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Social participation and depressive symptoms among older adults during the Covid-19 pandemic in Serbia: A cross-sectional study

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**ABSTRACT**

Objectives: To determine the predictors and level of social participation and depressive symptoms within the context of isolation during the COVID-19 pandemic and investigate if the residence and type of housing had a moderating role in the relationship between social participation and depressive symptoms.

Methods: This cross-sectional, comparative, and correlational study was conducted on a sample of 299 participants. Research instruments used in this study included: socio-demographic questionnaire, the Geriatric Depression Scale, the Maastricht Social Participation Profile, and Mini-Mental State Exam.

Results: Social participation was found to contribute negatively to symptoms of depression ($\beta = -0.245$, $p < .01$), with a higher level of depression being found in older adults living in nursing homes ($\beta = -0.152$, $p < .05$).

Conclusions: The study confirmed a strong relationship between social participation and depressive symptoms in the COVID-19 pandemic.

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in higher levels of connectedness and lower levels of loneliness. Emotional social support has been identified as adequate protection against depression, which can be even more significant than instrumental support. Less social participation and social interaction in old age have been linked to higher depressive symptoms. Social interaction gives people a sense of belonging and social identity, and opportunities to participate in various activities. According to the stress-buffering model, positive social support can buffer the harmful effects of stressful life events on depressive symptoms among older adults.

Previous studies have been contradictory regarding older adults’ level of social support. Some of them indicate lower social support in nursing homes, in contrast to research that revealed higher social support for older adults due to the many potential social partners. Research highlights various factors on which the level of social support depends, on the vital role of family size, connections, and family structure as a source of support in reducing depressive symptoms among older adults living in nursing homes and those living in their homes. People who have a small family size, live with their spouse, or in a private home, contact their children frequently, and take part in more social activities tend to have a low level of depressive symptoms. Another risk factor that determines the severity of depression living in rural areas; however, the residence type does not buffer the effects of social support on depressive symptoms.

During the COVID-19 pandemic in 2020, as a protective measure, the Serbian government-imposed limitations of movements and social contacts on adults over the age of 65, while those who resided in nursing homes spent most of their time in total isolation. According to studies conducted in other countries, these measures lead to lower social participation and loneliness in the elderly. The subjective sense of loneliness and isolation has been linked to numerous problems in older adults’ mental and physical health, the most common of which being higher rates of depression and higher mortality.

Therefore, the study aimed to determine the predictors and level of social participation and depressive symptoms in older adults in the situation of isolation due to the COVID-19 pandemic and whether decreased possibility for social participation increased depression.

The following research hypotheses from this conceptual framework were proposed:

1. Higher level of social participation would reduce the level of depression symptoms among older adults during the Covid-19 pandemic in Serbia; 
2. Gender, age, type of residence, place of residence, income, education, and marital status would be significantly associated with social participation and depressive symptoms in older adults; 
3. Type of residence would moderate the relationship between social participation and depression symptoms in older adults during the Covid-19 pandemic in Serbia; 
4. Place of residence would serve as a moderator between social participation and depression symptoms of older adults during the Covid-19 pandemic in Serbia. Therefore, we hypothesize that the evidence of (3) and (4) would indicate that living in one’s own home, in rural areas, will be a protective factor for older people with reduced social participation (due to a pandemic) from developing depressive symptoms.

**Methods**

**Research design**

A cross-sectional, comparative, and correlational study design using a self-assessment survey with a convenience sample of Serbian older adults. The STROBE Statement – Checklist for cross-sectional studies was used (Appendix A).

**Sample and setting in research**

The convenience sample comprised of 299 older adults (aged 60 and over), out of whom 110 (36.8%) resided in nursing homes and 189 (63.2%) lived in their own homes. Of the total sample, 173 (57.9%) participants lived in urban and 126 (42.1%) in rural areas.

The inclusion criteria were: over 60 years of age, intact orientation to space, time, and person, and a signed consent form for participation. Before completing the questionnaire, a cognitive screening was conducted using the Mini-Mental State Exam. Respondents who had a score of 25 or more were included in the study.

The exclusion criteria were: older adults with poor health, disoriented, persons with whom it was impossible to establish good collaboration, older adults unwilling to participate, and failing to comply. Also excluded are older adults with impaired vision, impaired hearing, speech and language disorders, psychiatric illness, and older adults suffering from or being treated for malignant diseases. To examine these issues, we used existing medical data owned by the respondents or that exist in the documentation of the nursing home. Considering the number of potential predictors for conducting hierarchical regression analysis, as well as data about the population size of older adults that satisfy requirements of our study at a significance level of $\alpha = 0.05$, power 95% and small effect size of 0.20, a minimum sample size of 192 subjects were needed for this study.

