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](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**

<table>
<thead>
<tr>
<th>TITLE (PROVISIONAL)</th>
<th>Link workers providing social prescribing and health and social care coordination for people with multimorbidity in socially deprived areas (The LinkMM trial): Protocol for a pragmatic randomised controlled trial.</th>
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</thead>
<tbody>
<tr>
<td>AUTHORS</td>
<td>Kiely, Bridget; Clyne, Barbara; Boland, Fiona; O’Donnell, Patrick; Connolly, Deirdre; O’Shea, Eamon; Smith, Susan</td>
</tr>
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**VERSION 1 – REVIEW**

<table>
<thead>
<tr>
<th>REVIEWER</th>
<th>Cindy Mann</th>
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<tr>
<td></td>
<td>University of Bristol, UK</td>
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<tr>
<td>REVIEW RETURNED</td>
<td>17-Aug-2020</td>
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</tbody>
</table>

**GENERAL COMMENTS**

Thank you for asking me to review the protocol for this interesting study. It is very clearly written and easy to follow except for one thing. If practices are expected to recruit 60 participants in total, 20 per month, surely they will need to randomly select and invite many more than 60 potential participants? If I have understood correctly the GPs will apply the inclusion and exclusion criteria and generate a register of potentially eligible participants and then screen them to identify all those they think might benefit from social prescribing. The protocol then states (p9, line 47) that GPs will be supported to select a random sample of 60 potential participants, to whom presumably the baseline questionnaires and consent forms will be sent. Maybe this process is repeated 3 times so that each practice invites 180 potential participants? Please can you clarify and also add the percentage of those invited you expect to consent, along with the rationale for your expectation.

Page 20 line 33. This sentence could be improved – maybe by substituting ‘provided’ instead of ‘for’ as the last word as it does not quite make sense as it stands.

<table>
<thead>
<tr>
<th>REVIEWER</th>
<th>Elida Zairina</th>
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<tbody>
<tr>
<td></td>
<td>Department of Pharmacy Practice, Faculty of Pharmacy, Universitas Airlangga, Surabaya, Indonesia</td>
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<tr>
<td>REVIEW RETURNED</td>
<td>20-Aug-2020</td>
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</table>

**GENERAL COMMENTS**

This study protocol has been written according to CONSORT statement and has comply with all the guidance. The results of the study will be useful for the community health practice. My questions to authors as follows: - Are there any maximum age limitation for participants? recruiting participants over 65 years old may have a few obstacles since participants need to be followed up for three months. Moreover,
the primary outcome data will be collected using self-administered questionnaire.
- Are participants need to have the ability to read and to communicate clearly since they need to fill the questionnaire.
- How to make sure that the intervention and the control group are balance in terms of the severity of morbidity? although the study is designed as pragmatic RCT, balance in both groups is also important.
- Are the authors going to limit the type of morbidity? the protocol said the GP will do the recruitment, are there any specific morbidity to consider?
- For the intervention, during the 3 months, what exactly that the linenworkers give to the intervention group? Are they giving an education? counselling? please make it more clearly in the methods
- What the authors will do to avoid some bias in the study? i.e. selection bias, and outcome assessor bias? I believe this has not been mentioned in the protocol.
- Are there any objective measurement during the follow up?

Overall, the protocol looks good. I look forward to the results of the study.

VERSION 1 – AUTHOR RESPONSE

Reviewer 1

1. Thank you for asking me to review the protocol for this interesting study. It is very clearly written and easy to follow except for one thing. If practices are expected to recruit 60 participants in total, 20 per month, surely they will need to randomly select and invite many more than 60 potential participants? If I have understood correctly the GPs will apply the inclusion and exclusion criteria and generate a register of potentially eligible participants and then screen them to identify all those they think might benefit from social prescribing. The protocol then states (p9, line 47) that GPs will be supported to select a random sample of 60 potential participants, to whom presumably the baseline questionnaires and consent forms will be sent. Maybe this process is repeated 3 times so that each practice invites 180 potential participants? Please can you clarify and also add the percentage of those invited you expect to consent, along with the rationale for your expectation.

