# Structured Personal Diabetes Care in Primary Health Care Affects Only Women's $HbA_{1c}$

ANNI B.S. NIELSEN, MA, RN, PHD[1]
NIELS DE FINE OLIVARIUS, MD[1]
DORTE GANNIK, MS, DSCSOC[1]
CHARLOTTE HINDSBERGER, MS, PHD[1,2]
HANNE HOLLNAGEL, DMSC[1]

**OBJECTIVE** — Diabetic men and women differ in lifestyle and attitudes toward diabetes and may benefit differently from interventions to improve glycemic control. We explored the relation between $HbA_{1c}$ (A1C), sex, treatment allocation, and their interactions with behavioral and attitudinal characteristics in patients with type 2 diabetes.

**RESEARCH DESIGN AND METHODS** — Six years after their diabetes diagnosis, a population-based sample of 874 primary care patients cluster-randomized to receive structured personal care or routine care reported lifestyle, medication, social support, diabetes-related consultations, and attitudes toward diabetes. Multivariate analyses were applied, split by sex.

**RESULTS** — A marked intervention effect on A1C was confined to the structured personal care women. The median A1C was 8.4% in structured personal care women and 9.2% in routine care women ($P < 0.0001$) and 8.5% in structured personal care men and 8.9% in routine care men ($P = 0.052$). Routine care women had a 1.10 times higher A1C than structured personal care women, ($P < 0.0001$, adjusted analysis). Structured personal care women had relatively more consultations than routine care women, but neither number of consultations nor other covariates helped to explain the sex difference in A1C. Irrespective of treatment allocation, women had more adaptive attitudes toward diabetes but lacked support compared with men.

**CONCLUSIONS** — In this study, the observed effect of structured personal care on A1C was present only among women, possibly because they were more inclined to comply with regular follow-up and had a tendency to have a more adaptive attitude toward diabetes.

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Research indicates that men and women differ in behavior and attitudes toward their diabetes: women tend to regulate their diabetes through diet, but they exercise less than men (1), report more negative impacts of diabetes (2–6), and use the health care system more often than men (7,8). Some studies have shown that women have poorer glycemic control than men (9–12), but others report no sex difference (13–17).

Social support (18–20) and knowledge of one's own diabetes are essential for diabetes management (21). The general practitioner and other persons in the patient's social context influence decisions about lifestyle (18,19), and motivation for adherence generally improves in supportive contexts (19,20).

In a Danish cluster-randomized, controlled trial, the "Diabetes Care in General Practice" (DCGP) trial (22), the intervention focused on provider behavior with negotiation of individualized treatment goals: the general practitioners were encouraged to evaluate the treatment with the patients, and the importance of diet and exercise was emphasized (22). In the DCGP, a marked improvement was shown in glycemic control after 6 years of intervention, together with a significantly higher number of diabetes-related consultations per year. These analyses were by intention to treat, and sex-differentiated analyses were not anticipated in the protocol (22,23). We performed a subgroup analysis to explore whether the variation in $HbA_{1c}$ (A1C) and knowledge, attitudes, lifestyle, and social support reflected the effects of the intervention and/or were sex differentiated.

## RESEARCH DESIGN AND METHODS

This is a cross-sectional subgroup study focusing on sex, performed 6 years after diabetes was diagnosed in patients participating in the DCGP (22), a pragmatic, open, controlled trial with randomization of practices to structured personal care or routine care.

In 1988, 484 volunteer general practitioners were randomly assigned to an intervention group and a comparison group (Fig. 1). Randomization produced two comparable patient groups (22).

Of 1,263 patients, 874 completed the final 6-year examination and were included in this substudy (Fig. 1). At least 97.5% of the diabetic patients included were considered to have type 2 diabetes (22). A similar proportion of patients in each group (190 vs. 199, $P = 0.21$) had no follow-up (22).