**Data collection**

The data were collected using paper and pencil techniques from March to May 2020, while movement restrictions were still in place. Researchers distributed self-reported questionnaires to two nursing homes and two retirees’ associations to assess older adults. The total number of residents in the two homes was 462, of which 321 accepted to participate in the study, and 22 residents were excluded from the study due to the low score on the Mini-Mental State Exam. All older adults who met the inclusion criteria were invited to participate in the study. After receiving participants’ verbal informed consent, researchers personally handed out and collected the questionnaires. There was no time limit for filling in questionnaires, and, if needed, every participant was offered help with writing the answers. In addition, all of the researchers were tested for COVID-19 beforehand to ensure the safety of all participants.

**Instruments**

Research instruments used in this study included: socio-demographic questionnaire (SDQ), the Geriatric Depression Scale (GDS), the Maastricht Social Participation Profile (MSPP), and Mini-Mental State Exam (MMSE).

Socio-demographic questionnaire (SDQ) included basic information such as gender, year of birth, place of residence (town/village), type of residence (nursing home/one’s own house), income, education, and marital status. SDQ also included questions on the existence of chronic diseases and disabilities.

The Maastricht Social Participation Profile (MSPP) is intended for persons over 60. MSPP assesses how often people participate socially and how many different types of social participation they were involved in in the past four weeks. It contains 25 items and has three sections: work (9 items), contact with friends (8 items), and contact with family (8 items). All items have the same answer format: (0) never, (1–3) less than once a week, (4–8) once or twice a week, (9+) more than twice a week. Two scores can be calculated for each index: diversity scores and frequency scores. Diversity scores refer to the number of items in the index on which a respondent scored at least one. Frequency scores reflect the mean score of the items in the index. In addition, the total diversity score refers to the number of...
indices on which a respondent had a score of at least one. Higher scores indicate more diverse or more frequent social participation. Cronbach’s $\alpha$ for MSPP in the original study on different groups of respondents was higher than 0.70.24

The Geriatric Depression Scale – GDS is a self-assessment scale that includes 15 items requiring yes/no answers. The items reflect the variability of symptoms linked to depression, including depressive mood, lack of motivation, being oriented toward the past instead of the future, cognitive difficulties, obsessive features, and anxiety.18 Of the 15 items, 10 indicated the presence of depression when answered positively, while the rest (question numbers 1, 5, 7, 11, 13) indicated depression when answered negatively. Scores of 0-4 are considered normal; 5-8 indicate mild depression; 9-11 indicate moderate depression and 12-15 indicate severe depression. In other studies, the analysis of the reliability of the GDS showed an internal consistency higher than 0.80 (Cronbach’s alpha).25,26

Mini-Mental State Exam16 is used in situations requiring rapid cognitive screening. The reliability of this instrument is good, with Cronbach’s alpha over 0.70.27 In this study, it was used to assess which older adults fulfilled the criteria for the study. It contains questions that assess mental orientation to time, space and person, memory, and concentration.

Ethical considerations

The Ethics Committees of the Faculty of Medicine, the University of Novi Sad, Serbia (16.07.2020.01-39/211), approved the implementation of this study and the administration of nursing homes and retiree associations where the study was conducted. Participation in the study was voluntary. All participants received written information concerning the aims of the study and that completing the set of self-report questionnaires was the expression of consent to participate in the study. Anonymous answers guaranteed data confidentiality.

Data analysis

The IBM® SPSS® Statistics 20.0 software program was used for analysis. Numerical variables are shown using mean values and standard deviations, and attributive variables using frequencies and percentages. Within comparative statistics, we used Pearson’s linear correlation coefficient, the hierarchical linear model, the multiple regression analysis, and the moderation analysis in which categorical variables were coded into dummy variables and models were tested in a two-step procedure. First, the cutoff values of risk probability were calculated at the significance level of 95% ($p<$0.05) (difference in statistical parameters is significant) and 99% ($p<$0.01) (difference in statistical parameters is highly significant).

