PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Can a nurse-led community based model of hypertension care improve hypertension control in Ghana? Results from the ComHIP cohort study.
AUTHORS	Adler, Alma; Laar, Amos; Prieto-Merino, David; Der, Reina; Mangortey, Debbie; Dirks, Rebecca; Lamptey, Peter; Perel, Pablo

VERSION 1 – REVIEW

REVIEWER	Lyne Cloutier Université du Québec à Trois-Rivières, Canada
REVIEW RETURNED	30-Oct-2018

GENERAL COMMENTS	ComHIP is a large cohort study testing a community-based model of hypertension care. Manuscript generally well written. Topic is of interest. This interesting study can certainly guide future interventions. However without of clear description of an eventual gap between what was planned and what really happened in term of intervention, it is difficult to say what it is that really worked in this case. Abstract Research objective: In the abstract, the objective appears to be the objective of the paper. It should be the objective of the study. In the abstract, results from secondary outcomes should be mentioned before other results. Intervention needs to be describe more clearly. How they were trained should be specified (how long, what content, certification? Recertification) basic training of the nurses? The intervention includes technology so this should also be clearly stated in the abstract and describe in the paper. Strength and limitations of the study In this section emphasis is put on the technological part of the study (SMS reminders etc). Was it an important part of the intervention? Not mentioned elsewhere in the paper? It is mentioned that “Blood pressure was checked with a minimum of three serial readings at regular intervals, but at a minimum of 6-monthly intervals” but some patients only had a 12 month appointment thus not respecting this. Limitations are not mentioned (either change the title of the section or add the limitations – no control group, large drop out rate etc). Introduction Line 40 to 42: in this study, nurses can screen and diagnose hypertension, initiate and adjust treatment. This should be highlighted in the abstract but also put into context as this is unusual in a nursing practice. Their level of education and specific training should be presented. Were they special authorizations needed for this study? Page 3

	Line 8 remove “accessible” antihypertensive drugs or something similar Line 18: [7]. instead of .[7] same for [9] and others. Participants : Blood pressure being the primary outcome, blood pressure measurement methods need to be specifically described. How and when was BP taken? What position? Rest period? Please cite which set of guidelines were followed for BP measurement. Who was measuring BP (nurse? Physician? Other?) should also be specified. Standardise protocol is mentioned in the data collection section but with no details or references. Who measured the BP is not mentioned in that section either. 20% of patients were obese. Was a specific cuff used for those patients? Participants had to have access to a mobile device to receive the messages. Was it an inclusion criteria? Please explain if this could have brought a selection bias. Participants with very high BP had a different follow-up but were they still included in the study? This should be mentioned. Was it the i/e crierias from the start? The intervention should be clearly identified in a separate section. Part of it is actually with the participants. Treatment is mentioned (line 6 page 5) but the guidelines are presented in a separate section. A table could be added. Was treatment provided (free medication or did the patient payed for the medication)? This is not mentioned and it could make an important difference for patient’s enrollment. If we are to accept that “this” intervention works, we need to be able to grasp exactly on what the intervention is for reproducibility purpose and how much of it we need to get these resultats. Did everyone receive the daily reminders? Weekly tips etc? The treatment goal should be stated first when the intervention is described. The pharmacotherapy is based on risk assessment (line 12 page 5) and risk assessment is also mentioned in other parts of the document. Please state what tool was used for the evaluation. Reference? Which levels were used to decide on monotherapy or multiple drug therapy? P5 line line 15: who reviewed and adjusted therapy? Was this “q three months review” intended for all? What if the patient only came at 6 months or 12 months? The intensity of follow-up needed for this type of intervention is an important issue so what was planned is interesting to not but what appended during the trial should also be described? The result section should also identified which patient received which intervention (or part of). Variables Main outcome: add mm Hg beside 140/90 In this section, it says that appointments at 6 months and 12 months were used but later it says around 6 and 12 (+ - a few months). This should be clarify and stated in the same manner. Other outcomes are mentioned (secondary outcomes) in the abstract but not mentioned again in this section (knowledge of risk factors) Statistical methods Review the description of education (4 categories mentioned but more are used in the Table 1. Please review the use of capital (or non capital letters in the Table 1) e.g. Primary, secondary etc. Results The characteristics of the participants enrolled but that did not come back should be presented in the Table one (n=712). How similar? Different are they from the participants? Table 1

	Treatment section: Change “no treatment” for diagnosed but no treatment Please state which BMI scale was used (normal is between X and X) – when results about this are mentioned, it should be written normal weight not normal. Table 3 page 12: The second and third line with 552 et 338 should be better described. Those numbers include the same patients. It should say (on the left) with at least one six months visit and with at least one 12 months. As it is, we tend to add 552, 338 and 712 (non participant) and it doesn’t add up to 1339. Maybe these two categories should not be used at all? What would they represent in the clinical setting? The patients that do only one of the two visits and the ones that do both could be different? Table 4 stages described in the text should have same terminology stge I, II or II vs mild moderate, severe. Table 5 angiotensin should read ACE inhibitor Secondary outcomes mentioned in the abstract are not presented in the result section neither is it discussed (awareness of risk factors)? Summary of results Presenting the follow-up at 6 and 12 months with 338 patients for 12 months is misleading. Only 263 had both 6 and 12 months follow up which represents 20%. Comparison with other studies Results and lost to follow up are compared which is interesting but the interventions are not discussed. What was more efficient? What is (are) the intervention (s) that work(s)?