### The intervention

The intervention general practitioners were instructed to give structured personal care, which included quarterly consultations and individualized goal setting for important risk factors. These general practitioners were supported by prompting, short clinical guidelines, feedback on individual patients, and a brief training program (22). The routine care doctors were free to decide and change treatment.

### Ethical considerations

All participants gave informed consent (22). The protocol was in agreement with the Helsinki Declaration and was ap-

From [1]The Research Unit and Department of General Practice, University of Copenhagen, Copenhagen, Denmark; and the [2]Department of Biostatistics, Institute of Public Health, University of Copenhagen, Copenhagen, Denmark.

Address correspondence and reprint requests to Anni B.S. Nielsen, The Research Unit for General Practice in Copenhagen, Oster Farimagsgade 5, P.O. Box 2099, DK-1014, Copenhagen K, Denmark. E-mail: a.nielsen@gpract.ku.dk.

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**Abbreviations:** DCGP, Diabetes Care in General Practice.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

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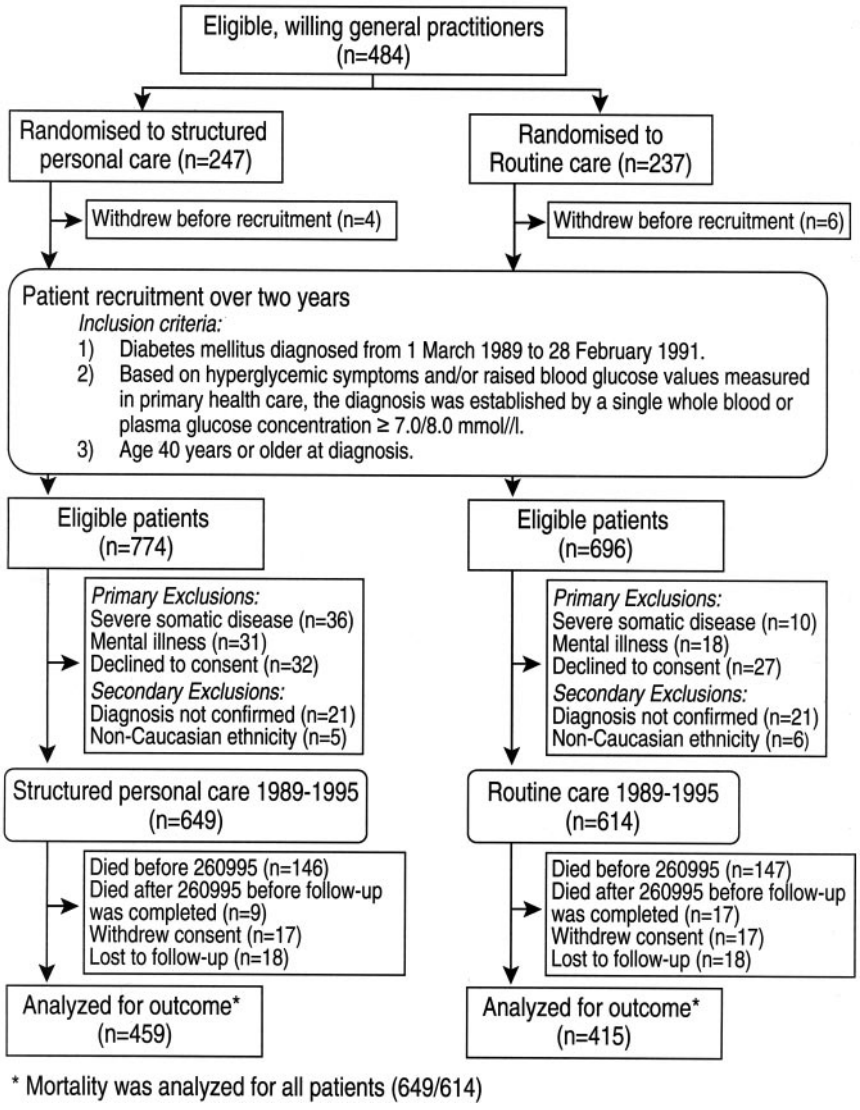


**Figure 1—***Flow of participants through the DCGP trial.*

proved by the ethics committees of Copenhagen and Frederiksberg (22).

