

## PEER REVIEW HISTORY

BMJ Open publishes all reviews undertaken for accepted manuscripts. Reviewers are asked to complete a checklist review form (<http://bmjopen.bmj.com/site/about/resources/checklist.pdf>) and are provided with free text boxes to elaborate on their assessment. These free text comments are reproduced below.

### ARTICLE DETAILS

|                            |  |
|----------------------------|--|
| <b>TITLE (PROVISIONAL)</b> | Measuring the impact of a social programme on healthcare: A 10-year retrospective cohort study in Trieste, Italy   |
| <b>AUTHORS</b>             | Castriotta, Luigi; Giangreco, Manuela; Cogliati-Dezza, Maria Grazia; Spanò, Marco; Atrigna, Enrico; Ehrenfreund, Claudia; Rosolen, Valentina; Paoletti, Flavio; Barbone, Fabio |

### VERSION 1 – REVIEW

|                        |  |
|------------------------|--|
| <b>REVIEWER</b>        | Mark Ward<br>Trinity College Dublin, Ireland |
| <b>REVIEW RETURNED</b> | 16-Mar-2020                                  |

|                         |  |
|-------------------------|--|
| <b>GENERAL COMMENTS</b> | <p>General comments</p> <p>This submission consists of an evaluation of a wide-ranging intervention and as such is a valuable topic. However, it is poorly executed in numerous parts and therefore difficult to assess the veracity or otherwise of the results.</p> <p>There is very little detail provided about the intervention, beyond a broad description. Also, as described, the intervention was limited to the delivery of healthcare services and is therefore difficult to see how it can be argued to have impacted on the social determinants of health, beyond the issue of access.</p> <p>Methodologically, it would seem more obvious to have tested the main outcomes before and after the intervention, assuming that data is available over that time period. This would go some way to minimising the effect of confounding, discussed below.</p> <p>The manuscript is also poorly written in parts which makes parts difficult to follow.</p> <p>Substantive comments</p> <p>The title is poor English. Suggest “Measuring the impact of a social programme on healthcare: A 10-year retrospective cohort study in Trieste, Italy.</p> <p>The literature review requires substantial improvement. The theoretical and empirical literature on the social determinants of health and the association between deprivation and health needs to be more fully addressed. The authors must also be clear on the distinction between individual- and area-level material deprivation. This is critical, particularly when suggesting mechanistic pathways to explain any associations between deprivation and health.</p> <p>The piece on material deprivation in the introduction is limited. Firstly, a definition of material deprivation would be useful. Also,</p> |
|-------------------------|--|

|  |  |
|--|--|
|  | <p>only one mechanism to explain the association between deprivation and mortality is provided. There are many more, for example, education, health behaviours, psycho-social etc.</p> <p>References should be provided to support each of the contentions discussed regarding Trieste at end of page 5, beginning page 6.</p> <p>Page 6. The description of the intervention belongs in the methods section, not the literature review. The description of the intervention is also very broad and lacks detail. This makes it difficult to assess the conclusion that the intervention worked.</p> <p>Each indicator included in the analyses should be fully described in the methods section – the Charlson Index, and the deprivation index used.</p> <p>The analysis does not appear to have taken account of the clustering of participants within geographic areas. A multilevel modelling approach is essential here as the analyses must control for fixed effects otherwise the authors cannot claim with any confidence that the effects they see are no simply due to differences between groups in certain areas.</p> <p>There is not enough detail provided in the methods and results sections to make an informed judgement on whether or not the results support the contention that the intervention was a success, for women at least. There is a host of potentially confounding factors that have not been considered.</p> <p>Furthermore, assuming that the same administrative data is available for the years prior to the intervention, would a before and after design not be better?</p> <p>Related to these points is the fact that there is very limited description provided of the MC and NMC groups so it is not possible to see how well matched or otherwise the two groups are. Why not provide a table with summary statistics of the indicators that the propensity score matching was done on?</p> <p>The Figures are next to impossible to read either on paper or screen. Also, shouldn't the estimate for all admissions fall between those for planned and urgent in Figure 1. Why are the points in this graph in different positions even though the coefficients are the same (is this just decimals?). The horizontal reference lines in Figures 3 and 4 are not positioned correctly.</p> <p>Should it be assumed that a lower risk of admission is a good thing? Could it be that women in the MC areas have the same needs as those in the NMC areas but they cannot access healthcare?</p> <p>In the limitations section, the authors state that there were residents in the NMC group who lived in areas that were part of the intervention. Why include these in the 'control' group at all?</p> <p>Conclusion - I don't see how the intervention 'working on the social determinants of health'. As described, the intervention was limited to the supply side, delivery of healthcare. Apart from access to healthcare, there is no mention of any intervention on individual</p> |
|--|--|

