Rome, 13th December 2021

Dear Editor,

Thank you for editing and having reviewed our manuscript NO: 72818, titled "Pregnancy-Related Psychopathology: A Comparison Between the Pre-Covid-19 and Covid-19–Related Social Restrictions Periods", by Daniela Chieffo, Carla Avallone, Annamaria Serio, Georgios D. Kotzalidis, Marta Balocchi, Ilaria De Luca, Daniele Hirsch, Angela Gonsalez del Castillo, Pierluigi Lanzotti, Giuseppe Marano, Lucio Rinaldi, Antonio Lanzone, Eugenio Mercuri, Marianna Mazza and Gabriele Sani, which we submitted to the World Journal of Psychiatry. We thank you and the two peer reviewers who completed their review of our manuscript for the effort put in the editorial process. We accepted all comments and complied to them in our revised version. We hope the revision will match their expectations and that it will be considered to be suitable for publication in the World Journal of Clinical Cases.

To facilitate re-review, we employed red-coloured characters to highlight differences between the old and the new version; deletions will not appear. To enhance clarity, we herewith respond to reviewers point-to-point, keeping the original issues raised and responding to each just underneath, in **bold** ***and*** *italics*. Thank you again for the appreciation of our work.

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3 Peer-review report

Reviewer #1: 1.The concept is interesting, but the number of cases is small. It is suggested to expand the sample size for further study.

> ***We thank Reviewer for having found our study interesting and worthy of further endeavour. As the Reviewer will realise, it is not possible to expand the sample, because we dealt with all eligible cases during the two time-periods. Including further cases would render invalid the two time-periods considered, i.e., January-February 2020 and January-February 2021. We should wait for January-February 2022, and this would be another period that would be expected to carry on about the same sample size as the two sample sizes we report here. It would increase the number of comparisons to carry out. Hence it is not advisable to procrastinate, thus concealing the message we need to convey to the scientific community in the name of future completion (highly problematic) of our study. Besides this, the small sample size has been duly acknowledged in the Limitations section.***

2.There are a few misnomers, for example, In the discussion section " We found the Covid-19 group of pregnant women to score lower on state anxiety then the Pre-Covid-19 group, "then" shoud be "than".

We thank Reviewer for this observation. We know it should be than instead of then, it was a misprint, a typo. We corrected it. We thank reviewer for useful suggestions that contributed to the improvement of our manuscript.

Reviewer #2: Thank you for having an opportunity to review the report by Dr. Chieffo D, et al. They reported a case-controlled study for the pregnancy related psychopathology with a comparison between the pre-Covid-19 and Covid-19 related social restrictions periods. The authors showed the negative data on their primary analysis and the assumed effect of social support during the pandemic for maternal depression and anxiety.

We thank Reviewer for careful reading and appreciation.

Although their scope is important, there are major and minor points which should be addressed for the acceptance.

We thank Reviewer for critical comments and attempted at addressing them adequately.

Major 1. In the manuscript, the eligibility of this study was not described and why their study has small samples was also not mentioned. The authors should provide the data about how many women were eligible at first and excluded from this study with a flowchart.

We produced a flowchart.

2. Moreover, in Table 1, the eligible women had high complication rate of psychiatric disorders in both samples and high rate of psychotherapy in the pre-Covid sample. Due to the unclearness of eligibility and these possible underlying confounders in this study, the external validity may be low and they might fail to prove their hypothesis. Therefore, the authors should clarify and discuss this concern.

We thank Reviewer for this observation and commented this point in Discussion.

3. In the introduction, although the authors pointed out that loneliness during this kind of pandemic had negative emotional effect, I think most of pregnant women do not have problem about loneliness. In fact, the eligible women in this study had enough social support. Instead, many pregnant women may have concerns about their own health and adverse effects on their fetus of the virus, many novel medications and vaccines, which should negatively affect maternal mental health. The authors should describe and discuss this point.

We thank Reviewer for this prompt and commented upon it in Introduction.

4. The authors should describe the rationale of the usage of STAI-Y and SCL-90R in this analysis. For example, why did they not select GAD-7? Moreover, please describe and discuss about the previous reports about STAI-Y and SCL-90R for pregnancy women.

We chose the STAI-Y instead of the GAD-7 because the latter does not investigate separately state and trait anxiety. For the same reason we did not use the Zung Anxiety Self Rating Scale. We did not add this in the text, as this excusatio non petita would render the text heavier than it should be. We have already cited those studies that used the STAI-Y in pregnant women, while those using the SCL-90R in pregnancy are 42. We added in Discussion a paragraph to summarise their results, although this interrupted the natural flow of the paper.

Minor 1. The authors should provide the duration, eligibility and the number of finally included women in the abstract.

We integrated these data in the Abstract.

2. The authors should provide the data about the domestic infection situation in their country during the research period.

We stated the infection spread status in our area.

3. The introduction is too long to understand. Please summarize briefly focusing on what is known and unknown.

What length has to do with understanding? We shortened the Introduction, but this might result in a loss of comprehension. It is surprising you asked this, while requiring to further discuss an issue in which you are apparently interested. Please note that readers' interests vary.

4. The authors should provide specific data about psychiatric disorders in Table 1.

We added disorders in Table 1.

5. Additionally, the authors should provide specific data about pregnancy complications in Table 1.

We provided data about complications of pregnancy in Table 1.

6. What is the difference between psychiatric disorders and current psychiatric disorders in Table 1?

We added lifetime so that you clarify your ideas.

7. What is "medical condition" in table 1? Please clarify it.

Medical conditions are conditions that pertain to the discipline of Internal Medicine. It is a widespread expression to denote physical conditions of medical interest.

8. What is "Stressful life events" in table 1? Please clarify it.

Stressful life events are all events in the life of the patient that constitute a stress, be it happy or nasty (having to move from neighbourhood, getting married, getting a promotion at job, being fired, loss of a loved one, having to serve for the military, being abandoned by a fiancée, and the like). These are listed in Sarason's or Paykel's questionnaires and are widely known, they don't need specification.