Results

Socio-demographic characteristics of the participants

The sample included 120 (40.1%) male and 179 (59.9%) female participants, the average age being 74.0 years (SD=7.61), in the range from 60 to 92 years of age. More than two-thirds of the participants were married (33.1%) or in a relationship (36.8%) and completed primary (35.1%) or high school (38.5%) education. In addition, nearly half of all participants (46.5%) assessed their income as being sufficient to fulfill their needs, while 23.7% assessed their income as barely sufficient for their needs. Other socio-demographic characteristics are shown in Table 1.

Reliability of the research instruments

The research instruments were shown to have a satisfactory level of reliability in terms of internal consistency determined by Cronbach’s alpha coefficients. Namely, Cronbach’s $\alpha$ for MSPP in this study was 0.79. Cronbach’s $\alpha$ for the GDS was 0.82, while the reliability of the Mini-Mental State Examination showed an internal consistency of 0.76.

Descriptive statistics and correlation coefficients MSPP and GDS

Table 2 shows average scores on MSPP and GDS for the entire sample as well as subsamples of older adults on their type and place of residence. MSPP has a range of 0 to 3, with average scores being 1.03 (SD=0.55) for the entire sample, 0.71 (SD=0.43) for the sample of older adults living in a nursing home, and 1.21 (SD=0.52) for the subsample of older adults living at home. The average scores on GDS were 6.61 (SD=2.17) out of 15 for our entire sample, 7.54 (SD=2.11)

Table 1. Socio-demographic characteristics of the study sample (in total and by subsamples).

| Sample description | Study sample | Total N (%) | Urban N (%) | Rural N (%) | Nursing home N (%) | Own home N (%) |
|--------------------|--------------|-------------|-------------|-------------|-------------------|----------------|
| Gender             |              |             |             |             |                   |                |
| Male               | 120 (40.1)   | 63 (36.4)   | 57 (45.2)   | 45 (40.9)   | 75 (39.7)         |
| Female             | 179 (59.9)   | 110 (63.6)  | 69 (54.8)   | 65 (59.1)   | 114 (60.3)        |
| Age (M±SD)         |              |             |             |             |                   |                |
| 75.7±6.15          |              |             |             |             |                   |                |
| Marital status     |              |             |             |             |                   |                |
| Married            | 99 (33.1)    | 43 (24.9)   | 56 (44.4)   | 10 (9.1)    | 89 (47.1)         |
| Divorced           | 10 (3.3)     | 7 (4)       | 3 (2.4)     | 7 (6.4)     | 3 (1.6)           |
| Widowed            | 55 (18.4)    | 30 (17.3)   | 25 (19.8)   | 33 (30)     | 22 (11.6)         |
| In a relationship   | 110 (36.8)   | 76 (43.9)   | 34 (27)     | 41 (37.3)   | 69 (36.3)         |
| Single             | 25 (8.4)     | 17 (9.8)    | 8 (6.3)     | 19 (17.3)   | 6 (3.2)           |
| Education          |              |             |             |             |                   |                |
| Primary school     | 105 (35.1)   | 39 (22.5)   | 66 (52.4)   | 43 (39.1)   | 62 (32.8)         |
| High school        | 115 (38.5)   | 71 (41)     | 44 (34.9)   | 33 (30)     | 82 (43.4)         |
| College            | 49 (16.4)    | 36 (20.8)   | 13 (10.3)   | 17 (15.5)   | 32 (16.9)         |
| University         | 30 (10.0)    | 27 (15.6)   | 3 (2.4)     | 17 (15.5)   | 13 (6.9)          |
| Income             |              |             |             |             |                   |                |
| Very good          | 32 (10.7)    | 25 (14.5)   | 7 (5.6)     | 13 (11.8)   | 19 (10.1)         |
| Sufficient         | 139 (46.5)   | 70 (40.5)   | 69 (54.8)   | 40 (36.4)   | 99 (52.4)         |
| Barely sufficient  | 71 (23.7)    | 36 (20.8)   | 35 (27.8)   | 22 (20)     | 49 (25.9)         |
| Insufficient       | 57 (19.1)    | 42 (24.3)   | 15 (11.9)   | 35 (31.8)   | 22 (11.6)         |
for a sample of older adults living in nursing homes, and 6.07 (SD=2.02) for those living at home.

On the sample of older adults living in nursing homes, the correlation between social participation and depressive symptoms was -0.224 (p < .01). In contrast, this correlation was -0.202 (p < .01) on a subsample of older adults living at home.

