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Association between full monitoring of biomedical and lifestyle target indicators and HbA_{1c} level in primary type 2 diabetes care: an observational cohort study (ELZHA-cohort 1)

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ABSTRACT

Objective Management of type 2 diabetes mellitus (T2DM) requires frequent monitoring of patients. Within a collective care group setting, doubts on the clinical effects of registration are a barrier for full adoption of T2DM registration in general practice. We explored whether full monitoring of biomedical and lifestyle-related target indicators within a care group approach is associated with lower HbA_{1c} levels.

Design Observational, real-life cohort study.

Setting Primary care data registry from the Hadoks (EerstelijnsZorggroepHaaglanden) care group.

Exposure The care group provides general practitioners collectively with organisational support to facilitate structured T2DM primary care. Patients are offered quarterly medical and lifestyle-related consultation.

Main outcome measure Full monitoring of each target indicator in patients with T2DM which includes minimally one measure of HbA_{1c} level, systolic blood pressure, LDL, BMI, smoking behaviour and physical exercise between January and December 2014; otherwise, patients were defined as 'incompletely monitored'. HbA_{1c} levels of 8137 fully monitored and 3958 incompletely monitored patients were compared, adjusted for the confounders diabetes duration, age and gender. Since recommended HbA_{1c} values depend on age, medication use and diabetes duration, analyses were stratified into three HbA_{1c} profile groups. Linear multilevel analyses enabled adjustment for general practice.

Results Compared with incompletely monitored patients, fully monitored patients had significantly lower HbA_{1c} levels (95% CI) in the first (−2.03 [−2.53 to −1.52] mmol/mol) (−0.19% [−0.23% to −0.14%]), second (−3.36 [−5.28 to −1.43] mmol/mol) (−0.31% [−0.48% to −0.13%]) and third HbA_{1c} profile group (−1.89 [−3.76 to −0.01] mmol/mol) (−0.17% [−0.34% to 0.00%]).

Conclusions/interpretation This study shows that in a care group setting, fully monitored patients had significantly lower HbA_{1c} levels compared with incompletely monitored patients. Since this difference might have considerable clinical impact in terms of T2DM-related risks, this might help general practices in care group settings to overcome barriers on adequate registration and thus improve structured T2DM primary care. From population health management perspective, we recommend a systematic approach to adjust the structured care protocol for incompletely monitored subgroups.

Strengths and limitations of this study

- The observational real-life design of this study prevented any interference with daily routines of GP practices, thus contributing to good reliability and representativeness of our findings.
- Because the availability of patients' data on age, medication use and diabetes duration allowed to conduct our analyses—in correspondence with professional GP guidelines—for specific HbA_{1c} threshold groups, the findings are relevant and useful for clinical practice.
- Taking into consideration that a missing registration does not necessarily reflect a lack of care but might be caused by technical or practical problems instead, the associations found in this study might be underestimated.

INTRODUCTION

Type 2 diabetes mellitus (T2DM) is a typical lifestyle-related disease.[1] The course of T2DM and potential complications are influenced by smoking behaviour,[2 3] BMI[4] and physical exercise.[5] Adopting a healthier lifestyle, for example cessation of smoking or weight loss, is known to be very demanding for individual patients.[6 7] It has been established that attention for non-conscious motivational factors affecting an individual's behaviour is important to realise sustained behavioural change.[8] In addition, to avoid relapse[9 10] and maintain long-term behavioural change, follow-up support for lifestyle-related themes is recommended.[11 12] Accordingly, in the Netherlands, a nationally acknowledged

scientific council of general practitioners (GPs) has determined professional guidelines for diabetes primary care.[13] In correspondence with the NICE guidelines,[14] it is recommended to monitor HbA_{1c} levels and also the biomedical target indicators systolic blood pressure and LDL as well as lifestyle-related indicators at least once a year.

However, for an average GP, providing structured primary diabetes care with sufficient attention for both biomedical monitoring and lifestyle adaptation[15] is reported to be challenging.[16] Therefore, in many Western countries, varying from the USA and Europe[17 18] to New Zealand,[19] an increasing number of GPs has delegated the regular structured primary diabetes care to nurse practitioners.

