

# Determining the Prevalence and Severity of Menopausal Symptoms in Post-Menopausal Women of Eluru, Andhra Pradesh, India, using the Menopause Rating Scale (MRS)

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#### **Abstract**

Background: This study aimed to assess the prevalence and severity of menopausal symptoms among women in Eluru, Andhra Pradesh, India, to better comprehend the specific challenges faced by rural women during this transitional phase. Methods: Post-menopausal women who visited the Rural Health and Training Center in Eluru between September-November 2021 and had one year of amenorrhea were included. A face-to-face interview administered a questionnaire to collect socio-demographic details and the Menopause Rating Scale (MRS) which contained 11 questions using a 4-point Likert scale. Microsoft Excel and SPSS-20, with one-way ANOVA test were used for data and statistical analysis. Results: A total of 100 respondents were included, aged between 45-60 years. Majority of the respondents (37%) were aged 45-50 years and were unskilled workers (53%) with a monthly income falling under the upper middle-class category (53%). Additionally, 61% belonged to nuclear families. Using the MRS, joint and muscle pains were the most prevalent symptoms (82%), followed by sleep problems (64%) and anxiety (57%). Heat discomfort was reported least frequently (25%). Age groups and symptom severity were found to be significantly associated, indicating that women between 45-50 years were more likely to experience mild-severe symptoms. Conclusion: This study identified a notable prevalence of menopausal symptoms among women in Eluru; however, limitations included the limited sample size and geographic scope. Retrospective data collection might have introduced recall bias. The study highlights the need for increased awareness and education on menopause. Community-based programs and health centers should be established to address these needs.

# Introduction

Menopause is a natural biological process that is generally defined as the time of cessation of ovarian function, resulting in permanent amenorrhea. At this stage, the menstrual cycle stops for longer than 12 months and is accompanied by a decrease in the levels of estrogen and progesterone. This period marks the end of a woman's reproductive life.1

Menopausal symptoms can manifest in various ways. These included vasomotor symptoms (hot flashes and night sweats), psychosocial symptoms (mood swings, anxiety, depression), physical symptoms (joint and muscle pain, sleep disturbances), and sexual symptoms (vaginal dryness and decreased libido). These symptoms often occur due to the hormonal and biological fluctuations that take place during menopause, and they can have a profound effect on a woman's daily life, relationships, and overall health.2

In the Indian context, the onset of menopause tends to occur at a relatively young age, with some women experiencing it as early as 30 to 35 years old.3 Furthermore, the proportion of menopausal women in the general population has increased

significantly in recent years due to rising life expectancy. By 2026, the number of women in India who are 45 years old or above is projected to reach 401 million, highlighting the substantial impact of menopause on a significant portion of the population.<sup>4</sup> Factors such as age at menarche, breastfeeding of multiple children, and age at first pregnancy have been found to be strongly correlated with menopausal age. 5 It is possible that the cultural practice of early marriage and subsequent early pregnancy in India may be contributing factors to the average age of menopause in the country.6

Despite advancements in developing nations, including India, the existing biomedical healthcare model primarily focuses on addressing the medical symptoms of menopause to minimize their impact on women's psychosocial transition during this phase. However, there is a considerable lack of awareness and understanding regarding the effects and challenges faced by women during menopause, particularly among communities.<sup>7, 8</sup>

Although India offers various programs for maternal and child health, family planning, and other health services, the attention given to women's health is mainly focused on sexual and

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reproductive health, with little to no consideration for postmenopausal or mid-life health.9 For example, Reproductive, Maternal, Neonatal, Child, and Adolescent Health (RMNCH+A) is a program under the National Health Mission (NHM) aimed at promoting lifecycle interventions, but it does not extend to health concerns beyond the reproductive years. <sup>10</sup> Moreover, rural areas often face significant challenges in accessing health care services. Shortages of female doctors and health staff in rural settings exacerbate these challenges, as these areas are often considered remote or challenging posts by health care providers. Consequently, rural women may encounter barriers in seeking timely and appropriate healthcare, particularly for conditions related to menopause and mid-life health. 11 Existing research also primarily focuses on northern and central India, with limited attention given to the unique socio-cultural and environmental factors influencing menopausal experiences in the southern regions.