9. If available, the demographic data for occupation and income level should be described in table 1.

We cannot detail them, they are too diverse. The Table is already too long and became longer as per your requests.

10. The data about the trimester of pregnant women should be shown as a categorical variable.

They are a categorical variable. We never said it was continuous.

11. In line 4 of page 10 in the result section, the authors mentioned "hospitalized samples". The eligibility is for hospitalized women or women at outpatient office? Please make it clearer.

We work in a hospital and our service is a day-hospital. As a result, all patients are hospitalised, albeit for only one day at a time. We clearly said in Methods what our service is, it can't be made clearer.

12. In the last sentence of the manuscript, the description of the citation is mistaken.

This is one point we regret to reject. If you look at Table 1 of the cited work, you will find out that some women reported deteriorated relationships with partner, although they were a minority. We did not change our phrasing. We remark that your Review is at odds with the comments of the other two reviewers, with many comments being misplaced. It seems like you tried to find breaches in our paper, so to reject it, but you have been unsuccessful in many respects. Acrimony is not a good property for fair reviewing. We thank Reviewer for useful suggestions which rendered our paper better (at least, we hope).

Reviewer #3: Good work.

We thank Reviewer for having appreciated our work. The remark that English was not of sufficient quality was seriously taken into consideration, so we subjected the manuscript to thorough revision for language, that allowed us to identify and correct misprints. Thank you again.

Pregnancy-Related Psychopathology: A Comparison Between the Pre-Covid-19 and Covid-19–Related Social Restrictions Periods

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The authors have read the STROBE Statement checklist of items, and the manuscript was prepared and revised according to the STROBE Statement checklist of items. Not perfect English, but perfect bureaucracy.

Running title: Psychopathology in Covid-19 times

Paper statistics: Running head: 33 characters, including spaces; Core tip, 84 words; Abstract, 377 words; Text, 4,943 words; Figures, 1; Tables 3; 84 References.

ABSTRACT

Background: The Covid-19 pandemic impacted in a still undefined way pregnant women's mental health. There are reports of mood and affect changes in the general population and the suggestion that similar changes occur also in the pregnant population. The greater vulnerability of women during the Covid-19 restrictions period may translate into the gestational period in a greater risk for mental disorders. We hypothesised that pregnant women in the pre-pandemic period would have less psychopathology and more psychological support than pregnant women during the pandemic restrictions period.

Aims: To compare pregnant women for anxiety, prenatal depression, psychopathology and social support before and after the awareness of the pandemic.

Methods: We administered to women willing to participate in their 2nd-3rd trimester of pregnancy the Edinburgh Postnatal Depression Scale (EPDS), the State-Trait Anxiety Inventory Form Y (STAI-Y), and the Symptom CheckList-90-Revised (SCL-90R); we further collected sociodemographic variables and explored women's social support. The comparison was cross-sectional. The first sample was termed nonCovid-19 because data were gathered before the Covid-19 outbreak (January-February 2020) was declared, the second sample Covid-19, because participants were already subjected to the Covid-19–related restrictive measures (January-February 2021). Since normal distribution was not met (Shapiro-Wilk test applied), we applied nonparametric Mann-Whitney's *U*-test to compare psychometric tests. Ethical standards were met.

Results: The nonCovid-19 group reported higher support from partner only, while the Covid-19 group reported multiple support (χ^2=9.7181; p=0.021); the nonCovid-19 group scored higher than the Covid-19 group only on state anxiety, among psychometric scales (STAI-Y1, nonCovid-19 median=39 [95% CIs 39.19 to 51.10] *vs.* Covid-19 median=32 [95% CIs 30.83 to 38.90]; Mann-Whitney's U=117.5, p=0.00596). Other measures did not differ meaningfully between the two groups. Scores on the EPDS, the state and trait subscales of the STAI-Y, and most SCL-90R subscales inter-correlated with one another. The anxiety component of the EPDS, EPDS-3A, correlated poorly with other measures, while it was the Global Symptom Index (GSI) of the SCL-90-R that correlated most strongly with most measures. Our results are at odds with most literature and do not confirm increased depression and anxiety rates in pregnant women during the pandemic.

Conclusions: The ability of pregnant women to deal with novel generalised threats involves mobilization of inner resources. Increasing sources of social support may have produced anxiolysis in the Covid-19 sample.

Keywords:

Covid-19 pandemic; Pregnancy; Social Support; Anxiety; Depression; Psychopathology

Core tip: Covid-19 pandemic's impact on women's mental health is currently undefined. We assessed anxiety, prenatal depression, and psychopathology in pregnant women, comparing a sample with data collected prior to Covid-19 with one post-Covid-19. The pre-Covid-19 sample scored higher on state anxiety than the post-Covid-19 group; the former reported more partner support, while the latter reported more multiple support. Results show that pregnant women did respond to Covid-19 threat and restriction with increased psychopathology, indicating the recruitment of inner resources, but modified their social support pattern.

Introduction.

