

The impact of intensive multifactorial treatment on perceptions of chronic care among individuals with screen-detected diabetes: results from the *ADDITION-Denmark* trial

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None.

SUMMARY

Objectives: To describe perceptions of chronic care among diabetes patients 6 years after diagnosis by screening and to examine the impact of intensive treatment on patients' perceptions of chronic care. **Methods:** The *ADDITION-Denmark* (2001–2006) trial compared the effects of intensive multifactorial therapy (IT) with routine care (RC) among individuals with screen-detected diabetes. Perceptions of chronic care were assessed using the Patient Assessment of Chronic Illness Care (PACIC) measure after 6-year follow-up ($n = 937$). Analysis was by intention-to-treat, accounting for clustering by general practice. **Results:** The mean (SD) summary PACIC score was 2.4 (0.79) in the RC and 2.4 (0.82) in the IT group. The highest mean (SD) PACIC subscale score was for Delivery System Design/Decision Support [RC: 3.2 (0.95), IT: 3.3 (0.91)] and the lowest was for Follow-up/Coordination [RC: 2.1 (0.84), IT: 2.1 (0.87)]. Perceptions of chronic care did not differ between trial groups. **Conclusions:** Compared to RC, an intensive multifactorial intervention was not associated with differences in perceptions of chronic care among patients with screen-detected diabetes after 6 years. Intensive treatment does not adversely affect perceptions of chronic care early in the course of the disease. However, there is potentially room for improvement in some aspects of chronic care.

What's known

There have been recent concerns about the intensity of diabetes treatment in clinical practice. This might be particularly pertinent for asymptomatic individuals found earlier in the disease trajectory, for who the burden of treatment might be higher than the burden of disease.

What's new

We assessed the impact of intensive treatment on perceptions of care in screen-detected diabetes patients 6 years after diagnosis. Our results suggest that perceptions of care did not differ between the intensive and routine care groups. This result should reassure family doctors and other health practitioners that they can intensively treat patients found to have screen-detected diabetes without any adverse effects on perceptions of chronic care.

Background

Type 2 diabetes is a chronic condition, which is largely treated in primary care settings across Europe, with inconsistencies in the quality of diabetes care between and within countries (1). The management of diabetes is largely dependent on self-care and 95% of diabetes management happens outside clinics, beyond providers' awareness and without direct provider influence (2). Previous research has demonstrated the efficacy of lifestyle and diet modification (3,4) and diabetes treatment adherence (5) for secondary prevention in diabetes. Supporting and improving self-management and self-care in people with diabetes can therefore help prevent complications, slow progression of the disease, enhance health-related quality of life, and reduce the economic burden of the disease on health care systems.

The Chronic Care Model (CCM) provides a conceptual framework to improve care for chronically ill

patients (6,7). The implementation of the CCM or its elements in diabetes care improves clinical parameters and chronic care, and in some cases, reduces health care costs (8,9). Some authors have argued that patient perceptions of care and views on service delivery should be seen as indicators of quality of care and thus be included in quality assessment (10,11). There is evidence that the quality of diabetes care is positively associated with patient satisfaction with provider of care (12) and that patient satisfaction with primary care is associated with improved diabetes outcomes (13).

There have been recent concerns about the intensity of diabetes treatment (14). This might be particularly pertinent for asymptomatic individuals found earlier in the disease trajectory, for who the burden of treatment might be higher than the burden of disease. The number of individuals found and treated early is expected to increase with the advent of national screening programmes (15). It is therefore

important to assess the potential impact of intensive treatment on perceptions of care among screen-detected individuals.

Using data from *ADDITION-Denmark*, a cluster randomised controlled trial comparing intensive multifactorial treatment with routine care (RC) among patients with screen-detected type 2 diabetes, we aimed to (i) describe patients' perceptions of chronic care, (ii) examine the predictors of perceptions of chronic care, and (iii) examine the impact of intensive multifactorial treatment on perceptions of chronic care at 6-years post-diagnosis.

Methods

The design and rationale of the Anglo-Danish-Dutch Study of Intensive Treatment in People with Screen Detected Diabetes in Primary Care (*ADDITION-Europe*) Study have been reported (16). The current analysis includes data taken exclusively from 6-year follow-up of the Danish arm of the *ADDITION-Europe* trial. In brief, the *ADDITION-Denmark* consists of two phases: a primary care based screening programme and a pragmatic, cluster randomised, parallel group trial comparing the effects of intensive multifactorial therapy (IT) with RC among individuals with screen-detected type 2 diabetes. Screening was undertaken between 2001 and 2006. 190 general practices in five regions in Denmark were randomly assigned to screening of registered patients aged 40–69 years without known diabetes followed by RC of diabetes or screening followed by IT. Patients were excluded if they had an illness with a life expectancy of less than 12 months, a psychological disorder, were housebound, pregnant or lactating. Overall, 1533 (RC = 623, IT = 910) eligible participants participated in the treatment phase of the *ADDITION-Denmark* study. Ethical approval of the study was attained from the local Science Ethics Committee of Aarhus County, Denmark (protocol no.: 20000183). The Danish Data Surveillance Authority permitted the collection and storage of data (journal no: 2000-41-0042). All participants provided informed consent. *ADDITION-Europe* is registered as NCT00237549.