### Questionnaires

The final 6-year examination included doctor questionnaires, information on hospital admissions for relevant conditions, blood and urine samples, weight measurement, and a patient questionnaire (22). The patient questionnaire was based on a literature review and interviews with type 2 diabetic patients. Experienced general practitioners and sociologists reviewed the questionnaire before pilot testing. It contained questions on knowledge about own blood glucose, attitudes toward treatment and diabetes, lifestyle, and social support. Knowledge was measured by two questions concerning the patients' knowledge of their own blood glucose level and knowledge of the general practitioner's view of their blood glucose level. Behavioral and attitudinal variables were gathered from questions concerning lifestyle (leisure time physical activity, dietary habits, and the patients' indication of change in lifestyle after diagnosis) and attitudes (the patients' feelings about the illness and whether they had worked intentionally with their illness). Furthermore, the patients reported whether they got the necessary support and understanding from family and significant others (social support).

The general practitioners reported the patients' antidiabetic treatment and the number of diabetes-related consultations within the last year. Practicing ophthalmologists reported the results of funduscopy.

### Biochemistry

Methods used for measurement of blood samples and urinary albumin concentration have previously been reported (22). A1C fraction was analyzed by ion-exchange high-performance liquid chromatography (reference interval: 5.4–7.4%).

### Statistical analyses

With multivariate linear regression analyses, we estimated the difference between the mean level of A1C in the structured personal care and the routine care groups, split by sex. An adjustment for interactions between age and diagnostic A1C accounted for a possible dissimilarity in the diagnostic A1C among the groups and within each group among persons of different age-groups. Differences in diabetes duration and BMI, interaction between the patients' physical activity level, antidiabetic medication, and dietary habits may explain a difference in A1C at follow-up. Additional analyses were therefore performed with adjustments of these factors. The analyses were not adjusted for general practitioner characteristics, as these factors did not predict their patients' glycemic control (24).

With multivariate logistic regression analyses, we examined whether all the patients in the structured personal care group or just the male or the female patients behaved differently from the routine group patients. If treatment allocation resulted in a sex-differentiated distribution of the covariate, type-of-care specific analyses were done. Otherwise, the association between sex and the covariate was adjusted for interactions between treatment allocation and age. With linear regression, we examined, in stepwise fashion, whether the effects of the covariate on A1C depended on treatment allocation (adjusted for age and diagnostic A1C) or sex (adjusted for interactions between age and treatment allocation or between treatment allocation and diagnostic A1C).

In all analyses, age was dichotomized ($<60$ or $\geq 60$ years). A1C was log transformed for distributional purposes. The nominal statistical significance level was $P < 0.05$. All results are given with a 95% CI. We did the analyses with the software PROC GENMOD (SAS, version 6.12) using generalized estimation equations methods to account for a clustering effect at the general practitioner level.

**Table 1—*Primary outcomes* and selected clinical and biochemical outcomes at the end of the study among women and men receiving structured personal and routine care***