The Covid-19 pandemic has impacted mental health of the general population. In Italy, the impact was found to be quite high[1], while in the extended Middle-East–North African region it was reported to be mild[2] and in Taiwan it was lower than in other countries[3]. This heterogeneous distribution grossly matches the impact of the virus on within-country Covid-19 morbidity and mortality[1-3]. The individual psychopathological issues were also differently affected; fear decreased from the first to the second wave in China, while depression increased[4]. Clinically meaningful mental distress levels rose from about 20% in the preCovid-19 period to about 30% one month into UK pandemic-related restrictions[5]. In a large multination-multilingual survey, 40% of respondents reported fair mental health, 50% had only moderate mental health, and 10% reported poor mental health[6]. In this study, as well as in other studies conducted in France[7], Spain[8], Jordan[9], and Israel[10], it emerged that poor social conditions were a risk factor for developing poor mental health. Women were found to be more vulnerable to poor mental health[5,7-8,10-11]. The increase in psychological distress during the lockdown was found to have a greater impact on women [5,12]. Loneliness was attributed a role in engendering depressive symptoms in a US sample during the pandemic[11]. The relationship between loneliness and depression is long known[13], while a link to anxiety became the focus of investigation much later[14]. During the pandemic, the proportion of lonely people in the general population increased due to the restrictive measures, so it is estimated that more people than before were exposed to depression and anxiety. In fact, during the COVID-19 pandemic period, a complex pattern of interrelationships among these constructs emerged, with loneliness and depression predicting each other across time, and loneliness predicting anxiety with the mediation of depression across time, independently from gender[15]. Loneliness, depression, and anxiety interact with negative thinking to boost each other in perinatal women and the chain may be interrupted or eased through social support[16]. However, most women during the pandemic have concerns about their own health and that of their foetus, that more than loneliness may impact their psychopathology.

This greater vulnerability of women during Covid-19 restrictions may translate into the gestational period in a greater risk for mental disorders[17]. Pregnant and postpartum women fear Covid-19 exposure or infection for themselves and/or foetus/baby; limited social support, and physical isolation and distancing may impact their mental health[18]. Perinatal women resulted to be at greater risk for psychopathology during the Covid-19 period in an analysis of the literature[17]. Covid-19–related social adversity affected negatively maternal mental health[19]. Pregnant women showed stronger increases in depression, anxiety, and negative affect than their non-pregnant counterparts, as well as reduced positive affect[20]. During the Covid-19 period,

about 60% of pregnant women scored positive on depression questionnaires, about 30.0% on anxiety questionnaires, about 20% reported high levels of stress, and about 20% clinically significant insomnia[21]. Summarizing, the perinatal period during Covid-19 times may be an at risk period for mental health according to current data. However, despite the bleak outlook for mental health during the Covid-19 period, there is hope that adequately addressing coping and resilience issues, mental health would not be adversely affected. In fact, dysfunctional coping has been linked to poor mental outcome, while emotion-focused coping has been associated with better mental outcomes[21]. Furthermore, in a general population sample, psychiatric symptoms increased acutely, but returned to baseline levels during sustained Covid-19 measures, pointing to the recruitment of internal resources related to resilience that may dampen the effect of the pandemic on mental health[22].

Since the influence of the pandemic in pregnancy and post-delivery has not been definitively established, having tested for psychopathology (depression, anxiety, and general psychopathology) a sample of pregnant women in their 2nd-3rd trimester of pregnancy during the pre-Covid-19 period (i.e., a period when the virus had not yet spread over the country, or at least, people in the country did not figure out it could represent a threat), we administered the same tests in women of comparable gestational ages after the Covid-19 outbreak and its consequent restrictions (when people in the country were aware of the threat the virus represented to their lives). We aimed at seeking possible differences in psychopathology between the two samples. We mainly focused depression and anxiety symptoms, but did not disregard general psychopathology. We also collected socio-demographic data to identify possible predictors of clinically significant symptoms in our sample of pregnant women.

Methods.

Study population.

Consecutive pregnant women who visited the Gynaecology and Obstetrics Day Hospital unit during the period January-February 2021, amidst the Covid-19 pandemic, underwent screening for depression, anxiety, and psychiatric symptoms. The visit included basic assessment, the completion of a sociodemographic data collection form, and the administration of specific questionnaires. This group has been defined as the Covid-19 group, despite its women screened negative for the virus. This sample has been compared with a sample of pregnant women whose data had been collected the same year period of the previous year (the nonCovid-19 group), when they knew nothing about the impending pandemic. Eligible were women willing to give birth and

to participate in the study. Among the 93 women visiting the service during the pre-pandemic period, only 21 provided free, informed consent for filling-in the proposed questionnaires, while during the corresponding Covid-19 pandemic period, 22 of 86 women provided content (Figure 1). Sociodemographic variables were not different between the women who accepted and those who did not. The reasons of refusal were most often lack of time and length of the Symptom CheckList-90-Revised (SCL-90R) questionnaire.

Please insert Table 1 about here

During the period of data collection of the Covid-19 sample, the infection had spread throughout Italy; however, in the north of Italy, the infection was widespread and very lethal, out of control, whereas in Rome, which is situated in central Italy, the spread was threatening, but under control.

Study design.

We compared data of the Covid-19 and the nonCovid-19 samples, both regarding scores on psychometric instruments and sociodemographic, family and personal clinical variables. The aim was to establish differences be Symptom CheckList-90-Revised (SCL-90R) between the pre-pandemic and the pandemic periods in psychological distress and psychopathology of childbearing women.

Instruments used.

The **Edinburgh Postnatal Depression Scale** (EPDS)[23] is a 10-item self-rated questionnaire screening the risk of depression during the peripartum over the past week. Initially developed for the identification of postpartum depression[23], the EPDS was later validated for prenatal screen as well[24-25]. The questionnaire refers to how the woman felt in the last seven days and each item is scored on a Likert-scale from 0 to 3, with each point receiving variable labels. Items 1 and 2 assess anhedonia, 3 guilt, 4 anxiety, 5 fear or panic, 6 helplessness, 7 sleep disorders, 8 sadness, 9 tendency to cry, and 10 tendency towards self-harm. Items 1, 2, and 4 are-scored according to an increasing severity gradient, all others are scored reversely. Higher scores indicate more risk of depression. In the original English version, a cutoff between 12 and 13 showed 86% sensitivity and 78% specificity; however, the authors suggested a threshold between 9 and 10 for community screening[23]. These cutoffs were adopted by both original developers and other investigators[26,27]. The Italian validation studies identified 9-10[28] and 12-13[29] as optimal cutoffs. In this study, we adopted the following cutoffs: total EPDS ≥13 for "risk for major depression", total EPDS 9-12 for "risk for mild depression". Three items of the EPDS (EPDS 3-A, items 3, 4 and 5) were found to cluster together on an anxiety factor in postpartum women, with optimum cutoff scores ranging 4-6 in different studies[30-34]. A higher cutoff was found to be best for postnatal anxiety (≥6)[31], with a

lower cutoff of ≥4 best fitting the antenatal period[33]. We endorsed the latter as a proxy for anxiety, as our sample was exclusively composed of prenatal women. However, the authors maintain that the scale does not confirm an anxiety disorder and does not distinguish whether anxiety scores on these three items are a feature of depression or a distinct entity. In the original study, the authors recommended to watch immediately the score on item 10 (self-harm) and refer the patient for further evaluation in case score is ≠0, a recommendation we adhered to strictly. The questionnaire has shown good psychometric properties, with positive predictive value (PPV) ranging 22-82% and negative predictive value 70-100%[35].

