

**Sleep quality and sex-related differences in an older adult population:  
a web-based cross-sectional study**

Emanuele Di Simone<sup>1</sup>, Noemi Giannetta<sup>2</sup>, Valerio Ragnoli<sup>3</sup>, Sara Dionisi<sup>4\*</sup>,  
Aurora De Leo<sup>1,5</sup>, Gloria Liquori<sup>5</sup>, Nicolò Panattoni<sup>6</sup>, Victoria D’Inzeo<sup>3</sup>,  
Laura Tafaro<sup>3</sup>, Vassilios Pappaspyropoulos<sup>7</sup>, Christian Napoli<sup>7</sup>, Fabio Fabbian<sup>8</sup>,  
Luciano De Biase<sup>3</sup>, Giovanni Battista Orsi<sup>6</sup> & Marco Di Muzio<sup>3</sup>

1. Nursing, Technical, Rehabilitation, Assistance and Research Direction - IRCCS Istituti Fisioterapici Ospitalieri - IFO, Rome, Italy
2. UniCamillus-Saint Camillus International University of Health and Medical Sciences; Rome, Italy;
3. Department of Clinical and Molecular Medicine, Sapienza University of Rome; Rome, Italy;
4. Nursing Technical and Rehabilitation Department - DaTeR Azienda Unità Sanitaria Locale di Bologna; Bologna, Italy;
5. Department of Biomedicine and Prevention - University of Rome Tor Vergata, Rome, Italy;
6. Department of Public Health and Infectious Diseases, Sapienza University of Rome, Italy.
7. Department of Medical Surgical Sciences and Translational Medicine, Sapienza University of Rome, Rome, Italy;
8. Department of Medical Sciences, University of Ferrara, Italy.

\* *Corresponding author:* Sara Dionisi, Nursing Technical and Rehabilitation Department - DaTeR Azienda Unità Sanitaria Locale di Bologna

E-mail: [sara.dionisi@uniroma1.it](mailto:sara.dionisi@uniroma1.it)

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**ABSTRACT**

**Introduction:** Aging has significant economic and social implications leading to an increase in chronic diseases and reduced autonomy of the elderly. Sleep disorders are common in the elderly, manifesting reduced sleep quality.

**Objective/Purpose:** The study aimed to measure the prevalence of sleep disorders in older adults and assess sex differences in sleep quality and sleep problems.

**Method:** A cross-sectional study based on an online survey was performed according to the STROBE checklist, using pre-validated questionnaires (Pittsburgh Sleep Quality Index) distributed to a sample of older adults. This is the first study evaluating sex differences in sleep quality and problems in the Italian population context using the Pittsburgh Sleep Quality Index assessment tool. The study was conducted in a university hospital in Rome from October 2020 to November 2020, on patients aged >65 years, independent in activities of daily living, with comorbidities and on treatment with up to 2 medications.

**Results:** 59 patients were included in the study, with an average age of 71.12 years. The results show that among males, the prevalence of poor sleep quality was 51.9%, while among females, the prevalence of poor sleep quality was 62.5%. According to Shapiro-Wilk, the Pittsburgh Sleep Quality Index was not normally distributed. Pittsburgh Sleep Quality Index total scores in males did not differ significantly from females.

**Conclusions:** Considering scientific literature, recent studies have highlighted the prevalence of sleep disorders in the elderly population and their underreporting. Providing early intervention not only improves the sleep quality of these people but may also reduce the risk of experiencing adverse health outcomes and susceptibility to frailty.

**Keywords:** sleep disorders, older adults, sleep quality, Pittsburgh Sleep Quality Index

## INTRODUCTION

The increasing growth in life expectancy has produced a natural demographic transition, with a progressively ageing population associated with other variables such as declining fertility and reduced youth mortality [1]. Globally, people aged 65 and older, referred to as "older adults," are the fastest-growing population [2]. Based on the recorded upward trend in population growth, the estimate is that about 16 per cent of the world's population will be 65 years and older by 2050 [3]. According to Italian National Institute of Statistics (ISTAT) data, 33.3 per cent of the Italian population is expected to be in this age group in 2065 [4].