| | Women | | | Men | | |
|---|---|---|---|---|---|---|
| | *n* (structured/ routine care) | Structured personal care | Routine care | *n* (structured/ routine care) | Structured personal care | Routine care |
| Primary outcomes† | | | | | | |
| Overall mortality | 309/288 | 90 (29.1) | 94 (32.6) | 340/326 | 126 (37.1) | 114 (35.0) |
| Diabetic retinopathy | 186/157 | 30 (16.1) | 29 (18.5) | 173/173 | 13 (7.5) | 16 (9.3) |
| Urinary albumin ≥15 mg/l | 139/110 | 30 (21.6) | 32 (29.1) | 110/124 | 26 (23.6) | 40 (32.3) |
| Myocardial infarction | 226/191 | 5 (2.2) | 7 (3.7) | 211/202 | 10 (4.7) | 11 (5.4) |
| Stroke | 225/194 | 7 (3.1) | 5 (2.6) | 221/211 | 11 (5.0) | 11 (5.2) |
| Clinical‡ | | | | | | |
| Body weight (kg) | 231/188 | 73.0 (64.9–84.0) | 75.0 (64.9–85.7) | 217/216 | 85.0 (77.2–95.0) | 85.3 (75.4–94.5) |
| Systolic blood pressure (mmHg) | 234/193 | 150 (140–160) | 155 (140–170) | 222/216 | 140 (130–156) | 150 (135–160) |
| Diastolic blood pressure (mmHg) | 234/193 | 80 (76–90) | 80 (79–90) | 222/216 | 80 (80–90) | 85 (76–90) |
| Biochemical‡ | | | | | | |
| Fasting plasma glucose (mmol/l)§ | 186/143 | 8.1 (6.3–9.9) | 9.2 (7.3–12.7) | 164/153 | 7.8 (6.5–11.0) | 8.5 (7.0–11.0) |
| A1C (%) | 229/193 | 8.4 (7.8–9.4) | 9.2 (8.1–10.5) | 221/215 | 8.5 (7.7–9.5) | 8.9 (7.8–10.2) |
| Total cholesterol (mmol/l) | 229/193 | 6.3 (5.7–7.1) | 6.4 (5.6–7.2) | 220/215 | 5.7 (5.0–6.5) | 5.8 (5.1–6.6) |
| Fasting triglyceride (mmol/l) | 212/166 | 1.80 (1.27–2.43) | 2.09 (1.43–2.84) | 206/184 | 1.77 (1.24–2.66) | 1.66 (1.15–2.63) |
| *n* (%) with glycosuria | 227/190 | 35 (15.4) | 58 (30.5) | 218/210 | 65 (29.8) | 90 (42.9) |

*Median follow-up period for structured personal care group was 7.41 years for mortality and 5.75 years for other outcomes; median follow-up period for routine care group was 7.32 years for mortality and 5.82 years for other outcomes. †Values are *n* (%) of group (mortality) or *n* (%) who completed follow-up examination and did not have the outcome at baseline (all other outcomes). ‡Values are median (interquartile range) unless stated otherwise. §Including only results from samples analyzed 1 day after sampling, or less. Reference range 5.4–7.4%.

**RESULTS** — At diagnosis, the median (interquartile range) age was 63.0 (53.8–71.4) years for the 459 structured personal care patients and 63.7 (54.6–71.6) years for the 415 routine care patients ($P = 0.87$). A similar proportion consisted of women: 51.2 vs. 47.7% ($P = 0.30$). The patient questionnaire was answered by 817 (93.5%) with no sex difference ($P = 0.15$).

### Sex differences between the structured personal care and the routine care groups

Table 1 indicates similar outcomes among the structured personal care and routine care women groups and the structured personal care and routine care men. An intervention effect on A1C is suggested among both women and men, but adjustment for baseline measurements is necessary.

The ratio between A1C at the 6-year follow-up shows that the intervention effect on A1C was confined to the structured personal care women (Table 2, *analysis a*) in analyses with adjustment for a clustering effect at the general practitioner level and interaction between diagnostic A1C and age. The intervention effect was still limited to women even after further adjustment (Table 2, *analysis b*).

