Self-compassion, metabolic control and health status in individuals with type 2 diabetes: a UK observational study

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STROBE Checklist

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Abstract

Aims: Self-compassion is a modifiable characteristic, linked with psychological well being and intrinsic motivation to engage in positive health behaviours. We aimed to explore levels of self-compassion in individuals with type 2 diabetes (T2DM) and their association with levels of depression, diabetes-related distress and glycaemic control.

Methods: A cross-sectional study in 176 patients with T2DM in Leicester, UK, using three self-report questionnaires: the Self Compassion Scale (SCS); Patient Health Questionnaire (PHQ-9), and Diabetes Distress Scale (DDS-17). Demographic data, medical history and blood samples were collected.

Results: Majority of participants were male (n=120, 68.2%), with median [IQR] age and HbA1_c of 66 [60, 71] years and 7.3 [6.7, 8.0] %, respectively. Multivariable analysis adjusting for age, gender, ethnicity and diabetes duration revealed significant association of all three scores with HbA1_c: per one standard deviation increase of each score, a -0.16% reduction in HbA1_c for SCS (p=0.027), 0.21% increase for PHQ-9 (p=0.012) and 0.33% increase for DDS-17 (p<0.001).

Conclusions: Higher levels of self-compassion and lower levels of depressive symptoms were associated with significantly better long-term diabetes control. These results reinforce the importance of emphasis on psychological parameters, including self-compassion, in the multi-disciplinary management of T2DM. We identify this as a potential area for intervention in UK practice.

Keywords: psychological aspects; metabolic control; observational study; cross-sectional

Introduction

Compassion at its simplest level is to be aware of the suffering of oneself and others and to be motivated to alleviate it. The essence of self-compassion is to treat oneself with kindness, avoiding harsh self-criticism and focusing on the acceptance of flaws [1]. A tendency for self-compassion is linked with psychological well-being and significantly predicts positive health behaviours most notable of which is self-management behaviour [2,3].

Globally, 415 million people have diabetes of which 90% is type 2 diabetes, with one in six hospital beds being occupied by patients with diabetes [4]. Diabetes is a complex chronic condition with the requirement for intensive self-management behaviours, including adherence to dietary and exercise advice and medication compliance, as well as monitoring of the effect of these through clinical measures including blood glucose levels and blood pressure control. A lack of engagement in these essential behaviours could result in poor health outcomes. Self-compassion is a key indicator of well-being and is linked with self-worth and body appreciation. Low levels of self-compassion, in particular these components of self-compassion will influence whether a patient with type 2 diabetes decides to both engage and persevere in self-management as well as healthcare professional led management of their condition [5]. It is therefore important to consider self-compassion levels in patients with diabetes as this may be an important determinant in the successful management of this challenging chronic condition [6].

Depression is linked to poor engagement in self-management and poor health outcomes in patients with coronary heart disease, stroke and diabetes mellitus [7]. Diabetes is associated with an increased risk of depression, twice that of those without diabetes, and depressive episodes in people with diabetes characteristically last longer and recur more frequently [8].

Along with depression, diabetes is associated with distress which is defined as the emotional burden of living with diabetes and characterised by the worries, concerns and fears of an

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individual struggling with a progressive and demanding chronic disease [9]. Diabetes distress is relatively common with a recent systematic review showing overall prevalence of 36% in people with type 2 diabetes [10]. Diabetes distress, particularly regimen-related distress, is associated with lower reported personal control and higher HbA1c level [11]. Individuals who are more self-compassionate have lower levels of anxiety [12], depression and lead healthier lifestyles [13].

The Self-Compassion Scale (SCS) developed by Neff is a 26 item, 5-point Likert scale questionnaire that measures positive subscales of mindfulness, common humanity and self-kindness and negative subscales of over-identification, isolation and self-judgment. It is a reliable validated and coherent measure of self-compassion [15]. SCS scores have strong predictive validity, with known groups validity [16], convergent validity [17] and high levels of agreement, (Cronbach's Alpha 0.87) [18, 19].