Intervention

Individuals were treated according to the group to which their practice was allocated: RC or IT. Details have been described previously (16,17). Intensification of treatment included funding for practices to facilitate more frequent contact and theory based diabetes education materials for participants. Family doctors were encouraged to introduce a stepwise target-led drug treatment regime to reduce hyperglycaemia, hypertension and hyperlipidaemia based on the

Steno-2 study (18). For the RC group, physicians were only provided with diagnostic test results and patients received standard diabetes care according to local recommendations (19).

Measures

ADDITION-Denmark health assessments included physiological and anthropometric measurements, venesection and the completion of questionnaires at baseline and 6-years post-diagnosis. Data collection methods have been described previously (16,20). Anthropometric and clinical measurements were undertaken by trained staff who were blind to study group following standard operating procedures. HbA_{1c} was analysed by DCCT aligned ion-exchange high-performance liquid chromatography using Tosoh G7 machines. Socio-demographic information [age, sex, age when completed full-time education (≤ 19 years or > 19 years of age)], lifestyle behaviours [smoking status (non-smoker/ex-smoker or current smoker), alcohol consumption [those who meet the guidelines on alcohol consumption and those who did not (men: ≤ 21 units/week or > 21 units/week; women: ≤ 14 units/week or > 14 units/week)], history of angina and/or myocardial infarction and/or stroke (yes/no), and intake of glucose-, hypertension- and lipid-lowering drugs and aspirin (yes/no) was collected using standardised self-report questionnaires. Physical activity was assessed using the validated International Physical Activity Questionnaire (IPAQ) and coded into low, medium and high categories according to published guidelines (21).

Patient perceptions of chronic care were assessed using the 20-item Patient Assessment Chronic Illness Care (PACIC) questionnaire (22,23), which is based on the CCM (24,25). It assesses the receipt of patient-centred care and emphasizes the key elements of modern self-management support such as collaborative goal settings, problem-solving and follow-up, and planned, proactive, and population-based care (23). The PACIC includes five subscales on a 5-point scale [range 1 (never) to 5 (always)] related to patient perceptions of chronic illness care: Patient Activation, Delivery System Design/Decision Support, Goal Setting/Tailoring, Problem Solving/Contextual, and Follow-up/Coordination. Each subscale is scored by averaging the items completed within that scale. The summary PACIC score is computed by averaging scores across all 20 items (23). The PACIC scores range from 1 to 5 with higher scores indicating patient's perception of a greater involvement in self-management and receipt of chronic illness care delivery (22,23). Cronbach's alpha for the overall PACIC score was 0.89.

Statistical analyses

Six year descriptive characteristics, including the PACIC measure, were summarised separately by trial group. We reported means (SD) for approximately normally distributed continuous variables, median (IQR) for skewed continuous variables and number (%) for categorical variables. Differences in baseline characteristics between participants who were included in the analysis and those who were not were compared using the χ^2 test for categorical data and the *t*-test or Mann–Whitney U for continuous data. An HbA_{1c} level of < 7% was defined as good blood glucose control (26). Overweight was defined as body mass index (BMI) ≥ 25 kg/m² and obesity as BMI ≥ 30 kg/m² (27). Raised systolic blood pressure was defined as ≥ 140 mmHg and raised total cholesterol as ≥ 5.0 mmol/l (28). We used univariable linear regression to examine the cross-sectional association between the summary PACIC score (dependent variable) and socio-demographic characteristics, cardiovascular risk factors, medication intake, and lifestyle variables. The summary PACIC score and PACIC subscales were analysed with normal errors regression in an intention-to-treat analysis. We took account of clustering (by GP practice) by including a robust standard error term in the model. All regression results are presented as unstandardised b-coefficients with their 95% confidence intervals. Statistical significance was set at $p < 0.05$. Statistical analyses were performed using SPSS for Windows 19.0 (SPSS, Inc., Chicago, IL).