The patients who were excluded from the Table 2, *analysis b*, due to lack of A1C measurements had diagnostic fasting plasma glucose values largely similar to those included in the analysis (women, structured personal care: $P = 0.15$, women, routine care: $P = 0.63$, men, routine care: $P = 0.11$, Wilcoxon test). Men excluded from the structured personal care group (mainly due to delayed A1C measurement at diagnosis or nonresponse to a question in the patient questionnaire) had a lower diagnostic fasting plasma glucose than the included structured personal care men; but their median (interquartile range) fasting plasma glucose did not differ at study end: 7.3 (5.9–10.6) vs. 8.1 (6.6–11.0) mmol/l ($P = 0.10$). Based on these results, it is unlikely that the missing values among structured personal care men biased the results.

The structured personal care women had relatively more consultations than the routine care women (Table 3), whereas the structured personal care men tended to have fewer consultations than the routine care men. No differences were found for use of insulin or oral antidiabetic medication, such as metformin (data not shown). Analysis by treatment allocation showed that routine care men tended not to know their general practitioners' views on their blood glucose values, but all the covariates had the same impact on A1C

**Table 2—*Two multivariate analyses on the ratio between A1C in routine care and structured personal care group at end of study****

| Treatment allocation | Women | *P* value | Men | *P* value |
|---|---|---|---|---|
| Analysis a† | | | | |
| Structured personal care | 1.00 | <0.001 | 1.00 | 0.12 |
| Routine care | 1.08 (1.05–1.12) | | 1.03 (0.99–1.06) | |
| Analysis b‡ | | | | |
| Structured personal care | 1.00 | <0.0001 | 1.00 | 0.27 |
| Routine care | 1.10 (1.06–1.14) | | 1.02 (0.98–1.06) | |

*The levels are estimated as medians but presented as ratio with 95% CI. †The analyses are adjusted for clustering effect at the general practitioner level, and interactions between diagnostic log(A1C) and age-group (<60 years and ≥60 years). ‡The analyses are adjusted for clustering effect at the general practitioner level, number of diabetes-related consultations, diabetes duration, BMI, interactions between diagnostic log(A1C) and age-group (<60 years and ≥60 years), and interactions between food habits, antidiabetic medication, and physical exercise.

**Table 3—*Logistic regression analyses of the influence of routine care on the patients' lifestyle, attitudes, social support, and knowledge about blood glucose level at end of study****

| | Treatment allocation (routine care = 1, structured personal care = 0) | | | |
|---|---|---|---|---|
| | Women | | Men | |
| | Odds ratio (95% CI) | *P* value | Odds ratio (95% CI) | *P* value |
| Has altered habits after diagnosis | | | | |
| Yes | 1.00 | 0.29 | 1.00 | 0.60 |
| No | 0.90 (0.73–1.10) | | 1.01 (0.97–1.05) | |
| Leisure time physical activity | | | | |
| High | 1.00 (0.92–1.08) | 0.18 | 0.99 (0.92–1.06) | 0.85 |
| Moderate | 1.00 | | 1.00 | |
| Low | 1.06 (0.95–1.18) | | 0.95 (0.79–1.14) | |
| Food habits | | | | |
| Diabetes diet† | 1.12 (0.96–1. 31) | 0.37 | 0.99 (0.82–1.19) | 0.84 |
| Full diet without sugar | 1.00 | | 1.00 | |
| Diet as nondiabetic subjects | 0.92 (0.73–1.15) | | 0.99 (0.94–1.04) | |
| Antidiabetic medication | | | | |
| Yes | 1.00 | 0.36 | 1.00 | 0.93 |
| No | 0.94 (0.84–1.07) | | 1.22 (0.82–1.83) | |
| Number of consultations/year | | | | |
| 0–1 | 1.05 (1.01–1.08) | 0.014 | 0.97 (0.89–1.04) | 0.08 |
| 2–4 | 1.01 (0.98–1.03) | | 0.93 (0.79–1.08) | |
| 5+ | 1.00 | | 1.00 | |
| Attitudes toward diabetes | | | | |
| The illness is unproblematic‡ | 1.00 | 0.35 | 1.00 | 0.85 |
| Work/worked with the illness§ | 0.97 (0.87–1.09) | | 0.97 (0.84–1.11) | |
| It is a strain | 1.28 (0.92–1.78) | | 1.00 (0.93–1.07) | |
| Social support | | | | |
| Full support | 1.00 | 0.36 | 1.00 | 0.26 |
| Handles it by oneself | 0.95 (0.82–1.10) | | 0.98 (0.96–1.01) | |
| Feels alone, misunderstood | 1.11 (0.87–1.41) | | 0.98 (0.95–1.01) | |
| Blood glucose level known | | | | |
| Yes | 1.00 | 0.70 | 1.00 | 0.84 |
| No | 0.99 (0.96–1.03) | | 0.97 (0.72–1.31) | |
| The general practitioner is satisfied with the blood glucose | | | | |
| Yes | 1.00 | 0.40 | 1.00 | 0.31 |
| No | 1.01 (0.98–1.04) | | 0.81 (0.49–1.32) | |
| Do not know | 1.01 (0.98–1.03) | | 2.59 (1.28–5.26) | |

