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

TITLE (PROVISIONAL)	Improving cancer care for underserved populations in an academic and community practice setting: protocol for a community health worker pilot navigation program
AUTHORS	Suen, Jonathan; Parrillo, Elaina; Hassoon, Ahmed; Peairs, Kimberly; Stanford, Olivia; Wenzel, Jennifer; Zabora, James; Dobs, Adrian

VERSION 1 – REVIEW

REVIEWER	Tanzi, Silvia University of Modena and Reggio Emilia Clinical and Experimental Medicine
REVIEW RETURNED	13-Sep-2022

GENERAL COMMENTS	A fascinating and complete protocol to help vulnerable cancer people. I only underscore a minor point: when researchers talk about "feasibility" they should indicate a standard to achieve>>>for example that 50 % of newly diagnosed people participated in the program (or if there is a precedent in the literature try to replicate this percentage) Moreover, to guarantee the reproducibility of the protocol, it's important to specify all the components of the intervention (for example training courses for health professionals, booklets for patients, number of appointments planned...) to check the FIDELITY of the program during the study period. Other researchers could replicate the same intervention or change some components if they fail during the implementation.

REVIEWER	Taylor, Sally The Christie NHS Foundation Trust, Christie Patient Centred Research
REVIEW RETURNED	14-Sep-2022

GENERAL COMMENTS	This is a well written manuscript detailing the protocol of an interesting and worthwhile study. Just a few minor points which could be included to strengthen the manuscript. Although it would not be the direct aim of this study, it may be worth mentioning some of the wider inequalities in cancer care and reasons for this such as later presentation within some ethnic groups leading to worse outcomes or the lack of participation of ethnic groups in clinical trials. The authors could provide a bit more information justifying the choice of outcome measures. There are many quality of life tools available and the authors state they have chosen a tool used in survivor and bone marrow

	transplant patients, neither of which are the target population for this study. The protocol does not include the collection of any qualitative data, this should be listed as a limitation as there is definitely scope for including some qualitative data collection to provide an added level of detail to the findings.

REVIEWER	Ohlsson Nevo, Emma Örebro University Faculty of Medicine and Health, University Health Care Research Center
REVIEW RETURNED	21-Sep-2022

GENERAL COMMENTS	Review of manuscript: bmjopen-2022-067270 Improving cancer care for Underserved Population in an Academic Setting and Community: A Protocol for a Community Health Worker Pilot Navigation Program Thank you for the honourable task to review this manuscript for BMJ open. The manuscript is addressing an important clinical issue of reducing the time from diagnose/first symptom to start of treatment. The main objective of this project is written in three different versions 1. Abstract : understand how the program influences patients' health care utilization within the period between their first diagnosis to initial treatment visit. 2. Manuscript: Describes a pilot program for assessing how the implementation of a CHW navigation program, focusing on problem-solving, will influence patients' treatment initiation and health care utilization for cancer treatment and care. 3. Objectives of the pilot study include assessing the technical and administrative feasibility and acceptability of program implementation for informing a larger-scale intervention study in the future Comment: A clear purpose and a clear aim with research questions would improve this manuscript.Then it also would be easier to describe the operationalization of the outcomes. The study protocol In context of the existing literature and current knowledge the background section, consist of adequate literature although lacking literature on health-literacy. Low Health-literacy is an important factor for low health behaviour. The design is a pre-test/post-test, hybrid effectiveness-implementation type-1 research design. This design will primarily evaluate the effectiveness of the pilot CHW navigation program in facilitating patients' initiation of cancer treatment, health care utilization for oncology care, and perceived health status (patient stress and quality of life). Eligible patients are those seeking cancer care with their first cancer in the JHH . system. Approx. 2155 patients will be contacted by two member of tha CHW team.

The pilot study is supposed to evaluate technical and administrative feasibility of the program through semi-structured discussion although unclear who will participate- and how the discussion will be analyzed.

The intervention

The intervention, the Community Health Worker navigation program adops the C.
O. P. E model Creativity, Optimism, Planning, and Expert information.

If the CHW is unable to meet the patient's specific needs at that time, the patient could leave the program. How will that be registered?

Comments; It is unclear when and how two persons will contact 2155 patient within the period between their first diagnosis to initial treatment visit. It seems like an impossible task. Furthermore, it is unclear what expert information and relevant guidance will be given. Is there a manual describing self-care or what steps to take? Will there be consistency?
I suggest following the advice on how to conduct complex intervention by the Medical Research Council (MRC).
New framework on complex interventions to improve health – UKRI
Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. Int J Nurs Stud. 2013 May;50(5):587-92. doi: 10.1016/j.ijnurstu.2012.09.010. Epub 2012 Nov 15. PMID: 23159157.

Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, Moore L, O'Cathain A, Tinati T, Wight D, Baird J. Process evaluation of complex interventions: Medical Research Council guidance. BMJ. 2015 Mar 19;350:h1258. doi: 10.1136/bmj.h1258. PMID: 25791983; PMCID: PMC4366184.

