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Patient-centred care, health behaviours and cardiovascular risk factor levels in people with recently diagnosed type 2 diabetes: 5 year follow-up of the ADDITION-plus trial cohort

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Abstract

Objective: To examine the association between the experience of patient-centred care (PCC), health behaviours and cardiovascular disease (CVD) risk factor levels among people with type 2 diabetes.

Design: Population-based prospective cohort study

Setting: 34 general practices in East Anglia UK, delivering organised diabetes care.

Participants: 478 recently diagnosed type 2 diabetes patients aged between 40 and 69 years enrolled in the ADDITION-Plus trial.

Main outcome measures: Self-reported and objectively measured health behaviours (diet, physical activity, smoking status), CVD risk factor levels (blood pressure, lipid levels, HbA_{1c}, BMI, waist circumference) and modelled 10 year CVD risk).

Results: Better experiences of PCC early in the course of living with diabetes were not associated with meaningful differences in self-reported physical activity levels including total activity energy expenditure (beta-coefficient: 0.080 MET hrs/day [95% CI: 0.017, 0.143], moderate-to-vigorous physical activity (MVPA; beta-coefficient: 5.328 minutes/day [95% CI: 0.796, 9.859]), and reduced sedentary time (beta-coefficient: -1.633 min/day [95% CI: -2.897, -0.368]). PCC was not associated with clinically meaningful differences in levels of HDL-cholesterol (beta-coefficient: 0.002 mmol/L [95% CI: 0.001, 0.004]) systolic blood pressure (beta-coefficient: -0.561 mm Hg [95% CI: -0.653, -0.468]), or diastolic blood pressure (beta-coefficient: -0.565 mm Hg [95% CI: -0.654, -0.476]). Over an extended follow up of five years, we observed no clear evidence that PCC was associated with self-reported, clinical or biochemical outcomes, except for waist circumference (beta-coefficient: 0.085 cm [95% CI: 0.015, 0.155]).

Conclusion: We found little evidence that experience of PCC early in the course of diabetes was associated with clinically important changes in health related behaviours or CVD risk factors.

Keywords

General practice, type 2 diabetes, cardiovascular risk, patient-centred care, physical activity, diet

Strengths and limitations of this study

- Our study is the first to use objective measures of health behaviours to examine the impact of patient-centred care in recently diagnosed type 2 diabetes.
- The study duration is five years with high rates of follow up.
- We included a large number of GP surgeries that reflects the average UK GP list size, number of doctors/nurses and diabetes prevalence.
- Patient-centred care was only measured at a single time point.
- The majority of our participants were Caucasian males with high levels of education and employment, thereby limiting the generalisability of our findings

Introduction

Type 2 diabetes is a common condition mostly managed in general practice. Despite current lifestyle and medication treatments, patients with diabetes still have high rates of cardiovascular disease (CVD) morbidity and mortality. [1] Patient-centred care (PCC) is considered the cornerstone of UK general practice and may play an important role in the management of CVD risk factor levels.[2] By understanding individual health beliefs, considering patient preferences, and developing mutual management plans, GPs may be able to positively influence health behaviours such as diet, physical activity, smoking and alcohol intake, each of which are known to influence CVD risk factor levels. [6] This potentially effective and cost-effective role for GPs in influencing patient health behaviours has recently been emphasised in national and international health policy.[9–11] The majority of supporting evidence comes from observational data reporting inverse associations between PCC and CVD risk factor levels.[3] Trial findings have been more variable with some studies reporting no effect from interventions promoting PCC, while others report reduced CVD risk factor levels including HbA_{1c}, blood pressure, cholesterol and BMI. [4–7] There is currently insufficient evidence to confirm whether PCC influences CVD risk factor levels among patients with diabetes, and the mechanism to explain any associations remains unclear. We hypothesize that the mechanism linking PCC to CVD risk factor levels is through patient health behaviours.[8]

The majority of diabetes care occurs in general practice where there is increasing pressure on GP consultation time. This is leading to a range of alternative chronic disease management strategies such as more routinised care, telehome care and remote monitoring, each of which may diminish PCC.[12–14] With the need to optimize efficiency as well as effectiveness in diabetes care, it is increasingly important to assess the experience of PCC in improving disease risk. Evidence for the role of PCC in cost-effective diabetes care is needed to inform policy and has implications for the management of chronic disease more widely.

We aimed to quantify the association between the experience of PCC delivered by GPs and CVD risk factor levels at one and five year follow-up in a well characterised cohort of recently diagnosed type 2 diabetes patients. To enable better understanding of the potential mechanisms underlying this association, we also examined associations between PCC and health behaviours.

Methods

Study design

A detailed description of the *ADDITION-Plus* study design and rationale can be found elsewhere.[15] In brief, *ADDITION-Plus* is a randomised controlled trial among 34 general practices across East Anglia, UK. *ADDITION-Plus* examined the efficacy of a facilitator-led, theory-based behaviour change intervention for individuals with recently diagnosed type 2 diabetes. In total 478 out of 1,109 eligible individuals agreed to participate and were individually randomised to receive either intensive treatment alone ($n = 239$) or intensive treatment plus a facilitator-led individual behaviour change intervention ($n = 239$). The trial was not designed to influence patient-practitioner interactions and there were no differences in health behaviours or CVD risk factor levels between trial groups at one year, and no differences in the proceeding multivariate analyses between trial arms. Therefore, data for this analysis were pooled and treated as a cohort analysis. Participants in the trial were followed up for five years. All measurements were taken at baseline, one and five year follow-up, except for objectively measured physical activity which was assessed at one and five year follow up, and PCC at one-year follow-up..

Measurements and outcomes

Self-reported health behavior

Physical activity and dietary intake were assessed by self-report using the validated EPAQ-2 (EPIC physical activity questionnaire) and semi-quantitative food frequency questionnaire.[16,17] Alcohol intake and smoking status (categorized as never smoked, ex-smoker or current smoker) were assessed by self-report questionnaire.