Results

Of those alive at 6-year follow-up, 1277/1416 (90.2%) *ADDITION-Denmark* participants attended a health assessment at a local clinical research facility; complete PACIC data were available for 937 participants. Individuals who were included in the analysis ($n = 937$) were slightly younger (59.6 vs. 60.4 years respectively) and included more men (59% vs. 54%) at baseline than those who were not included ($n = 596$). Both trial groups were similar for baseline BMI, HbA_{1c}, total cholesterol and systolic blood pressure.

Participant characteristics at the 6-year follow-up are presented in Table 1. In both trial groups, the mean age of participants was 66 years and average diabetes duration was 5.9 years. Fewer participants in the RC group (67.1%) had completed their full-time education >19 years compared to the IT group (75.4%). On average, the cohort was obese [RC: mean BMI 30.6 (5.3) kg/m², IT: mean BMI 30.7 (5.4) kg/m²], with slightly elevated systolic blood pressure (RC: 135.9 (18.02) mmHg, IT: 133.9 (17.05) mmHg) and good glycaemic control [RC:

mean HbA_{1c}: 6.5% (0.82), IT: mean HbA_{1c}: 6.5% (0.85)]. A significant proportion of participants were current smokers (RC: 23.5%; IT: 21.1%). A higher proportion of participants in the IT group were prescribed cardio-protective medication compared to the RC group.

Perceptions of chronic care

At the 6-year health assessment, the PACIC item 'Satisfied that my care was well organized' achieved the highest mean score (SD) in both groups [RC: 3.9 (1.09), IT: 4.0 (1.01)], and the PACIC item 'Encouraged to attend programs in the community that could help me' had the lowest mean score in the RC [1.5 (0.92)] and IT group [1.7 (1.06)] (Table 2). The PACIC mean subscale scores were similar in both trial groups: the highest average score was for 'Delivery System Design/Decision Support' [RC: 3.2 (0.95), IT: 3.3 (0.91)] and the lowest average score was for 'Follow-up/Coordination' [RC: 2.1 (0.84), IT: 2.1 (0.87)]. The mean summary PACIC score was 2.4 (0.81) in the overall cohort, and 2.4 (0.79) in the RC and 2.4 (0.82) in the IT group.

Predictors of perceptions of chronic care

There was no association between the majority of socio-demographic characteristics, cardiovascular risk factors, medication intake and lifestyle behaviour variables with the summary PACIC score at 6 year follow-up (Table 3). However, participants with raised total cholesterol reported a lower summary PACIC score [$\beta = -0.18$ (-0.31, -0.06)] and participants taking glucose-lowering drugs reported a higher summary PACIC score [$\beta = 0.14$ (0.02, 0.26)].

Impact of intensive multifactorial treatment on perceptions of chronic care

There was no difference in the summary PACIC score between the trial groups [$\beta = 0.07$ (-0.06, 0.20)] nor between the PACIC subscales and trial group (Table 4). The difference in PACIC scores was highest for the Delivery System Design/Decision Support sub-scale ($\beta = 0.11$) and lowest for the Problem-solving/Contextual Counselling sub-scale ($\beta = 0.04$); however, none of the differences reached statistical significance.

Discussion

Compared to RC, an intensive multifactorial intervention was not associated with differences in perceptions of chronic care among patients with screen-detected diabetes after a mean follow-up of 6 years. Most participants in the RC and the IT groups reported that they were satisfied that their

Table 1 Participant characteristics in the *ADDITION-Denmark* study 6 years after diagnosis

Category	Characteristics	Total n	Routine care	Intensive treatment	
	Patients	937	39.7 (372)	60.3 (565)	
Socio-demographics	Diabetes duration (years)	937	5.9 (1.34)	5.9 (1.39)	
	Age (years)	937	65.6 (6.7)	65.5 (6.9)	
	Male sex*, % (n)	937	59.1 (220)	59.1 (334)	
Cardiovascular risk factors	Full-time education completed at > 19 years, % (n)	835	67.1 (228)	75.4 (373)	
	Caucasian ethnicity*, % (n)	933	97.8 (353)	98.5 (528)	
	HbA _{1c} (%)	933	6.5 (0.82)	6.5 (0.85)	
	HbA _{1c} < 7%	933	79.0 (293)	80.0 (454)	
	BMI (kg/m ²)	937			
	Men	554	30.2 (4.46)	30.4 (4.61)	
	Women	383	31.3 (6.30)	31.3 (7.04)	
Medication intake	Systolic blood pressure (mmHg)	936	135.9 (18.02)	133.9 (17.05)	
	Total cholesterol (mmol/l)	935	4.4 (0.81)	4.2 (0.94)	
	History of angina and/or myocardial infarction and/or stroke, % (n)	899	15.0 (54)	16.7 (90)	
	Glucose-lowering drugs, % (n)	936	52.2 (194)	63.1 (356)	
	Hypertension-lowering drugs, % (n)	936	73.4 (273)	81.2 (458)	
	Lipid-lowering drugs, % (n)	936	76.9 (286)	83.0 (468)	
	Aspirin, % (n)	936	44.4 (165)	77.3 (436)	
	Lifestyle	Current smoker, % (n)	924	23.5 (86)	21.1 (118)
		Alcohol consumption, % (n)	913		
		Men (≤ 21 units/week)	540	81.7 (174)	85.6 (280)
Women (≤ 14 units/week)		373	94.6 (141)	92.4 (207)	
Alcohol consumption (units per week) [†]		913	5.0 (1.0; 13.0)	4.0 (1.0; 12.0)	
Physical activity [‡] , % (n)		908			
Low	153	17.5 (63)	16.4 (90)		
Moderate	263	26.4 (95)	30.7 (168)		
High	492	56.1 (202)	52.9 (290)		