Biological factors, which are very complex to define, will be one of many characteristics differentiating populations and uncorrelated social and economic factors, such as retirement age [5]. Ageing has impactful economic and social implications, as it is a process that encompasses the decline of the body as a whole and the physical and mental capacity that increase with advancing age, leading to an increase in chronic diseases and reduced autonomy in this segment of the population [6]. At the Central Nervous System level, the various implications of its degeneration lead to functional alterations, sometimes even compatible with chronic degenerative cognitive diseases. These alterations include memory deficit, impaired balance maintenance, and sleep disorders [7]. The physiological changes that commonly occur with ageing influencing the sleep cycle bring the appearance of some natural disorders. The concomitance with comorbidities affects the individual's physical and mental health, causing them to feel depressed and helpless, very often also due to chronic pain[8-9]. The study of sleep quality and disorders is widespread among older people and nurses [1,8].

Sleep disorders are common in older adults and are present in up to 40-70% of the specific population, manifesting reduced sleep quality. The main features of sleep disorders in the elderly can be attributed to sleep-maintenance insomnia, repeated nocturnal awakenings, and decreased total sleep with a general decrease in sleep quality [10]. Sleep is a normal physiological process

with a crucial therapeutic action and is characterised by a reduction in response to external stimuli and perceptual isolation. A key health element is the sleep-wake cycle, a constituent part of the circadian rhythm, regulated by the anterior hypothalamus and subject to influence by (already known) factors, such as light/darkness alternation, temperature, the action of certain hormones, and a psychological component [9]. The literature shows that the population needs to be aware of the importance of the health of lifestyles that ensure a regular circadian rhythm, sleep and light/darkness alternation [11]. Sleep regulation consists of the S-process, which regulates sleep stages, and the C-process, which controls the circadian pacemaker [12]. Sleep is divided into two phases NREM (Non-Rapid Eye Movement) and REM (Rapid Eye Movement) phase [13].

In older adults, there are some changes in sleep architecture [9]. First, there is an anticipation of the time of lying down in bed and an earlier awakening. There is also an increased sleep latency, that is, an increase in the period of being stationary in bed before falling asleep. At the same time, however, there is a reduction in the total sleep duration, which manifests fragmentation and an increase in nocturnal awakenings due to external stimuli. All this is reflected by an increase in daytime sleep, which is directly proportional to advancing age; it is found that 25 per cent of people aged 75 to 84 years report sleeping during the day [14].

Nicturia and polyuria occur in various conditions, such as diabetes and prostatic hypertrophy. The use of drugs such as diuretics and substances such as coffee and alcohol exacerbate them. These conditions are risk factors for nighttime falls in adult patients [14]. Bilotta states that increasing age leads to increasing frailty, which correlates strongly with falls [15]. The WHO states that 35% of people older than 65 experience a fall yearly, exceeding 42% once they reach 70 years of age [16].

Moreover, some studies have found a strong correlation between low sleep quality and the risk of falling in the elderly [17,18]. The same correlation is found with the use of some medications for the treatment of sleep disorders, including sedative-hypnotic drugs. In addition, the presence of nicturia, precisely in the sleep component related to increased nocturnal awakenings, is among the

risk factors for falls during the night [17].

Finally, gender is a determining factor in human health, and women are more predisposed to the onset of sleep disorders, as they have a physiological vulnerability related to hormonal changes, in which alterations in sleep architecture occur, during the premenstrual period, pregnancy, and menopause [19–22].

About the findings in the literature, the ageing process of the population, which physiologically involves a decline in the body, also has important aspects to focus on. At the level of the central nervous system, one of the main problems that may emerge concerns alterations in the sleep cycle. Such alterations can affect a person's well-being by representing an important risk factor for possible related adverse events. Considering these scientific premises, the present study therefore aims to measure the prevalence of sleep disturbances in older adults to be able to identify strategies that may limit the risk of adverse events.

**Objective:** The present study aims to measure the prevalence of sleep disturbance in older adults by assessing sex differences in sleep quality and sleep disturbance.

## **MATERIALS AND METHODS**

### **Study design**

A cross-sectional study based on an online survey was performed, following the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines for cross-sectional study [23] to improve the quality of reporting using a pre-validated questionnaire distributed to a sample of inpatients older adults (Supplementary file 1).