It is known that implementing structured primary diabetes care and delegation of tasks to a nurse practitioner has considerable impact on the organisation of the GP practice.[20 21] For example, in the USA, an evaluation of the recent Comprehensive Primary Care (CPC) programme revealed a need to refine practice workflows, to incorporate new staff roles and to overcome incompatibility of health technology systems.[22] To improve the delivery of structured primary diabetes care in the Netherlands, most GPs have joined together in local 'care groups'.[23] Care groups negotiate collective structured diabetes care protocols with the funding institutions of Dutch primary care, namely local health insurance companies. For GPs, participation in a care group is voluntary. However, the logistic and quality support to individual GP practices, which is part of the care group approach, might be seen as an incentive for care group participation. That is, the agreements between care groups and health insurance companies on structured diabetes care protocols enable GPs to offer high-quality intensive primary diabetes care. To illustrate, on an annual basis, four consultations at the GP practice with an explicit focus on lifestyle support as well as complementary allied health (eg, annual screening of fundus and feet) are facilitated. All patients who receive diabetes care in GP practice are eligible for participation in the structured care protocol. It is known that providing a structured diabetes care protocol is associated with better monitoring of patients.[24] In addition, adequate registration of the diabetes-related patient health indicators is associated with improvement of the care process.[25] The costs of this protocol are fully covered by health insurance companies. For patients, participation is free of charge.

According to a recent study, care group participation is associated with improvement of the proportion of patients with full monitoring of biomedical and lifestyle-related target indicators.[26] However, a review on chronic care programmes in primary care reported that doubts among care providers on the clinical effects of an intervention are a barrier for adoption.[27] To our knowledge, little is known about the relationship between full monitoring of biomedical as well as lifestyle-related target diabetes indicators in a care group setting and clinical health outcomes. The HbA_{1c} level is established as a key diabetes health indicator.[28] Therefore, this study aims to investigate the association between full monitoring of biomedical and lifestyle-related diabetes target indicators and HbA_{1c} level in patients with T2DM who receive a structured diabetes care protocol facilitated by a care group.

RESEARCH DESIGN AND METHODS

Study design and population

Data were used of T2DM patients from the observational Eerstelijns Zorggroep Haaglanden (ELZHA) cohort, which is based on primary care registry data from a care group in the western part of the Netherlands. In January 2015, the care group numbered 168 GP practices (n=24 459 patients with T2DM). On a periodical basis, GP members share an overview of their patients' monitoring data with the care group. In February 2017, all GP practices were informed in writing and, based on an opt-out procedure, GP members were invited to participate in this cohort. For the present study, pseudonymised data on monitoring of diabetes target indicators and HbA_{1c} levels from patients were used from the calendar year 2014. Patients receiving continuously structured primary diabetes care from January 2014 through December 2014 at the same GP practice were included. At least one registration of HbA_{1c} in 2014 was necessary for inclusion. Since systolic blood pressure and LDL guidelines are specified for patients aged ≤80 years, patients aged ≥80 years were excluded. Patients were also excluded in case of missing data on age, gender or disease duration. Finally, since missing of data on medication use was partly caused by technical problems, patients without registration of medication prescription were also excluded.

Exposure

Details of the ELZHA cohort study have been described previously (Van Bruggen *et al*, submitted). In short, within a care group setting, GPs are able to invite all their T2DM patients with primary care treatment for this structured care protocol. During a standard diabetes consultation or at time of diagnosis, patients are informed about this care protocol. Patients who provide consent to be enrolled can join the structured primary care protocol. The protocol includes a quarterly diabetes consultation, in which diabetes-related target indicators are checked and lifestyle education is provided, combined with complementary allied health such as an annual foot check, fundus screening and dietician's counselling. To facilitate the organisation and quality control of this protocol, GP practices receive practical and logistical support, including a computerised system to improve the care process and outcomes. Measurement of the diabetes target indicators (HbA_{1c} level, systolic blood pressure, LDL level, BMI, smoking behaviour and physical exercise) took place in 2014 at the end of each quarter. In the present study, patients were regarded as 'fully monitored'

when each target indicator was registered at least once between January and December 2014. If one or more target indicators were not registered minimally one time in calendar year 2014, patients were defined as 'incompletely monitored'.