Recently, studies have shown an association between self-compassion as measured with the SCS and improved diabetes control [15]. A cross-sectional analysis of 310 Australian adults with diabetes showed that greater self-compassion was associated with improved self-management behaviour, HbA1c levels and psychological well-being as well as significantly better internal locus of control [20].

Self-compassion levels have been seen to be modifiable; a randomised controlled trial in New Zealand involving 63 patients with diabetes (over 80% of these individuals had type 1 diabetes) were randomised to either an eight week Mindful Self-Compassion (MSC) protocol or control group (CG). Employing the intervention of an eight week MSC program was associated with improvement in levels of self-compassion, depression and diabetes related distress. Metabolic improvement was also identified with this intervention, with on average a reduction in HbA1c level of 10mmol/mol (almost 1%) between baseline and three month follow up in participants in the MSC group [21].

The aim of the present study, following on from those in Australia and New Zealand, was to explore the levels of self-compassion as well as depression and diabetes-related distress in a multi-ethnic population of individuals with T2DM in Leicester, United Kingdom (UK).

FOR PEER REVIEW

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Methods

Participants

A cross-sectional study was carried out in 176 participants with T2DM in Leicester, UK, using questionnaires as part of a larger study (Chronotype Of Patients with Type 2 Diabetes and Effect on Blood Sugar Control, CODEC). The CODEC study (ethics reference number 16/WM/0457), with broad inclusion criteria, aimed to compare glycaemic control between chronotypes, ‘early’ and ‘late’, in individuals with T2DM (STROBE checklist for cross-sectional study is reported in the Supplementary Material). Three validated self-report questionnaires were used: the Self Compassion Scale (SCS) and the Patient Health Questionnaire (PHQ-9), to screen for depression; and the Diabetes Distress Scale (DDS-17), to screen for distress.

Data was collected between 3rd January and 15th December 2017. The CODEC study is ongoing and aiming to recruit 2447 participants; eligibility criteria for the study include participants willing and able to give informed consent for participation in the study with an established diagnosis of type 2 diabetes (of greater than six months duration) with an HbA_{1c} below 10% (86 mmol/mol), aged between 18 and 75 years, with a good command of the English language.

Procedures

Participants were recruited through postal mailing of potentially eligible patients with type 2 diabetes that had been identified through database searches of primary care practices and secondary care, hospital outpatient clinic lists. Interested participants, who had returned a reply slip, were then contacted by telephone and those eligible, according to the above criteria, were booked in for a study visit at the Leicester Diabetes Centre. During the study

visit participants were given a paper copy of each questionnaire and asked to complete this at home and return it to the department in a stamped addressed envelope.

Individuals attended the Leicester Diabetes Centre following overnight fasting. Following informed consent for the study, demographic information was collected in a self-report questionnaire

Measures

Participants were asked to give details of their age, gender and ethnicity as well as duration of diabetes and any significant co-morbidities. HbA_{1c} and cholesterol levels were checked in a fasting blood sample prior to complete further questionnaires at home.

The SCS was completed by participants; this uses a five point Likert Scale (1-5 relating to Almost never to Almost always) which is completed for 26 statements relating to elements of self-compassion [15]. These 26 statements are subdivided into positive attributes (with questions relating to self-kindness, common humanity and mindfulness) and negative components of self-compassion (comprising self-judgement, isolation, over-identified). This therefore subdivides the 26-item questionnaire into four or five statements for each subcomponent of the scale. The scale then classifies an individual level of self-compassion as low, medium or high depending on this overall mean score, with a score of 1-2.5 indicating an individual low in self-compassion, 2.5-3.5 moderate levels, and 3.5-5.0 reflects an individual high in self-compassion. The same method and ranges can be applied to the positive and negative subscales to reflect degree of self-compassion in these areas.

Participants simultaneously completed the PHQ-9, a widely used depression screening tool in non-psychiatric settings [22]. This involves individuals scoring 9-items, looking at recent (in the preceding two weeks) frequency of certain thoughts and feelings. These are ranked by the participant from 0-3, reflecting not at all to nearly every day. A cut off point for positive

screening diagnosis of depression is indicated by a score greater or equal to 10, with a higher score reflecting a higher frequency of depressive symptoms being experienced by the participant.