To bridge this knowledge gap, this study aimed to evaluate the prevalence and severity of menopausal symptoms among women in Eluru, Andhra Pradesh, in Southern India. By examining the common symptoms experienced by women who met the inclusion criteria, this study sought to shed light on the challenges faced during this transitional period, which could ultimately help in developing targeted interventions, improving healthcare services, and enhancing the overall well-being of women in rural India during their menopausal years.

#### **Aims and Objectives**

Hence, the primary objective of this study was to ascertain the prevalence and assess the severity of menopausal symptoms in postmenopausal women in Eluru. Furthermore, it aims to explore potential sociodemographic factors, including age, monthly per capita income, and type of family structure, associated with the severity of menopausal symptoms among these women.

#### **Methods**

# **Design and Setting**

The present study was an analytical cross-sectional study that adhered to the STROBE guidelines. The study was conducted during September, October, and November 2021 at the Rural Health and Training Center (RHTC) in Eluru, which serves as a primary healthcare facility catering to the healthcare needs of the rural population in the region. This was a significant setting for this study, as it provided access to a diverse population of postmenopausal women. This article has been reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) checklist for cross-sectional studies (*Supplementary Material*). 12

#### **Inclusion and Exclusion Criteria**

The present study used convenience sampling method, and all women visiting the Rural Health and Training Center (RHTC) in Eluru, India, who had experienced at least one year of amenorrhea and were willing to provide informed consent, were included in the study. We excluded individuals who were unwilling to

participate, those with medically or surgically induced menopause (i.e., previous history of hysterectomy), or women using hormone replacement therapy (HRT) to eliminate the influence of exogenous hormonal interventions on menopausal symptom presentation. Women with a known history of tumors, tuberculosis, rheumatoid arthritis, or osteoarthritis were also excluded from the study to minimize the impact of specific medical conditions known to present symptoms that could mimic or exacerbate menopausal symptoms.

These criteria were applied to ensure that the study focused on naturally occurring menopausal symptoms among a homogeneous group of participants, and to minimize potential confounding factors associated with induced menopause or specific medical conditions.

#### **Study Tools**

A pre-designed and ethically approved questionnaire, consisting of three sections, was administered by the researchers via face-to-face structured interviews. The first section included an informed consent form provided in both the English and Telugu languages. The second section collected sociodemographic data, including information on age, occupation, type of family (nuclear or joint), and monthly income based on Per Capita Income. The third section employed the Menopause Rating Scale (MRS), which is a well-established health-related quality of life scale developed in the early 1990s, and has since been used by researchers such as Armo et al. and Sushmitha et al. in various regions across India to evaluate menopausal symptoms on women's quality of life. <sup>13,14,15</sup>

The scale comprises 11 items, with each item scored from 0 to 4, where 0 indicates no complaints and 4 represents very severe complaints. Scores for each item are then summed up, and the total scores were then classified into five grades, ranging from "none," "mild," "moderate" and "severe." The scale assesses the quality of life across three independent dimensions: somatic, psychological, and urogenital.<sup>13</sup>

### **Data Entry and Analysis**

Microsoft Excel 2010 and Statistical Package for Social Sciences (SPSS) version 20 were used to analyze the data. Sociodemographic variables and the prevalence of menopausal symptoms were documented in terms of frequency and percentage. To explore associations between sociodemographic factors and the items on the MRS, one-way Analysis of Variance (ANOVA) with a 95% Confidence Interval (CI) was employed. Statistical significance was set at p <0.05. ANOVA was considered as an appropriate statistical test to explore potential differences in these scores across different sociodemographic factors, allowing for a comprehensive assessment of the impact of these factors on the severity of menopausal symptoms.

#### **Ethical Issues**

The study was approved by the Institutional Ethics Committee (IEC) of the Alluri Sitarama Raju Academy of Medical Sciences,

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with approval number IEC/ASR/APPROVAL/023/2021. The study adhered to ethical guidelines, ensuring voluntary participation of individuals without coercion. Confidentiality was maintained by anonymizing participant data through the use of study IDs instead of personal identifiers.