Outcomes

The outcome of this study was HbA_{1c} level and this was computed in two steps. First, for each quarter, a mean HbA_{1c} value was calculated based on all available HbA_{1c} measures in that quarter. Based on the mean HbA_{1c} levels of all quarters, a mean was computed for the whole calendar year. HbA_{1c} level is presented in mmol/mol and %.

Analysis

For patient's characteristics, categorical variables were reported as numbers and percentages. Continuous variables were reported as means with SD or, when non-normally distributed, as medians with IQR. Baseline characteristics of excluded patients were, if available, compared with the study population. Linear multilevel analyses were conducted to compare HbA_{1c} levels of fully monitored and incompletely monitored patients. Multilevel analyses allowed to adjust the individual observations (level 1) for GP practice (level 2). In addition, the analyses were adjusted for patient's age, duration of diabetes and gender, which are relevant possible confounders with regard to HbA_{1c} outcomes.

Tailored on specific key patient's characteristics (age, intensity of medication treatment and disease duration), professional Dutch GP guidelines recommend differentiated HbA_{1c} targets for three different patient profile groups based on age and prescribed medication. Details on the scientific determination of these target values are presented in the guidelines.[13] To summarise, (1) for patients aged <70 years and for older patients with a mild treatment regime (only metformin monotherapy prescription or lifestyle coaching), a target HbA_{1c} value of 53 mmol/mol (7.0 %) is recommended; (2) for patients aged ≥70 years who need more intensive treatment and were diagnosed with diabetes <10 years previously, a target HbA_{1c} value of 58 mmol/mol (7.5 %) is recommended; (3) for patients aged ≥70 years who need more intensive treatment and were diagnosed with diabetes ≥10 years previously, a target HbA_{1c} value of 64 mmol/mol (8.0 %) is recommended. In the present study, since missing data on medication might reflect administrative omissions rather than absence of medication treatment, patients without data on medication were excluded.

In view of the relevance for clinical practice, separate multilevel analyses were conducted and reported for each of these HbA_{1c} profile groups. In addition, in a non-stratified multilevel analysis, we tested whether the magnitude of the effect found in HbA_{1c} profiles 2 and 3 differed significantly from HbA_{1c} profile 1. A p value<0.05 was considered statistically significant; for interaction, a p value<0.1 was considered statistically significant.

Descriptive statistics were analysed using SPSS, V.24.0. Multilevel analyses were performed using ML WiN (V.2.28).

Patient and public involvement

Since this study was targeted on a GP-supporting approach of structured primary diabetes care, patients were not actively involved.

Ethical considerations

Since the pseudonymised patients' data contained only age and gender, the data could be aggregated without enabling investigators to identify individual patients. Due to the high number of patients, informed consent of individual patients was not required.

RESULTS

This study included 167 GP practices (99%) with a total of 24 198 patients with T2DM; of these, 12 095 patients met the inclusion criteria (for a detailed flowchart of inclusion, see figure 1). By definition, in this population, HbA_{1c} was always monitored, as not having an HbA_{1c} measure available was an exclusion criterion for the present study. Comparing characteristics of the excluded patients (n=12 103 patients) with the study population (n=12 095 patients, see online supplementary table 1), in excluded patients mean HbA_{1c} level (50.32 mmol/mol, SD=12.8 mmol/mol; 6.76%, SD=3.32%, 7.535 registrations missing) was slightly lower than in the study population (52.5 mmol/mol, SD=1.07 mmol/mol; 6.95%, SD=3.16%). Comparing the median diabetes duration of excluded patients (5 years, IQR: 3–9, 63 registrations missing) to the study population (6 years, IQR: 3–10), no substantial differences were found. Regarding median age, excluded patients (71 years, IQR: 60–82, 2917 registrations missing) were older than included patients (median: 64 years, IQR: 56–71 years) and slightly more often women (50% [n=4251; 3530 registrations missing] vs 45% [n=5477]). More detailed characteristics of our study population, classified by HbA_{1c} profile and monitoring completeness, are presented in table 1. Of patients who were incompletely monitored, information on physical exercise was most often missing, followed by smoking, BMI, LDL and systolic blood pressure (figure 2).