The DDS-17 was also implemented to look at potential distress areas that people with diabetes experience [23]. In the scale, 17 items are listed and participants are asked to quantify the degree in which each item negatively impacts on their life (from 1 to 6, i.e. not a problem to a very serious problem). A mean item score of 3 or more indicates moderate distress. There are subscales within the DDS-17 looking at Emotional Burden (5 items), Physician-related Distress (4 items), Regimen-related Distress (5 items) and Interpersonal distress (3 items); similarly, a score of 3 or higher in any subscale is considered clinically relevant.

Statistical analysis

Continuous and categorical data are described as median and interquartile range and number and percentage, respectively. Correlations are graphically shown in scatter plots and statistical expressed as Spearman's rho. Multivariable complete-case associations between HbA_{1c} and each of the three scores were adjusted for age, gender, ethnicity and duration of diabetes; associations were also assessed following standardisations (z-score) of the three scores. Analyses were performed with Stata v.15 and results are reported with bootstrap 95% confidence intervals (5000 replications).

Results

172 participants completed demographic data and the entirety of the questionnaire booklet (SCS, PHQ-9 and DDS-17), with data disregarded for patients in which this was incomplete as mean questionnaire scores were unable to be calculated. The majority of participants were male (n=120, 68.2%) and white (n=146, 83%). The median (IQR) age and HbA_{1c} of participants completing the questionnaires was 66 (60, 71) years and 7.3 (6.7, 8.0) % [56 (49-64) mmol/mol], respectively (**Table 1**). The median (IQR) age at onset of diabetes was 53 (46, 60) years, with a median duration of diabetes of 11 years (6, 18). The most common self-reported co-morbidities in these participants were hypertension (68.7%, n=121) and dyslipidaemia (62.2%, n=109). Median (IQR) cholesterol level in these participants was 4.1 (3.5, 4.8) mmol/L. 11.9% of participants (n=21) had suffered from myocardial infarction, 9.1% (n=16) had undergone a coronary artery bypass graft and 4.5% (n=8) had been diagnosed with heart valve disease.

The median (IQR) of total self-compassion score was 3.37 (2.94, 3.73), indicating overall moderate levels of self-compassion in these individuals; 12.5% (n=22) demonstrated low levels of self-compassion, 50% (n=88) moderate and 37.5% (n=66) high. The median (IQR) positive subscale component score was moderate [2.88 (2.25, 3.58)] and negative subscale component high [3.99 (3.08, 4.55)]. 172 participants completed the PHQ-9 screening tool (median [IQR] score: 3 [0, 9]) and 175 the DDS-17 (1.47 [1.18, 2.29]).

Total SCS was found to be significantly and inversely correlated with HbA_{1c} level (ρ -0.19; $p=0.008$). SCS was also inversely correlated with PHQ-9 (ρ -0.58; $p<0.001$) and DDS-17 (ρ -0.40; $p<0.001$), indicating lower levels of depressive symptoms and diabetes-related distress in individuals with higher levels of self-compassion (**Figure 1**).

On multivariable analysis adjusting for age, gender, ethnicity and duration of diabetes, a significant negative association was found between total SCS and HbA_{1c}: per one standard

deviation (SD) increase of SCS (0.69), there was a -0.16% (-1.8 mmol/mol) reduction of HbA_{1c} for SCS (p=0.027). Conversely, a SD increase of PHQ-9 (6.5) and DDS-17 (0.90) was associated with a 0.21% (2.3 mmol/mol) and 0.33% (3.6 mmol/mol) increase of HbA_{1c} (p=0.012 and p<0.001, respectively) (**Table 2**). This analysis indicates significantly lower levels of self-compassion and higher levels of depressive symptoms in individuals with poorer glycaemic control demonstrated by a higher HbA_{1c} level. In multivariable model, age was positively associated with total SCS (p<0.001) while DDS-17 score was inversely associated with age (p<0.001) and higher in white British (p=0.001). The assessment of the variance in models progressively adjusted for confounders and scores indicates that the diabetes distress could have more relevance than other scores in explaining HbA_{1c} variations (**Table 3**).