Objective measures of health behaviour

Physical activity was measured using a combined heart rate and movement sensor (Actiheart, CamNtech, Cambridge, UK) worn for at least three consecutive days, as described previously.[16] Resulting time-series data were summarised into physical activity energy expenditure (PAEE, in kJ/kg/day) – a measure of total physical activity, sedentary time (hours/day) and moderate-to-vigorous physical activity (min/day).[18] Plasma vitamin C levels (which offer an objective biomarker measure of fruit and vegetable intake) [17] were measured using a Fluoroskan Ascent FL fluorometer. [17,19]

Clinical and biochemical measures

Clinical and biochemical measures were collected by trained staff following standardised protocols, as described elsewhere.[15] Blood pressure was calculated as the mean of three measurements using an automatic sphygmomanometer. Body weight and height were measured in light clothing and without shoes using a scale (SECA, UK) and a fixed rigid stadiometer, respectively. [15] Venous blood samples were collected for analysis of lipid levels and HbA_{1c}. Modelled 10 year cardiovascular risk was calculated using the UK Prospective Diabetes Study (UKPDS) risk engine (version 3.0).

Patient-centred care

Participants completed a questionnaire on PCC experiences in relation to their GPs over the preceeding year, in relation to diabetes care using the consultation and relational empathy (CARE) measure at one year follow-up.[20] The CARE measure is a holistic, patient-centred, uni-dimensional measure assessing the quality of consultations in terms of the 'human' aspects (empathic process) of care in the context of a doctor-patient interaction, from the patient's perspective. The CARE questionnaire has been shown to be meaningful to patients, acceptable and easy to complete. It has been developed and extensively validated within the primary care setting, where the vast majority of type 2 diabetes care occurs in the UK.[21] The CARE measure includes 10 questions based on a Likert scale ranging from 1 to 5. A CARE summary measure was derived by summing the individual scores from the 10 individual questions, with a possible range of 10-50. [21]

Statistical Analysis

Participant characteristics were summarised at baseline, one and five year follow-up using means (SDs) or frequencies. Participants with incomplete data across time points were excluded from the analyses. Multivariate linear regression models were constructed to examine the prospective associations between baseline and one year follow-up, and between one and five year follow-up between patient-centred care measures and: 1) change in self-reported health behaviours; 2) change in objective health behaviours; 3) changes in biochemical and clinical measures, and 4) change in modelled 10 year cardiovascular risk. As physical activity was not measured objectively at baseline, this was examined cross-sectionally at one year. All models were adjusted, based on a priori reasoning, for age, sex, socio-economic group, ethnicity, trial group, relevant medication use (ie change in blood pressure, lipid or diabetes medications). Statistical analysis was performed using STATA/SE 13.1 (STATA-Corp, College Station, TX). Statistical significance was set at $P<0.05$.

Results

Participant characteristics

396 *ADDITION-Plus* participants had complete data and were included in these analyses. Participants had a mean (SD) age of 61 (6.9) years;the majority were Caucasian (96%) and male (63%) (Table 1). 74% of participants were in part or full-time employment and most continued in full-time education after the age of 16 years (61%). Baseline mean (SD) HbA_{1c} was 7.1 (1.4)% (49.7 mmol/mol) (1.3). Change in clinical and biochemical variables at baseline, one and five year follow-up are summarised in Table 2. Mean BMI, waist circumference, HbA_{1c}, blood pressure and cholesterol levels improved over the five years of follow-up. The mean (SD) CARE score was 39 (9.8) at one-year follow-up. There were no significant differences in age, sex, ethnicity, employment status, social class, education, smoking status, blood pressure, lipid profile, waist circumference and ten-year modelled cardiovascular risk between participants with and without missing data for these analyses.

Self-reported health behaviours

Analysis of change from baseline to one year follow-up showed that participants reporting better experiences of PCC were more likely to increase their self-reported physical activity by small amounts, including total activity energy expenditure (beta-coefficient: 0.080 MET hrs/day [95% CI: 0.017, 0.143], moderate-to-vigorous physical activity (MVPA; beta-coefficient: 5.328 minutes/day [95% CI: 0.796, 9.859]), and reduce sedentary time (beta-coefficient: -1.633 min/day [95% CI: -2.897, -0.368]). (Table 3) We observed no clear associations between PCC and self-reported diet or alcohol intake. Over a longer follow-up from one to five years, there was no clear evidence that better experiences of PCC were associated with change in self-reported physical activity, diet or alcohol intake(Table 3). We have not reported on change in smoking status as too few (n=12) participants quit or started smoking to enable this to be examined.

Objective health behaviours

Over the first year of follow up, there was no evidence that better experience of PCC were associated with objectively measured physical activity or diet (fruit and vegetable intake measured with plasma vitamin C levels). Similarly, analysis of change between one and five years also demonstrated no associations between PCC and objectively measured diet or physical activity. These results are summarised in Table 3.

Clinical and biochemical measures

Analysis of change over the first year of follow-up demonstrated that participants with better experiences of PCC had marginally greater increases in HDL-cholesterol (beta-coefficient: 0.002 mmol/L [95% CI: 0.001, 0.004]) and decreases in both systolic blood pressure (beta-coefficient: -0.561 mm Hg [95% CI: -0.653, -0.468]) and diastolic blood pressure (beta-coefficient: -0.565 mm Hg [95% CI: -0.654, -0.476]). As shown in Table 3, there were no other associations between baseline and one year in clinical and biochemical measures. Over the longer five year follow up, there were no associations between PCC and clinical or biochemical outcomes, except for waist circumference (beta-coefficient: 0.085 cm [95% CI: 0.015, 0.155]) which increased with higher PCC.

Discussion

Better experience of PCC early after the diagnosis of type 2 diabetes was associated with a small, but not clinically meaningful change in self-reported physical activity, time spent sedentary, and improvements in HDL-cholesterol and blood pressure at one year. This was not reflected in the objective measures of physical activity. Over the longer term, we found no evidence to suggest that PCC was associated with changes in health behaviours or CVD risk factor levels. This study provides insufficient evidence that patients with recently diagnosed type 2 diabetes who have better experiences of PCC are more likely to improve cardiovascular risk factor levels via changes in patient health behaviours.

To the best of our knowledge, this is the first study to use objective measures of health behaviours alongside self-reported health behaviours to quantify the impact of experiences of PCC in a population with recently diagnosed type 2 diabetes. Furthermore, it includes a relatively long duration of follow-up of five years. We observed discrepancies in associations between PCC and self-reported, and objectively measured physical activity and diet. This highlights the

potential bias associated with patient self-report questionnaires in previous studies. Other strengths include the use of a large number of GP surgeries which reflect average UK GP list sizes, diabetes prevalence, doctor or nurse whole time equivalent and patient experiences of diabetes care. Further, more than 50% of practices that were approached agreed to participate in the original study. The participant follow-up rate was also high at 95% at year follow-up and 83% at the five year follow-up. In relation to previous literature on PCC, this cohort study also includes a relatively large sample size. Additional strengths include our measure of PCC; while some previous studies have used non-specific and non-validated patient satisfaction questionnaires as a marker of PCC, we used the validated CARE measure. [4,7,20,22] The validity and reliability of the CARE measure has been extensively demonstrated, and applied in over 3,000 general practice consultations in areas of high and low deprivation and across multiple health conditions.