|  |   |
|--|---|
|  | <p>level social determinants of health e.g. education, social class, income, health behaviours etc.</p> <p>Minor comments:<br/>Typo in CIs reported in the results section of abstract, reads 0.39 (0.18-0.32). Replace 0.32 with 0.82.</p> <p>Last paragraph page 4 “it has been showed” should be “has been shown”.</p> <p>Page 5 line 16 – Appropriate not appropriated.</p> <p>Page 9 line 24. I do not understand what is meant by "steady residents". Is this people resident for the follow-up period?</p> <p>Page 10. Table 1 is inserted in the middle of a sentence. Furthermore, the first part of this sentence makes no sense</p> <p>The word coherently is misused a number of times in the discussion.</p> |
|--|---|

|                        |   |
|------------------------|---|
| <b>REVIEWER</b>        | Dr Anteo Di Napoli<br>National Institute for Health Migration and Poverty - INMP, Rome, Italy |
| <b>REVIEW RETURNED</b> | 29-Mar-2020   |

|                         |   |
|-------------------------|---|
| <b>GENERAL COMMENTS</b> | <p>This article provides a very interesting picture on a community-based intervention project conducted in an Italian city, Trieste. The project started in 2006, in eight deprived neighbourhoods of the city, known as “Habitat Microaree”; it consisted of facilitating access to social services and outpatient healthcare facilities, coordinating intersectoral public services and specifically planning hospital discharge.</p> <p>The aim of the study was to assess the impact of the project on healthcare comparing hospital admissions and Emergency Department access between the residents in the microareas and the not resident in the microareas, where the services offered by the project were not provided.</p> <p>The 16,256 subjects enrolled in the two groups were matched through propensity score, using as matching variables, sex, age, the Caranci deprivation index, the Charlson index, the use of drugs for hypertension, diabetes and ulcer, and they have been followed-up for 8 years.</p> <p>The authors found among subjects resident in “Habitat Microaree” a slight reduction of first hospitalization hazard for all causes and a more relevant reduction of urgent admissions in females. The strongest evidences were observed for psychiatric disorders, in females, in particular for psychosis. Furthermore, the findings show a reduction of multiple hospital admissions for all causes in females, in particular for fractures and of first access to Emergency Department for white codes, both in females and in males. More in general, the authors concluded that the project was more effective among females.</p> <p>The study is very interesting, well designed and conducted for statistical analysis approach, and the results are clearly described. However, I have some observations about the manuscript.</p> <p>The authors suggest as limit of their study the generalizability, due to the findings that HM project was more effective among females. I agree with the doubt about the generalizability, but my concern was related to a little depth in the description of the context where</p> |
|-------------------------|---|

|  |   |
|--|---|
|  | <p>the study was conducted. The authors should better explain how much the population of Trieste is similar or different to other Italian cities, in terms of socioeconomic and health status characteristics. For example, the Italian Atlas of mortality inequalities by education level (Epidemiol Prev 2019; 43 (1) Suppl 1:1-120. doi: 10.19191/EP19.1.S1.002) showed a mortality excess, compared with the mean national values, both for men and women for all causes of death, for all and specific malignant neoplasms, but also for suicide among women (a reduction of admissions for psychiatric disorders among women was the strongest result of the project). A more detailed description of the context could help the readers to fully understand the relevance of this very interesting community-based intervention project.</p> |
|--|---|

### VERSION 1 – AUTHOR RESPONSE

Reviewer(s)' Comments to Author:

**Reviewer: 1**

Reviewer Name: Mark Ward

Institution and Country: Trinity College Dublin, Ireland

Please state any competing interests or state 'None declared': None declared

Please leave your comments for the authors below

General comments

This submission consists of an evaluation of a wide-ranging intervention and as such is a valuable topic. However, it is poorly executed in numerous parts and therefore difficult to assess the veracity or otherwise of the results.