Compared with incompletely monitored patients, fully monitored patients had lower mean HbA_{1c} levels in all three HbA_{1c} profiles. In addition, fully monitored patients had a longer duration of diabetes than incompletely monitored patients.

The crude analysis showed that compared with incompletely monitored patients, the mean HbA_{1c} of fully monitored patients was significantly lower in the first profile (−1.95 [95% CI −2.41; −1.49] mmol/mol) (−0.18% [−0.22%; −0.14%]), second profile (−2.03 [95% CI −3.41;−0.66] mmol/mol) (−0.19% [−0.31%; −0.06%]) and third profile (−1.53 [95% CI −2.96;−0.10] mmol/mol) (−0.14% [−0.27%; −0.01%]) (table 2). Multilevel

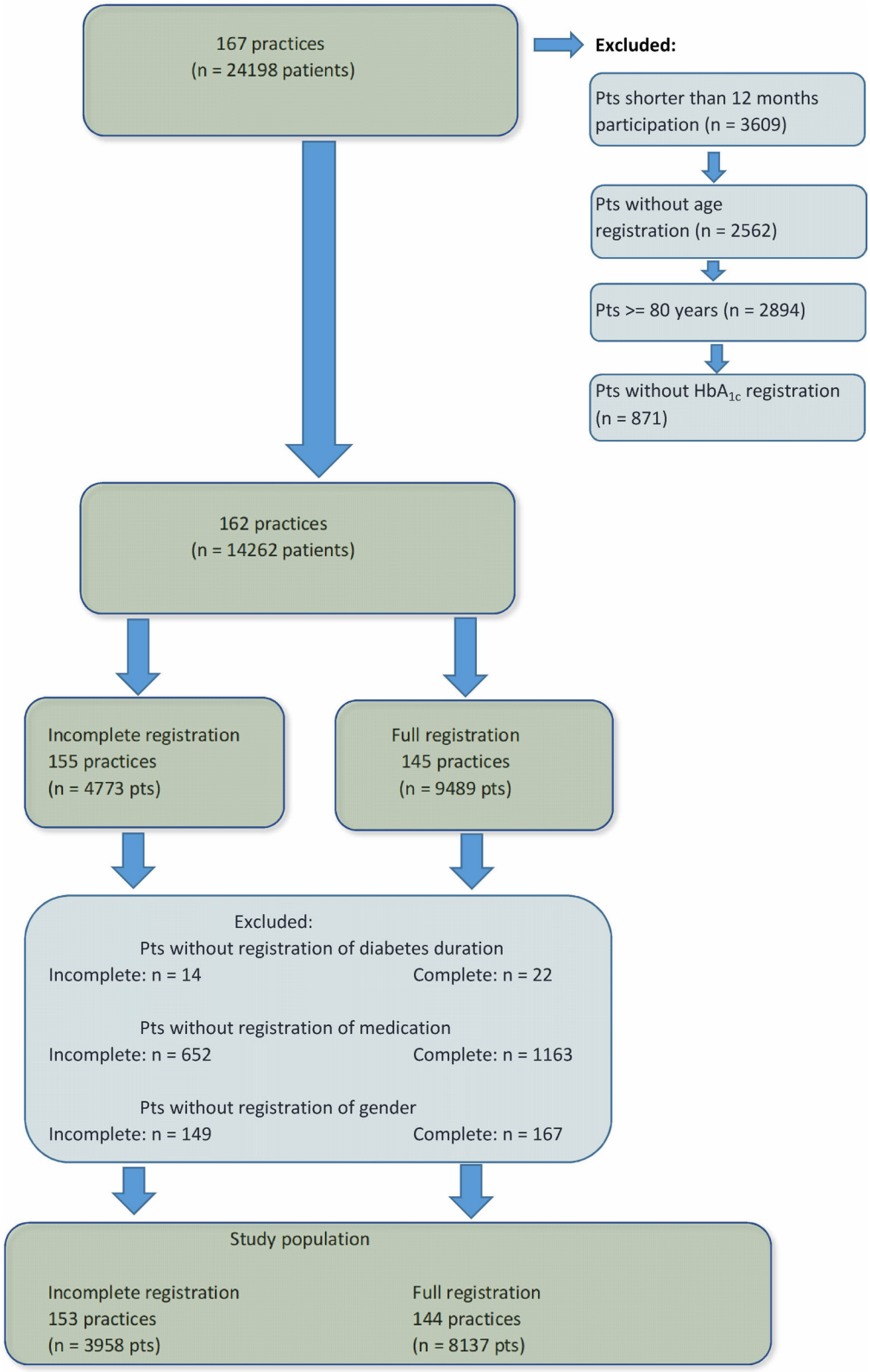

Figure 1 Flow chart of patient inclusion. Pts, patients.

analyses with adjustment for diabetes duration, age and gender revealed similar significant associations in the first (−2.03 [95% CI −2.53; −1.52] mmol/mol) (−0.19% [−0.23%; −0.14%]), second (−3.36 [95% CI −5.28; −1.43] mmol/mol) (−0.31% [-0.48%; −0.13%]) and third profile (−1.89 [95% CI −3.76; −0.01] mmol/mol) (−0.17% [−0.34%; 0.00%]). The magnitude of these associations did not significantly differ between the HbA_{1c} profile groups (p=0.44 and p=0.35 for the second and third profiles, respectively, compared with the first profile).