# **Results**

A total of 109 responses were collected, of which seven were excluded due to incomplete collection of data, and two were excluded because they did not meet the stipulated inclusion criteria, particularly concerning the requirement of at least one year of amenorrhea or other specified criteria. Therefore, the responses of the 100 participants were included in the analysis.

# **Socio-demographic Characteristics**

<u>Table 1</u> shows the respondents' sociodemographic characteristics. The age of the participants ranged from 45 to 60 years, with the majority (37%) of participants belonging to the 45-50 age group, and most (53%) of the participants were unskilled workers.

Regarding monthly income, participants' responses were categorized based on their per capita income (PCI). The majority (53%) earned Rs. 3,766-7,532 per month (~45-90 USD), which, according to the revised modified BG Prasad's scale, falls under the upper middle-class category. Additionally, information on

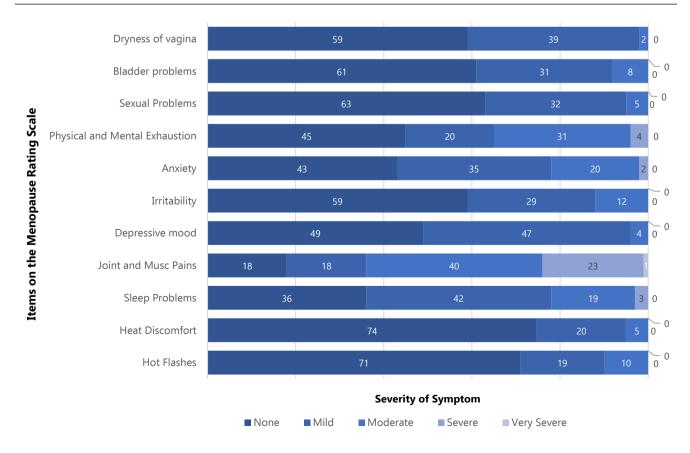
the type of family revealed that most women (61%) belonged to nuclear families.

Table 1. Socio-demographic Characteristics of the Respondents.

Characteristic	n (%)
Age Groups (years)	
45-50	37
50-60	30
>60	33
Occupation	
Homemaker	31
Unskilled Worker	55
Semi-Skilled Worker	10
Skilled Worker	2
Professional	2
Income per month (INR)*	
<1,129 (Lower class)	6
1,130-2,259 (lower middle class)	14
2,260-3,765 (middle class)	23
3,766-7,532 (upper middle class)	53
>7,533 (upper class)	4
Type of Family	
Joint	39
Nuclear	61

**Legend:** \*Categories are according to the revised classification of BG Prasad's socioeconomic status for 2020.

Figure 1. Severity of Symptoms Reported by Participants in the Menopause Rating Scale.



*Table 2.* Grading of Severity of Symptoms on the Menopause Rating Scale.

Grading	n (%)
<5	31
5-10	37
11-15	28
>15	4

# **Menopause Rating Scale (MRS)**

Participants scored the items on the Menopause Rating Scale (MRS) on a scale of 0–4. The severity of the symptoms, as reported by the participants, is shown in *Figure 1*.

The grading of symptom severity and the total number of participants in each grade are shown in *Table 2*. Four participants had a total score of > 15, indicating the need to manage their problems.

*Table 3.* Total Number of Respondents who Reported the Item as a Problem.

Item	n (%)
Somatic (Mean=3.3, SD=1.9)	
Hot Flashes	29
Heat Discomfort	25
Sleep Problems	64
Joint and Muscle Pains	82
Psychological (Mean=2.8, SD=2.5)	
Depressive mood	51
Irritability	41
Anxiety	57
Physical and Mental Exhaustion	55
Urogenital (Mean=1.3, SD=1.6)	
Sexual Problems	37
Bladder problems	39
Dryness of vagina	41

*Table 3* summarizes the number of participants who reported each item on the subscale as a problem (scoring 1-4). Among these symptoms, joint and muscle pain were the most frequently reported (82%), followed by sleep problems (64%). Anxiety was the most common psychological symptom (57%). Heat discomfort was the least frequently reported symptom (25%) in this study. The overall mean score for each subscale is also presented, with somatic symptoms being the most reported symptoms (Mean=3.3, SD=1.9), and urogenital items being the least reported symptoms overall, (Mean=1.3; SD=1.6).