Values are means (SD) or % (n) unless stated otherwise; BMI, body-mass index; HbA_{1c}, glycosylated haemoglobin. *Measured at baseline, [†]median (25th; 75th percentile); [‡]physical activity was assessed using the validated International Physical Activity Questionnaire (IPAQ).

care was well organised. While our findings suggest that intensive treatment does not adversely affect perceptions of chronic care early in the course of the disease, the overall mean summary PACIC score was quite low.

The mean summary PACIC score [RC: 2.4 (0.79), IT: 2.4 (0.82)] and some of the PACIC mean subscales [ranging from 2.1 (0.84) to 3.2 (0.95) in the RC group and from 2.1 (0.87) to 3.3 (0.91) in the IT group] in *ADDITION-Denmark* were lower compared to previous studies examining perceptions of chronic care among patients with diabetes. For example, in a Dutch cohort of diabetes patients (mean age 69 years), the mean summary PACIC score was 3.2 (1.0) and PACIC subscale scores ranged from 2.0 (0.8) to 3.9 (1.1) (29). A higher average summary PACIC score [3.2 (0.9)] was also reported in American (mean age 64 years) (22) and in Spanish-speaking diabetes patients (mean age 64 years) [3.2 (0.8)] (30). In contrast to these

studies, *ADDITION-Denmark* participants were screen-detected and largely asymptomatic. As such, our participants did not have had long-term experience of engaging with chronic care delivery services, and may have reported lower perceptions of care than the cohorts of clinically diagnosed patients described above. Among *ADDITION-Denmark* participants the PACIC subscale 'Delivery System Design/Decision Support' [RC: 3.2 (0.95), IT: 3.3 (0.91)] was rated most highly, which is in line with previous studies (mean score ranging from 3.3 (0.9) (31) to 3.9 (1.1) (29) or 3.95 (0.98) (30)).

The aim of the CCM is to encourage informed, activated patients to interact with a proactive and prepared practice team (7). The PACIC instrument offers direct guidance on which components of chronic care could be improved. For example, in our cohort, individual Goal-Setting/Tailoring and Follow-up/Coordination of diabetes patients could be improved. Participants also reported low scores for

Table 2 Results for the summary PACIC score, subscales and individual items in the *ADDITION-Denmark* study 6 years after diagnosis ($n = 937$)