A number of limitations of our study also warrant discussion. We measured PCC at a single time point at one year follow up which may explain differences between one and five year results. Further, because doctor-patient relationships are dynamic and are established or changed over time ,[23] we were not able to examine how changes in experiences of PCC might affect health behaviours and CVD risk factor levels. The majority of participants were Caucasian males with high levels of education and employment, thereby limiting the generalisability of our findings as experiences of PCC and diabetes care may differ in a more ethnically diverse or socially deprived populations. The majority of participants reported high CARE scores which, due to hetereogeneity, will likely have reduced our ability to identify associations with health outcomes. Finally,we also conducted a number of hypothesis tests and as a result we cannot exclude the role of chance as a plausible explanation for our findings.

Previous studies examining the association of interventions to alter PCC and CVD risk factor levels in type 2 diabetes have reported mixed results. This may be related to the fact that PCC is a broad term with multiple descriptions and measures, and therefore a high level of heterogeneity exists between studies on this subject. [24] We found positive associations, albeit clinically not meaningful, between PCC and self-reported physical activity level, blood pressure and HDL-cholesterol, that is – people with better PCC experiences reported being more physically active and had higher HDL-cholesterol levels and lower blood pressures at one year. This is consistent with some previous observational and trial data [25–29], except our study includes objective measures and therefore overcomes some of the limitations associated with previous self-reported data. Several studies have also reported inverse associations between PCC and non HDL-cholesterol [25,28,29], BMI, HbA_{1c} [30–33] and cardiovascular risk [34]. We did not observe such associations at one or five year follow-up. [7,25,32] Differences may have been because our study was underpowered to detect these changes, or might be related to our measure of PCC. Our study is the first to use the CARE measure as a specific marker of PCC focusing on empathy in recently diagnosed type 2 diabetes patients that were followed up over a five year period.[21] These differences, as well as the potential role of chance, may also explain the positive, albeit small, unexpected association between PCC and waist circumference.

Further, baseline measures also vary across studies which may explain differences in findings. For example, mean HbA_{1c} in participants in our cohort at baseline was 7.1%. A recent large study in type 2 diabetes within secondary care demonstrated significant reductions in HbA_{1c} following a PCC intervention.[33] This study suggested that a PCC approach may be most effective in improving glycaemic control when baseline HbA_{1c} is over 8.5%, and reported modest effects in patients with an HbA_{1c} below 7%. Previous studies in primary care have similarly demonstrated a greater effect of PCC when baseline HbA_{1c} was high [30–32]. We therefore carried out a post-hoc analysis including only participants with HbA_{1c} over 8.5% at baseline, and found stronger associations between PCC, physical activity,

and HbA_{1c}, non-HDL cholesterol and BMI, but these associations did not reach statistical significance, likely owing to the reduction is sample size and therefore statistical power.

The literature is bedeviled with lack of clear definition and measures of PCC in terms of interactions with health professionals.[24,36,37] More frequent use of standardised and validated measures of PCC in future research will reduce heterogeneity and allow comparison between studies on PCC. Further, most studies use self-reported measures of health behaviours which are prone to reporting error and bias, as demonstrated by the lack of consistency between our subjective and objective assessments. Social desirability bias may be one explanation for the higher levels of self-reported health behaviours compared to objective health behaviours observed in our study. This highlights the need for future research to include objective measures of outcomes. Further, we could not exclude reverse causality as a potential explanation for this and previous findings. Future well conducted trials alongside qualitative work are essential to explore the mechanism linking PCC, health behaviours and outcomes. Also, we found stronger associations between PCC among people with poor glycaemic control, albeit not significant. This has been suggested previously [33], and future research will need to stratify disease severity and patient groups to further examine the role of PCC in these particular groups of patients.

Current NHS health care policy emphasizes the importance of 'making every contact count', and highlights the role that GPs have to play in modifying health behaviours and secondary disease risk. Our study provides insufficient evidence to exclude that PCC is associated with improvements in health related behaviours or CVD risk factor levels in the first five years following diagnosis. Although PCC is preferred by our patients and often considered a moral imperative or the 'right thing' for clinicians to do, it is important to adequately balance PCC against evidence-based disease management strategies in type 2 diabetes.[35]

Ethical approval: All participants provided written informed consent, and ethics committee approval was obtained from the Eastern Multi-Centre Research Ethics Committee (reference number: 02/5/54). The trial was registered as **ISRCTN 99175498.**

Competing interests: We have read and understood the policy on declaration of interests and declare that we have no competing interests**.** All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: all authors had financial support from the University of Cambridge for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work."

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Contributors: HD conducted the analysis of the data, wrote the analysis plan, drafted and revised the paper. AJMC conducted analysis and revised the paper. RKS revised the paper. SJG and ALK initiated the project, designed the ADDITION trial and data collection tools, implemented the trial, monitored data collection for the whole trial, and revised the paper. SJG is guarantor.

Transparency declaration: SJG can affirm that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted

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Table 1: Baseline characteristics in the ADDITION-Plus trial cohort (n =396)

Variables	Mean ± SD
Socio-demographic characteristics	
Male sex, n (%)	252 (63.1)
Age at baseline (years)	61 (6.9)
White ethnic origin, n (%)	379 (96)
Employed, n (%)	296 (74)
Social Class, n (%)	
High	170(43.4)
Manual	173(44.3)
non-manual	48(12.2)
Education, n (%)	
Full-time education finished at <16years	150 (38.4)
Full-time education finished at 16-18years	172 (44.0)
Full-time education finished at >18years	69 (17.6)
Past Medical History	
History of angina, n (%)	47(10.7)
History of hypertension, n (%)	175(40.2)
History of any cardiovascular disease including AF	50(11.6)
History of myocardial infarct, n (%)	31(7.26)
History of hypercholesterolemia, n (%)	197(46.9)
History of stroke, n (%)	13(3.1)
Self-reported drug use	
Any glucose-lowering drug, n (%)	126(32)
Any antihypertensive drug, n (%)	280(71)
Any cholesterol-lowering drug, n (%)	205(52)
Self-reported lifestyle	
Physical activity Energy Expenditure , mean (SD) (kJ/kg/day)	29(7.4)
Smoking status, n (%)	
Current smoker	55(14)
Ex-smoker	196(49.7)
Never smoker	142(36)
Alcohol per week (units), mean (SD)	9(13.9)