Author Response

Thank you for raising this and providing us with the opportunity to clarify. Each practice is to recruit 60 participants, but as you have correctly pointed out they will need to invite more than that to achieve this number. The recruitment section has been revised to clarify the process and provide additional detail. Please note that due to Covid 19 related delays the intervention is now one month long and so recruitment is continuing until 10 weeks before the trial end date.

To clarify GPs will be supported arrange their list of potential participants in random order and begin by inviting the first 30 from the list, double-checking that they meet eligibility criteria. The text has been revised to clarify this:

“Once this register of potentially eligible patients is created, GPs will be supported to arrange the list in random order and select the first 30 potential participants to invite.”
“The research team will update the GP practices on a fortnightly basis of who has returned consent forms. The GPs will be encouraged to remind anyone who had verbally agreed to take part during the phone call stage, but not yet returned a consent form to do so. At monthly intervals the GPs will be asked to invite another 30 patients from the randomly ordered list of potential participants until the total of 60 participants has been reached. Recruitment will end 10 weeks before the end of the study to allow for sufficient time for baseline data collection, randomisation and delivery of the intervention. The expected recruitment rate is 60% based on the quasi-experimental evaluation of the Glasgow links worker project (20) where 50% of potential participants were recruited and our own pilot where 70% of invited participants returned consent and baseline questionnaires.”

Page 20 line 33. This sentence could be improved – maybe by substituting ‘provided’ instead of ‘for’ as the last word as it does not quite make sense as it stands.

Author Response

Thank you- revised as suggested.

“As a recent systematic review on link worker interventions concluded there is insufficient evidence “to judge either success or value for money” and “future evaluations must be comparative by design and consider when, by whom, for whom, how well and at what cost” interventions are provided (19).”

Reviewer: 2

This study protocol has been written according to CONSORT statement and has comply with all the guidance. The results of the study will be useful for the community health practice.

Author response

Many thanks for taking the time to review our protocol and for your helpful comments. Please find individual responses to your questions below.

My questions to authors as follows:

1. Are there any maximum age limitation for participants? Recruiting participants over 65 years old may have a few obstacles since participants need to be followed up for three months.

Author Response

There is no maximum age limit however those with a terminal illness, lack of capacity to consent or living in a residential setting will be excluded as per the exclusion criteria.

1. Moreover, the primary outcome data will be collected using self-administered questionnaire.

Author Response

If required a member of the research team can assist participants with the questionnaires as specified under Data Collection. We are using simple validated measures for the primary outcomes. See also response to point 2.
2. Are participants need to have the ability to read and to communicate clearly since they need to fill the questionnaire.

Author Response

Estimated functional illiteracy rates in Ireland are around 16% so this is a limitation especially in deprived areas where rates are likely to be higher. We are taking steps to mitigate this, by offering assistance and including health care utilisation data from records as an objective outcome. During the recruitment process, the GP will ask if participants require assistance from the research team with completing the questionnaires. Please see below from the recruitment section

“A letter of invitation, patient information leaflet, consent and baseline questionnaires will be sent to eligible participants and GP teams will follow up with phone calls to explain the study and see if potential participants require assistance completing the baseline questionnaires. One in six Irish adults are functionally illiterate and so it is assumed that at least this number will require their GP to verbally explain the study and need assistance with completion of the baseline questionnaires (30). Once they have consented, a member of the research team can assist them with baseline data collection either face to face at the practice or over the phone.”

We acknowledge however that this is a limitation in the Strengths and Limitations section and may result in a biased sample.

- “The large number of patient reported outcomes is consistent with the Medical Research Council guidance on evaluating complex interventions, but could be off putting to people with lower literacy levels, creating a biased sample.”

We will be collecting data on education level and can compare this to education levels for the local areas to see how representative our sample is. However, education level does not necessarily translate into literacy level.

3. How to make sure that the intervention and the control group are balance in terms of the severity of morbidity? although the study is designed as pragmatic RCT, balance in both groups is also important.

Author Response

Randomisation will be stratified by practice and age. It would be difficult to measure and adjust for severity of morbidity in advance, but adjustments in analysis will be made for any significant differences in baseline between the two groups

“The primary analysis will be adjusted for baseline scores and stratification variables, age and practice. Subsequent models will adjust for severity of multimorbidity.”