PACIC*	Routine care	Intensive treatment
Individual PACIC items		
1. Asked for my ideas when we made a treatment plan	2.3 (1.18)	2.4 (1.21)
2. Given choices about treatment to think about	1.9 (1.06)	2.1 (1.17)
3. Asked to talk about any problems with my medicines or their effects	2.6 (1.40)	2.6 (1.34)
4. Given a written list of things I should do to improve my health	2.2 (1.30)	2.4 (1.30)
5. Satisfied that my care was well organized	3.9 (1.09)	4.0 (1.01)
6. Shown how what I did to take care of my illness influenced my condition	3.4 (1.25)	3.5 (1.19)
7. Asked to talk about my goals in caring for my illness	2.4 (1.28)	2.5 (1.30)
8. Helped to set specific goals to improve my eating or exercise	2.6 (1.27)	2.6 (1.26)
9. Given a copy of my treatment plan	1.7 (1.17)	1.8 (1.21)
10. Encouraged to go to a specific group or class to help me cope with my chronic illness	1.7 (1.14)	1.7 (1.16)
11. Asked questions, either directly or on a survey, about my health habits	2.5 (1.29)	2.5 (1.26)
12. Sure that my doctor or nurse thought about my values and my traditions when they recommended treatments	3.5 (1.35)	3.4 (1.37)
13. Helped to make a treatment plan that I could do in my daily life	2.2 (1.34)	2.3 (1.39)
14. Helped to plan ahead so I could take care of my illness even in hard times	2.1 (1.25)	2.2 (1.30)
15. Asked how my chronic illness affects my life	2.3 (1.30)	2.3 (1.27)
16. Contacted after a visit to see how things were going	1.7 (1.08)	1.7 (1.12)
17. Encouraged to attend programs in the community that could help me	1.5 (0.92)	1.7 (1.06)
18. Referred to a dietician, health educator, or counsellor	2.1 (1.34)	2.0 (1.28)
19. Told how my visits with other types of doctors, like an eye doctor or surgeon, helped my treatment	2.8 (1.49)	3.0 (1.45)
20. Asked how my visits with other doctors were going	2.2 (1.39)	2.3 (1.44)
PACIC subscales		
Patient Activation	2.3 (1.01)	2.4 (1.06)
Delivery System Design/Decision Support	3.2 (0.95)	3.3 (0.91)
Goal Setting/Tailoring	2.2 (0.94)	2.2 (0.93)
Problem Solving/Contextual	2.5 (1.05)	2.6 (1.08)
Follow-up/Coordination	2.1 (0.84)	2.1 (0.87)
Summary PACIC score		
Male	2.4 (0.79)	2.4 (0.82)
Female	2.4 (0.76)	2.5 (0.78)
	2.3 (0.84)	2.4 (0.88)

Values are means (SD); *Source: Glasgow et al. (23).

the item: 'encouraged to attend programs in the community'. This information could be useful for health planners in Denmark and elsewhere in order to achieve a coordinated health system.

In terms of predictors of perceptions of chronic care, our results are in broad agreement with previous studies, which report few associations between various patient or medical characteristics and the PACIC measure. Aragonés et al. reported no significant associations between socio-demographic (e.g. age, education, years living in the US) characteristics and the summary PACIC score in Spanish-speaking diabetes patients in the US (30). The results of a US study among type 2 diabetes patients showed that the summary PACIC score was significantly associated with the quality of diabetes care received and with physical activity level but was unrelated to

patient characteristics (22). Taggart et al. found that the summary PACIC score was positively related to having good or very good health over the last 12 months, whereas having a degree/diploma, being employed, retired, married/cohabiting, type and duration of chronic conditions had negative effect on the total PACIC score (32). We found that participants with raised total cholesterol reported a lower summary PACIC score, while participants taking glucose-lowering drugs reported a higher summary PACIC score. This suggests that patients who were being treated for their raised cardiovascular risk factor levels reported higher perceptions of chronic care delivery. This supports our conjecture that individuals who engage with health services have higher perceptions of chronic care than those who do not. The relationship between patient perceived

Table 3 Univariable association between the summary PACIC score and socio-demographic characteristics, cardiovascular risk factors, medication intake and lifestyle behaviours in the *ADDITION-Denmark* study 6 years after diagnosis

Characteristics	Total <i>n</i>	Unstandardised β -coefficients (95% CI)	p-value
Socio-demographics			
Age (years)	937	0.002 (−0.01 to 0.01)	0.558
Sex (men = 0)	937	−0.03 (−0.14 to 0.08)	0.607
Full-time education completed at > 19 years (=0)	835	−0.03 (−0.14 to 0.09)	0.643
Cardiovascular risk factors			
HbA _{1c} (%) (continuous)	933	0.05 (−0.02 to 0.11)	0.140
BMI (kg/m ²) (continuous)	937	0.002 (−0.01 to 0.01)	0.742
Systolic blood pressure (mmHg) (continuous)	936	−0.002 (−0.01 to 0.001)	0.134
Total cholesterol (mmol/l) (continuous)	935	−0.09 (−0.15 to −0.03)	0.002
HbA _{1c} (< 7% = 0)	933	0.05 (−0.07 to 0.18)	0.410
BMI (<25 kg/m ² = 0)	937	0.02 (−0.13 to 0.17)	0.830
Systolic blood pressure (< 140 mmHg = 0)	936	0.05 (−0.15 to 0.06)	0.360
Total cholesterol (< 5 mmol/l = 0)	935	−0.18 (−0.31 to −0.06)	0.004
Cardiovascular history			
History of angina and/or myocardial infarction and/or stroke (no = 0)	899	−0.04 (−0.21 to 0.14)	0.692
Medication intake			
Glucose-lowering drugs (no = 0)	936	0.14 (0.02 to 0.26)	0.023
Hypertension-lowering drugs (no = 0)	936	0.03 (−0.08 to 0.14)	0.599
Lipid-lowering drugs (no = 0)	936	0.08 (−0.05 to 0.21)	0.213
Aspirin (no = 0)	936	0.09 (−0.02 to 0.20)	0.127
Lifestyle behaviours			
Smoking status (non-/ex-smoker = 0)	924	0.05 (−0.07 to 0.17)	0.419
Alcohol consumption (according to guidelines = 0)	913	−0.09 (−0.22 to 0.04)	0.187
Physical activity (high = 0)	908		
Low		−0.11 (−0.24 to 0.02)	0.087
Moderate		−0.01 (−0.14 to 0.13)	0.942