Older adults in urban areas had an average score of 0.93 (SD =0.48), and those living in rural areas were 1.15 (SD = 0.61) on the scale of social participation. Concerning depressive symptoms, urban dwellers scored 6.98 (SD = 2.09) on average, and those living in rural areas 6.09 (SD = 2.18). Correlation between social participation and depressive symptoms on a subsample from urban population was -0.362 (p < .01), and -0.225 (p < .01) for those from the rural population.

**Predictors of social participation and depressive symptoms**

Multiple regression analysis was performed to determine predictors of social participation and depressive symptoms (Table 3). Categorical variables were pre-coded into dummy variables, and reference groups are listed in Table 3.

About predicting social participation, the model is statistically significant in total (R = .556, p < .01), and it explains approximately 31% of social participation variance. Significant predictors of social participation were: age ($\beta = -0.282$, p < .01), type of residence ($\beta = .271$, p < .01), income ($\beta = -0.138$, p < .05) and education ($\beta = .174$, p < .05). Social participation declined with age. Older adults living in their own homes scored higher on the scale of social participation than those living in nursing homes. Older adults with very good or sufficient income had a higher level of social participation than those assessing their income as barely sufficient or insufficient. Older adults with primary school education scored higher on this scale than those with higher educational levels so that we saw a decline in depressive symptoms with the rise of the education level.

**Analysis of moderating effects of the type and place of residence**

In order to check if the type of residence moderated the relationship between social participation and depressive symptoms, a hierarchical regression analysis was performed (Table 4). The type of residence was coded as a dummy variable, whereas living in a nursing home was coded as 0, and living at home as 1. The model was statistically significant in the first block of hierarchical regression analysis (R = 0.335, p < .01). Social participation was found to contribute negatively to symptoms of depression ($\beta = -0.245$, p < .01), with a higher level of depression being found in participants living in nursing homes ($\beta = -0.152$, p < .05). In the second block of hierarchical analysis, the interaction between social participation and type of residence was introduced. The change that occurred in the model by adding this interactive effect was not statistically significant ($\Delta R^2 = 0.002$, p > .05). In the second block the main effect of social participation ($\beta = -0.308$, p < .01) and the main effect of the type of residence ($\beta = -0.141$, p < .05) were registered as significant predictors, whereas their interaction was not statistically significant ($\beta = 0.073$, p > .05). We conclude that although it has a significant main effect, the type of residence does not moderate the relationship between social participation and depressive symptoms.

In order to check the moderating role of the place of residence in the relationship between social participation and depressive symptoms, a procedure was also performed by hierarchical regression

Table 2

| Total range | Total Mean (SD) | Nursing home Mean (SD) | Own home Mean (SD) | Urban Mean (SD) | Rural Mean (SD) |
|-------------|----------------|------------------------|--------------------|----------------|-----------------|
| MSPP        | 0 - 3          | 1.03 (0.55)            | 0.71 (0.43)        | 1.21 (0.52)    | 0.93 (0.48)     | 1.15 (0.61)     |
| GDS         | 0 - 15         | 6.61 (2.17)            | 7.54 (2.11)        | 6.07 (2.02)    | 6.98 (2.09)     | 6.09 (2.18)     |

**Table 3**

Predictors of social participation and depressive symptoms.

| Variable (ref. group) | Social participation ($R = 0.556^{**}$) | Depressive symptoms ($R = 0.376^{**}$) |
|-----------------------|----------------------------------------|----------------------------------------|
|                       | $B$ (S.E.) | $\beta$ | $p$ | $B$ (S.E.) | $\beta$ | $p$ |
| Gender (male)          | .009 (.057) | .008 | .874 | .187 (.252) | .042 | .457 |
| Age                   | -.020 (.004) | -.282 | .000 | -.001 (.019) | -.005 | .943 |
| Type of residence (nursing home) | .307 (.070) | .271 | .248 | -.648 (.282) | -.148 | .222 |
| Place of residence (urban) | .074 (.064) | .067 | .115 (.134) | .049 | .392 |
| Income (very good)     | -.082 (.030) | -.138 | .007 | .150 (.134) | .095 | .609 |
| Education (primary school) | .099 (.030) | .174 | .001 | -.350 (.134) | -.155 | .009 |
| Marital status (single) | .010 (.020) | .027 | .614 | -.059 (.087) | -.040 | .496 |

**p < .01

$^{**}p < .01$
analysis in two blocks (Table 5), the same as in checking whether the type of housing moderated the relationship between social participation and depressive symptoms. In the first block, social participation stood out as a significant predictor ($\beta = -0.305$, $p < .01$), while the place of residence did not contribute to explaining depressive symptoms. After introducing the interaction in the second block, the main effect of social participation remained significant ($\beta = -0.363$, $p < .01$), whereas neither a significant main effect of the place of residence ($\beta = -0.004$, $p > .05$) nor the interaction between social participation and place of residence was registered ($\beta = 0.089$, $p > .05$). The residence did not moderate the relationship between social support and depressive symptoms.

