LDL cholesterol and triglycerides), blood pressure, or heart rate at any visit.

Satisfaction with care
At the end of education (visit 2), the proportion of participants who were highly satisfied with the diabetes information they received during the study had increased in the CM group from 44.5% at baseline to 80.7% and in the regular-care group from 46.9% at baseline to 66.4%. The difference between the CM and regular-care education groups was statistically significant for the overall population (\( P = 0.006 \)) and for participants in Spain (\( P < 0.001 \)). At visit 3, the differences between the education groups were not significant (overall population \( P = 0.255 \), Spain \( P = 0.035 \)). No differences between the CM and regular-care groups at any visit were demonstrated for participants in Germany.

Goal attainment
At the end of education (visit 2), 59.9% of participants in the CM group compared to 47.5% of participants in the regular-care group reported high attainment of their personal therapeutic goals (ratings of 6 or 7). The difference between the CM and regular-care education groups was statistically significant for the overall population (\( P = 0.016 \)) and for participants in Spain, where 71.9% of participants in the CM group compared to 40.0% of participants in the regular-care group reported high goal attainment at visit 2 (\( P < 0.001 \)). At visit 3, the differences between education groups were not significant (overall population \( P = 0.208 \), Spain \( P = 0.046 \)). No differences between the CM and

Figure 4. PAID scores at each visit for the overall population (A), Germany (B), and Spain (C). Data are shown as median and IQR. \( P \) values were determined using the Wilcoxon rank sum test.
regular-care groups were demonstrated for participants in Germany.

**Discussion**

This was the first randomized study to compare the effectiveness of CM-based education and regular care in adults with type 2 diabetes in Europe. The immediate objective of any form of education is to improve knowledge and understanding of diabetes and its management. Six months after the end of education (visit 3), diabetes-related knowledge, as measured by ADKnowl, had improved in both education groups, but without a significant difference between the CM and regular-care groups in the overall population. Important differences were noted between Germany and Spain. In Germany, regular care was significantly superior to CM. In Spain, CM was significantly superior to regular care in terms of diabetes-related knowledge.

In Germany, diabetes education is well established as part of regular care, and there are multiple education programs certified by the Federal Insurance Agency and reimbursed (including HCP time to deliver the education). It has been estimated that 1.7 million individuals with type 2 diabetes have participated in structured education programs during the past 10 years in Germany. In the regular-care group, 78.3% of subjects in Germany participated in (non-CM) structured education programs during the education period.

In Spain, hospitals and primary health care centers are more flexible regarding the content and design of the education provided; there is no national diabetes education and awareness program. In Spain, 13.5% of regular-care subjects participated in (non-CM) structured education programs, and the CM group participants were more satisfied with diabetes care and achieved higher goal attainment than the regular-care group participants. There was no such difference for the participants in Germany. However, it remains unclear to what extent cultural differences between Spain and Germany or differing opinions of educators contributing to the country-specific CM maps may have contributed to the country-specific differences observed.

Overall, CM group participants were highly satisfied with the diabetes information received during the study (80.8% highly satisfied vs. 66.4% in the regular-care group at visit 2, \( P = 0.006 \)). This was reflected by a high attendance; 84.5% of all CM group participants attended all four education sessions.

In accordance with the concept of “continuum of care,” improved diabetes knowledge should lead to increased patient empowerment, which is essential to achieving changes in self-care behavior and lifestyle that, in turn, will improve clinical outcomes. Improvement of diabetes knowledge is only the first step. Diabetes empowerment scores increased in both education groups at visit 3. Country-level analyses revealed no clinically relevant differences between the two education groups.

In terms of diabetes self-care (as measured by the SDSCA), only foot care had improved in both education groups, and there were no overall or country-level differences between education groups. The follow-up period of 6 months post-education might have been too short to achieve significant changes in behavior.

The major long-term goal of diabetes education is to improve glycemic control and thereby reduce the risk of vascular diabetes complications. Mid-term decreases in A1C have been demonstrated in the majority of trials using various structured group or individual education programs, although in some studies, A1C on average did not decrease. Norris et al. conducted a meta-analysis of randomized trials to evaluate diabetes self-management education programs (individual or group education) compared to regular care or other educational interventions (as controls). In those studies with follow-up periods of ≥ 4 months, the difference in A1C between the program and control groups was 0.26% in favor of the program group (95% CI 0.05–0.48%) at the end of follow-up (nine studies, 1,893 patients, baseline A1C 9.4%).

In the current study, which included individuals with near-target baseline A1C levels (median 7.2% for the CM group and 7.0% for the regular-care group), A1C decreases from baseline (median 0.1–0.2%) were smaller than those observed elsewhere. Six months post-education, participants in the current study achieved median A1C levels of 6.9% in the CM group and 6.8% with regular care. There was no significant difference between the education groups.

In the recently published IDEA study, which used the U.S. version of the CM, mean decreases in A1C of –0.27% with CM and –0.24% with regular care after 6.8 months were similar to our study in a diabetes population with a minimum A1C of 7% and with 40% of participants having a baseline A1C of > 8%.