Values are unstandardised b-coefficients (95% confidence interval); models are adjusted for standard error by computing a cluster robust standard error for GP practice.

quality of care and health outcomes can be bilateral: perceived good care or satisfaction with care may be associated with better health outcomes (13), for example, through medical compliance (33) and loyalty to physicians (34). On the other hand, improved health outcomes may be associated with increased satisfaction of care.

There was no difference in perceptions of chronic care between individuals receiving RC and intensive treatment in the *ADDITION-Denmark* trial. The trial was undertaken during a time when targets for cholesterol and blood pressure levels became stricter for diabetes patients. This resulted in smaller than expected differences between the treatment groups for cardiovascular risk factors, prescribed medication and cardiovascular disease outcomes (17). The largest differences between groups were observed early in the course of the trial, and 1-year differences in cardiovascular risk factors between the groups were not maintained at 5 years (35,36). The intervention was

associated with a non-significant 17% reduction in cardiovascular events over 5 years (17). The lower than expected CVD event rate in the *ADDITION* trial suggests that the 5 year duration of follow-up may be insufficient to detect a potential difference between groups. Event rates appeared to diverge from 4 years suggesting that further follow up of this trial is justified to examine whether early intensive multifactorial treatment reduces cardiovascular risk in the long term as seen in the UKPDS. At the current time, health practitioners should consider treating multiple cardiovascular risk factors early and intensively in the diabetes disease trajectory, where the rate of CVD risk progression may be slowed (37). Given the overall trial results the potential for observing differences in perceptions of chronic care between the two study groups in the current trial may have been reduced. Our findings are in line with the main *ADDITION-Europe* trial (38), where there were no clinically significant differences in a range of

Table 4 Univariable association between the summary PACIC score, PACIC subscales and trial group in the *ADDITION-Denmark* study 6 years after diagnosis ($n = 937$)

Trial group (routine care = 0)	Unstandardised β -coefficients (95% CI)	p-value
Summary PACIC score	0.07 (−0.06 to 0.20)	0.263
PACIC subscales		
Patient Activation	0.10 (−0.05 to 0.26)	0.202
Delivery System Design/ Decision Support	0.11 (−0.03 to 0.26)	0.129
Goal Setting	0.05 (−0.09 to 0.19)	0.482
Problem-solving/Contextual Counselling	0.04 (−0.12 to 0.20)	0.602
Follow-up/Coordination	0.08 (−0.05 to 0.22)	0.216

Values are unstandardised β -coefficients (95% confidence interval); models are adjusted for standard error by computing a cluster robust standard error for GP practice.

patient-reported outcome measures between treatment groups after 6 years of follow-up.

Study strengths include the randomised trial design, the large sample of screen-detected diabetes patients, and the examination of a wide range of potential predictors of perceptions of chronic care. 90% of participants returned for a follow-up health assessment at 6 years. However, there are a number of limitations in our study. The sample was largely Caucasian and middle-aged, which restricts generalizability to other populations. There were a few differences between individuals who were included in the analysis and those who were not. However, these differences were small and not in one direction, so are unlikely to affect the outcome. Patients' self-reported behaviours may have been influenced by recall and social desirability bias. The PACIC measure was not available in the whole *ADDITION-Europe* cohort and was not measured at baseline, so we could not investigate change over time. However, individuals were not in receipt of chronic care delivery at baseline so this examination was not possible. Finally, we explored a number of possible predictors of perceptions of chronic care and conducted multiple significance tests, which mean that our results should be interpreted with caution as some significant associations may have occurred by chance.

Conclusions

Compared to RC, intensive multifactorial treatment was not associated with differences in perceptions of

chronic care among patients with screen-detected diabetes over 6 years. While it remains uncertain whether early intensive treatment reduces cardiovascular events, our findings suggest that such treatment does not adversely affect perceptions of chronic care early in the course of the disease. The results should reassure family doctors and other health practitioners that they can intensively treat patients found to have screen-detected diabetes without any adverse effects on perceptions of chronic care. The low overall score suggests that there is potentially room for improvement in some aspects of chronic care.