### **Study Population.**

The study population was selected according to a non-probability convenience sampling model. The

choice of this sampling model was chosen by the researchers for the ease of recruiting the sample in the Public University Hospital of Rome where the study was conducted. The sample was selected based on specific social and clinical conditions detectable from the medical record, which allowed us to define the inclusion and exclusion criteria set out in the following paragraphs. Specifically, all elderly patients admitted to the hospital were selected, excluding emergency rooms and emergency departments. The choice not to include patients admitted to emergency departments is given by the fact that, in these contexts, the clinical conditions of the person could make both recruitment and completion of the questionnaires difficult.

Each eligible patient was explained the purpose of the study and was presented with the informed consent for participation. Each eligible patient was explained the purpose of the study and given informed consent to participate. Once the consent to participate was obtained through the signature of all participants, the link to access the online questionnaire completion was sent by e-mail. The online compilation of the questionnaire took place through Google Form platform. Anonymity was guaranteed through the assignment of an ID when completing the questionnaire. The study was conducted in a University Hospital in the city of Rome from October 2020 to November 2020.

### **Ethical consideration**

All participants consented to the processing of data as required by EU Regulation 2016/679 [24]. To conduct the study, a formal request was submitted to the Ethics Committee, which was accepted and authorized on 04/26/2017 through the documentation identified with protocol number 343/17.

### **Inclusion criteria**

Patients with the following characteristics were included in the study: absence of progressive neurological diseases (Alzheimer's, Parkinson's) or cognitive deterioration, ability and confidence with the computer and use of the Internet, presence of no more than 2 comorbidities, treated with no

more than 2 drugs, age  $\geq 65$  years. The user's skills in the use of the smartphone were assessed at the time of the application for participation in the study through the filling out of the questionnaire itself.

**Exclusion criteria.**

Patients with no difficulties in space, time and orientation; and patients younger than 65 years of age with cognitive impairment or progressive neurological disease (Alzheimer's, Parkinson's) and with more than 2 comorbidities were excluded from this study.

**Instruments**

The Pittsburgh Sleep Quality Index (PSQI) is a retrospective scale used to assess standardised sleep quality [25]. It allows the assessment of possible sleep distribution and discriminates between "good" and "bad" sleepers. It constitutes a self-assessment of patients' sleep quality over the previous month [25].

This questionnaire consists of 19 items, grouped into 7 domains. The seven domains consist of sleep quality, sleep latency, sleep duration, sleep efficiency, sleep disturbance, sleep regulation, medication use, and diurnal dysfunctionality.

The overall score, ranged 0 to 21, is calculated by adding the scores of seven components, from 0 (no difficulty) to 3 scores (severe difficulty). Higher scores indicate worse sleep quality. Usually, a global score higher than five means relevant sleep disturbances in at least two components or moderate challenges in more than three components [25]. Poor sleep quality is defined as when the PSQI score is  $\geq 5$  points; good sleep quality is when the PSQI score is  $\leq 5$  points.

The patient fills out the questionnaire and chooses one of the four multiple-choice answers in each item that best describes his sleep over the past month.

The Italian PSQI showed an overall reliability coefficient (Cronbach's  $\alpha$ ) of 0.835, indicating a high



degree of internal consistency [26], which was used in this study.

### Statistical analysis

Statistical software IBM SPSS Statistics®, version 26 [27], was used in the statistical procedure. All data is analysed using descriptive analysis through absolute frequencies and percentages. Regarding continuous variables, authors used measures of central tendency like mean and standard deviation (SD) and median with interquartile range [Q<sub>1</sub>, Q<sub>3</sub>]. The Shapiro-Wilk test was used to test the normal distribution. According to Shapiro-Wilk, the PSQI were not normally distributed. Based on this consideration, the Mann–Whitney U-test was used. Statistical significance was set at  $p < 0.05$  [28].

## RESULTS

### Sociodemographic characteristics of the study sample

A total of 59 older adults were included in this study. The median and interquartile ranges for the age of the study participants were 69.00 (65–91). The sample's mean age and standard deviation were 71.12 ( $\pm$  6.24). Overall, 54.2% (n=32) patients were females, and 45.8% (n=27) were males.

#### *Prevalence of sleep quality*

Using the PSQI assessment tool, among the study participants, the prevalence of poor sleep quality was 57.6% (n=34); the prevalence of good sleep quality was 42.2% (n=25).