A 2007 data-mining assessment of educational intervention outcomes in type 2 diabetes (18 studies) tested whether measurement of knowledge affected reduction in A1C levels post-intervention and demonstrated no significant difference. A systematic review by Duke et al. found an advantage in terms of A1C for individual education (vs. regular care) only in the subgroup of participants having a baseline A1C > 8%. In our study, median baseline A1C levels may have been too low and median changes from baseline too small to reveal any difference between the two treatment groups or between patients from Spain and those from Germany. In addition, a 6-month trial may be insufficient in duration to expect a change in clinical parameters as a consequence of improvements in knowledge. However, research suggests that clinical outcomes are unlikely to change unless there is knowledge.

There was no minimum A1C criterion for inclusion in the current study; HCPs recruited individuals they believed to be in need of education or re-education. The low baseline A1C levels suggest that HCPs were referring participants for reasons other than glycemic control (e.g., not adhering to medication, not
empowered to perform self-care, or future initiation of insulin).

People with diabetes participating in self-management programs may also experience an improvement in quality of life.24 In the current study, pain/discomfort and general health status (as measured with the EQ-5D) improved in both education groups, overall and for each country; there was no difference between education groups. Diabetes-related distress (as measured with the PAID scale) also was reduced in both education groups and in both countries. German CM group participants had less distress than regular-care group participants at both post-baseline visits. A similar advantage over the control group had been achieved with the German MEDIAS-2 program.23 There was no such difference for the participants from Spain.

The current study has several limitations. Participants were followed for only 6 months after the intervention, providing no evidence of the sustainability of the observed behavioral changes, which may require regular reinforcement.25,32 Studies with longer education and follow-up periods are needed.

Second, the study was conducted in two European countries only (Spain and Germany), and results cannot be generalized to other countries with different cultures, health care systems, or patient education programs provided as part of regular care.

Furthermore, it is unclear as to whether the effectiveness of the CM program is attributable to the theoretical models that underpin the intervention,9 the visual presentation of information, the expertise of facilitators, or other attributes. All educational programs suffer the same difficulty in identifying their “active ingredient(s).”16

In the current study, regular-care group participants also demonstrated improvements in diabetes-specific knowledge and glycemic control that may be attributable to the high level of regular care (particularly in Germany). Unfortunately, detailed data were not collected about the programs received by patients in the regular-care cohort. Also, no detailed data were available regarding the skills of the individual diabetes educators and whether they used the CM education tools as they were trained to do. Furthermore, their training in how to use CM education tools might also have resulted in changes in how they provided regular care.

The observed changes from baseline in both groups may also be related to the fact that patients volunteering for clinical trials are particular motivated, or they may be related to increased HCP contact.37 Also, it remains unclear if study participation in itself may have contributed to the beneficial effects on diabetes knowledge and glycemic control.37

An additional limitation was that the study had to be open-label. Therefore, potential bias regarding recruitment38 and the results of patient questionnaires (e.g., self-care and treatment satisfaction) cannot be excluded. We attempted to minimize between-site variability and selection bias (as seen, for example, in the trial by Davies et al.31) by randomizing patients within the site. This may have led to some “bleeding” of participant engagement from HCPs trained in CM methodology into their interactions with participants randomized to the regular-care group, or vice versa.

Learning effects for completion of the ADKnowl are also possible. To minimize these effects, participants did not receive an evaluation of their scores or the correct answers after completing the questionnaire. Furthermore, the ADKnowl was presented first (of the patient-reported outcome questionnaires). This ensured that participants did not gain information from later questionnaires (e.g., the SDSCA) and complete the ADKnowl based on this information.

A virtue of the study was its high retention rate, indicating that there was no selection bias caused by a selective loss of participants who did not benefit from education.

In conclusion, the study showed significant difference between the two education groups in the overall population. In participants from Germany, where regular care frequently includes structured education programs and participants started from high baseline knowledge levels, regular care was superior to CM. In Spain, where no structured national diabetes education and awareness programs are in place, CM was superior to regular care. Country-specific differences should be considered when using CM.

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Feature Article / Reaney et al.


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Matthew Reaney, MSc, is a health outcome senior research scientist and Simon Cleall, MSc, is a senior research scientist for statistics at Eli Lilly & Company Ltd., in Windlesham, Surrey, U.K. Esther Gil Zorno is the health improvement and internationalization manager at the Ministry of Health and Social Policy in Madrid, Spain. Alain Golay, MD, is a professor at University Hospital in Geneva, Switzerland. Norbert Hermanns, MD, is a professor at the Research Institute of the Diabetes Academy in Bad Mergentheim, Germany. Ute Petzinger, MSc, is a project statistician at Accovion GmbH in Eschborn, Germany. Veikko Koivistö, MD, PhD, is a medical consultant at Lilly Deutschland GmbH in Bad Homburg, Germany.

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