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Author contributions

RKS, LK and HTM conceived the study question. AS and HTM collected the PACIC data. LK analysed and interpreted the data. LK, RKS, AS, and HTM drafted the manuscript. All authors critically revised the manuscript for important intellectual content and approved the final version.

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References

- 1 Kanavos P, Van den Aardweg S, Schurer W. Diabetes expenditure, burden of disease and management in 5 EU countries: LSE Health, London School of Economics; 2012. <http://www2.lse.ac.uk/LSEHealthAndSocialCare/research/LSEHealth/MTRG/LSEDiabetesReport26Jan2012.pdf> (accessed May 13, 2014).
- 2 Wagner J. Behavioral interventions to promote diabetes self-management. Preface. *Diabetes Spectrum* 2011; **24**(2): 61–2.
- 3 Avery L, Flynn D, van Wersch A, Sniehotta FF, Trenell MI. Changing physical activity behavior in type 2 diabetes: a systematic review and meta-analysis of behavioral interventions. *Diabetes Care* 2012; **35**(12): 2681–9.
- 4 Gregg EW, Chen H, Wagenknecht LE et al. Association of an intensive lifestyle intervention with remission of type 2 diabetes. *JAMA* 2012; **308**(23): 2489–96.
- 5 Asche C, LaFleur J, Conner C. A review of diabetes treatment adherence and the association with clinical and economic outcomes. *Clin Ther* 2011; **33**(1): 74–109.
- 6 Wagner EH. Chronic disease management: what will it take to improve care for chronic illness? *Eff Clin Pract* 1998; **1**(1): 2–4.
- 7 Bodenheimer T, Wagner EH, Grumbach K. Improving primary care for patients with chronic illness. *JAMA* 2002; **288**(14): 1775–9.
- 8 Bodenheimer T, Wagner EH, Grumbach K. Improving primary care for patients with chronic illness: the chronic care model, Part 2. *JAMA* 2002; **288**(15): 1909–14.
- 9 Nutting PA, Dickinson WP, Dickinson LM et al. Use of chronic care model elements is associated with higher-quality care for diabetes. *Ann Fam Med* 2007; **5**(1): 14–20.
- 10 Jenkinson C, Coulter A, Bruster S, Richards N, Chandola T. Patients' experiences and satisfaction with health care: results of a questionnaire study of specific aspects of care. *Qual Saf Health Care* 2002; **11**(4): 335–9.
- 11 Danielsen K, Garratt AM, Bjertnaes OA, Pettersen KI. Patient experiences in relation to respondent and health service delivery characteristics: a survey of 26,938 patients attending 62 hospitals throughout Norway. *Scand J Public Health* 2007; **35**(1): 70–7.
- 12 Narayan KM, Gregg EW, Fagot-Campagna A et al. Relationship between quality of diabetes care and patient satisfaction. *J Nat Med Assoc* 2003; **95**(1): 64–70.
- 13 Alazri MH, Neal RD. The association between satisfaction with services provided in primary care and outcomes in Type 2 diabetes mellitus. *Diabet Med* 2003; **20**(6): 486–90.
- 14 Gerstein HC, Miller ME, Byington RP et al. Effects of intensive glucose lowering in type 2 diabetes. *N Engl J Med* 2008; **358**(24): 2545–59.
- 15 NHS. *Putting Prevention First. NHS Health Check: Vascular Risk Assessment and Management. Best Practice Guidance*. London: Department of Health, NHS, 2009.
- 16 Lauritzen T, Griffin S, Borch-Johnsen K et al. The ADDITION study: proposed trial of the cost-effectiveness of an intensive multifactorial intervention on morbidity and mortality among people with type 2 diabetes detected by screening. *Int J Obes Relat Metab Disord* 2000; **24**(Suppl. 3): S6–11.
- 17 Griffin SJ, Borch-Johnsen K, Davies MJ et al. Effect of early intensive multifactorial therapy on 5-year cardiovascular outcomes in individuals with type 2 diabetes detected by screening (ADDITION-Europe): a cluster-randomised trial. *Lancet* 2011; **378**(9786): 156–67.
- 18 Gaede P, Vedel P, Larsen N, Jensen G, Parving H, Pedersen O. Multifactorial intervention and cardiovascular disease in patients with type 2 diabetes. *N Engl J Med* 2003; **348**(5): 383–93.
- 19 Royal College of General Practitioners in Denmark. *Type 2 Diabetes in General Practice - Diagnosis and Treatment*. Copenhagen, Denmark: Royal College of General Practitioners, 1999.