### Discussion

Various aspects of the life of older adults, as well as their needs, change with age. The quality and quantity of social networks and social participation activities also change. Apart from age, social participation is affected by personal factors (gender, health, income, and education), contextual factors (social support, physical limitations, and inclusion possibilities), and common events typical of old age, particularly nursing or loss of a spouse. Isolation due to the COVID-19 pandemic brought new and unexpected challenges to the older adults and other limited ways and possibilities for social participation.17

Our study aimed to determine the predictors and level of social participation and depressive symptoms in older adults in the situation of isolation due to the COVID-19 pandemic in Serbia and check whether reduced possibilities for social participation increased depression. Social participation represents a vital resource that affects individuals in different domains. Reduced or absent social relationships among older adults are considered an essential public health issue since they are known to increase the risk of depression. Studies that investigated depression among older adults have found that reduced social participation, social networks, and social support are strongly associated with an increased risk of depression.29

Research has shown that older adults tend to participate less in social activities than other age groups and that this type of limited participation has a significant effect on their physical and mental health.30 In the pandemic situation, the level of loneliness is even more pronounced.31 Our results showed low social participation and pronounced depressive symptoms in older adults in the context of the COVID-19 pandemic. The results of our study confirmed a negative contribution of social participation to depressive symptoms, which is similar to the results had been obtained by other studies.26,31

These results were expected if we considered that social participation, defined as “social distribution of individual resources” through active involvement in collective social activities such as religious activities, sporting, cultural and political events, is crucial for older adults considering their social ties reduced after retirement.29

This study also aimed at verifying if the place of residence (urban/rural) and type of residence (nursing home/own house) have a moderating role in the relationship between social participation and depressive symptoms in older adults. Results indicated that neither the type of residence nor the place of residence moderated the relationship between social participation and depressive symptoms. The relationship between social participation and depression remains the same regardless of a person lives in urban or rural areas or resides in a nursing home or their own house. Isolation and reduced social participation led to more pronounced depressive symptoms in all older adults. For older adults to have a good quality of life, it is essential to ensure active aging and, in the pandemic situation, to promote social interaction in the community and nursing homes alike.11

Our study also indicated higher levels of depression in participants living in nursing homes, which emphasizes that this group of elderly requires special mental health care in the COVID-19 pandemic. Depression is widely spread in the population of older adults, especially those living in nursing homes.32,33 Although being placed in a nursing home can provide safety and comprehensive care, it also includes adjusting to a completely different environment and can imply dependence, loss, and grieving. New residents of nursing homes can be particularly prone to depression since the act of moving from one’s own home can be stressful in its own right and increase the risk of depression12; the challenges only get more complex in the situation of a pandemic.20

Health decline in older adults living in institutions affects their relationships and everyday interactions and can cause isolation, separation from others, loneliness, and severe manifestations of depression.34 The prevalence of depression in older adults living in nursing homes is almost twice as high as that for the older adults living in the community.35 Although depressive disorders in old age can be prevented, they often go unnoticed in nursing home residents, therefore untreated.32 This all culminates in the pandemic situation and can result in lower quality of life in those affected, poorer physical functioning, premature death, and higher hospitalization rates.7

Our results yielded higher scores on the depressive symptoms scale for the older adults living in urban than for those living in rural areas. Although the impact of variations in lifestyles of the older adults residing in urban vs. rural areas on their physical health has been the focus of many studies, far less attention has been paid to the issue of how city life affects the mental health of the elderly. Issues that are vital if we consider that both the risks and the protective factors change with age.36 Depression in older adults is less influenced by genetic factors and more under social and environmental factors.39 Therefore, it is expected that the isolation during the COVID-19 pandemic would have consequences in this area. Residents of rural areas in developed countries have higher depression rates36, linked to the availability of health institutions.37

Studies show that older adults with higher educational levels or higher income have a significantly higher probability of participating in social activities.38 Results of our study align with those findings and point to the negative impact of old age on social participation. Other studies have also confirmed this relationship between old age and social participation.35 We obtained higher scores on the scale of social participation for older adults living at home than for those living in nursing homes. The reason for this finding can be the lack of well-designed activities in nursing homes and an abundance of free time that their residents are unable to fill with constructive activities, making their lives revolve around instrumental activities (feeding, changing, bathing, etc.).