The **State-Trait Anxiety Inventory Form Y** (STAI-Y)[36]. Charles Spielberger developed his concept of state and trait anxiety after Cattell and Schneier[37] (1958), to measure two different, albeit keen constructs, one responsive to environmental change (state) and the other relatively invariant (trait) in the mid-sixties[38] and published the X-form version a few years later[39]. Thirteen years later, they developed and validated their definitive Y-form, which differed in some respects from the X-form, with simpler forms of sentences and reversely directed items[40]. The inventory consists of two self-rated sheets with 20 statements each. Every item is scored 1 to 4 according to Likert scales, with the state Y1 referring to "how you feel *right now*", with responses being 1=Not at all, 2=Somewhat, 3=Moderately so, and 4=Very much so, and the trait Y2 referring to "how you *generally* feel", with responses being 1=Almost never, 2=Sometimes, 3=Often, and 4=Almost always. Higher scores indicate higher anxiety levels. Items 3, 4, 6, 7, 9, 12, 13, 14, 17, and 18 of the state form Y1 and 22, 24, 25, 28, 29, 31, 32, 35, 37, 38, and 40 of the trait form Y2 count as they are scored, while all others are scored inversely (1 counts 4, 2 counts 3, 3 counts 2, and 4 counts 1). The best fit is for a four-factor model, consisting of state anxiety present, state anxiety absent, trait anxiety present, and trait anxiety absent, each corresponding to the directly scored and to reverse items of each subscale[41]. This model provided for higher than 0.70 alpha composite reliability, convergent validity, and discriminant validity. Correlations between state anxiety present and trait anxiety present, and high correlation between state anxiety absent and trait anxiety absent were high (r=0.770 and =0.923, respectively)[41].

Although there is still debate for the cutoffs of the STAI-Y[42], gender was found not to affect scores[43]. The developers of the scale provided the following cutoffs, which we followed in classifying our patients, i.e., 20-39 indicates low anxiety, 40-59 moderate, and 60-80 high anxiety, independently from the version used (state or trait)[36]. The STAI-Y2 showed an area under the curve of 84.7% for a cutoff of ≥52, with a 81.3% sensitivity and 77.5% specificity, a positive predictive value (PPV) of 41.9%, and a negative predictive value (NPV) of 95.4% in a recent study[44], but the resulting cutoff has not been generally adopted.

Symptom CheckList-90-Revised (SCL-90R) [45]. It is a self-rated 90-item questionnaire exploring nine psychological domains. It evolved from a previous 58-item self-rated questionnaire, which was developed at Johns Hopkins in Baltimore, Maryland, with the intention to rate symptom severity along five dimensions, i.e., obsessive-compulsive behaviour (O-C), anxiety (ANX), depression (DEP), somatization (SOM), and interpersonal sensitivity (I-S); scores were then combined to produce a total distress score[46]. The revised version deleted some items from the first version and added 45 new items referring to four new dimensions, i.e., hostility (HOS), phobic anxiety (PHOB), paranoid ideation (PAR), and psychoticism (PSY). The instrument contains items coding for eating and sleep problems. In particular, three items, i.e., 44 (Trouble falling asleep), 64 (Awakening in the early morning), and 66 (Sleep that is restless or disturbed), clustered to form the SLEEP dimension[47], which we used in this study. The distress related to each item during the last week is scored on a five-point 0-4 Likert scale, where 0 is not at all, 1 is a little bit, 2 is moderately, 3 is quite a bit, and 4 is extremely. The instrument provides for three general indexes, i.e., the Global Severity Index (GSI), obtained by adding all scores and dividing by 90, the Positive Symptom Total (PST), i.e., the total number of symptoms on which the respondent scored >0, and the Positive Symptom Distress Index (PSDI), obtained by adding all scores on the 90 items and dividing by the PST. Despite good internal coherence for all subscales (α values 0.70-0.96), the SCL-90-R shows factor-structure instability, suggesting that the most reliable index to adopt is the GSI[48]. The tool showed to be able to discriminate between community dwellers and psychiatric patients, with an area-under-the-curve (AUC) of 83 %, Glass's $\Delta = 1.4$, Cohen's $d = 1.1$, and diagnostic odds ratio 12.5[49]. A cutoff of a GSI ≥ 0.57 has been suggested as a cutoff for a German sample[50] to distinguish normal from psychiatric cases, but in a Chilean inmate population this figure rose to 1.42[51].

Ethics statement. Participants provided written informed consent, in accordance with all applicable regulatory and Good Clinical Practice guidelines and in full respect of the Ethical Principles for Medical Research Involving Human Subjects, as adopted by the 18th World Medical Association General Assembly (WMA GA), Helsinki, Finland, June 1964, and subsequently amended by the 64th WMA GA, Fortaleza, Brazil, October 2013. The study received approval from the local ethics committee (Ethics Committee of the Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Università Cattolica del Sacro Cuore of Rome, Rome, Italy). Written informed consent has been obtained from all participants.