- 20 Charles M, Fleischer J, Witte DR et al. Impact of early detection and treatment of diabetes on the 6-year prevalence of cardiac autonomic neuropathy in people with screen-detected diabetes: ADDITION-Denmark, a cluster-randomised study. *Diabetologia* 2013; **56**(1): 101–8.
- 21 Craig CL, Marshall AL, Sjoström M et al. International physical activity questionnaire: 12-country reliability and validity. *Med Sci Sports Exerc* 2003; **35**(8): 1381–95.
- 22 Glasgow RE, Whitesides H, Nelson CC, King DK. Use of the Patient Assessment of Chronic Illness Care (PACIC) with diabetic patients: relationship to patient characteristics, receipt of care, and self-management. *Diabetes Care* 2005; **28**(11): 2655–61.
- 23 Glasgow RE, Wagner EH, Schaefer J, Mahoney LD, Reid RJ, Greene SM. Development and validation of the Patient Assessment of Chronic Illness Care (PACIC). *Med Care* 2005; **43**(5): 436–44.
- 24 Wagner EH, Austin BT, Von Korff M. Organizing care for patients with chronic illness. *Milbank Q* 1996; **74**(4): 511–44.
- 25 Von Korff M, Gruman J, Schaefer J, Curry SJ, Wagner EH. Collaborative management of chronic illness. *Ann Intern Med* 1997; **127**(12): 1097–102.
- 26 American Diabetes Association. Standards of medical care in diabetes—2007. *Diabetes Care* 2007; **30**(Suppl. 1): S4–41.
- 27 WHO. *Obesity and overweight. Fact sheet N°311*. Geneva, WHO, 2011. <http://www.who.int/mediacentre/factsheets/fs311/en/>(accessed May 14, 2014).
- 28 WHO. *A Comprehensive Global Monitoring Framework, Including Indicators, and A Set Of Voluntary Global Targets for the Prevention and Control of Noncommunicable Diseases*. Geneva: WHO, 2012. http://www.who.int/nmh/events/2012/discussion_paper3.pdf (accessed May 14, 2014).
- 29 Wensing M, van Lieshout J, Jung HP, Hermens J, Rosemann T. The Patients Assessment Chronic Illness Care (PACIC) questionnaire in The Netherlands: a validation study in rural general practice. *BMC Health Serv Res* 2008; **8**: 182.
- 30 Aragones A, Schaefer EW, Stevens D, Gourevitch MN, Glasgow RE, Shah NR. Validation of the Spanish translation of the Patient Assessment of Chronic Illness Care (PACIC) survey. *Prev Chronic Dis* 2008; **5**(4): A113.
- 31 Szececsenyi J, Rosemann T, Joos S, Peters-Klimm F, Miksch A. German diabetes disease management programs are appropriate for restructuring care according to the chronic care model: an evaluation with the patient assessment of chronic illness care instrument. *Diabetes Care* 2008; **31**(6): 1150–4.
- 32 Taggart J, Chan B, Jayasinghe UW et al. Patients Assessment of Chronic Illness Care (PACIC) in two Australian studies: structure and utility. *J Eval Clin Pract* 2011; **17**(2): 215–21.
- 33 Francis V, Korsch BM, Morris MJ. Gaps in doctor-patient communication. Patients' response to medical advice. *N Engl J Med* 1969; **280**(10): 535–40.
- 34 Safran DG, Montgomery JE, Chang H, Murphy J, Rogers WH. Switching doctors: predictors of voluntary disenrollment from a primary physician's practice. *J Fam Pract* 2001; **50**(2): 130–6.
- 35 Janssen PG, Gorter KJ, Stolk RP, Rutten GE. Randomised controlled trial of intensive multifactorial treatment for cardiovascular risk in patients with screen-detected type 2 diabetes: 1-year data from the ADDITION Netherlands study. *Br J Gen Pract* 2009; **59**(558): 43–8.
- 36 Webb DR, Khunti K, Gray LJ et al. Intensive multifactorial intervention improves modelled coronary heart disease risk in screen-detected Type 2 diabetes mellitus: a cluster randomized controlled trial. *Diabet Med* 2012; **29**(4): 531–40.
- 37 Black JA, Sharp S, Wareham NJ et al. Does early intensive multifactorial therapy reduce modelled cardiovascular risk in individuals with screen-detected diabetes? Results from the ADDITION-Europe cluster randomized trial. *Diabet Med* 2014; **31**(6): 647–56.
- 38 Van den Donk M, Griffin SJ, Borch-Johnsen K et al. Effect of early intensive multifactorial therapy compared to routine care on self-reported health status, general wellbeing, diabetes specific quality of life and treatment satisfaction in screen-detected type 2 diabetes patients: the ADDITION-Europe study. *Diabetologia* 2013; [Epub ahead of print].

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