4. Are the authors going to limit the type of morbidity? the protocol said the GP will do the recruitment, are there any specific morbidity to consider?

Author response

No. The GPs have been advised that any two long term conditions (lasting to or expected to last for longer than 6 months) including both physical or mental health conditions are sufficient to meet the inclusion criteria. An additional line has been added to the Eligibility- Participants Section for clarity
“There will be no predefined conditions, other than the conditions should be chronic, that is lasting or expected to last more than 6 months.”

4. For the intervention, during the 3 months, what exactly that the linkworkers give to the intervention group? Are they giving an education? counselling? Please make it more clearly in the methods

Author Response

Additional detail has been provided in the methods section, quoted below. The link workers will not be providing education or counselling services, but they may support participants to access these supports in a variety of ways. To adapt to the Covid 19 public health restrictions link workers will include online supports and courses as part of their mapping exercises.

“The link worker will offer to follow up and support participants to implement their plan and attend these activities during the one-month trial period. It is expected that support will broadly fall into one of four categories, informational (supplying information on resources, directing to websites etc.), Instrumental (making an appointment on behalf of a participant or accompanying them to an appointment), appraisal (helping participants to makes changes using behaviour change techniques such as motivational interviewing) or emotional (listening and encouraging when participants face challenges). As support is tailored to the needs of the individual it will vary. All link worker activity will be captured in a specifically designed client management database, including details of the initial assessment, priority health and social issues, goals set, community resources referred to and attended, number of follow ups and the type of support provided, as per the categories outlined above. This will be fully reported in a parallel process evaluation and briefly described in the main trial report.”

“In the context of the ongoing Covid-19 pandemic, online and individual resources will also be identified for those unable to attend group activities.”

5. What the authors will do to avoid some bias in the study? i.e. selection bias, and outcome assessor bias? I believe this has not been mentioned in the protocol.

Author Response

There will be inherent selection bias as this is a pragmatic RCT design where the GPs select participants based on the GPs perception of psychosocial need and capacity to benefit from a link worker intervention. This does however reflect how a link worker service would operate in real world clinical settings. In order to report this process more transparently GPs have been asked to record why they felt each participant they invited would benefit from a link worker intervention.

See amended details on recruitment:

“The GP team will screen this list of patients with multimorbidity to identify all patients who they would refer to a link worker and thus create a register of potentially eligible patients. This process is based on our pilot study findings and is designed to reflect real world conditions where GPs refer patients they identify as having a psychosocial need that would benefit from a social prescribing approach to a link worker”

Those performing the data analysis will be blinded to participant status, as per the randomisation details. It is not possible to blind participants, GPs or link workers due to the nature of the intervention
6. Are there any objective measurement during the follow up?

Author Response

Health care utilisation will be measured directly from participant’s primary care records. It will be extracted by a member of the research team. Please see detailed items under secondary outcomes. This data will be collected for the month leading up to recruitment to the trial, the month after recruitment and for the month prior to 9 months from recruitment for the observational follow up study.

Overall, the protocol looks good. I look forward to the results of the study.

Thank you!

VERSION 2 – REVIEW

<table>
<thead>
<tr>
<th>REVIEWER</th>
<th>Cindy Mann</th>
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<td>UNIVERSITY OF BRISTOL, UK</td>
<td></td>
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<tr>
<td>REVIEW RETURNED</td>
<td>19-Nov-2020</td>
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</tbody>
</table>

| GENERAL COMMENTS  | Thank you for the various clarifications which significantly strengthen the paper. I look forward to seeing the results of the study. |

<table>
<thead>
<tr>
<th>REVIEWER</th>
<th>Elida Zairina</th>
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<td></td>
</tr>
<tr>
<td>REVIEW RETURNED</td>
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| GENERAL COMMENTS  | The authors have addressed my suggestions and comments on the manuscript in an acceptable way. I have no further comments. |

VERSION 2 – AUTHOR RESPONSE

Many thanks for the reviews and accepting the article for publication. We have deleted the conclusion section.