Discussion

Significant correlations were observed between results of the three different self-report questionnaires that participants completed; SCS, PHQ-9 and DDS-17. Higher levels of SCS were significantly associated with lower levels of both depressive symptoms (PHQ-9) and diabetes distress (DDS-17).

Similarly to the results of previous studies in Australia and New Zealand [21,20], this study demonstrated that higher levels of self-compassion were significantly associated with a lower HbA_{1c} level indicating better long-term diabetes control in these individuals. Leicester is one of the most ethnically and culturally diverse cities in the UK, with 51% of the city's population identifying themselves as White British in the 2011 census, compared with 86% across England as a whole [24]. The majority of participants were white British, but our study population comprised individuals of multiple ethnicities including Indian (10%), Black Caribbean (2%), Black African (2%), and Pakistani (2%). In addition to the results of previous studies from other countries, we have also demonstrated a significant positive association between levels of depressive symptoms (PHQ-9) and HbA_{1c} level in this multi-ethnic UK population.

Diabetes is a long-term condition which is associated with debilitating complications including cardiovascular disease, stroke, retinopathy, neuropathy and nephropathy. Retinopathy is a major cause of preventable sight loss, peripheral neuropathy leads to foot ulceration and amputations, and nephropathy results in progressive kidney failure [25]. Prevention of the development of micro and macrovascular complications in individuals with T2DM requires engagement in regular multi-disciplinary healthcare measures [26]. Due to the broad eligibility criteria in this study, our population included a wide spectrum of individuals with T2DM not specifically patients at high-risk of these complications, but our results support current recommended practice in diabetes management. Optimal diabetes

management is described as the combination of glucose-lowering medication, structured education and self-management programmes with dietary and physical activity advice, as well as psychological input [27].

Although psychological support is an integral component of optimal diabetes care, which is recommended in both national and international diabetes guidelines [28-30], access to this support is not widespread [31,32]. Fragmentation of National Health Service physical and mental health services in the UK results in unmet needs, with a recent Diabetes UK survey finding that only 24% of people with diabetes have been offered emotional or psychological support when it was required [33]. Rates of psychological problems are much higher in individuals with diabetes than the general population [34]. Reduced psychological well-being including depression, anxiety or diabetes-related distress, have been linked to poorer self-care, less medication adherence, poor glycaemic control and increased risk of complications [35,11,36].

Looking at self-compassion support in particular, two well established education programmes are currently available which aim to increase individual's levels of self-compassion: these are the Compassionate Mind Training (CMT) and the Mindful Self-compassion Program (MSC) [37,36]. CMT was developed in the UK and is aimed at counteracting feelings of inferiority and lack of self-worth by promoting capacity to cultivate inner compassion mindfully and access, tolerate and direct affiliative emotions towards self and others, with enhanced sense of caring and belonging [32]. CMT has been studied in the UK in individuals suffering from eating disorders, acquired brain injury and chronic pain, with results suggesting it is associated with improved psychological well-being and ability to manage the condition [38-40]. MSC was developed in the USA by Kristin Neff, it is an eight week intervention of 2.5 hour sessions, or alternatively a five day intensive program, that aims to help individuals develop skills in self-soothing, mindfulness and to use encouragement to motivate oneself

rather than criticism. This has been studied in individuals with diabetes and has been shown to enhance self-compassion, mindfulness and wellbeing in a randomised control trial [21,37]. The results of the study we have carried out to assess current levels of self-compassion, depression and diabetes-related distress was limited by population size and reflective solely of patients with T2DM. These were individuals with T2DM with a wide range of diabetes duration and glycaemic control, with relatively low levels of depressive symptoms and diabetes-related distress. Our results have reiterated the importance of a focus on psychological parameters in the multi-disciplinary management of patients with diabetes, and we have highlighted that psychological elements, most notably diabetes related distress, significantly and independently impact upon glycaemic control.

We underline the need for studies to assess an optimal structured psychological programme to be developed and potentially incorporated within the routine management of patients with diabetes, with a focus on enabling individuals to have the tools to increase their levels of self-compassion and reduce levels of depression and diabetes distress, and to integrate these skills into their daily lives. Future research into the development of a psychological programme specifically for individuals with diabetes, based upon the current training programs available, is warranted specifically initially in individuals with poorer and glycaemic control and likely higher levels of depressive symptoms and diabetes related distress, to review whether this will aid optimisation of glycaemic control in these individuals, with the aim of minimising future morbidity.

