PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	The use and impact of social prescribing: A mixed methods feasibility study protocol
AUTHORS	Jani, Anant; Liyanage, Harshana; Hoang, Uy; Moore, Lucy; Ferreira, Filipa; Yonova, Ivelina; Tzortziou Brown, Victoria; de Lusignan, Simon

VERSION 1 – REVIEW

REVIEWER	Carolyn Wallace University of South Wales/ PRIME Centre Wales/ Wales School for Social Prescribing Research.
REVIEW RETURNED	13-Mar-2020

GENERAL COMMENTS	Thank you for the opportunity to review this manuscript. I have the following comments: The manuscript in the first half of the document is confusing. I wasn't sure if this was a pilot study or feasibility study until p15. It was then that the actual parameters for understanding feasibility were made known. This should be identified earlier. The abstract is does not wholly reflect the protocol itself for example it isn't clear who the participants are. There are multiple aims throughout the document. The aim in the abstract is not the same as p8, the study design on p9 and p20 discussion. This needs addressing to be consistent and to address the issue of feasibility and not the main study later on. I would suggest that the authors use this following statement used in the conclusion...'This feasibility study will enable us to test approaches to understand the use and impact of social prescriptions.' The definition used for SP comes from the Bikerdike review which used literature up to 2016. Its a little different to the NHS England definition currently used and so I would recommend changing it. This would reflect the context within which this study is set. It should also acknowledge that this is only one model of SP and that there are other models based in the community emerging. I was a little surprised to read about this study idea when there are software solutions on the market which can provide a similar framework (and dashboard discussed) and are being used by some GP practices. The protocol needs to provide a consistent view as to data used, for example its only on p21 that we are introduced to the idea that the data used will be for a homeless subgroup. This is in the discussion section. The authors should review the protocol for other inconsistencies.

	A detailed qualitative sampling framework should be included. The questions to be used for the focus group- its not clear how they were derived. Patient and Public involvement is an expected standard in research these days. Especially as we have the UK Six Standards for PPI. I would question the practical use of the framework to be developed without the involvement of patients or the public throughout the design development etc. How do you know that the framework developed will be usable for both third sector and patients? I appreciate that the authors have identified that ethical approval is not required. I must admit that that is not my experience when accessing large NHS anonymised datasets and interviewing NHS and /or third sector staff. University ethics is usually required as a minimum. There is an assumption that SP staff in primary care are employed by the NHS. Our experience is that it is a mixed economy.

REVIEWER	Dawn Carnes Queen Mary University of London University College of Osteopathy University of Applied Sciences Western Switzerland
REVIEW RETURNED	02-Apr-2020

GENERAL COMMENTS	This is a mixed methods feasibility study using a retrospective audit of data (and a matched cohort study?), a qualitative focus group study and a survey. The aim of each study could be clearer and more consistent, the aims seem to change throughout the manuscript. For example the aim in the abstract, the body of the text (at the end of the introduction) and aim with the study design are all slightly different. The objectives are far more complicated than the aim(s) and introduce new elements adding to the complexity of the study. The 4 objectives points contain multiple objectives and I am not sure if they are achievable based on the information given, for example the Patient Reported Outcome Measures, do they exist already? or are you exploring the possibility of collecting them? The authors are clearly very familiar with the database they propose to explore, but for the novice reader it was a little confusing to understand how you are going to sample and identify your population and what variables were available to extract and how you were going to match and pair your 'cases' for the cohort study. I would also have liked to have had more information about the participants in the focus groups and the survey, it was not clear who and how these people were to be recruited. I am surprised that you state ethics approval is not required for this part of the study as I thought it would be essential, especially if the focus groups include patients. There have been other mixed method evaluations of social prescribing that might have informed this protocol further. These have explored the identification of those suitable for social prescribing, delivery of the intervention and implementation and outcomes. One study in particular also did matched cohort study using a propensity matched control (Carnes et al 2017 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5735927/). I hope these comments are helpful, I appreciate how hard it is to write mixed methods protocols.

VERSION 1 – AUTHOR RESPONSE

Reviewer Name: Carolyn Wallace

- The manuscript in the first half of the document is confusing. I wasn't sure if this was a pilot study or feasibility study until p15. It was then that the actual parameters for understanding feasibility were made known. This should be identified earlier.

o We indicated in the original title of the manuscript that this was a feasibility study and we have now also changed the abstract text in line with the reviewer's recommendation to make it more explicit that this is a feasibility study. We have also added in a sentence in the introduction to highlight that we are doing a feasibility study and have used the language the Reviewer has suggested below, which we have also included in the description of the Aim.