Values are presented as mean (SD) unless specified

Table 2: Clinical variables of participants with complete data at all three time points

	N	Baseline	one year follow up	five year follow up
Clinical characteristics				
BMI (kg/m²)	383	32.4(5.6)	31.8 (5.1)	31.9 (5.4)
Waist circumference (cm)	383	109.9 (13.0)	108.6 (12.8)	107.9 (13.6)
HbA_{1c} (%), mean (SD)	387	7.1(1.4)	6.6 (0.9)	6.9 (0.9)
Systolic blood pressure (mm Hg)	396	136.8 (19.7)	130.2(17.7)	132.2 (16.4)
Diastolic blood pressure (mm Hg)	396	80.7 (10.6)	76.4 (9.5)	73.9 (9.8)
Total cholesterol (mmol/L)	390	4.9 (1.06)	4.3(0.8)	4.2(0 .9)
HDL cholesterol (mmol/L)	390	1.2 (0 .3)	1.2 (0.3)	1.3 (0.3)
LDL cholesterol (mmol/L)	390	2.9 (0.9)	2.3 (0 .7)	2.1(0.7)

Values are mean (SD)

Table 3 : Linear associations between patient-centred care and outcomes at one year and five year follow-up in Addition-Plus cohort

		Changes from 0-1 year follow up				Changes from 1-5 year follow up			
Variable	**N**	**Co-efficient**	**95% CI**		**P-value**	**Co-efficient**	**95% CI**		**P-value**
Self-reported Measures									
Total activity energy expenditure (MET hrs/day)	371	0.080	0.017	0.143	0.01	-0.037	-0.318	0.243	0.79
Sedentary time (min/day)	371	-1.633	-2.897	-0.368	0.01	0.014	-0.010	0.037	0.25
Moderate to vigorous physical activity (min/day)	371	5.328	0.796	9.859	0.01	-0.241	-0.880	0.400	0.46
Energy intake (kJ/day)	371	0.920	-3.960	5.810	0.71	0.012	0.001	0.001	0.51
Alcohol per week (units)	371	0.022	-0.037	0.081	0.47	-0.022	-0.085	0.041	0.49
Objectively measured health behaviours									
Physical activity energy expenditure (kJ/kg/day)[a]	308	-0.001	-0.166	0.164	0.99	-0.014	0.850	-0.100	0.08
Plasma Vitamin C (µmol/L)	303	-0.231	-0.462	<0.001	0.05	-0.040	-0.100	0.020	0.17
Clinical and biochemical measures									
HbA_{1c} (%)[b]	387	-0.006	-0.015	0.004	0.23	0.004	-0.005	0.013	0.39
Systolic blood pressure (mm Hg)[c]	396	-0.561	-0.653	-0.468	0.01	0.107	-0.053	0.267	0.19
Diastolic blood pressure (mm Hg)[c]	396	-0.565	-0.654	-0.476	0.01	0.064	-0.031	0.159	0.19
Total cholesterol (mmol/L)[d]	390	0.002	-0.006	0.011	0.58	0.001	-0.008	0.010	0.83
HDL cholesterol (mmol/L) [d]	390	0.002	0.001	0.004	0.03	-0.002	-0.004	0.001	0.17
LDL cholesterol (mmol/L) [d]	390	0.007	0.001	0.014	0.07	0.001	-0.007	0.007	0.99
Waist circumference (cm)	383	-0.060	-0.120	0.011	0.07	0.085	0.015	0.155	0.02
BMI (kg/m²)	383	-0.010	-0.031	0.006	0.19	0.013	-0.010	0.036	0.27
Modelled UKPDS 10-year cardiovascular risk [e]	390	0.001	-0.001	<0.001	0.54	0.001	-0.001	0.001	0.51

[a] measured at one year only
[b] adjusted for sex, age, ethnicity, social class and hypoglycaemic medication
[c] adjusted for sex, age, ethnicity, social class and anti-hypertensive medication
[d] adjusted for sex, age, ethnicity, social class and lipid lowering therapy
[e] adjusted for sex, age, ethnicity, social class, lipid lowering therapy, anti-hypertensive and hypoglycaemic medication

STROBE Statement—checklist of items that should be included in reports of observational studies

Patient-centred care, health behaviours and cardiovascular risk factor levels in people with recently diagnosed type 2 diabetes: 5 year follow-up of the ADDITION-plus trial cohort

	Item No	Recommendation
Title and abstract	1	(*a*) Cohort study in title included page 1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found – provided on page 1
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported – included this page 2
Objectives	3	Stated on page 1
Methods		
Study design	4	Present key elements of study design early in the paper – included this page 1
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection (clearly included, general practice) page 1 and page 3
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up. Explained follow up at one and five years. Page 3
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable – included exposures and outcomes page 3
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group, page 3
Bias	9	Describe any efforts to address potential sources of bias – discussed in limitations page 5-6
Study size	10	Explain how the study size was arrived at- explained from ADDITION trial page 2
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why page 2
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding Page 4
		(*b*) Describe any methods used to examine subgroups and interactions
		(*c*) Explain how missing data were addressed – excluded from analysis page 4
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *High follow up rate discussed, page 4 and 5*
		(*e*) Describe any sensitivity analyses - nad

Continued on next page

Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed, page 4 and 5
		(b) Give reasons for non-participation at each stage n/a
		(c) Consider use of a flow diagram n/a
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders, table provided page 11 and 12
		(b) Indicate number of participants with missing data for each variable of interest page 11
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount) page 11
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time page 11
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included page 1, and results on page 4 and table on page 11
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses - NA
Discussion		
Key results	18	Summarise key results with reference to study objectives page 5
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias page 5 and 5
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence page 6
Generalisability	21	Discuss the generalisability (external validity) of the study results page 6 and 7
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based, page 8

BMJ Open

Patient-centred care, health behaviours and cardiovascular risk factor levels in people with recently diagnosed type 2 diabetes: 5 year follow-up of the ADDITION-plus trial cohort

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Patient-centred care, health behaviours and cardiovascular risk factor levels in people with recently diagnosed type 2 diabetes: 5 year follow-up of the ADDITION-plus trial cohort

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Abstract

Objective: To examine the association between the experience of patient-centred care (PCC), health behaviours and cardiovascular disease (CVD) risk factor levels among people with type 2 diabetes.