There is very little detail provided about the intervention, beyond a broad description. Also, as described, the intervention was limited to the delivery of healthcare services and is therefore difficult to see how it can be argued to have impacted on the social determinants of health, beyond the issue of access.

Methodologically, it would seem more obvious to have tested the main outcomes before and after the intervention, assuming that data is available over that time period. This would go some way to minimising the effect of confounding, discussed below.

The manuscript is also poorly written in parts which makes parts difficult to follow.

## **Substantive comments**

*Thank you so much for your revision and comments. We have addressed all the concerns you raised and had the manuscript edited by a native English speaker.*

**The title is poor English. Suggest “Measuring the impact of a social programme on healthcare: A 10-year retrospective cohort study in Trieste, Italy.**

*Thank you for the suggestion. We modified the title as proposed.*

**The literature review requires substantial improvement. The theoretical and empirical literature on the social determinants of health and the association between deprivation and health needs to be more fully addressed. The authors must also be clear on the distinction between individual- and area-level material deprivation. This is critical, particularly when suggesting mechanistic pathways to explain any associations between deprivation and health.**

*We improved the introduction and the literature as requested.*

**The piece on material deprivation in the introduction is limited. Firstly, a definition of material deprivation would be useful. Also, only one mechanism to explain the association between deprivation and mortality is provided. There are many more, for example, education, health behaviours, psycho-social etc.**

*We improved the introduction as requested.*

**References should be provided to support each of the contentions discussed regarding Trieste at end of page 5, beginning page 6.**

*The reference was indicated in the bibliography of the manuscript and is: Demography in Figures. National Institute of Statistics. Available from: <http://demo.istat.it/>*

**Page 6. The description of the intervention belongs in the methods section, not the literature review. The description of the intervention is also very broad and lacks detail. This makes it difficult to assess the conclusion that the intervention worked.**

*We added further details and a summary table on the interventions delivered to the residents of the Microareas, at the beginning of the methods section.*

**Each indicator included in the analyses should be fully described in the methods section – the Charlson Index, and the deprivation index used.**

*The requested descriptions have been included in the manuscript in the methods section.*

**The analysis does not appear to have taken account of the clustering of participants within geographic areas. A multilevel modelling approach is essential here as the analyses must control for fixed effects otherwise the authors cannot claim with any confidence that the effects they see are not simply due to differences between groups in certain areas.**

*Thank you for your comment. Perhaps the purpose of the study was not entirely clear. The purpose of the study wasn't to compare different types of access to health services among the 8 Microareas, but to compare the different access to health services between those who could benefit from the intervention, simply because they resided in one of the selected Microareas, and those who could not benefit from the intervention because they resided in neighboring non-microarea quarters of Trieste. We therefore considered two distinct groups: the MP group that received the intervention and the*

*NMP group that did not receive the intervention. The aim of the study is now better defined at the end of the introduction.*

**There is not enough detail provided in the methods and results sections to make an informed judgement on whether or not the results support the contention that the intervention was a success, for women at least. There is a host of potentially confounding factors that have not been considered.**

*The HM project can be considered effective if it succeeds in addressing the residents' health needs by promoting adherence to prevention, and to diagnostic and structured therapeutic programs. The effectiveness of the HM project can be measured in terms of reduction of urgent accesses to the Regional Health System (e.g. access to emergency department and urgent hospitalizations). The management of the health status of an individual allows for: (1) implementation of integrated programs for the improvement of patient health; (2) optimization of the use of human and economic resources<sup>1</sup>. The management of a person's health determines a reduction in the number of unscheduled accesses<sup>2</sup> (access to emergency department and urgent hospitalizations). The effectiveness of the HM project in addressing the health needs of the microarea residents was assessed by comparing residents in Microarea with residents in neighboring non-microarea quarters. The question we wanted to answer was "What would have likely happened if the project hadn't taken place?"*

*We are aware that there are confounding factors that we could not include in our models but the information we used was that available in the Regional Repository of MicroData (an administrative database). We have now included additional details concerning the interventions delivered to the MP group in the methods section and have better specified the aim of the study, in the final paragraph of the introduction.*