- The abstract is does not wholly reflect the protocol itself for example it isn't clear who the participants are.

o We have modified the abstract to make it clearer who the participants are and also changed the text to more clearly reflect a consistent aim, linked to the Reviewer's comment below.

- There are multiple aims throughout the document. The aim in the abstract is not the same as p8, the study design on p9 and p20 discussion. This needs addressing to be consistent and to address the issue of feasibility and not the main study later on. I would suggest that the authors use this following statement used in the conclusion...'This feasibility study will enable us to test approaches to understand the use and impact of social prescriptions.'

o We have changed the aim in the abstract, main text and study design to match the conclusion/discussion and have used the sentence suggested by the Reviewer.

- The definition used for SP comes from the Bikerdike review which used literature up to 2016. Its a little different to the NHS England definition currently used and so I would recommend changing it. It should also acknowledge that this is only one model of SP and that there are other models based in the community emerging.

o We have added in the NHS England definition instead of the one used by Bickerdike.

- I was a little surprised to read about this study idea when there are software solutions on the market which can provide a similar framework (and dashboard discussed) and are being used by some GP practices.

o The key distinction between the existing software solutions are that they are only commercially available and are not nationally representative. The RCGP RSC is a nationally representative sentinel network that has been in use by national health authorities in England (currently Public Health England) for over 50 years to monitor influenza. Furthermore, because the RSC is nationally representative, insights from our analyses are used to guide policy decisions. Finally, all of our source codes are made publicly available and are not commercially sensitive, which is unlike the existing software solutions.

- The protocol needs to provide a consistent view as to data used, for example its only on p21 that we are introduced to the idea that the data used will be for a homeless subgroup. This is in the discussion section.

o We have changed this throughout the manuscript, including in the abstract, to make it clearer that the outcomes analyses will be done on a subgroup of individuals recorded as being homeless.

- A detailed qualitative sampling framework should be included.

o The format of the group meetings for WP2 are actually advisory group meetings rather than formal focus groups; this was a mistake in the original protocol. This has been changed in the text. Given the advisory nature of these meetings, a qualitative sampling framework is not appropriate.

- The questions to be used for the focus group- its not clear how they were derived.

o We have added in some text clarifying that these topics were agreed in consultation with the NHS England personalised care team working on social prescribing.

- I would question the practical use of the framework to be developed without the involvement of

patients or the public throughout the design development etc. How do you know that the framework developed will be usable for both third sector and patients?
o We actually intended to invite patients and public as advisors for the advisory group meetings but did not make this explicit; we have changed the text in the 'Patient and Public Involvement' section to make this more explicit.
- I appreciate that the authors have identified that ethical approval is not required. I must admit that that is not my experience when accessing large NHS anonymised datasets and interviewing NHS and /or third sector staff. University ethics is usually required as a minimum. There is an assumption that SP staff in primary care are employed by the NHS. Our experience is that it is a mixed economy.
o For WP1, the HRA tool identified that the study is classified as an audit of current practice and does not require ethics approval. For WP2, we used language that may have been misleading in the original protocol in that we termed the meetings as 'focus groups', whereas they are actually advisory group meetings, the results of which will not be published. We agree with the author that the involvement will be of NHS staff but, again, their involvement will be in their capacity as advisors rather than research subjects. We have clarified this throughout the text.