Statistics. We expressed sociodemographic parameters as means and standard deviations (SDs) and used the *t*-test to compare the two groups when the variables were continuous and as number (N) and percentages when the variable were nominal and used the χ^2-test to compare the two

groups. We used Pearson's *r* coefficient to assess correlations. We preliminarily tested normality of distribution with the Shapiro-Wilk test[52]. The test produced values of W=0.9219, p=0.0062 for the EPDS, W=0.8810, p=0.0003 for the STAI-Y, and W=0.7752, P<0.000001 for the SCL-90, which all were not compatible with normal distribution. Hence, we turned to the non-parametric Mann-Whitney *U*-test and expressed psychometric data as medians and 95% confidence intervals (95% CIs). We applied the Bonferroni correction[53] to address multiple testing. This brought the cutoff for statistical significance originally set at P<0.05 (and valid for sociodemographic comparisons) down to P<0.0125 for the psychometric comparisons (for intra-SCL-90 comparisons this was P<0.0045), while for correlations, we applied no correction as it could be too conservative and expose to type-II error[54]. A biostatistician (GM) processed all data using the SPSS version 26.0 (IBM SPSS Statistics for Windows, Version 26.0. Armonk, NY: IBM Corporation, 2019).

Results. The pre-Covid-19 (N=21) and Covid-19 (N=22) groups did not differ for age (mean age [years]=35.714±5.763 *vs*. 34.591±8.342; t=-0.511; p=0.612, not significant [ns]) or gestational age (mean [weeks]=19.476±4.792 *vs*. 17.636±6.616; t=1.040; p=0.304, ns).

Table 1 shows the sociodemographic characteristics of the two samples. The only measure on which the nonCovid-19 and Covid-19 groups differed was on the type of support, with the nonCovid-19 group reporting higher support from partner only, whereas the Covid-19 group reported multiple support, which comprises partners, parents and relatives, and friends (χ^2=9.7181; p=0.021) (Table 1). However, total support was almost identical between the two groups.

Please insert Table 1 about here

Table 2 shows the comparison between the Pre-Covid-19 and post Covid-19 outbreak hospitalized samples on their scores on psychometric questionnaires. The two samples did not differ on their EPDS scores, total or EPDS-3A; all women scored 0 on the suicidal ideation item. The Pre-Covid-19 sample scored higher on the state anxiety questionnaire only.

Please insert Table 2 about here

There were 4 cases out of 21 (19.05%) in the Pre-Covid-19 group who scored positive for risk for major depression on the EPDS total (≥13), with 3 cases between 9 and 12, i.e., risk for mild depression (14.28%), while 14 cases (66.67%) scored lower than all cutoffs (no depression); 5 (23.81%) scored positive on the EPDS-3A (≥4), and none (0%) on the EPDS suicide item 10. In the Covid-19 sample, there were 2 cases out of 22 (9.09%) scoring positive for risk for major depression (EPDS total ≥13), 7 (31.82%) scored 9-12 (risk for mild depression), and 13 (59.09%)

scored lower than 9 (no depression), while 10 (45.45%) scored positive on the three-item anxiety component of the EPDS (-3A) and none (0%) scored ≠0 on the suicide item 10. The two groups did not differ.

According to the cutoffs provided by Spielberger et al.[36], we classified 11 (52.38%) patients from the PreCovid-19 sample and 18 (81.82%) from the Covid-19 sample as low anxiety on the STAI-Y1, 6 (28.57%) from the PreCovid-19 and 4 (18.18%) from the Covid-19 sample as moderate, while 4 (19.05%) patients from the PreCovid-19 group and none (0%) from the Covid-19 group scored in the high anxiety range. The two groups differed meaningfully, with the PreCovid-19 group scoring more in the severe range than the Covid-19 sample (χ^2=8.116; p=0.03933, two-sided). Regarding the STAI-Y2 form, 14 (66.67%%) patients from the PreCovid-19 group and 16 (72.73%) from the Covid-19 group scored in the low anxiety range, 7 (33.33%) from the PreCovid-19 and 6 (27.27%) from the Covid-19 samples scored in the moderate anxiety range, and no patient from either group scored in the high anxiety range (0% for both samples). The two groups did not differ meaningfully (χ^2=0.187; p=0.74699, two-sided).

Correlations are shown in **Table 3**. It is of note that the EPDS-3A correlated poorly with other measures, while the GSI of the SCL-90-R correlated most strongly with most measures.

Please insert Table 3 about here

Discussion

In the current study we investigated pregnancy-related depression, anxiety, and psychopathology in two distinct samples. One sample was assessed during the Pre-Covid-19 period and the other during the Covid-19 restrictions period. We found the Covid-19 group of pregnant women to score lower on state anxiety than the Pre-Covid-19 group. The two groups did not differ for their baseline characteristics, save for the type of support the women received during their pregnancy, where the prevailing modality turned to multiple in Covid-19 times.

We would have expected greater psychopathology in the post-restrictions Covid-19 sample of pregnant women, as reports mostly indicated a rise in anxiety[55], depression[56,57], sleep disorders[58], and post-traumatic symptoms[59-60]. In fact, in a meta-analysis, Yan et al.[61] found pregnant women during the Covid-19 pandemic to have a higher relative risk for cumulative anxiety/depression than women in the same locations before the pandemic. Another meta-analysis found increased anxiety from the pre-pandemic to the Covid-19 pandemic period in perinatal women, but the increase in depression was not significant[62]. We here found a *decreased*

score of state anxiety in pregnant women amidst the pandemic period that could point to pregnant women feeling worse in better times, a paradoxical finding indeed.