*Table 4.* Association between Socio-Demographic Characteristics and Grades of Severity.

Variables		Grades of S	Severity (n)	
Type of Family	None	Mild	Moderate	Severe
Joint	10	15	13	1
Nuclear	21	20	17	3
P Value*		0.	08	
Per Capita Income	None	Mild	Moderate	Severe
<1,129	2	4	0	0
1,130 – 2,259	7	2	5	0
2,260 – 3,765	9	8	5	1
3,766 – 7,532	12	21	18	2
>7,533	1	0	2	1
P Value		0.3	661	
Age Groups	None	Mild	Moderate	Severe
45-50	10	9	16	2
50-60	11	12	6	1
>60	10	14	8	1

Legend: \*P value=0.0098 (<0.05) was considered significant.

# Association Between Socio-Demographic Factors and Items on the MRS

A one-way ANOVA test was conducted to examine the associations between sociodemographic factors and grades of symptom severity, as shown in *Table 4.* 

There was no significant association between family type, per capita income, and symptom severity grades. However, age groups showed a significant association, with an F-statistic value of 7.64 and a p-value <0.05. Women in the 45-50 age group were thus observed to be more likely to experience mild to severe symptoms.

## **Discussion**

The present study aimed to identify the prevalence and severity of menopausal symptoms in women in Eluru and explore the associations between sociodemographic factors and symptom severity. Our study has several noteworthy findings.

Among the 100 women considered, a majority (37%) belonged to the 45-50 age group, indicating a younger than average menopausal age group of approximately 50 years. This finding aligns with previous studies in India, which have reported a relatively early onset of menopause among Indian women compared to Western populations, such as the review by Pallikadavanth et al. and Prasad et al.<sup>4,17</sup> It is also important to note that this is different from the younger age of menopause as reported by the 1996 data from, and suggests that women in rural India also experience similar patterns of menopausal symptoms as reported elsewhere.

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In India, the national classification of labor is as follows: unskilled workers (e.g., construction workers, peons), semi-skilled workers (e.g., bearers, assistant electricians), skilled workers (e.g., electricians, mechanics, tailors), and professionals (e.g., teachers, doctors). We found that most of the participants in our study were unskilled workers (53%) and earned an income of Rs. 3,766-7,532 per month (53%), which according to B.G. Prasad's socioeconomic scale (2020), falls under the upper middle class category. A nuclear family system is defined as 'a two generation family consisting of a father and mother and children or a single parent and his/her children', while a joint family is defined as 'three or more generations living together, having a single line of authority, either patrilineal or matrilineal. An overall 61% of women in our study belonged to nuclear families.

The type of family (joint/nuclear) and socioeconomic status can potentially affect the severity of menopausal symptoms. Joint families may provide more familial support, which could mitigate the psychological impact of symptoms, and higher socioeconomic status may offer better access to healthcare resources, leading to more effective management of symptoms.<sup>20</sup> However, the extent of these influences may vary across different cultural and geographical contexts. The present study found no significant association between the type of family (joint/nuclear) and the severity of symptoms. This contrasts with studies by Vijayalakshmi et al., Thakur et al., and Sushmitha et al., who observed a significant association between socioeconomic status and symptom severity. 15, 21, 22 This could be due to the limited sample size of the various socioeconomic groups in our study. Furthermore, the present study found no significant association between per capita income and severity of symptoms, while Karmakar et al. noted a significant association between vasomotor symptoms and type of family. 1 These discrepancies highlight the need for more comprehensive research incorporating larger and diverse samples across different regions to better understand the relationship between socioeconomic factors, family type, and menopausal symptoms.