Table 1 Characteristics of the study population, classified by HbA_{1c} profile and monitoring completeness

	HbA_{1c} profile 1* *Target HbA_{1c}: 53 mmol/mol (7.0%)*		HbA_{1c} profile 2† *Target HbA_{1c}: 58 mmol/mol (7.5%)*		HbA_{1c} profile 3‡ *HbA_{1c}: 64 mmol/mol (8.0%)*	
	Incomplete n=3345	Complete n=6794	Incomplete n=396	Complete n=656	Incomplete n=217	Complete n=687
HbA_{1c} level: mean (SD) mmol/mol	53.51 (12.31)	51.56 (10.51)	55.91 (11.66)	53.87 (10.60)	55.12 (10.57)	53.60 (8.98)
HbA_{1c} level: mean (SD) %	7.05 (1.13)	6.87 (0.96)	7.27 (1.07)	7.08 (0.97)	7.19 (0.97)	7.06 (0.82)
Diabetes duration, years: median (IQR)	3 (3–8)	7 (4–10)	3 (3–7)	7 (4–8)	13 (11–16)	13 (11–15)
Age (years): median (IQR)	61 (54–67)	62 (55–68)	74 (72–76)	74 (71–76)	74 (72–77)	74 (72–76)
Gender: % women (n)	44 (1465)	46 (3106)	46 (183)	45 (297)	51(110)	46 (316)

*Profile 1: patients aged <70 years, and older patients with a mild treatment regime (only metformin monotherapy prescription).
†Profile 2: patients aged ≥70 years who need more intensive treatment and diagnosed with diabetes <10 years ago.
‡Profile 3: patients aged ≥70 years who need more intensive treatment and diagnosed with diabetes ≥10 years ago.