<sup>1</sup>[http://www.salute.gov.it/imgs/C\\_17\\_pagineAree\\_4893\\_listaFile\\_itemName\\_0\\_file.pdf](http://www.salute.gov.it/imgs/C_17_pagineAree_4893_listaFile_itemName_0_file.pdf)

<sup>2</sup><https://www.england.nhs.uk/wp-content/uploads/2014/03/red-acsc-em-admissions.pdf>

**Furthermore, assuming that the same administrative data is available for the years prior to the intervention, would a before and after design not be better?**

*We chose to carry out a cohort study (matching microarea residents with non-microarea residents, as described in materials and methods) instead of a before and after study for the following reasons: (1) in order to detect an effect of the intervention (in terms of reduction in urgent accesses to the regional health system) a long observation period is necessary (2006-2015); (2) by virtue of this aspect, it is important to consider the same amount of observation time before the implementation of the intervention; (3) we also had to take into account the stable residence of the subjects inside and outside the intervention area (Microarea) for the entire study period (before and after the intervention) to avoid a selection bias on the intervention's effect. The number of subjects we could have included in the before and after study would have been only a small part of the microarea residents: only the people who have always been resident in the Microarea and those who have never be resident in the Microarea for the entire period of study (before and after the intervention).*

**Related to these points is the fact that there is very limited description provided of the MC and NMC groups so it is not possible to see how well matched or otherwise the two groups are. Why not provide a table with summary statistics of the indicators that the propensity score matching was done on?**

*Please find attached below as part of the answer to the reviewer, the requested description of the MP and NMP groups showing the distribution of each matching variable. We feel that this table is not sufficiently informative to be included in the results because the statistical analyses, which are reported in the manuscript, were conducted taking the latency period of two years and the stable*

residence of subjects within and outside the Microarea into account. For this reason, in the models we adjusted also for Charlson index, 2001 deprivation index by Caranci, age at the start of follow-up and stratified for sex.

|   |        | MP<br>(n=10.588) | NMP<br>(n=10.588) | p-value |
|---|--------|------------------|-------------------|---------|
| Sex<br>n (%)  | F      | 5.742 (54,23%)   | 5.722 (54,04%)    | 0,78    |
|   | M      | 4.846 (45,77%)   | 4.866 (45,96%)    |         |
| Charlson index<br>n (%)   | 0      | 9.366 (88,46%)   | 9.370 (88,50%)    | 0,55    |
|   | 1      | 486 (4,59%)      | 474 (4,48%)       |         |
|   | 2      | 377 (3,56%)      | 371 (3,50%)       |         |
|   | 3      | 153 (1,45%)      | 173 (1,63%)       |         |
|   | 4      | 70 (0,66%)       | 76 (0,72%)        |         |
|   | 5      | 44 (0,42%)       | 38 (0,36%)        |         |
|   | 6      | 24 (0,23%)       | 33 (0,31%)        |         |
|   | 7      | 14 (0,13%)       | 16 (0,15%)        |         |
|   | 8      | 38 (0,36%)       | 22 (0,21%)        |         |
|   | 9      | 7 (0,07%)        | 6 (0,06%)         |         |
|   | 10     | 6 (0,06%)        | 3 (0,03%)         |         |
|   | 11     | 2 (0,02%)        | 4 (0,04%)         |         |
|   | 12     | 1 (0,01%)        | 0 (0,00%)         |         |
|   | 13     | 0 (0,00%)        | 1 (0,01%)         |         |
|   | 15     | 0 (0,00%)        | 1 (0,01%)         |         |
| Hypertension drugs (ATC: 'C02',<br>'C03', 'C04', 'C07', 'C08')<br>n (%) | Use    | 2.830 (26,73%)   | 2.840 (26,82%)    | 0,88    |
|   | No use | 7.758 (73,27%)   | 7.748 (73,18%)    |         |
| Diabetes drugs (ATC: 'A10A', 'A10B',<br>'A10X')<br>n (%)                | Use    | 631 (5,96%)      | 649 (6,13%)       | 0,6     |
|   | No use | 9.957 (94,04%)   | 9.939 (93,87%)    |         |
| 2001 deprivation index by Caranci<br>n (%)                              | 1      | 390 (3,68%)      | 388 (3,66%)       | 0,99    |
|   | 2      | 1.005 (9,49%)    | 1.010 (9,54%)     |         |
|   | 3      | 487 (4,60%)      | 486 (4,59%)       |         |

|  |   |                |                |      |
|--|---|----------------|----------------|------|
|  | 4 | 514 (4,85%)    | 516 (4,87%)    |      |
|  | 5 | 8.192 (77,37%) | 8.188 (77,33%) |      |
| Age at the start of follow-up median (IQR) |   | 54 (35 - 67)   | 53 (35 - 68)   | 0,88 |