Reviewer Name: Dawn Carnes
- The aim of each study could be clearer and more consistent, the aims seem to change throughout the manuscript. For example the aim in the abstract, the body of the text (at the end of the introduction) and aim with the study design are all slightly different. The objectives are far more complicated than the aim(s) and introduce new elements adding to the complexity of the study.
o Review 1 also had similar comments and we have modified the text in the abstract, introduction, aims and methods to create a more internally consistent aim throughout.
- The 4 objectives points contain multiple objectives and I am not sure if they are achievable based on the information given, for example the Patient Reported Outcome Measures, do they exist already? or are you exploring the possibility of collecting them?
o We have changed the language in the objectives section to more accurately match the spirit of this feasibility study which is to explore what is actually feasible with the data we have access to – everything we are doing in this feasibility study is very much exploratory and will inform future studies. Patient Report Outcome measures are not mentioned in the study protocol but Patient Activation Measures are mentioned and these are routinely, though heterogeneously, collected in primary care records and have SNOMED codes associated with them. Our goal with this feasibility study is to explore whether they can be used as a consistent measure to track how patients are responding to their social prescriptions.
- The authors are clearly very familiar with the database they propose to explore, but for the novice reader it was a little confusing to understand how you are going to sample and identify your population and what variables were available to extract and how you were going to match and pair your 'cases' for the cohort study.
o We have tried to make this clearer in the abstract and the rest of the text by adding a short description of the RCGP-RSC in the abstract and introduction stressing that the general practices making up the sentinel network cover over 4,000,000 patients and whose dataset consists of twice weekly extracts of general practice electronic health record data. Further to this, and in line with Reviewer 1's comments, we have attempted to clarify the subgroup sample analysis by highlighting that the cohort we are going to use for the outcomes comparison is individuals recorded as being homeless, which was mentioned in the discussion but not elsewhere in the text.
- I would also have liked to have had more information about the participants in the focus groups and the survey, it was not clear who and how these people were to be recruited.
o We have modified the text in the 'Study setting and sample' section with some further clarifications to address the Reviewers comment: "For WP2, we will approach and recruit people in person and through existing departmental contacts within the University of Oxford and University of Surrey Departments of Primary Care as well as through our contacts within primary care networks in

Oxfordshire and Surrey, where members of our study team work. Individuals will be recruited if they have any experience working within primary care (which will include general practitioners, practice nurses, allied health professionals and link workers) and are within travelling distance of the University of Oxford or the University of Surrey to attend advisory group meetings on our premises."
- I am surprised that you state ethics approval is not required for this part of the study as I thought it would be essential, especially if the focus groups include patients.
o We apologise for the confusion on this section, Reviewer 1 also commented on this. For WP1, the HRA tool identified that the study is classified as an audit of current practice and does not require ethics approval. For WP2, we used language that may have been misleading in that we termed the meetings as 'focus groups', whereas they are actually advisory group meetings, the results of which will not be published. We agree with the author that the involvement will be of NHS staff but, again, their involvement will be in their capacity as advisors rather than research subjects. We have clarified this throughout the text.
- There have been other mixed method evaluations of social prescribing that might have informed this protocol further. These have explored the identification of those suitable for social prescribing, delivery of the intervention and implementation and outcomes. One study in particular also did matched cohort study using a propensity matched control (Carnes et al 2017 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5735927/).
o We have added in references in the introduction to studies conducted in 2018-19 after the 2017 Bickerdike et al systematic review. The key difference between these studies and our feasibility study is the breadth, depth and nationally representative nature of the data available on the quantitative aspects of our study, namely because we have access to data from the RCGP-RSC, which represents over 500 nationally representative GP practices across England covering over 4,000,000 patients.

VERSION 2 – REVIEW

REVIEWER	Dawn Carnes University College of Osteopathy, UK Queen Mary University of London University of Applied Sciences and the Arts Western Switzerland
REVIEW RETURNED	05-May-2020

GENERAL COMMENTS	This is much clearer, thank you for addressing the points the reviewers made. I have two comments/queries that I believe, if addressed, may help the reader understand the protocol rationale more: 1. One of the purposes of the advisory group is to develop a questionnaire survey to investigate 'consensus' from 'others' about the groups views. It is not clear who this survey is being sent to and why consensus is needed. 2. I am still unsure why a sub group of homeless people have been chosen to investigate the criteria for identifying those who may benefit from social prescribing and their health outcomes. It seems a very specific group to which the findings may not be generalisable or indeed help answer your bigger research questions.

VERSION 2 – AUTHOR RESPONSE

Reviewer Name: Dawn Carnes
- One of the purposes of the advisory group is to develop a questionnaire survey to investigate

'consensus' from 'others' about the groups views. It is not clear who this survey is being sent to and why consensus is needed.
o We have gone through the manuscript and in every place where we have mentioned the survey we have indicated that the individuals taking the survey will be primary care professionals from the RCGP RSC.
- I am still unsure why a sub group of homeless people have been chosen to investigate the criteria for identifying those who may benefit from social prescribing and their health outcomes.
o We have made this more clear in the text now by indicating that the reason why we are focusing on this subset is because we have experience working with this group for other projects being conducted within the RCGP RSC.

We hope the above changes are in line with your and the Reviewer's comments and hope the revised manuscript is acceptable for publication in BMJ Open.