In terms of specific symptoms on the MRS, joint and muscle pain were the most frequently reported (82%), followed by sleep problems (64%). These findings align with studies conducted by Gyawali et al. in Nepal and Singh et al., in rural Delhi.<sup>23, 24</sup> However, it is worth noting that heat discomfort was the least common symptom (25%) in our study, which is in contrast to the findings of Pandey et al., who also noted that it is one of the more common findings in studies outside Nepal.<sup>25</sup> This may be attributed to cultural factors and the conservative nature of reporting sexual health-related symptoms among women in rural India.<sup>25, 27</sup>

Regarding psychological symptoms, anxiety was the most commonly reported (57%), which is similar to studies by Poomalar et al. and Ayranci et al., while the study conducted by Singh et al. in rural Delhi reported depression to be more common.<sup>24, 28, 29</sup> Furthermore, a study by Bernis and Reher in Spain noted that women in urban areas were found to be more affected by these psychological symptoms than rural women.<sup>30</sup> The lower frequency of urogenital symptoms compared to the other two

subscales is another interesting observation, which was also noted by Armo et al. in Chhattisgarh. 14 This trend aligns with previous research by Joshi et al. and Anukriti et al., indicating the hesitancy among women in rural India to report such symptoms, possibly due to cultural conservatism surrounding sexual health matters. 31,32 Women in rural India also have different customs and beliefs regarding reproductive health, and these cultural, and religious, beliefs and values have a significant role in shaping women's experiences during the menopausal period.<sup>33</sup> Studies by Mackey et al., and Hunter et al., observed a positive effect of religion on the mental health of midlife South Asian women, and observed that their belief in a higher power allowed them to cope with stressors.<sup>34, 35</sup> Therefore, promoting religious and spiritual practices among religious women and reassessing cultural norms are crucial to support women during this transitional phase, and these findings underscore the importance of researchers approaching these sensitive topics with cultural sensitivity and discretion, and suggests a need for further investigation into the sociocultural factors influencing women's perceptions and experiences in discussing these issues openly.<sup>27,30</sup>

Our study found that women in the 45-50 age group were more likely to experience mild to severe menopausal symptoms than women in other age groups. This is consistent with previous studies, indicating that the perimenopausal period is characterized by more severe symptoms than the postmenopausal phase.<sup>36</sup> Thus, it is important for healthcare providers to recognize the increased symptom burden during this transitional phase and provide appropriate support and management strategies.

#### Limitations

Although our study provides valuable insights into menopausal symptoms among women in rural India, it has some limitations. The sample size was restricted to one area of Eluru, which may limit the generalizability of the findings. A larger and more diverse sample encompassing women from various rural areas would provide a more comprehensive understanding of menopausal symptoms in this population. The convenience sampling method employed in our study could also introduce a selection bias and impact the generalizability of the findings. The recruitment of participants from the Rural Health and Training Center in Eluru may not fully represent the entire spectrum of women experiencing menopausal symptoms in rural areas, potentially excluding those who did not seek healthcare or access a specific health center during the study period. The exclusion of such individuals might influence the representation and variation in menopausal symptom experiences within the broader rural community. Additionally, the retrospective nature and selfreporting of the data collected from older women may have introduced recall bias owing to the longer time span since their menopausal transition, highlighting the need for caution when interpreting the results.

These limitations emphasize the necessity of more inclusive sampling methods and prospective study designs to attain a more nuanced understanding of menopausal symptoms and their implications among women in rural India. Mediboina A, et al.

#### Conclusion

The prevalence of menopausal symptoms among women in Eluru highlights the critical need for targeted interventions and enhanced awareness programmes. Despite the limitations of our study, notably the restricted sample size, our findings emphasize the urgency to address menopause-related challenges in rural communities. A crucial finding of our study was the lack of awareness among the majority of women regarding menopause and the management of associated symptoms through interventions such as exercise and yoga. 37, 38 This presents a significant opportunity for healthcare initiatives focused on education and awareness-building among women and their families. By fostering a deeper understanding of menopausal transitions and their management, these initiatives could substantially improve the quality of life of women in rural areas. Furthermore, our study underscores the need to establish community-based programs and health centers dedicated to addressing menopausal health concerns. Collaborative efforts involving ASHA workers, MLHP professionals, Anganwadi centers, and female village volunteers can play a pivotal role in disseminating information, offering support, and providing accessible healthcare services to menopausal women.