In our sample, 4 of 21 (19.05%) pregnant women in the Pre-Covid-19 sample and 2 of 22 (9.09%) pregnant women in the Covid-19 sample met criteria for clinically significant depression (total EPDS scores ≥13). These results are dissimilar from those of a Turkish study, which found 35.4% of pregnant women in Covid-19 times to score ≥13[63], and from those of a Canadian survey, which found 37% depression and 57% anxiety[64]. The results of a large multinational study[65] were less alarming and more similar to ours, with 15% EPDS-assessed depression during pregnancy and 11% GAD-7–measured anxiety. We found 52.38% of the PreCovid-19 sample and 81.82% from the Covid-19 sample to score low on anxiety, 28.57% of PreCovid-19 and 18.18% of the Covid-19 sample to score moderate, and 19.05% PreCovid-19 participants and 0% of the Covid-19 group to score high on anxiety. This does not compare with those of Preis et al.[66], who found 21.1% of their pregnant women during Covid-19 with no-to-minimal anxiety symptoms, 35.6% with mild anxiety, 21.6% with moderate anxiety, and 21.7% with severe anxiety. This cannot be due only to the different instrument used (we used the STAI-Y and they used the GAD-7).

Another Turkish study found even higher anxiety levels in pregnant women (62.6%), even though the proportion was less than that of the non-pregnant women (72.3%)[67]; these authors used the same tool to assess anxiety as we did, i.e., the STAI-Y, the same used by an Italian study which found a 68% prevalence of anxiety[68]. However, these authors assessed women in all trimesters of pregnancy, while we included women in the 2nd and 3rd trimesters; Saccone et al.[68] found anxiety symptoms to be more severe during the first trimester; so it is possible that part of the difference could be attributed to the timing of the sampling; furthermore, they used a less stringent cutoff than Yassa et al.[67]. These large differences might be attributed to the different settings, methodologies, and to cultural factors. Our results are more similar to those of a Chinese study, which found low rates of both anxiety and depression in pregnant women during Covid-19, that were lower than those of non-pregnant women[69]. These results matches our idea that during difficulties, pregnant women recruit psychological resources allowing them to better address their new needs. Our results do not match those of a large meta-analysis, which found proportions of 30% for depression, 34% for anxiety, and 18% for comorbid depression and anxiety[70], while similar rates for both anxiety (31.9%) and depression (31.4%) were found by another meta-analysis of studies conducted during the early phase of the pandemic[71]. It should be said that our pre-pandemic period much overlaps with the early pandemic phase of most Chinese studies. In fact, in Wu T et al.[71], 62 studies were Chinese out of a total of 66.

We found that social support for pregnant women was different between the PreCovid-19 and the Covid-19 pandemic periods, in that pregnant women before the pandemic tended to rely more on partner support than on other types of support, while in the pandemic period had turned to a multiple support type. This does not mean that they received less support from their partner, but rather that they used additional support from their environment. This could be the result of a greater social cohesion under the threat of the pandemic or be related to other pandemic-related factors. For example, during the pandemic, access to pregnant women by their support providing figures is restricted[72], so it could be that women during this period turn to whatever support they may find. Lower perceived support, as measured through the Multidimensional Scale of Perceived Social Support has been reported in Ireland among pregnant women during the pandemic[73]. Here we did not find reduced support compared to the previous pre-pandemic period by assessing support through direct interview, but rather a redistribution between social support types. It is possible that beyond different methodological differences, there are cultural and other reasons that underpin the difference between the two European countries. Social support in pregnant women has been investigated in northern Italy in one study[74], and was found to correlate negatively to depression and anxiety; however, this study quantified the extent of social support without focusing on support pattern as we did. Support has been shown to reduce anxiety in pregnant women during the pandemic in various studies assessing it through specific scales[16,75-77]. The way we collected social support data (categories) prevent us from correlating them with anxiety scores, but it is possible that the high support perceived by women in our sample could match the lower than expected anxiety levels.

Both samples, especially the pre-pandemic one, had higher rates of occurrence of psychopathology than the normally expected. Since there has been a high rate of refusal to complete the questionnaires, it is possible that there has been a selection bias, in that only women who were aware of having psychopathological problems that were prompted to adhere to the study.

The SCL-90R has been used in pregnant women to assess psychopathology in a number of studies also in the Covid-19 period. One Spanish study compared pre-pandemic to Covid-19 pandemic pregnant women and found more depression, insomnia, and phobic anxiety in the Covid-19 pandemic sample[78]. In a Chinese study comparing pregnant healthcare workers with pregnant women from the general population, higher prevalence rates of psychological symptoms of SCL-90R somatization, anxiety, and hostility were found among pregnant healthcare workers [79]. An Italian study of a Covid-19 pandemic sample found high SCL-90R global scores [80], which we did not find.

Limitations. The small samples and the fact that each participant was not her own control limit the generalisability of results. The cross-sectional nature of the design further limits the generalisation of the results. A strength of this study is that it compared two temporally near samples, one aware and one unaware of Covid-19. There are few studies comparing the two periods. A longitudinal design could have drawn better data. Women testing positive for Covid-19 have shown a peculiar pattern of anxiety and depression curves, with anxiety scores rapidly decreasing and returning to baseline levels, while depressive scores tended to subside more sluggishly[81]. Our data are limited to women testing negative for Covid-19 and may not extend to those testing positive; however, the latter showed similar rates of anxiety and depression in a case-control study[82]. To address multiple testing and control for type-I statistical error, we applied the extremely conservative Bonferroni correction[53], which is however too conservative and may expose to type-II error; however, the obtained results dispelled the possibility that potentially significant results could go undetected due to excessive restriction of the significance cutoff. Furhermore, we did not quantify social support through specifically dedicated scales, but rather we focused on support pattern. This may be a limitation, but focusing on pattern, which is an important characteristic of social support, may constitute a strength of our study.