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Author Contributions

AM supervised the project and drafted the first version of the manuscript. FZ undertook the statistical analysis. SC conceived the initial study idea. EB, AH, MJD designed the CODEC study. LD collected data. All Authors revised the manuscript for important intellectual content.

Conflict of Interest

SC has received speaker fees or educational funding, or both, from Janssen, Eli Lilly, Novo Nordisk, Takeda, Astra Zeneca, and Boehringer Ingelheim and grants in support of investigator-initiated trials from Boehringer Ingelheim and Janssen. KK has acted as a consultant and speaker for Novartis, Novo Nordisk, Sanofi-Aventis, Lilly and Merck Sharp & Dohme. He has received grants in support of investigator and investigator-initiated trials from Novartis, Novo Nordisk, Sanofi-Aventis, Lilly, Pfizer, Boehringer Ingelheim and Merck Sharp & Dohme. MJD has acted as consultant, advisory board member and speaker for Novo Nordisk, Sanofi-Aventis, Lilly, Merck Sharp & Dohme, Boehringer Ingelheim, AstraZeneca and Janssen and as a speaker for Mitsubishi Tanabe Pharma Corporation. She has received grants in support of investigator and investigator-initiated trials from Novo Nordisk, Sanofi-Aventis and Lilly Other Authors: none

Data availability statement

The datasets generated or analysed during the current study are not publicly because CODEC is an on-going study. Statistical codes are available from FZ.

Statement of Human and Animal Rights

All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008.

Statement of Informed Consent

Informed consent was obtained from all patients for being included in the study.

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Figures legends

Figure 1: Correlations between individual parameters for the included participants

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Table 1: Baseline characteristics of included participants

Variable	N	Group	Value
Self-Compassion Scale score			
Total	176	-	3.37 (2.94, 3.73) / 3.29 (0.69)
Positive	176	-	2.88 (2.25, 3.58) / 2.87 (0.95)
Negative	176	-	3.99 (3.08, 4.55) / 3.76 (0.97)
Age (years)	175	-	66 (60, 71) / 64 (8)
Age at diagnosis of Diabetes Mellitus (years)	175	-	53 (46, 60) / 52 (10)
Duration Diabetes Mellitus (years)	175	-	11 (6, 18) / 12 (8)
HbA1 _c		-	
%	176	-	7.3 (6.7, 8.0) / 7.4 (1.0)
mmol/mol	176	-	56 (49, 64) / 57 (11)
PHQ-9 score	172	-	3.0 (0, 9.0) / 5.4 (6.5)
DDS-17 score	175	-	1.47 (1.18, 2.29) / 1.84 (0.90)
Total cholesterol (mmol/l)	170	-	4.1 (3.5, 4.8) / 4.3 (1.0)
Sex		Male	120 (68.2%)
		Female	56 (31.8%)
Ethnicity		Non-White	30 (17.0%)
		White	146 (83.0%)
Myocardial Infarction		No	153 (86.9%)
		Yes	21 (11.9%)
		Unknown	2 (1.1%)
Heart valve disease		No	167 (94.9%)
		Yes	8 (4.5%)
		Unknown	1 (0.6%)
Heart Failure		No	171 (97.2%)
		Yes	4 (2.3%)
		Unknown	1 (0.6%)
Atrial Fibrillation		No	163 (92.6%)
		Yes	9 (5.1%)
		Unknown	4 (2.3%)
Angina		No	157 (89.2%)
		Yes	16 (9.1%)
		Unknown	3 (1.7%)
Stroke		No	166 (94.3%)
		Yes	9 (5.1%)
		Unknown	1 (0.6%)
Coronary artery bypass graft		No	160 (90.9%)
		Yes	16 (9.1%)
Leg Angioplasty		No	170 (96.6%)
		Yes	5 (2.8%)
		Unknown	1 (0.6%)
Peripheral Vascular Disease		No	156 (88.6%)
		Yes	19 (10.8%)
		Unknown	1 (0.6%)
Hypertension		No	55 (31.3%)
		Yes	121 (68.7%)
Dyslipidaemia		No	58 (33.1%)
		Yes	109 (62.2%)
		Unknown	8 (4.6%)
Gestational diabetes mellitus		No	170 (96.6%)
		Yes	5 (2.8%)
		Unknown	1 (0.6%)
Polycystic ovary syndrome		No	168 (95.5%)
		Yes	6 (3.4%)
		Unknown	2 (1.1%)
Thyroid dysfunction		No	159 (90.3%)
		Yes	15 (8.5%)
		Unknown	2 (1.1%)