DISCUSSION

This study explored whether monitoring completeness of biomedical and lifestyle-related diabetes target indicators in a care group setting is associated with HbA_{1c} level. In all HbA_{1c} profile groups—defined based on patient age, intensity of medication treatment and disease duration—we found that fully monitored patients had lower HbA_{1c} levels than incompletely monitored patients; the differences ranged from 1.89 mmol/mol (0.17 %) to 3.36 mmol/mol (0.31 %), indicating that adequate diabetes monitoring of biomedical and lifestyle indicators in primary care is associated with better HbA_{1c} levels. To our knowledge, this is the first study to analyse the association between systematic diabetes monitoring in primary care and HbA_{1c} levels. Apart from one longitudinal Dutch study on structured primary diabetes care in a care group setting that reported a sharp decrease in the proportion of patients with a HbA_{1c} level ≥53 mmol/mol,[24] research on absolute HbA_{1c} differences is scarce and findings appear to be somewhat inconsistent.[29–32] Therefore, caution is required when comparing our findings with any earlier studies. However, for each 1% (10.9 mmol/mol) reduction in mean HbA_{1c}, a significant decrease in health risks has been reported, ranging from 21% for any endpoint related to diabetes including deaths to 14% for myocardial infarction and 37% for microvascular complications.[33] Further, our finding that registration of physical exercise was most often lacking is in line with an earlier small-sized study in which only 19% of patients with T2DM reported 'being guided properly' with regard to physical exercise.[34]

Our finding that compared with incomplete monitoring, full monitoring of patients is associated with a lower HbA_{1c} level might be explained by continuity of care in several ways. First, if patients are monitored at least once a year, an increasing HbA_{1c} level might be noticed at an early stage, resulting in fast and adequate treatment. Second, periodic monitoring and coaching of patients with regard to weight loss, smoking cessation and physical exercise contributes to enduring lifestyle adaptation,[11 12] which may lead to lower HbA_{1c} levels.[35]

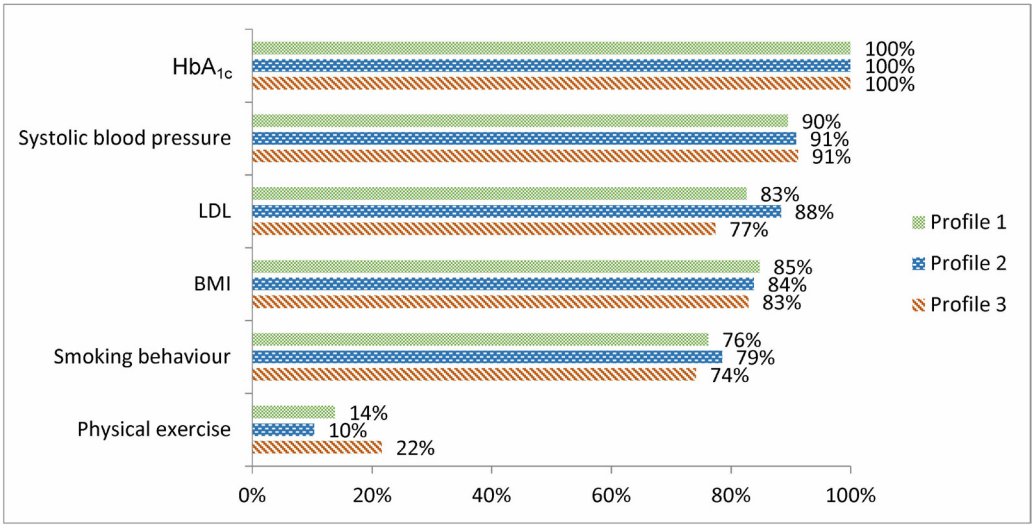

Figure 2 Overview of registered indicators in incompletely monitored patients within HbA_{1c} profile. HbA1c, Haemoglobin A_{1c}.

Table 2 Multilevel analyses evaluating the HbA_{1c} difference of fully monitored patients compared with incompletely monitored patients, stratified for HbA_{1c} profile

	Profile 1			Profile 2			Profile 3		
	B	95% CI	P value	B	95% CI	P value	B	95% CI	P value
Model 1*									
mmol/mol	−1.95	−2.41 to −1.49	<0.001	−2.03	−3.41 to −0.66	0.004	−1.53	−2.96 to −0.10	0.037
%	−0.18	−0.22 to −0.14		−0.19	−0.31 to −0.06		−0.14	−0.27 to −0.01	
Model 2†									
mmol/mol	−2.03	−2.53 to −1.52	<0.001	−3.36	−5.28 to −1.43	0.001	−1.89	−3.76 to −0.01	0.049
%	−0.19	−0.23 to −0.14		−0.31	−0.48 to −0.13		−0.17	−0.34 to 0.00	

*Crude analysis.
†Multilevel analysis adjusted for age, diabetes duration and gender.