*The influence of routine care is tested on each single variable. All analyses are adjusted for clustering effect at the general practitioner level and age-group (<60 years and ≥60 years). †Diet with certain amounts of selected foodstuffs. ‡Life is not altered/the illness is unproblematic. §Work/have worked with the illness to cope or adapt.

regardless of treatment allocation (data not shown).

### Other sex differences

Table 4 shows several sex differences, e.g., that women exercise less and show more adaptive attitudes toward diabetes, but they lack support compared with men. No differences were found for type of antidiabetic medication (data not shown). All covariates had the same effect on A1C for men and women (data not shown).

**CONCLUSIONS** — Six years after the introduction of structured personal diabetes care, the effect in the form of a lowering of A1C was seen in women only. Although unrelated to A1C, women in the structured personal care group had more diabetes-related consultations than women in the routine care group. Differences in lifestyle, social support, and attitudes were not related to the intervention, but solely to sex: women exercised less than men, consumed a healthier diet, and found their illness to be more unproblematic, but indicated lack of support.

### Study strengths and limitations

The population-based patient sample and the long follow-up in a successfully completed randomized, controlled trial speaks in favor of our results, but we used explorative subgroup analyses. These may be justified because they may indicate which treatment elements might have generated the effect (18,25) and whether the intervention is more/less effective in specific patient subgroups (18). One limitation was the use of self-reported questionnaire data, because patients may have overestimated actual behavior to provide a socially desirable response (26,27).

### The sex effect of structured personal care on A1C

Studies of the association between glycemic control and sex in persons with type 2

**Table 4—*Logistic regression analyses of the influence of being female on the patients' lifestyle, attitudes, social support, and knowledge about blood glucose level at end of study****

| | Sex (women = 1, men = 0) | |
|---|---|---|
| | Odds ratio (95% CI) | *P* value |
| Has altered habits after diagnosis | | |
| Yes | 1.00 | 0.19 |
| No | 0.78 (0.55–1.13) | |
| Leisure time physical activity | | |
| High | 0.50 (0.29–0.86) | <0.001 |
| Moderate | 1.00 | |
| Low | 1.54 (1.15–2.06) | |
| Food habits | | |
| Diabetes diet† | 1.84 (1.35–2.50) | <0.0001 |
| Full diet without sugar | 1.00 | |
| Diet as nondiabetic subjects | 0.64 (0.42–0.97) | |
| Antidiabetic medication | | |
| Yes | 1.00 | 0.37 |
| No | 0.88 (0.66–1.16) | |
| Number of consultations/year | | |
| 0–1 | 0.94 (0.63–1.40) | 0.75 |
| 2–4 | 0.88 (0.64–1.22) | |
| 5+ | 1.00 | |
| Attitudes toward diabetes | | |
| The illness is unproblematic‡ | 1.00 | <0.01 |
| Work/worked with the illness§ | 0.64 (0.48–0.86) | |
| It is a strain | 1.16 (0.70–1.93) | |
| Social support | | |
| Full support | 1.00 | <0.0001 |
| Handle it by oneself | 2.28 (1.61–3.24) | |
| Feels alone, misunderstood | 3.07 (1.96–4.82) | |
| Blood glucose level known | | |
| Yes | 1.00 | 0.48 |
| No | 1.12 (0.81–1.55) | |
| The general practitioner is satisfied with the blood glucose | | |
| Yes | 1.00 | 0.15 |
| No | 1.21 (0.86–1.71) | |
| Do not know | 1.47 (0.97–2.23) | |