As shown in Table 1, participants reported a median bedtime of 11.00 pm [22:00, 24:00], a median wake time of 07.00 am [06:00, 08:00]. Most participants 64.4%, (n=38) self-reported a “fairly good” quality of sleep; only 15.3% (n=9) of participants reported a good quality of sleep.

Variable	Mean $\pm$ SD median [Q1, Q3]
Bedtime	21:45:00 $\pm$ 4:44:07 23:00:00 [22:00, 24:00]
Wake time	07:08:58 $\pm$ 01:09:05 07:00:00 [06:00, 08:00]
Total sleep time (h)	6.593 $\pm$ 1.45 7.00 [5.50, 7.00]
During the past month, how often have you had trouble sleeping because you:	
a) Cannot get to sleep within 30 mins	0.93 $\pm$ 1.065 <b>1.00 [0.00, 2.00]</b>
b) Wake up in the middle of the night or early in the morning	1.22 $\pm$ 1.121 <b>1.00 [0.00, 2.00]</b>
c) Have to get up to use the bathroom	2.03 $\pm$ 1.059 <b>2.00 [1.00, 3.00]</b>
d) Cannot breathe comfortably	0.17 $\pm$ 0.461 <b>0.00 [0.00, 0.00]</b>
e) Cough or snore loudly	0.56 $\pm$ 0.876 <b>0.00 [0.00, 1.00]</b>
f) Feel too cold	0.41 $\pm$ 0.698 <b>0.00 [0.00, 1.00]</b>
g) Feel too hot	0.80 $\pm$ 0.979 <b>0.00 [0.00, 2.00]</b>
h) Have bad dreams	0.63 $\pm$ 0.849 <b>0.00 [0.00, 1.00]</b>
i) Have pain	0.93 $\pm$ 1.096 <b>1.00 [0.00, 2.00]</b>
<b>PSQI total score</b>	6.4237 $\pm$ 3.00 <b>7.00 [4.00, 9.00]</b>

**Table 1.** Pittsburgh Sleep Quality Index (PSQI) descriptive statistics on the overall sample

Specific questions on trouble sleeping in the last month showed 49.2% (n=29) were not having difficulties getting sleep within 30 minutes; 35.6 % (n=21) reported that they did not wake up in the middle of the night or early morning. However, during the past month, 47.5% (n=28) used to get up to use the bathroom thrice or more times a week. Most of the sample, self-reported no breathing

problems (86.4%, n=51) and coughing or snoring loudly (64.4%, n=38). Most of the sample did not report difficulties in sleeping due to being too cold or too hot (41=69.5% and 31=52.5% respectively) or bad dreams (34=57.6%) or having pain (29=42.9%) during the last month. However, anxiety and concerns due to personal and familiar problems were the troubles sleeping in the previous month reported by 40.7% (n=24) of the sample.

As shown in Table 2, most participants reported good sleep efficacy (40.7% with scores  $\geq 85\%$ ; 35.6% with scores between 75-84%), no use of sleep medication in the past month (72.9%), low levels of sleep disturbance (78.0% with a score of 1) and low levels of daytime dysfunction (78.0% with component scores of 0 or 1).

Variable	Full sample ( $M \pm SD$ ) <i>n=59</i>	Females ( $M \pm SD$ ) <i>n=32</i>	Males ( $M \pm SD$ ) <i>n=27</i>	Females vs Males <i>p-value</i>
Age	71.12 $\pm$ 6.240	70.59 $\pm$ 6.04	71.74 $\pm$ 6.52	0.45
Bedtime	21:47:02 $\pm$ 4:34:54	21:58:35 $\pm$ 3:47:08	21:28:53 $\pm$ 5:43:36	0.31
Wake time	07:08:58 $\pm$ 01:09:05	06:58:07 $\pm$ 00:58:29	07:21:51 $\pm$ 01:19:04	0.27
Total sleep time (h)	6.59 $\pm$ 1.45	6.51 $\pm$ 1.52	6.685 $\pm$ 1.39	0.91
PSQI total score	6.42 $\pm$ 3.00	6.78 $\pm$ 3.25	6.00 $\pm$ 2.67	0.38
<b><i>PSQI component scores</i></b>				
Sleep duration	1.08 $\pm$ 0.82	1.13 $\pm$ 0.87	1.04 $\pm$ 0.75	0.87
Sleep efficacy	0.91 $\pm$ 1.05	1.03 $\pm$ 0.99	0.77 $\pm$ 1.12	0.20
Sleep latency	0.92 $\pm$ 0.95	1.16 $\pm$ 1.08	0.63 $\pm$ 0.68	0.06
Sleep disturbances	1.21 $\pm$ 0.40	1.23 $\pm$ 0.42	1.19 $\pm$ 0.39	0.70
Sleep quality	1.08 $\pm$ 0.67	1.06 $\pm$ 0.71	1.11 $\pm$ 0.64	0.78
Sleep medication	0.54 $\pm$ 1.02	0.53 $\pm$ 1.04	0.56 $\pm$ 1.01	0.76
Daytime dysfunction	0.67 $\pm$ 0.70	0.65 $\pm$ 0.70	0.70 $\pm$ 0.72	0.78