Since fully monitored patients with T2DM have significantly lower HbA_{1c} levels, their risk of any diabetes-related health complication is lower compared with incompletely monitored patients. Thus, in general, incomplete monitoring of a patient should be interpreted as an important sign of diabetes-related health risks—especially since incomplete records might be caused by no-show and also by low patient motivation, missing of prescribed lab tests and limited overall adherence to diabetes treatment. As reported by others,[36] a tailored approach based on data registry and adjusted to patients' characteristics (eg, monitoring completeness) is recommended. This might encourage awareness in GP practice regarding adequate diabetes management and might help GPs to overcome barriers on full adoption of the care group monitoring approach. In addition, the present findings might be relevant for other structured diabetes primary care settings that focus on frequent monitoring and adequate registration of diabetes-related health outcomes such as the CPC Plus programme in the USA.[37]

The present study is characterised by several strengths. First, in our view, an important strength of this study is the design: although randomised clinical trials might help to eliminate bias, adequate powering and generalisability are familiar problems,[38] whereas observational studies allow to include large study populations. For example, in this study, all patients participating in a structured primary diabetes care programme were enrolled, thereby contributing to high representativeness of our study population. Second, generally, since our study design did not interfere with the daily routine of GP practices, we assume adequate reliability of our findings. Thus, the observational real-life setting in our study reflects the reality of diabetes monitoring and HbA_{1c} levels in primary care. Our design is in line with other studies that also used a pragmatic approach to conduct diabetes-related studies in primary care.[39–41] Third, since patients were included if they participated for at least 1 year at the same GP practice, bias caused by intermediate moving or referral to hospital diabetes care was avoided, which contributes to the stability and, thus, the validity of our findings. Finally, conducting separate analyses for each HbA_{1c} profile group allowed adjustment for the variety in the recommended HbA_{1c} target values.

Nevertheless, this study is also subject to some limitations that need to be mentioned. First, since no control group was included, no causal relationship between monitoring completeness and HbA_{1c} level can be proven. Second, a missing registration does not necessarily mean that the care has not been provided. For example, missings might be caused by technical problems or lack of time for registration. Patients being considered erroneously as 'incompletely monitored' might have underestimated the associations found, although we did correct our analyses for age, diabetes duration, gender and GP practice.

For future research, it might be useful to analyse the context of diabetes target monitoring and explore whether the association that we found reflects a causal relationship between monitoring completeness and HbA_{1c} level. In addition, from the GP perspective, examining potential barriers to complete monitoring, including potential benefits such as an increase of the proportion of patients with HbA_{1c} levels within recommended values, might provide keys to improvement of the monitoring process. To ameliorate the primary diabetes care of incompletely monitored patients, exploration of their preferences and needs is suggested. In addition, an evaluation of financial costs and benefits of this care approach is recommended.

To summarise, in patients with T2DM within a care group setting, full monitoring of biomedical and lifestyle target indicators is associated with lower HbA_{1c} levels compared with incomplete monitoring. These differences might be expected to have a considerable clinical impact in terms of diabetes-related risks. We recommend a systematic approach to analyse the needs of incompletely monitored patient groups and to adjust the structured care protocol for these subgroups in terms of population health management.

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Contributors SvB analysed data and wrote the manuscript. SPR analysed data and reviewed the manuscript. MJK reviewed and edited the manuscript. TNB reviewed the manuscript. NHC reviewed the manuscript and contributed to the discussion. MEN is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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Competing interests None declared.

Patient consent for publication Not required.

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Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement The data that support the findings of this study are available from the corresponding author on request.

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