*The influence of being a woman is tested on each single variable. All analyses are adjusted for clustering effect at the general practitioner level and age-group (<60 years and ≥60 years). †Diet with certain amounts of selected foodstuffs. ‡Life is not altered/the illness is unproblematic. §Work/have worked with the illness to cope or adapt.

diabetes are inconclusive: in contrast to our finding, the U.K. Prospective Diabetes Study revealed no sex difference in A1C (28), but men had higher A1C levels than women in a lifestyle intervention study among obese patients (29). A cross-sectional study of insulin-treated patients with a median duration of diabetes of 16.5 years showed that men had a higher A1C level than women (30). Neither of the studies (29,30), however, further explored the observed glycemic sex difference. Descriptive studies, with a mean diabetes duration of 1–10 years, do not show that men in general have higher A1C levels than women: in some studies women had higher A1C levels than men (9–12), but in others men and women had equal levels (13–17).

The DCGP study showed an increased number of consultations in the intervention group (22), but inclusion of sex in the analyses showed that structured personal care men tend to have fewer consultations than routine care men (Table 3). The higher number of consultations among structured personal care women than among routine care women may have been important for the sex-differentiated intervention response on A1C in our study although the analysis revealed no direct association between number of consultations and A1C. Regular follow-up improves the patient's opportunity for information exchange with the general practitioner about medication, diet, and exercise and gives the opportunity to alter or reinforce previous treatment goals on glycemic control (23). A meta-analysis on the effect of self-management education on glycemic control also suggests that increased contact time between patient and physician reduces the A1C level (31). Furthermore, the structured personal care doctors were encouraged to evaluate the treatment and treatment goal with the patients, and this specific consultation style may have promoted greater patient participation in treatment decisions (32–34) and more supportive care (34,35), all factors that may have been of importance to regimen adherence (32–35) and glycemic control (34,35) for the structured personal care women.

In addition, compared with men, the more adaptive attitude of women toward their illness may have been a helpful resource in their efforts to improve glycemic control. The attitude difference may indicate that men, irrespective of treatment allocation, in contrast to women, feel that they work harder in trying to cope with the limitations in freedom and lifestyle (36), even when full support is provided. In general, men experienced more support than women. This may reflect women's care-giving responsibilities in the family (37). Our results support previous suggestions of a sex difference in how to manage diabetes (1): women in both treatment groups typically did less exercise than men, but reported a healthier diet.

## Implications

Because improvements of A1C among patients in the structured personal care group were confined to women, it may be necessary to make an extra effort to optimize the treatment of men. Future researchers will have to decide how consultation frequency and a consultation style tailored to men's needs can contribute to this end.

In summary, in this subgroup analysis, the effect of a multifaceted intervention on glycemic control was limited to women. Among behavioral and attitudinal variables, this difference in outcome was reflected only in the relatively higher frequency of diabetes-specific general practitioner consultations in women receiving structured personal diabetes care

compared with women receiving routine care. When the treatment of diabetic patients in family practice includes elements similar to those in this intervention, the caregivers/practitioners should acknowledge that women may achieve better results than men, perhaps because they are more inclined to comply with regular follow-up and have a tendency to perceive their illness as unproblematic despite their difficulties in finding support.

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