Skivington K, Matthews L, Simpson SA, Craig P, Baird J, Blazeby JM, Boyd KA, Craig N, French DP, McIntosh E, Petticrew M, Rycroft-Malone J, White M, Moore L. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. BMJ. 2021 Sep 30;374:n2061. doi: 10.1136/bmj.n2061. PMID: 34593508; PMCID: PMC8482308.

Overall impression:
This protocol is premature and need to be improved. It is unclear how the aim and purpose of the study will be fulfilled.
A clearly description of the methods is needed. A suggestion is to first study the reasons for delay in those areas and then describe the interventions to improve.

VERSION 1 – AUTHOR RESPONSE

<table>
<tr><td colspan="2"><u>Reviewer #1:</u> Dr. Silvia Tanzi, University of Modena and Reggio Emilia Clinical and Experimental Medicine
<u>Comments to the Author:</u>
A fascinating and complete protocol to help vulnerable cancer people</td></tr>
<tr><td>Reviewer #1 Feedback</td><td>Author Response</td></tr>
<tr><td>I only underscore a minor point: when researchers talk about "feasibility" they should indicate a standard to achieve>>>for example that 50 % of newly diagnosed people participated in the program (or if there is a precedent in the literature try to replicate this percentage).</td><td>Thank you for underscoring this point! We have clarified in the texts that “feasibility” in our study is assessing the <i>process of implementing</i> the program vs. the outcome (i.e., reach of the target demographic). In this respect, we are not targeting an <i>a priori</i> benchmark (e.g., 50%). Rather, we are identifying and noting the necessary resources and personnel for supporting the program’s operations.</td></tr>
<tr><td>Moreover, to guarantee the reproducibility of the protocol, it's important to specify all the components of the intervention (for example training courses for health professionals, booklets for patients, number of appointments planned...) to check the FIDELITY of the program during the study period. Other researchers could replicate the same intervention or change some components if they fail during the implementation.</td><td>Thank you for this comment on fidelity and its importance in the reproducibility of this work. We added additional information to the methods section (p. 11). Specifically, that CHWs used scripted questions to deliver the intervention. However, we also believe that flexibility in the delivery of the intervention is essential in this work. CHWs asked different questions based upon the patient’s diagnosis status and this will allow the intervention to be individualized to the patient’s needs. This tailored approach is also in accordance with the guidance provided across the six cancer centers through the Alliance to Advance Patient-Centered Cancer Care (“Alliance”), of which this program is affiliated.</td></tr>
<tr><td colspan="2"><u>Reviewer #2</u>: Dr. Sally Taylor, The Christie NHS Foundation Trust
<u>Comments to the Author:</u>
This is a well written manuscript detailing the protocol of an interesting and worthwhile study. Just a few minor points which could be included to strengthen the manuscript</td></tr>
<tr><td>Reviewer #2 Feedback</td><td>Author Response</td></tr>
<tr><td>Although it would not be the direct aim of this study, it may be worth mentioning some of the wider inequalities in cancer care and reasons for this such as later presentation within some ethnic groups leading to worse outcomes or the lack of participation of ethnic groups in clinical trials.</td><td>We appreciate this thoughtful comment on the wider inequalities of cancer care. This study utilized area deprivation index scores rather than race and/or ethnicity in the sampling approach. We have added literature to the discussion section commenting on disparities in social determinants of health that affect timely engagement with cancer care and participation in research (p.16)</td></tr>
</table>

The authors could provide a bit more information justifying the choice of outcome measures. There are many quality of life tools available and the authors state they have chosen a tool used in survivor and bone marrow transplant patients, neither of which are the target population for this study.	Thank you for this feedback. Our program is part of a broader network of pilot programs coordinated by the Alliance to Advance Patient-Centered Cancer Care ("Alliance"), an initiative supported by the Merck Foundation. We have included a reference to this project structure and clarified that the outcome measures fulfilled the goals of the Alliance to harmonize measurements across the six sites.
The protocol does not include the collection of any qualitative data, this should be listed as a limitation as there is definitely scope for including some qualitative data collection to provide an added level of detail to the findings.	We agree that qualitative data would add to the findings. However, we had conducted a qualitative sub-study for another related program and did not incorporate one for this current study to avoid overlap. (Choi, Y., Parrillo, E., Wenzel, J. *et al.* Optimizing cancer survivorship in primary care: patient experiences from the Johns Hopkins Primary Care for Cancer Survivors clinic. *J Cancer Surviv* (2022). https://doi.org/10.1007/s11764-022-01166-3)

Reviewer #3: Dr. Emma Ohlsson Nevo, Örebro University Faculty of Medicine and Health, Örebro University Faculty of Medicine and Health

Comments to the Author:
Thank you for the honourable task to review this manuscript for BMJ open. The manuscript is addressing an important clinical issue of reducing the time from diagnose/first symptom to start of treatment.

Overall Impression:

This protocol is premature and need to be improved. It is unclear how the aim and purpose of the study will be fulfilled.
A clearly description of the methods is needed. A suggestion is to first study the reasons for delay in those areas and then describe the interventions to improve.