Design: Population-based prospective cohort study

Setting: 34 general practices in East Anglia UK, delivering organised diabetes care.

Participants: 478 recently diagnosed type 2 diabetes patients aged between 40 and 69 years enrolled in the ADDITION-Plus trial.

Main outcome measures: Self-reported and objectively measured health behaviours (diet, physical activity, smoking status), CVD risk factor levels (blood pressure, lipid levels, HbA_{1c}, BMI, waist circumference) and modelled 10 year CVD risk).

Results: Better experiences of PCC early in the course of living with diabetes were not associated with meaningful differences in self-reported physical activity levels including total activity energy expenditure (beta-coefficient: 0.080 MET hrs/day [95% CI: 0.017, 0.143] (p=0.01)) , moderate-to-vigorous physical activity (MVPA; beta-coefficient: 5.328 minutes/day [95% CI: 0.796, 9.859] (p=0.01)), and reduced sedentary time (beta-coefficient: -1.633 min/day [95% CI: -2.897, -0.368] (p=0.01)). PCC was not associated with clinically meaningful differences in levels of HDL-cholesterol (beta-coefficient: 0.002 mmol/L [95% CI: 0.001, 0.004](p=0.03)) systolic blood pressure (beta-coefficient: -0.561 mm Hg [95% CI: -0.653, -0.468](p=0.01)), or diastolic blood pressure (beta-coefficient: -0.565 mm Hg [95% CI: -0.654, -0.476] (p=0.01)). Over an extended follow up of five years, we observed no clear evidence that PCC was associated with self-reported, clinical or biochemical outcomes, except for waist circumference (beta-coefficient: 0.085 cm [95% CI: 0.015, 0.155] (p=0.02)).

Conclusion: We found little evidence that experience of PCC early in the course of diabetes was associated with clinically important changes in health related behaviours or CVD risk factors.

Keywords

General practice, type 2 diabetes, cardiovascular risk, patient-centred care, physical activity, diet

Strengths and limitations of this study

- Our study is the first to use objective measures of health behaviours to examine the impact of patient-centred care in recently diagnosed type 2 diabetes.
- The study duration is five years with high rates of follow up.
- We included a large number of GP surgeries that reflects the average UK GP list size, number of doctors/nurses and diabetes prevalence.
- Patient-centred care was only measured at a single time point.
- The majority of our participants were Caucasian males with high levels of education and employment, thereby limiting the generalisability of our findings

Introduction

Type 2 diabetes is a common condition mostly managed in general practice. Despite current lifestyle and medication treatments, patients with diabetes still have high rates of cardiovascular disease (CVD) morbidity and mortality. [1] Patient-centred care (PCC) is considered the cornerstone of UK general practice and may play an important role in the management of CVD risk factor levels.[2] By understanding individual health beliefs, considering patient preferences, and developing mutual management plans, GPs may be able to positively influence health behaviours such as diet, physical activity, smoking and alcohol intake, each of which are known to influence CVD risk factor levels. [3] This potentially effective and cost-effective role for GPs in influencing patient health behaviours has recently been emphasised in national and international health policy.[4–6] The majority of supporting evidence comes from observational data reporting inverse associations between PCC and CVD risk factor levels.[7] Trial findings have been more variable with some studies reporting no effect from interventions promoting PCC, while others report reduced CVD risk factor levels including HbA_{1c}, blood pressure, cholesterol and BMI. [3,8–10] There is currently insufficient evidence to confirm whether PCC influences CVD risk factor levels among patients with diabetes, and the mechanism to explain any associations remains unclear. We hypothesize that the mechanism linking PCC to CVD risk factor levels is through patient health behaviours.[11]

The majority of diabetes care occurs in general practice where there is increasing pressure on GP consultation time. This is leading to a range of alternative chronic disease management strategies such as more routinised care, telehome care and remote monitoring, each of which may diminish PCC.[12–14] With the need to optimize efficiency as well as effectiveness in diabetes care, it is increasingly important to assess the experience of PCC in improving disease risk. Evidence for the role of PCC in cost-effective diabetes care is needed to inform policy and has implications for the management of chronic disease more widely.

We aimed to quantify the association between the experience of PCC delivered by GPs and CVD risk factor levels at one and five year follow-up in a well characterised cohort of recently diagnosed type 2 diabetes patients. To enable better understanding of the potential mechanisms underlying this association, we also examined associations between PCC and health behaviours.

Methods

Study design

A detailed description of the *ADDITION-Plus* study design and rationale can be found elsewhere.[15] In brief, *ADDITION-Plus* is a randomised controlled trial among 34 general practices across East Anglia, UK. *ADDITION-Plus* examined the efficacy of a facilitator-led, theory-based behaviour change intervention for individuals with recently diagnosed type 2 diabetes. In total 478 out of 1,109 eligible individuals agreed to participate and were individually randomised to receive either intensive treatment alone ($n = 239$) or intensive treatment plus a facilitator-led individual behaviour change intervention ($n = 239$). The trial was not designed to influence patient-practitioner interactions and there were no differences in PCC measures, health behaviours, CVD risk factor levels between trial groups at one year, and no differences in the proceeding multivariate analyses between trial arms. Therefore, data for this analysis were pooled and treated as a cohort analysis. Participants in the trial were followed up for five years. All measurements were taken at baseline, one and five year follow-up, except for objectively measured physical activity which was assessed at one and five year follow up, and PCC at one-year follow-up. All participants gave written informed consent, and the study was approved by the Eastern Multi-Centre Research Ethics Committee (reference number 02/5/54). The trial is registered as ISRCTN99175498.

Measurements and outcomes

Self-reported health behavior

Physical activity and dietary intake were assessed by self-report using the validated EPAQ-2 (EPIC physical activity questionnaire) and semi-quantitative food frequency questionnaire.[16,17] Alcohol intake and smoking status (categorized as never smoked, ex-smoker or current smoker) were assessed by self-report questionnaire.