Values are median (interquartile range) / mean (standard deviation) for continuous variables;

number (percentage) for categorical variables. 30 11 20, D-70451 Stuttgart, Germany, <http://www.thieme.de/fz/eced>

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Table 2: Multivariable associations between HbA1c and Self-compassion, PHQ-9 or DDS-17

Score	HbA1c (%)		HbA1c (mmol/mol)		p-value
	Estimate	95% CI	Estimate	95% CI	
Self-compassion	-0.238	-0.449, -0.027	-2.600	-4.909, -0.291	0.027
Patient Health	0.032	0.007, 0.057	0.348	0.077, 0.618	0.012
Diabetes Distress Scale - 17	0.366	0.188, 0.543	3.997	2.058, 5.936	<0.001
	Standardised Estimate	95% CI	Standardised Estimate	95% CI	
Self-compassion	-0.164	-0.309, -0.018	-1.790	-3.379, -0.200	0.027
Patient Health	0.207	0.046, 0.369	2.267	0.504, 4.031	0.012
Diabetes Distress Scale - 17	0.327	0.169, 0.486	3.579	1.843, 5.315	<0.001

Estimates for each score are adjusted for age, gender, ethnicity, and duration of diabetes.
Standardised estimates were obtained following standardisation of each score (PHQ 9, DDS and SCS) to z-score; they indicate the increase in HbA1c per 1 standard deviation increase in the specific score to facilitate the comparisons across scores.

Table 3: Variance explanation in progressively adjusted models

Progressive adjustment	R ²	Progressive adjustment	R ²	Progressive adjustment	R ²	Progressive adjustment	R ²	Progressive adjustment	R ²	Progressive adjustment	R ²
0	0.093	0	0.093	0	0.093	0	0.093	0	0.093	0	0.093
1	0.125	1	0.125	2	0.183	2	0.183	3	0.119	3	0.119
2	0.177	3	0.130	1	0.177	3	0.189	1	0.130	2	0.189
3	0.182	2	0.182	3	0.182	1	0.182	2	0.182	1	0.182

Outcome variable: HbA1c; **Variables:** **0** = Age, gender, ethnicity, duration of diabetes; **1** = Patient Health; **2** = Diabetes Distress Scale; **3** = Self-compassion.

Fig. 1

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

Self-compassion, metabolic control and health status in individuals with type 2 diabetes: a UK observational study

	Item	Recommendation	Page
Title and abstract	1	(a) Indicate the study’s design with a commonly used term in the title or the abstract	2
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	3	State specific objectives, including any prespecified hypotheses	4-5
Methods			
Study design	4	Present key elements of study design early in the paper	6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	6
Participants	6	Cross-sectional study—Give the eligibility criteria, and the sources and methods of selection of participants	6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	7-8
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	7-8
Bias	9	Describe any efforts to address potential sources of bias	8
Study size	10	Explain how the study size was arrived at	8
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6-8
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	8
		(b) Describe any methods used to examine subgroups and interactions	NA
		(c) Explain how missing data were addressed	8
		(d) Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	NA
		(e) Describe any sensitivity analyses	NA
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	7-8
		(b) Give reasons for non-participation at each stage	7
		(c) Consider use of a flow diagram	-
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Table 1
		(b) Indicate number of participants with missing data for each variable of interest	Table 1
		Cross-sectional study—Report numbers of outcome events or summary measures	Table 1
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	Table 2
		(b) Report category boundaries when continuous variables were categorized	NA

		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
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	9-10
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	13
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	11-12
Generalisability	21	Discuss the generalisability (external validity) of the study results	12-13
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	14

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.