Conclusion

The studies that focused on maternal mental health during the Covid-19 pandemic period, just as other projected or data-driven studies, are extremely rapidly accumulating, but their quality is heterogeneous. They alternate small sample sizes like ours with huge databases. The Covid-19 pandemic led to an increase in publishing about Covid-19 with few or ill-collected data on which others commented. While some recognised the lack of appropriately collected data ("It may take time to generate sufficient and sound evidence"), they nevertheless went on to state "but we can safely speculate that pregnant women are at increased risk of developing mental health problems such as depression, anxiety, and post-traumatic stress symptoms"[83]. Future studies should employ longitudinal designs and verify the course of anxiety, depression, stress and PTSD-related symptoms, and sleep problems, but also psychotic symptoms in women who are pregnant and in those who are not. The timing of testing is important, as women's responses are moulded though the media and responsible professional information provision and mental health markers may wax and wane during the pandemic on the basis of global response[81]. Another important point is the use of specific instruments for depression and anxiety in the perinatal period, as most studies used different assessments (some narrative and not validated) and some instruments showed not to be enough reliable, as in our case the EPDS-3A, which correlated poorly with other instruments (Table 3).

The real effects of the pandemic are difficult to assess if adequate instruments are not used. Social isolation and Covid-19 threat may affect mood in pregnancy unpredictably, as they may both improve it or worsen it, improve or deteriorate relationships with others[84] or recruit human resources that help overcoming pandemic-related stress[22].

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Ethical approval. The study received approval from the local ethics committee (Ethics Committee of the Fondazione Policlinico Universitario Agostino Gemelli IRCCS, Università Cattolica del Sacro Cuore of Rome, Rome, Italy). Patients completed a free and informed consent form and volunteered participating in the study.

Author contributions: DC conceived the study and designed it with MM, GS, and CA; GDK, CA, MB, IDL, and DH carried out literature searches and provided the first draft with MM, AMS AGdC, PL, MM, CA, DH, and EM viewed patients, conducted interviews and administered psychometric tests, GM, LR, MB, GDK, AL, CA, IDL and PL implemented the database and curated data; AL, EM, LR, MM, DC, and GS supervised the writing of the manuscript, CA, GDK, and MM provided the final version. All authors made substantial contributions to the conception and design of the study, in acquisition of data, analysed and interpreted data; drafted the article and made critical revisions related to important intellectual content of the manuscript; viewed and approved the final version of the article.

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Table 1. Sociodemographic characteristics of the nonCovid-19 (N=21) and the Covid-19 (N=22) samples.

Parameter	**Pre-Covid-19**	**Covid-19 period**	**Statistic**	***p***
Age, years ($\bar{x}$±SD)	35.714±5.763	34.591±8.342	t=-0.511	0.612
Gestational age, weeks	19.476±4.792	17.636±6.616	t=1.040	0.304
Country of origin				
Italy	17	18		
Romania	1	0		
Ukraine	1	1	χ^2=0.1018	0.750
Belgium	1	0		
Brazil	1	1		
Ecuador	0	1		
Gabon	0	1		
Educational level				
Primary school	0	0		
Middle school	4	5	χ^2=0.0879	0.957
High school	9	9		
College/University/Postgraduate	8	8		
Partner				
Yes	20	20	χ^2=0.0017	0.967
No	1	2		
Past pregnancies				
No	9	9	χ^2=0.0323	0.857
Yes	12	13		
Past abortions				
No	14	13	χ^2=0.0393	0.843
Yes	7	9		
Past abortion types				
None	14	13		
Spontaneous	4	6	χ^2=0.414	0.813
Induced	1	0		
Both	2	3		
Medical conditions			χ^2=0.3718	0.542

Yes	4	7		
No	17	15		
Psychiatric disorders (lifetime)				
Yes	10 (5 major depressive, 3 anxiety, 1 bipolar, 1 schizotypal personality)	6 (3 major depressive, 3 anxiety)	χ^2=1.1324	0.287
No	11	16		
Psychotherapy				
Yes	6	1	χ^2=2.9585	0.085
No	15	21		
Psychopharmacological treatment				
Yes	3	1	χ^2=0.3295	0.566
No	18	21		
Family psychiatric history				
Yes	6	8	χ^2=0.0482	0.826
No	15	14		
Current psychiatric disorder				
Yes	6	8	χ^2=0.0482	0.826
No	15	14		
Stressful life events				
Yes	7	13	χ^2=1.9234	0.165
No	14	9		
Significant pregnancy complications				
Yes	4 (3 emesis gravidarum, 1 pre-eclampsia)	3 (emesis gravidarum)	χ^2=0.2308	0.631
No	17	19		
Support				
Yes	20	21	χ^2=0.477	0.490
No	1	1		
Type of support			χ^2=9.7181	**0.021121***

None	1	1
Partner	13	4
Relatives and friends	4	6
Multiple	3	11

All significant results in **bold**. *P<0.05; SD=standard deviation; t=t value of the Student's t-test; $\bar{x}$=mean; χ^2=chi-squared test, all Yates corrected.

Table 2. Scores on the psychometric instruments used in the Pre-Covid-19 (N=21) and the Covid-19 (N=22) samples. Mann-Whitney *U*-test.

Measure (medians [95%CIs] for all measures)	**Pre-Covid-19**	**Covid-19 period**	**Mann-Whitney's *U***	***p***
EPDS total score	6 [4.92 to 9.94]	7.5 [5.64 to 9.64]	213	0.6672
EPDS-3A (anxiety cluster, items 3, 4, and 5)	2 [1.52 to 3.24]	3 [2.64 to 4.36]	150.5	.05238
EPDS-suicide item 10	0 [0 to 0]	0 [0 to 0]	231	0.99202
STAI-Y1 state	39 [39.19 to 51.10]	32 [30.83 to 38.90]	117.5	**0.00596***
STAI-Y2 trait	33 [31.70 to 39.45]	31 [29.49 to 36.42]	193.5	0.36812
SCL-SOM (somatization)	0.583 [0.47 to 1.00]	0.25 [0.27 to 0.66]	793.5	0.54186
SCL-O-C (obsessive-compulsive)	0.4 [0.39 to 0.92]	0.1 [0.15 to 0.52]	631	0.20408
SCL-I-S (interpersonal sensitivity)	0.222 [0.148 to 0.66]	0.0555 [0.08 to 0.44]	533	0.4654
SCL-DEP (depression)	0.462 [0.45 to 1.12]	0.1155 [0.17 to 0.54]	674.5	0.17068
SCL-ANX (anxiety)	0.6 [0.50 to 1.26]	0.1 [0.13 to 0.42]	526.5	0.09692
SCL-HOS (hostility)	0.167 [0.22 to 0.64]	0.167 [0.06 to 0.19]	512	0.18024
SCL-PHOB (phobic anxiety)	0 [0.05 to 0.43]	0 [0.02 to 0.25]	394	0.86502
SCL-PAR (paranoid ideation)	0.167 [0.15 to 0.74]	0 [0.12 to 0.43]	438	0.70394
SCL-PSY (psychoticism)	0 [0.06 to 0.48]	0 [0.05 to 0.18]	432	0.63836
SCL-SLEEP (sleep disorder)	0.333 [0.33 to 1.26]	0.333 [0.30 to 0.9148]	474.5	0.96012
SCL-GSI (Global Symptom Index)	0.311 [0.34 to 0.81]	0.1665 [0.16 to 0.42]	838	0.56868