The practical implications of our findings extend beyond the identification of prevalent symptoms; they call for a proactive approach to empower women with the knowledge and resources necessary to navigate the menopausal phase while acknowledging and incorporating their cultural and religious customs into menopausal care. Health policies should be introduced to specifically address the reproductive needs of elderly patients. By leveraging community-based support systems and healthcare infrastructure, we can bridge the

information gap, destigmatize menopausal experiences, and facilitate improved health outcomes for women in rural regions, thereby improving their quality of life during this transitional phase.

# **Summary – Accelerating Translation**

**Title:** Determining the Prevalence and Severity of Menopausal Symptoms in Post-Menopausal Women of Eluru, Andhra Pradesh using the Menopause Rating Scale (MRS)

**Main Problem to Solve:** Menopausal symptoms among rural women are often overlooked, leading to inadequate support and management strategies.

**Aim of the Study:** This study aimed to assess the prevalence and severity of menopausal symptoms among women in Eluru, Andhra Pradesh, to better understand the challenges they face during this transitional phase.

**Methods:** We interviewed post-menopausal women at the Rural Health and Training Center in Eluru between September and November 2021. We collected socio-demographic details and used the Menopause Rating Scale (MRS) to assess symptom severity.

**Results:** Among 100 women aged 45 to 60 years, joint and muscle pains were the most prevalent symptoms (82%), followed by sleep problems (64%) and anxiety (57%). Women aged 45-50 were more prone to experiencing mild to severe symptoms.

**Conclusion:** This study highlights the significant prevalence of menopausal symptoms among rural women in Eluru. Incorporation of religious and cultural sensitivity while interacting with these patients is essential. Increased awareness and education about menopause, for women and their families, are also crucial, along with the development of targeted health policies, community-based programs and health centers.

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#### **Author Contributions**

Conceptualization: P.P, G.S.K. Data Curation: A.M, P.P, G.S.K. Formal Analysis: A.M, P.P, G.S.K. Funding Acquisition: P.P Methodology: A.M, P.P, G.S.K. Project Administration: P.P, G.S.K. Resources: P.P, G.S.K. Supervision: P.P, G.S.K. Writing - Original Draft: A.M, P.P, G.S.K. Writing - Review Editing: A.M, P.P, G.S.K.

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# **Supplementary Material**

STROBE Statement—Checklist of Items that Should be Included in Reports of Observational Studies.

Section	Item No.	Recommendation	Page No.
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
	1	(b) Provide in the abstract an informative and balanced summary of what was done and what was found	3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants		(a) Cohort study—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	
		Case-control study—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls	5
	6	Cross-sectional study—Give the eligibility criteria, and the sources and methods of selection of participants	
		(b) Cohort study—For matched studies, give matching criteria and number of exposed and unexposed	
		Case-control study—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5
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	5
Bias	9	Describe any efforts to address potential sources of bias	
Study size	10	Explain how the study size was arrived at	5
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	
Statistical methods		(a) Describe all statistical methods, including those used to control for confounding	5
		(b) Describe any methods used to examine subgroups and interactions	
	12	(c) Explain how missing data were addressed	
	12	Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	5
		( <u>e</u> ) Describe any sensitivity analyses	

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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
	.5	(b) Give reasons for non-participation at each stage	7
		(c) Consider use of a flow diagram	
Descriptive data		(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	7
	14*	(b) Indicate number of participants with missing data for each variable of interest	
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	
Outcome data		Cohort study—Report numbers of outcome events or summary measures over time	
	15*	Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results		(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	7
	16	(b) Report category boundaries when continuous variables were categorized	
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	7
Discussion			
Key results	18	Summarise key results with reference to study objectives	8
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	8
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	8
Generalisability	21	Discuss the generalisability (external validity) of the study results	8-9
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	1