**Note.** the range for the PSQI component score variables is 0 to 3. For all PSQI variables, higher scores indicate worse sleep.

**Table 2.** Pittsburgh Sleep Quality Index (PSQI) and components: descriptive statistics and sex differences

### Sex differences in sleep

Sex differences in sleep quality and PSQI component levels are shown in Table 2. Females reported going to bed 30 minutes later than males. At the same time, females reported waking up 23 minutes before than males. However, no significant differences were found between the two groups ( $p=0.31$ ;

$p=0.27$ ).

Using the PSQI assessment tool, among the males, the prevalence of poor sleep quality was 51.9% ( $n=14$ ), and good sleep quality was 48.1% ( $n=13$ ). While among females, the prevalence of poor sleep quality was 62.5% ( $n=20$ ), and the majority of good sleep quality was 37.5% ( $n=12$ ).

According to Shapiro-Wilk, the PSQI were distributed elsewhere. PSQI total scores in males (Median= 6.0) did not differ significantly from females (Median = 7.0),  $U= 489.000$ ,  $z= 0.873$ ,  $p=0.38$ . No differences were found regarding the sleep duration ( $U=441.500$ ,  $z=0.156$ ,  $p=0.87$ ), sleep efficacy ( $U= 510.000$ ,  $z= 1.271$ ,  $p=0.20$ ), sleep latency ( $U= 544.500$ ,  $z=1.821$ ,  $p=0.06$ ), sleep disturbance ( $U= 435.500$ ,  $z= 0.378$ ,  $p=0.70$ ), sleep quality ( $U= 417.000$ ,  $z= -0.268$ ,  $p=0.78$ ), sleep medication ( $U=416.500$ ,  $z= -0.302$ ,  $p=0.76$ ) and daytime dysfunction ( $U=416.000$ ,  $z= 0.788$ ,  $p=0.78$ ) between males and females patients included.

## DISCUSSION

This observational study aimed to measure sleep disorder prevalence in older adults. The secondary endpoint of this study was to assess sex differences in sleep quality and disorders. The assessment tool used to achieve this goal was the Pittsburgh Sleep Quality Index (PSQI), a self-assessment of the quality of sleep in patients in the last month [25].

In our findings, among the study participants, the prevalence of poor sleep quality was 57.6%, consistent with a previous study reporting high rates of poor sleep quality, ranging from 40% to 70%, among older adults [9]. As mentioned in the introduction, sleep problems may be caused or exacerbated by institutional settings.

According to our findings, most participants reported good sleep efficacy (40.7% with scores  $\geq 85$ ; 35.6% with scores between 75-84%), no use of sleep medication in the past month (72.9%), low levels of sleep disturbance (78.0% with a score of 1) and low levels of daytime dysfunction (78.0% with component scores of 0 or 1). These results are consistent with other studies [29,30].

Some epidemiological studies have shown that women experience more stress, anxiety and depression than men [31,32]. Based on this consideration, the secondary outcome of this study was to assess sex differences in sleep quality and problems among - older - men and women.

The prevalence of poor sleep quality was high in both male and female older adults. More than 60% of female and 50% of male older adults were categorised as poor sleepers. These findings are similar to another study's result [33].

However, in our findings, sex differences were not statistically significant. These findings agree with Zhu and colleagues [30], while these results contrast with some of the previous studies, where elderly females had a higher poor sleep quality than older men [33-35]. Specifically, stress, alcohol consumption and physical exercise are the variables related to a good or poor quality of sleep, according to Quan et al. [33].