### Conclusion

Many studies worldwide have confirmed the negative impact of COVID-19 on mental health.20,21 The study we conducted in Serbia included older adults living in different types and places of residence and confirmed a strong relationship between social participation and depressive symptoms in the COVID-19 pandemic. Social and physical distancing negatively affected mental well-being, specifically among

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**Table 5**

Moderation effects of the place of residence in the relationship between depression and social participation.

|                  | $R$  | $\Delta R^2$ | $B$  | S.E. | $\beta$ | $p$ |
|------------------|------|--------------|------|------|---------|-----|
| **First block**  |      |              |      |      |         |     |
| Social participation                   | -0.305 | 0.091 | -0.305 | 0.000 |
| Place of residence                             | -0.008 | 0.112 | -0.004 | 0.941 |
| **Second block**  |      |              |      |      |         |     |
| Social participation                   | -0.363 | 0.073 | -0.363 | 0.003 |
| Place of residence                             | -0.009 | 0.112 | -0.004 | 0.937 |
| Interaction                                      | 0.138  | 0.113 | 0.089  | 0.222 |

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older adults living in a nursing home. This study provides important clinical and public health implications. We established that reduced social participation of the older adults in the pandemic situation leads to depression, which suggests a need for creating and implementing preventive strategies both in clinical and community settings. Furthermore, adaptive strategies using modern technology are needed to reduce loneliness and depression and promote participation when live contact is made impossible.

Limitations

In order to obtain a homogeneous sample, all cognitive impairment older adults were excluded from the study, which certainly is a significant limitation of this study. Only older adults who are cognitively, socially, and functionally preserved participated in this research, so it is impossible to generalize the obtained results to all persons older than 60 years. Also, the authors did not know the real reason for placing the respondents in a nursing home and whether this could affect the research. In the research, we did not have data on the level of social participation and depression in this sample before the Covid-19 pandemic. Therefore, we cannot claim that the current situation is a product of isolation due to the pandemic. In the end, we found a strong link between social participation and higher levels of depressive symptoms, but for a complete understanding of this link in a pandemic situation, additional research is needed.

Ethical considerations

The Ethics Committees of the Faculty of Medicine, the University of Novi Sad, Serbia (16.07.2020.01-39/211), approved the implementation of this study and the administration of nursing homes and retiree associations where the study was conducted.

Funding source

This research did not receive any special support from financial agencies in the public, commercial or non-profit sector.

Declaration of Competing interest

None.

Appendix A

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

| 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 |
| | (b) Provide in the abstract an informative and balanced summary of what was done and what was found | 1 |
| Introduction | 2 | Explain the scientific background and rationale for the investigation being reported | 2-3 |
| Background/rationale | 3 | State specific objectives, including any prespecified hypotheses | 4-5 |
| Objectives | 4 | Present key elements of study design early in the paper | 5 |
| Methods | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection | 5-6 |
| Study design | 6 | Give the eligibility criteria, and the sources and methods of selection of participants | 6 |
| Setting | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable | |
| Participants | 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 | |
| Bias | 9 | Describe any efforts to address potential sources of bias | |
| Study size | 10 | Explain how the study size was arrived at | 6 |
| Quantitative variables | 11 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why | |
| 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 | 8 |
| | (c) Explain how missing data were addressed | |
| | (d) If applicable, describe analytical methods taking account of sampling strategy | |
| | (e) Describe any sensitivity analyses | |
| Results | 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 | 9 |
| | (b) Give reasons for non-participation at each stage | |
| | (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 | 9-10 |
| Outcome data | 15* | (b) Indicate number of participants with missing data for each variable of interest | |
| Main results | 16 | Report numbers of outcome events or summary measures | |
| | (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 | |
| | (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 | 11-12 |
| Discussion | 18 | Summarise key results with reference to study objectives | 12-15 |
| 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 | 16 |
| Interpretation | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence | 12-16 |
| Generalisability | 21 | Discuss the generalisability (external validity) of the study results | |
| Other information | 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 | |