**The Figures are next to impossible to read either on paper or screen. Also, shouldn't the estimate for all admissions fall between those for planned and urgent in Figure 1. Why are the points in this graph in different positions even though the coefficients are the same (is this just decimals?). The horizontal reference lines in Figures 3 and 4 are not positioned correctly.**

*We modified the figures as requested. In figure 1 the hazard ratio of total admissions was 0.95 and the hazard ratio of urgent admissions was 0.954, for this reason the points in the graph are in a slightly different position. In the table below the graph, the two hazard ratios are reported rounded to 0.95. The horizontal reference lines in figures 3 and 4 have been repositioned.*

**Should it be assumed that a lower risk of admission is a good thing? Could it be that women in the MC areas have the same needs as those in the NMC areas but they cannot access healthcare?**

*Yes, it is a good result to have a lower risk of urgent hospitalization. No, the access to health services for microarea residents could not be lower than that for non-microarea residents, because the HM intervention focused, among other aspects, on the improvement of access to health services. Further details have been included in the methods section to better describe the HM interventions.*

**In the limitations section, the authors state that there were residents in the NMC group who lied in areas that were part of the intervention. Why include these in the 'control' group at all?**

*This is a retrospective cohort study, the 8 Microareas were established on 1.1.2006 and the period of study was between the 1.1.2006 to 31.12.2015. Our analysis focused only on stable residents (within and outside the 8 Microareas established on 1.1.2006), and thus we excluded individuals who alternated periods living in a Microarea with periods living in a non-Microarea. Later on, during the study period, between 2009-2012, new Microareas were established. This event, subsequent to the start of follow-up, happened during the period of observation. We decided that if we excluded the non-microarea subjects who had subsequently become new microarea residents from the initial population established at the beginning of the follow up (1.1.2006), we could have incurred in a selection bias. Furthermore, as mentioned in the manuscript, the decision to retain these subjects could only lead to possible underestimation of the effectiveness of the intervention.*

**Conclusion - I don't see how the intervention 'working on the social determinants of health'. As described, the intervention was limited to the supply side, delivery of healthcare. Apart from access to healthcare, there is no mention of any intervention on individual level social determinants of health e.g. education, social class, income, health behaviours etc.**

*We are agree with you. Unfortunately, the available data from the administrative database RRMD concerned health determinants (hospital admissions) and not social determinants. The aim of our study was to evaluate the effectiveness of the interventions in terms of reduction of urgent hospital admissions.*



Minor comments:

**Typo in CIs reported in the results section of abstract, reads 0.39 (0.18-0.32). Replace 0.32 with 0.82.**

*Corrected in the revised manuscript.*

**Last paragraph page 4 “it has been showed” should be “has been shown”.**

*Corrected in the revised manuscript.*

**Page 5 line 16 – Appropriate not appropriated.**

*Corrected in the revised manuscript.*

**Page 9 line 24. I do not understand what is meant by "steady residents". Is this people resident for the follow-up period?**

*Steady residents are all the subjects included in the analysis cohort. We excluded from the initial matched cohort all the subjects who alternated periods living in a Microarea with periods living in a non-Microarea during the follow-up period. ‘Steady residents’ was used as a synonym of stable residents. In the text we have replaced the term steady with stable.*

**Page 10. Table 1 is inserted in the middle of a sentence. Furthermore, the first part of this sentence makes no sense**

*We have modified the sentence as requested.*

**The word coherently is misused a number of times in the discussion.**

*We have modified the text of the discussion as suggested*

**Reviewer: 2**

Reviewer Name: Dr Anteo Di Napoli

Institution and Country: National Institute for Health Migration and Poverty - INMP, Rome, Italy

Please state any competing interests or state ‘None declared’: None declared

Please leave your comments for the authors below

**This article provides a very interesting picture on a community-based intervention project conducted in an Italian city, Trieste. The project started in 2006, in eight deprived neighbourhoods of the city, known as “Habitat Microaree”; it consisted of facilitating access to social services and outpatient healthcare facilities, coordinating intersectoral public services and specifically planning hospital discharge.**