Reviewer #3 Feedback	**Author Response**
The main objective of this project is written in three different versions 1. Abstract: understand how the program influences patients' health care utilization within the period between their first diagnosis to initial treatment visit.	We agree with this comment and have harmonized our language across the protocol abstract, introduction, and methods section. We have emphasized that we have two overall objectives, which are to: (1) the program's influences on patients' health care utilization within the period between their first diagnosis to initial treatment visit, and (2) the feasibility and acceptability of program implementation.

2. Manuscript: Describes a pilot program for assessing how the implementation of a CHW navigation program, focusing on problem-solving, will influence patients’ treatment initiation and health care utilization for cancer treatment and care. 3. Objectives of the pilot study include assessing the technical and administrative feasibility and acceptability of program implementation for informing a larger-scale intervention study in the future Comment: A clear purpose and a clear aim with research questions would improve this manuscript. Then it also would be easier to describe the operationalization of the outcomes.	
In context of the existing literature and current knowledge the background section, consist of adequate literature although lacking literature on health-literacy. Low Health-literacy is an important factor for low health behaviour.	We agree that health literacy is an important factor to consider. Health literacy levels are associated with the social factors that are considered in the calculation of area deprivation. We have added additional literature in the methods section to discuss how our sampling strategy targets patients from areas with high area deprivation indices, where patients are also more likely to have lower health literacy levels (p. 9). Additionally, we have added literature to the discussion section regarding how CHW models of care have been shown to be effective in improving health outcomes in underserved populations (p. 15).
The design is a pre-test/post-test, hybrid effectiveness-implementation type-1 research design. This design will primarily evaluate the effectiveness of the pilot CHW navigation program in facilitating patients' initiation of cancer treatment, health care utilization for oncology care, and perceived health status (patient stress and quality of life). Eligible patients are those seeking cancer care with their	We appreciate this thoughtful feedback. We are assessing the *acceptability* of the program with the CAGs through semi-structured discussions (p.12). The investigator team will be assessing the *feasibility* of program implementation.

first cancer in the JHH . system. Approx. 2155 patients will be contacted by two member of tha CHW team. The pilot study is supposed to evaluate technical and administrative feasibility of the program through semi-structured discussion although unclear who will participate- and how the discussion will be analyzed.	
If the CHW is unable to meet the patient's specific needs at that time, the patient could leave the program. How will that be registered?	We have added details clarifying that all engagements between CHWs and participants are documented through encounter notes, which will be reviewed by the investigator team.
It is unclear when and how two persons will contact 2155 patient within the period between their first diagnosis to initial treatment visit. It seems like an impossible task. Furthermore, it is unclear what expert information and relevant guidance will be given. Is there a manual describing self-care or what steps to take? Will there be consistency?	Thank you for the opportunity to clarify: The estimated 2,155 patients only represent the number of people within hospital records who would be eligible for the study based on our inclusion criteria, and not the number of patients the program is attempting to enroll. Regarding the expert information and relevant guidance given, the staff CHWs refer to an existing database of resources such as local social services offering transportation support for attending medical appointments. The CHWs refer to the same database for all patients contacted. However, the relevant resource for patients is dependent on what the CHW's needs assessment identifies and thus information will vary depending on patients' and/or caregivers' respective needs. The consistency across patients is the source from where information is drawn, but the type of information offered is individualized. This feature of the program aligns with the goals of the Alliance to Advance Patient-Centered Cancer Care, which stipulates the imperative for tailored approaches for patients that reflects both their needs and the capacity of the respective cancer centers within the Alliance.
I suggest following the advice on how to conduct complex intervention by the Medical	We thank the reviewer for providing excellent reference articles for complex interventions. We have cited these articles within the manuscript to emphasize (1) the importance of

Research Council (MRC). New framework on complex interventions to improve health – UKRI Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. Int J Nurs Stud. 2013 May;50(5):587-92. doi: 10.1016/j.ijnurstu.2012.09.010. Epub 2012 Nov 15. PMID: 23159157. Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, Moore L, O'Cathain A, Tinati T, Wight D, Baird J. Process evaluation of complex interventions: Medical Research Council guidance. BMJ. 2015 Mar 19;350:h1258. doi: 10.1136/bmj.h1258. PMID: 25791983; PMCID: PMC4366184. Skivington K, Matthews L, Simpson SA, Craig P, Baird J, Blazeby JM, Boyd KA, Craig N, French DP, McIntosh E, Petticrew M, Rycroft-Malone J, White M, Moore L. A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. BMJ. 2021 Sep 30;374:n2061. doi: 10.1136/bmj.n2061. PMID: 34593508; PMCID: PMC8482308.	incorporating the assessment of feasibility and acceptability within the design of a complex intervention to ensure real world applicability (p. 8) and (2) that flexibility is a key component in many interventions and has allowed us to tailor this pilot program to the individualized needs of both our cancer patients and their caregivers (p. 11).

VERSION 2 – REVIEW

REVIEWER	Taylor, Sally The Christie NHS Foundation Trust, Christie Patient Centred Research
REVIEW RETURNED	14-Nov-2022

GENERAL COMMENTS	I am satisfied with the changes made by the authors and have no further comments