Statistically significant results in **bold**. *P<0.0125. ***Abbreviations:*** 95%CIs, ninety-five percent confidence intervals; EPDS, Edinburgh Postnatal Depression Scale; SCL, Derogatis' Symptom Check-list-90 item questionnaire; SD, standard deviation; STAI, State-Trait Anxiety Inventory; $\bar{x}$, mean.

Table 3. Correlation matrix for the psychometric scales.

	EPDS total	EPDS-3A	STAI-Y1	STAI-Y2	SCL-SOM	SCL-OC	SCL-INT	SCL-DEP	SCL-ANX	SCL-HOS	SCL-PHOB	SCL-PAR	SCL-PSY	SCL-SLEEP	SCL-GSI
EPDS total	-	0.703***	0.61***	0.53***	0.4602**	0.4673**	0.3278*	0.44**	0.4233**	0.3454*	0.1706	0.4185**	0.1675	0.6013***	0.458**
EPDS-3A	0.703***	-	0.1561	0.1108	0.2996	0.225	0.2065	0.2553	0.2744	0.2194	0.2133	0.2297	0.1519	0.3224*	0.2858
STAI-Y1	0.61***	0.1561	-	0.7365***	0.4101**	0.5533**	0.4736**	0.6443***	0.6568***	0.4417**	0.2841	0.4448**	0.2532	0.4705**	0.574***
STAI-Y2	0.53***	0.1108	0.7365***	-	0.4623**	0.585***	0.5083***	0.5457***	0.5145***	0.4041**	0.3112*	0.5736***	0.3359*	0.5024***	0.5644***
SCL-SOM	0.4602**	0.2996	0.4101**	0.4623**	-	0.7321***	0.6493***	0.723***	0.5977***	0.7221***	0.6816***	0.6684***	0.652***	0.6091***	0.8345***
SCL-OC	0.4673**	0.225	0.5533**	0.585***	0.7321***	-	0.7634***	0.8937***	0.7555***	0.7149***	0.5539***	0.8873***	0.6972***	0.5762***	0.9174***
SCL-INT	0.3278*	0.2065	0.4736**	0.5083***	0.6493***	0.7634***	-	0.7977***	0.6119***	0.6796***	0.6925***	0.8046***	0.7961***	0.396**	0.8512***
SCL-DEP	0.44**	0.2553	0.6443***	0.5457***	0.723***	0.8937***	0.7977***	-	0.8588***	0.7255***	0.6221***	0.8443***	0.7751***	0.5262***	0.9535***
SCL-ANX	0.4233**	0.2744	0.6568***	0.5145***	0.5977***	0.7555**	0.6119***	0.8588***	-	0.7571***	0.4613**	0.6853***	0.6115***	0.5563***	0.8535***
SCL-HOS	0.3454*	0.2194	0.4417**	0.4041**	0.7221***	0.7149***	0.6796***	0.7255***	0.7571***	-	0.5406***	0.6628***	0.6504***	0.5008***	0.8195***
SCL-PHOB	0.1706	0.2133	0.2841	0.3112*	0.6816***	0.5539***	0.6925***	0.6221***	0.4613**		-	0.5855***	0.6864***	0.295	0.7034***
SCL-PAR	0.4185**	0.2297	0.4448**	0.5736***	0.6684***	0.8873***	0.8046***	0.8443***	0.6853***	0.6628***	0.5855***	-	0.8686***	0.6187***	0.9035***
SCL-PSY	0.1675	0.1519	0.2532	0.3359*	0.652***	0.6972***	0.7961***	0.7751***	0.6115***	0.6504***	0.6864***	0.8686***	-	0.4808**	0.8479***
SCL-SLEEP	0.6013***	0.3224*	0.4705**	0.5024***	0.6091***	0.5762***	0.396**	0.5262***	0.5563***	0.5008***	0.295	0.6187***	0.4808**	-	0.6395***
SCL-GSI	0.458**	0.2858	0.574***	0.5644***	0.8345***	0.9174***	0.8512***	0.9535***	0.8535***	0.8195***	0.7034***	0.9035***	0.8479***	0.6395***	-

*P<0.05 [grey background]; **P<0.01 [light grey background]; ***P<0.001 [black background]; white squares, not significant. **Abbreviations**: EPDS, Edinburgh Postnatal Depression Scale; EPDS-3A, anxiety cluster of the EPDS; SCL, Derogatis' Symptom Check-list-90 item questionnaire (ANX, anxiety; DEP, depression; GSI, Global Symptom Index; HOS, hostility; I-S, interpersonal sensitivity; O-C, obsessive-compulsive; PAR, paranoid ideation; PHOB, phobic anxiety; PSY, psychoticism; SLEEP, sleep disorder; SOM, somatization); SD, standard deviation; STAI, State-Trait Anxiety Inventory. No Bonferroni correction was applied.

Figure legends.

Figure 1. Flowchart of study design.