**The aim of the study was to assess the impact of the project on healthcare comparing hospital admissions and Emergency Department access between the residents in the microareas and the not resident in the microareas, where the services offered by the project were not provided.**

**The 16,256 subjects enrolled in the two groups were matched through propensity score, using as matching variables, sex, age, the Caranci deprivation index, the Charlson index, the use of drugs for hypertension, diabetes and ulcer, and they have been followed-up for 8 years.**

**The authors found among subjects resident in “Habitat Microaree” a slight reduction of first hospitalization hazard for all causes and a more relevant reduction of urgent admissions in females. The strongest evidences were observed for psychiatric disorders, in females, in particular for psychosis. Furthermore, the findings show a reduction of multiple hospital admissions for all causes in females, in particular for fractures and of first access to Emergency Department for white codes, both in females and in males. More in general, the authors concluded that the project was more effective among females.**

**The study is very interesting, well designed and conducted for statistical analysis approach, and the results are clearly described. However, I have some observations about the manuscript.**

**The authors suggest as limit of their study the generalizability, due to the findings that HM project was more effective among females. I agree with the doubt about the generalizability, but my concern was related to a little depth in the description of the context where the study was conducted. The authors should better explain how much the population of Trieste is similar or different to other Italian cities, in terms of socioeconomic and health status characteristics. For example, the Italian Atlas of mortality inequalities by education level (Epidemiol Prev 2019; 43 (1) Suppl 1:1-120. doi: 10.19191/EP19.1.S1.002) showed a mortality excess, compared with the mean national values, both for men and women for all causes of death, for all and specific malignant neoplasms, but also for suicide among women (a reduction of admissions for psychiatric disorders among women was the strongest result of the project). A more detailed description of the context could help the readers to fully understand the relevance of this very interesting community-based intervention project.**

*Thank you so much for your revision and comments. We have included more information concerning Trieste adding the following sentences in the introduction:*

*In the last census conducted in Italy by the National Institute of Statistics in 2011, 27.6% of people residing in Trieste were over 65 years of age (vs 20.5% in Italy) and life expectancy at birth was 79 years for males and 83.6 years for females (vs 79.5 for males and 84.4 for females in Italy). In Trieste, the mortality rate for all causes was 14.5 per 1000 inhabitants (vs 10.0 per 1000 inhabitants in Italy) and the birth rate was 7.3 per 1000 inhabitants (vs 9.2 per 1000 inhabitants in Italy). Fifty percent of the population was not in the labour force (vs 49.2 in Italy) and 4.7% were looking for a job (vs 5.8% in Italy); 52.7% of residents in Trieste had a low education level (vs 58.7% in Italy), 32.0% had a high*

school diploma (vs 30.2% in Italy) and 16.3% had a university degree or higher (vs 11.5% in Italy).  
[16]

#### VERSION 2 – REVIEW

|                        |                                     |
|------------------------|-------------------------------------|
| <b>REVIEWER</b>        | Mark Ward<br>Trinity College Dublin |
| <b>REVIEW RETURNED</b> | 28-May-2020                         |

|                         |   |
|-------------------------|---|
| <b>GENERAL COMMENTS</b> | It appears that I have been cast in the role of Reviewer 2 on this occasion. Despite this, I do hope that the authors have found my earlier suggestions helpful and in the constructive spirit they were intended. The authors have done a very good job of addressing my previous comments. The manuscript has been greatly improved throughout and the addition of more detail on the intervention is very welcome. |
|-------------------------|---|

|                        |   |
|------------------------|---|
| <b>REVIEWER</b>        | Anteo Di Napoli<br>National Institute for Health, Migration and Poverty - INMP, Rome, Italy |
| <b>REVIEW RETURNED</b> | 28-May-2020   |

|                         |   |
|-------------------------|---|
| <b>GENERAL COMMENTS</b> | I confirm that the study is very interesting, well designed and conducted for statistical analysis approach, and the results are clearly described. In the revised form the paper has improved and partially the limits about the generalizability have been partially removed. The authors gave a description of the characteristics of Trieste's population with the regard to the national ones. |
|-------------------------|---|