Objective measures of health behaviour

Physical activity was measured using a combined heart rate and movement sensor (Actiheart, CamNtech, Cambridge, UK) worn for at least three consecutive days, as described previously.[16] Resulting time-series data were summarised into physical activity energy expenditure (PAEE, in kJ/kg/day) – a measure of total physical activity, sedentary time (hours/day) and moderate-to-vigorous physical activity (min/day).[18] Plasma vitamin C levels (which offer an objective biomarker measure of fruit and vegetable intake) [17] were measured using a Fluoroskan Ascent FL fluorometer. [17,19]

Clinical and biochemical measures

Clinical and biochemical measures were collected by trained staff following standardised protocols, as described elsewhere.[15] Blood pressure was calculated as the mean of three measurements using an automatic sphygmomanometer. Body weight and height were measured in light clothing and without shoes using a scale (SECA, UK) and a fixed rigid stadiometer, respectively. [15] Venous blood samples were collected for analysis of lipid levels

and HbA_{1c}. Modelled 10 year cardiovascular risk was calculated using the UK Prospective Diabetes Study (UKPDS) risk engine (version 3.0).

Patient-centred care

PCC is a challenging concept to study or measure as there are multiple definitions and tools within the literature. At its core, PCC seeks to encompass the management of biophysical markers, alongside the human experience of disease. The CARE measure is a holistic tool that attempts to capture PCC with a focus on the quality of consultations in terms of the 'human' aspects. (empathic process of care) This is in the context of a doctor-patient interaction and from the patient's perspective. The CARE questionnaire is a measure that has been shown to be meaningful to patients, acceptable and easy to complete. It has been developed and extensively validated within the primary care setting, where the vast majority of type 2 diabetes care occurs in the UK.[20] The CARE measure includes 10 questions based on a Likert scale ranging from 1 to 5. A CARE summary measure was derived by summing the individual scores from the 10 individual questions, with a possible range of 10-50. [20]Participants completed a questionnaire on PCC experiences in relation to their GPs over the preceeding year, in relation to diabetes care using the consultation and relational empathy (CARE) measure at one year follow-up.[21]

Statistical Analysis

Participant characteristics were summarised at baseline, one and five year follow-up using means (SDs) or frequencies. Participants with incomplete data across time points were excluded from the analyses. Multivariate linear regression models were constructed to examine the prospective associations between baseline and one year follow-up, and between one and five year follow-up between patient-centred care measures and: 1) change in self-reported health behaviours; 2) change in objective health behaviours; 3) changes in biochemical and clinical measures, and 4) change in modelled 10 year cardiovascular risk. As physical activity was not measured objectively at baseline, this was examined cross-sectionally at one year. All models were adjusted, based on a priori reasoning, for age, sex, socio-economic group, ethnicity, trial group, relevant medication use (ie change in blood pressure, lipid or diabetes medications). Statistical analysis was performed using STATA/SE 13.1 (STATA-Corp, College Station, TX). Statistical significance was set at $P<0.05$.

Results

Participant characteristics

396 *ADDITION-Plus* participants had complete data and were included in these analyses. Participants had a mean (SD) age of 61 (6.9) years;the majority were Caucasian (96%) and male (63%) (Table 1). 74% of participants were in part or full-time employment and most continued in full-time education after the age of 16 years (61%). Baseline mean (SD) HbA_{1c} was 7.1 (1.4)% (49.7 mmol/mol) (1.3). Change in clinical and biochemical variables at baseline, one and five year follow-up are summarised in Table 2. Mean BMI, waist circumference, HbA_{1c}, blood pressure and cholesterol levels improved over the five years of follow-up. The mean (SD) CARE score was 39 (9.8) at one-year follow-up. There were no significant differences in age, sex, ethnicity, employment status, social class, education, smoking status, blood pressure, lipid profile, waist circumference and ten-year modelled cardiovascular risk between participants with and without missing data for these analyses.

Self-reported health behaviours

Analysis of change from baseline to one year follow-up showed that participants reporting better experiences of PCC were more likely to increase their self-reported physical activity by small amounts, including total activity energy expenditure (beta-coefficient: 0.080 MET hrs/day [95% CI: 0.017, 0.143], moderate-to-vigorous physical activity (MVPA; beta-coefficient: 5.328 minutes/day [95% CI: 0.796, 9.859]), and reduce sedentary time (beta-coefficient: -1.633 min/day [95% CI: -2.897, -0.368]). (Table 3) We observed no clear associations between PCC and self-reported diet or alcohol intake. Over a longer follow-up from one to five years, there was no clear evidence that better experiences of PCC were associated with change in self-reported physical activity, diet or alcohol intake(Table 3). We have not reported on change in smoking status as too few (n=12) participants quit or started smoking to enable this to be examined.

Objective health behaviours

Over the first year of follow up, there was no evidence that better experience of PCC were associated with objectively measured physical activity or diet (fruit and vegetable intake measured with plasma vitamin C levels). Similarly, analysis of change between one and five years also demonstrated no associations between PCC and objectively measured diet or physical activity. These results are summarised in Table 3.

Clinical and biochemical measures

Analysis of change over the first year of follow-up demonstrated that participants with better experiences of PCC had marginally greater increases in HDL-cholesterol (beta-coefficient: 0.002 mmol/L [95% CI: 0.001, 0.004]) and decreases in both systolic blood pressure (beta-coefficient: -0.561 mm Hg [95% CI: -0.653, -0.468]) and diastolic blood pressure (beta-coefficient: -0.565 mm Hg [95% CI: -0.654, -0.476]). As shown in Table 3, there were no other associations between baseline and one year in clinical and biochemical measures. Over the longer five year follow up, there were no associations between PCC and clinical or biochemical outcomes, except for waist circumference (beta-coefficient: 0.085 cm [95% CI: 0.015, 0.155]) which increased with higher PCC.

Discussion

Better experience of PCC early after the diagnosis of type 2 diabetes was associated with a small, but not clinically meaningful change in self-reported physical activity, time spent sedentary, and improvements in HDL-cholesterol and blood pressure at one year. This was not reflected in the objective measures of physical activity. Over the longer term, we found no evidence to suggest that PCC was associated with changes in health behaviours or CVD risk factor levels. This study provides insufficient evidence that patients with recently diagnosed type 2 diabetes who have better experiences of PCC are more likely to improve cardiovascular risk factor levels via changes in patient health behaviours.