Beyond sex differences, many studies show that PSQI was significantly correlated with higher depression and anxiety [36,37]. According to that, most of our participants declared that anxiety and concerns due to personal and familiar problems were the troubles sleeping last month.

To our knowledge, this is the first study evaluating sex differences in sleep quality and problems in the Italian population context using the PSQI assessment tool.

### **Limitations**

This study has several limitations - first, the sample size. Our overall study population was fit but small, which may limit the applicability of our findings, so we recommend caution in interpretation above all for the results in sex differences. For this reason, Cronbach's alpha is also inadequate (0.38), suggesting the need to increase the sample through a larger observational study. In this study, the sampling power was not calculated due to the choice of the sampling method.

All these further limits the generalisation of the results. In addition, the sleep quality measurement was based on a web self-reported evaluation without additional data such as sedentary, alcohol

consumption or residence of the sample to contextualise sleep quality with conditions like traffic, lighting, or recreation nightlife activities. Finally, due to the way the authors administered the instrument (web-based survey), an accurate response rate could not be assessed.

## **CONCLUSION**

Considering the scientific literature, several studies have highlighted the prevalence of sleep disorders in the elderly population and their underestimation [29,38]. Furthermore, the elderly population is often subjected to the use of multiple drugs that can lead to physiological changes that can in turn affect the quality of sleep [39-42]. A therapeutic plan with diuretics, for example, could influence the quality of sleep. In fact, nocturia seems to be prevalent in the elderly population. It can be associated with an increased risk of falls and negative outcomes for the continuity of sleep, continuously fragmented by awakenings. While frailty does not imply the existence of sleep disorders, on the contrary, these are correlated with a risk of cognitive and physical defects when they precede the onset of dementia [43]. Analysing the quality of sleep of elderly people, in relation to their socio-health condition could be very useful to identify interventions aimed at improving certain situations. Providing early intervention not only improves the quality of sleep for these people but can also reduce the risk of experiencing negative health outcomes and susceptibility to frailty.

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## **Conflict of interest**

The authors report no conflict of interest.

**Authors' contribution**

Study design: V.R., M.D.M., N.G.; C.C.; Data collection: V.D.I., V.R., E.D.S., S.D.; Data analysis: N.G., A.D.L., G.L., N.P.; Study supervision: G.B.O.; C.N., M.D.M.; V.P.; L.T.; F.F.; P.S.L.; Manuscript writing: N.G.; V.R.; N.P.; M.M.; Critical revisions for important intellectual content: M.D.M

**Acknowledgements**

None.

## Supplementary material

STROBE Statement—Checklist of items that should be included in reports of *cross-sectional studies*.

	Item No	Recommendation	Page No
<b>Title and abstract</b>	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	1
<b>Introduction</b>			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	1-2
Objectives	3	State specific objectives, including any prespecified hypotheses	1-2
<b>Methods</b>			
Study design	4	Present key elements of study design early in the paper	3-4
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	3-4
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	3-4
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	3-4
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	3-4
Bias	9	Describe any efforts to address potential sources of bias	3-4
Study size	10	Explain how the study size was arrived at	3-4
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	3-4
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	3-4
		(b) Describe any methods used to examine subgroups and interactions	3-4
		(c) Explain how missing data were addressed	3-4
		(d) If applicable, describe analytical methods taking account of sampling strategy	-
		(e) Describe any sensitivity analyses	n.a.
<b>Results</b>			
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	4-6
		(b) Give reasons for non-participation at each stage	4-6
		(c) Consider use of a flow diagram	4-6
Descriptive data	14*	(a) Give characteristics of study participants (e.g. demographic, clinical, social) and information on exposures and potential confounders	4-6
		(b) Indicate number of participants with missing data for each variable of interest	4-6



Outcome data	15*	Report numbers of outcome events or summary measures	4-6
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g. 95% confidence interval). Make clear which confounders were adjusted for and why they were included	4-6
		(b) Report category boundaries when continuous variables were categorized	n.a.
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n.a.
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	n.a.
<b>Discussion</b>			
Key results	18	Summarise key results with reference to study objectives	6-7
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	6-7
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	6-7
Generalisability	21	Discuss the generalisability (external validity) of the study results	6-7
<b>Other information</b>			
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	7

\*Give information separately for exposed and unexposed groups.

**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](http://www.strobe-statement.org).

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