To the best of our knowledge, this is the first study to use objective measures of health behaviours alongside self-reported health behaviours to quantify the impact of experiences of PCC in a population with recently diagnosed type 2 diabetes. Furthermore, it includes a relatively long duration of follow-up of five years. We observed discrepancies in associations between PCC and self-reported, and objectively measured physical activity and diet. This highlights the potential bias associated with patient self-report questionnaires in previous studies. Other strengths include the use of a large number of GP surgeries which reflect average UK GP list sizes, diabetes prevalence, doctor or nurse whole time equivalent and patient experiences of diabetes care. Further, more than 50% of practices that were approached agreed to participate in the original study. The participant follow-up rate was also high at 95% at year follow-up and 83% at the five year follow-up. In relation to previous literature on PCC, this cohort study also includes a relatively large sample size. Additional strengths include our measure of PCC; while some previous studies have used non-specific and non-validated patient satisfaction questionnaires as a marker of PCC, we used the validated CARE measure. [8,10,21,22] The validity and reliability of the CARE measure has been extensively demonstrated, and applied in over 3,000 general practice consultations in areas of high and low deprivation and across multiple health conditions.

A number of limitations of our study also warrant discussion. We measured PCC at a single time point at one year follow up which may explain differences between one and five year results. Further, because doctor-patient relationships are dynamic and are established or changed over time ,[23] we were not able to examine how changes in experiences of PCC might affect health behaviours and CVD risk factor levels. The majority of participants were Caucasian males with high levels of education and employment, thereby limiting the generalizability of our findings as experiences of PCC and diabetes care may differ in a more ethnically diverse or socially deprived populations. The majority of participants reported high CARE scores which, due to homogeneity , will likely have reduced our ability to identify associations with health outcomes. Finally,we also conducted a number of hypothesis tests and as a result we cannot exclude the role of chance as a plausible explanation for our findings.

Previous studies examining the association of interventions to alter PCC and CVD risk factor levels in type 2 diabetes have reported mixed results. This may be related to the fact that PCC is a broad term with multiple descriptions and measures, and therefore a high level of heterogeneity exists between studies on this subject. [24] We found positive associations, albeit clinically not meaningful, between PCC and self-reported physical activity level, blood pressure and HDL-cholesterol, that is – people with better PCC experiences reported being more physically active and had higher HDL-cholesterol levels and lower blood pressures at one year. This is consistent with some previous observational and trial data [25–29], except our study includes objective measures and therefore overcomes some of the limitations associated with previous self-reported data. Several studies have also reported inverse associations between PCC and non HDL-cholesterol [25,28,29], BMI, HbA_{1c} [30–32] and cardiovascular risk [33]. We did not observe such associations at one or five year follow-up. [10,25,31] Differences may have been because our study was underpowered to detect these changes, or might be related to our measure of PCC. Our study is the first to use the CARE measure as a specific marker of PCC focusing on empathy in recently diagnosed type 2 diabetes patients that were followed up over a five year period.[20] These differences, as well as the potential role of chance, may also explain the positive, albeit small, unexpected association between PCC and waist circumference.

Further, baseline measures also vary across studies which may explain differences in findings. For example, mean HbA_{1c} in participants in our cohort at baseline was 7.1%. A recent large study in type 2 diabetes within secondary care demonstrated significant reductions in HbA_{1c} following a PCC intervention.[32] This study suggested that a PCC

approach may be most effective in improving glycaemic control when baseline HbA_{1c} is over 8.5%, and reported modest effects in patients with an HbA_{1c} below 7%. Previous studies in primary care have similarly demonstrated a greater effect of PCC when baseline HbA_{1c} was high [22,30,31,34]. We therefore carried out a post-hoc analysis including only participants with HbA_{1c} over 8.5% at baseline, and found stronger associations between PCC, physical activity, and HbA_{1c}, non-HDL cholesterol and BMI, but these associations did not reach statistical significance, likely owing to the reduction is sample size and therefore statistical power.

The literature is bedeviled with lack of clear definition and measures of PCC in terms of interactions with health professionals.[24,35,36] More frequent use of standardised and validated measures of PCC in future research will reduce heterogeneity and allow comparison between studies on PCC. Further, most studies use self-reported measures of health behaviours which are prone to reporting error and bias, as demonstrated by the lack of consistency between our subjective and objective assessments. Social desirability bias may be one explanation for the higher levels of self-reported health behaviours compared to objective health behaviours observed in our study. This highlights the need for future research to include objective measures of outcomes. Further, we could not exclude reverse causality as a potential explanation for this and previous findings. Future well conducted trials alongside qualitative work are essential to explore the mechanism linking PCC, health behaviours and outcomes. Also, we found stronger associations between PCC among people with poor glycaemic control, albeit not significant. This has been suggested previously [32], and future research will need to stratify disease severity and patient groups to further examine the role of PCC in these particular groups of patients.

Current NHS health care policy emphasizes the importance of 'making every contact count', and highlights the role that GPs have to play in modifying health behaviours and secondary disease risk. Our study provides insufficient evidence to exclude that PCC is associated with improvements in health related behaviours or CVD risk factor levels in the first five years following diagnosis. Although PCC is preferred by our patients and often considered a moral imperative or the 'right thing' for clinicians to do, it is important to adequately balance PCC against evidence-based disease management strategies in type 2 diabetes.[37]

Ethical approval: All participants provided written informed consent, and ethics committee approval was obtained from the Eastern Multi-Centre Research Ethics Committee (reference number: 02/5/54). The trial was registered as **ISRCTN 99175498.**

Competing interests: We have read and understood the policy on declaration of interests and declare that we have no competing interests**.** All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare no financial relationships with any organisations that might have an interest in the submitted work in the previous three years; no other relationships or activities that could appear to have influenced the submitted work.

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Contributors: HD conducted the analysis of the data, wrote the analysis plan, drafted and revised the paper. AJMC conducted analysis and revised the paper. RKS revised the paper. SJG and ALK initiated the project, designed the ADDITION trial and data collection tools, implemented the trial, monitored data collection for the whole trial, and revised the paper. SJG is guarantor.

Transparency declaration: SJG can affirm that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted

Data sharing:

No additional data available.

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Table 1: Baseline characteristics in the ADDITION-Plus trial cohort (n =396)

Variables	Mean ± SD
Socio-demographic characteristics	
Male sex, n (%)	252 (63.1)
Age at baseline (years)	61 (6.9)
White ethnic origin, n (%)	379 (96)
Employed, n (%)	296 (74)
Social Class, n (%)	
High	170(43.4)
Manual	173(44.3)
non-manual	48(12.2)
Education, n (%)	
Full-time education finished at <16years	150 (38.4)
Full-time education finished at 16-18years	172 (44.0)
Full-time education finished at >18years	69 (17.6)
Past Medical History	
History of angina, n (%)	47(10.7)
History of hypertension, n (%)	175(40.2)
History of any cardiovascular disease including AF	50(11.6)
History of myocardial infarct, n (%)	31(7.26)
History of hypercholesterolemia, n (%)	197(46.9)
History of stroke, n (%)	13(3.1)
Self-reported drug use	
Any glucose-lowering drug, n (%)	126(32)
Any antihypertensive drug, n (%)	280(71)
Any cholesterol-lowering drug, n (%)	205(52)
Self-reported lifestyle	
Physical activity Energy Expenditure , mean (SD) (kJ/kg/day)	29(7.4)
Smoking status, n (%)	
Current smoker	55(14)
Ex-smoker	196(49.7)
Never smoker	142(36)
Alcohol per week (units), mean (SD)	9(13.9)

Values are presented as mean (SD) unless specified

Table 2: Clinical variables of participants with complete data at all three time points

	N	Baseline	one year follow up	five year follow up
Clinical characteristics				
BMI (kg/m²)	383	32.4(5.6)	31.8 (5.1)	31.9 (5.4)
Waist circumference (cm)	383	109.9 (13.0)	108.6 (12.8)	107.9 (13.6)
HbA_{1c} (%), mean (SD)	387	7.1(1.4)	6.6 (0.9)	6.9 (0.9)
Systolic blood pressure (mm Hg)	396	136.8 (19.7)	130.2(17.7)	132.2 (16.4)
Diastolic blood pressure (mm Hg)	396	80.7 (10.6)	76.4 (9.5)	73.9 (9.8)
Total cholesterol (mmol/L)	390	4.9 (1.06)	4.3(0.8)	4.2(0 .9)
HDL cholesterol (mmol/L)	390	1.2 (0 .3)	1.2 (0.3)	1.3 (0.3)
LDL cholesterol (mmol/L)	390	2.9 (0.9)	2.3 (0 .7)	2.1(0.7)

Values are mean (SD)

Table 3 : Linear associations between patient-centred care and outcomes at one year and five year follow-up in Addition-Plus cohort

		Changes from 0-1 year follow up				Changes from 1-5 year follow up			
Variable	**N**	**Co-efficient**	**95% CI**		**P-value**	**Co-efficient**	**95% CI**		**P-value**
Self-reported Measures									
Total activity energy expenditure (MET hrs/day)	371	0.080	0.017	0.143	0.01	-0.037	-0.318	0.243	0.79
Sedentary time (min/day)	371	-1.633	-2.897	-0.368	0.01	0.014	-0.010	0.037	0.25
Moderate to vigorous physical activity (min/day)	371	5.328	0.796	9.859	0.01	-0.241	-0.880	0.400	0.46
Energy intake (kJ/day)	371	0.920	-3.960	5.810	0.71	0.012	0.001	0.001	0.51
Alcohol per week (units)	371	0.022	-0.037	0.081	0.47	-0.022	-0.085	0.041	0.49
Objectively measured health behaviours									
Physical activity energy expenditure (kJ/kg/day)[a]	308	-0.001	-0.166	0.164	0.99	-0.014	0.850	-0.100	0.08
Plasma Vitamin C (µmol/L)	303	-0.231	-0.462	<0.001	0.05	-0.040	-0.100	0.020	0.17
Clinical and biochemical measures									
HbA_{1c} (%)[b]	387	-0.006	-0.015	0.004	0.23	0.004	-0.005	0.013	0.39
Systolic blood pressure (mm Hg)[c]	396	-0.561	-0.653	-0.468	0.01	0.107	-0.053	0.267	0.19
Diastolic blood pressure (mm Hg)[c]	396	-0.565	-0.654	-0.476	0.01	0.064	-0.031	0.159	0.19
Total cholesterol (mmol/L)[d]	390	0.002	-0.006	0.011	0.58	0.001	-0.008	0.010	0.83
HDL cholesterol (mmol/L) [d]	390	0.002	0.001	0.004	0.03	-0.002	-0.004	0.001	0.17
LDL cholesterol (mmol/L) [d]	390	0.007	0.001	0.014	0.07	0.001	-0.007	0.007	0.99
Waist circumference (cm)	383	-0.060	-0.120	0.011	0.07	0.085	0.015	0.155	0.02
BMI (kg/m²)	383	-0.010	-0.031	0.006	0.19	0.013	-0.010	0.036	0.27
Modelled UKPDS 10-year cardiovascular risk [e]	390	0.001	-0.001	<0.001	0.54	0.001	-0.001	0.001	0.51

[a] measured at one year only
[b] adjusted for sex, age, ethnicity, social class and hypoglycaemic medication
[c] adjusted for sex, age, ethnicity, social class and anti-hypertensive medication
[d] adjusted for sex, age, ethnicity, social class and lipid lowering therapy
[e] adjusted for sex, age, ethnicity, social class, lipid lowering therapy, anti-hypertensive and hypoglycaemic medication

STROBE Statement—checklist of items that should be included in reports of observational studies

Patient-centred care, health behaviours and cardiovascular risk factor levels in people with recently diagnosed type 2 diabetes: 5 year follow-up of the ADDITION-plus trial cohort

	Item No	Recommendation
Title and abstract	1	(*a*) Cohort study in title included page 1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found – provided on page 1
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported – included this page 2
Objectives	3	Stated on page 1
Methods		
Study design	4	Present key elements of study design early in the paper – included this page 1
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection (clearly included, general practice) page 1 and page 3
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up. Explained follow up at one and five years. Page 3
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable – included exposures and outcomes page 3
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group, page 3
Bias	9	Describe any efforts to address potential sources of bias – discussed in limitations page 5-6
Study size	10	Explain how the study size was arrived at- explained from ADDITION trial page 2
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why page 2
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding Page 4
		(*b*) Describe any methods used to examine subgroups and interactions
		(*c*) Explain how missing data were addressed – excluded from analysis page 4
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *High follow up rate discussed, page 4 and 5*
		(*e*) Describe any sensitivity analyses - nad

Continued on next page

Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed, page 4 and 5
		(b) Give reasons for non-participation at each stage n/a
		(c) Consider use of a flow diagram n/a
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders, table provided page 11 and 12
		(b) Indicate number of participants with missing data for each variable of interest page 11
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount) page 11
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time page 11
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included page 1, and results on page 4 and table on page 11
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses - NA
Discussion		
Key results	18	Summarise key results with reference to study objectives page 5
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias page 5 and 5
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence page 6
Generalisability	21	Discuss the generalisability (external validity) of the study results page 6 and 7
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based, page 8