REVIEWER	Lesli Skolarus University of Michigan, Ann Arbor, USA
REVIEW RETURNED	27-Nov-2018

GENERAL COMMENTS	The authors present the results a large cohort study of a multi-component community blood pressure intervention in Ghana. The manuscript is well written and the interpretation of the results is candid and scientifically very honest. 1. Information on how the primary outcome was assessed would be helpful? Who took the blood pressures? How many blood pressures were taken? Were they to be taken at a scheduled clinical appointment? Or at a research visit? 2. The authors recommend staff incentives as a way to increase participant retention. I am wondering if participant incentives were used to facilitate retention? For example, to help pay for childcare or transportation to assess outcomes? 3. How was the cloud based health records linked to SMS used to capture clinic visits? Other than the time where the system was down, was this system used to assess the visit coutcome? 4. How was hypertensive awareness assessed? 5. I was surprised that most of the participants were aware of their hypertension and taking medications. How would the authors recommend reaching a population without a diagnosis of hypertension and less controlled at baseline?

VERSION 1 – AUTHOR RESPONSE

Reviewer(s)' Comments to Author:

Reviewer: 1,

Reviewer Name: Lyne Cloutier

Institution and Country: Université du Québec à Trois-Rivières, Canada

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

Please leave your comments for the authors below ComHIP is a large cohort study testing a community-based model of hypertension care. Manuscript generally well written. Topic is of interest. This interesting study can certainly guide future interventions. However, without of clear description of an eventual gap between what was planned and what really happened in term of intervention, it is difficult to say what it is that really worked in this case.

Abstract

Research objective: In the abstract, the objective appears to be the objective of the paper. It should be the objective of the study.

We have changed this to:

to evaluate the effectiveness of the Community-Based Hypertension Improvement Project (ComHIP) in increasing hypertension control.

In the abstract, results from secondary outcomes should be mentioned before other results.

Thank you, this has now been done.

Intervention needs to be describe more clearly. How they were trained should be specified (how long, what content, certification? Recertification) basic training of the nurses? The intervention includes technology so this should also be clearly stated in the abstract and describe in the paper.

Thank you. We addressed this comment in the abstract and main body of the paper. In the abstract we added the text:

“Patients received three types of reminder and adherence messages. We used CommCare, a cloud based system, as a case management and referral tool.” In the main text we added information about nurse training.

We have also included details about training in the manuscript. Finally we have added in the ComHIP clinical guidelines as an appendix.

Strength and limitations of the study

In this section emphasis is put on the technological part of the study (SMS reminders etc). Was it an important part of the intervention? Not mentioned elsewhere in the paper?

We had discussed this in the fifth paragraph of the introduction, I have now moved this to the methods section, in an “intervention section”.

It is mentioned that “Blood pressure was checked with a minimum of three serial readings at regular intervals, but at a minimum of 6-monthly intervals” but some patients only had a 12 month appointment thus not respecting this.

I have changed this to: Protocol stated that blood pressure would be checked with a minimum of three serial readings at regular intervals, but at a minimum of 6-monthly intervals

Limitations are not mentioned (either change the title of the section or add the limitations – no control group, large drop out rate etc).

I added the point: a limitation of the study was that it did not include a control group

Introduction

Line 40 to 42: in this study, nurses can screen and diagnose hypertension, initiate and adjust treatment. This should be highlighted in the abstract but also put into context as this is unusual in a nursing practice. Their level of education and specific training should be presented. Were they special authorizations needed for this study?

We have now included more information on training in the text, as well as added the ComHIP clinical guidelines as an appendix. This method of management is not that unusual in rural sub-Saharan African communities where severe shortages of physicians mean that often nurses are the only available providers.

Page 3

Line 8 remove “accessible” antihypertensive drugs or something similar Line 18: [7]. instead of .[7] same for [9] and others.

I have changed this to Anti-hypertensive drugs

Participants :

Blood pressure being the primary outcome, blood pressure measurement methods need to be specifically described. How and when was BP taken? What position? Rest period? Please cite which set of guidelines were followed for BP measurement. Who was measuring BP (nurse? Physician? Other?) should also be specified. Standardise protocol is mentioned in the data collection section but with no details or references. Who measured the BP is not mentioned in that section either. 20% of patients were obese. Was a specific cuff used for those patients?

This was described ion page five. Based on reviewer comments, we have now also added the statement: “Community members were screened by CHOs, LCS, or CVD nurses, using Omron M6 BP monitors that came with a cuff size of 42cm which is about the 2nd largest cuff size in the market for those machines. Though the project requested for nurses to report cases of patient with bigger upper arms that required bigger cuff sizes, throughout the implementation, no such reports was received”

We have also attached a version of the ComHIP guidelines to be included as an appendix.

Participants had to have access to a mobile device to receive the messages. Was it an inclusion criteria? Please explain if this could have brought a selection bias.

We have added “Patients had to have access to a mobile phone to be enrolled in the programme. However, in order to negate loss of patients, patients without phones were not necessarily excluded based on this, rather, they were encouraged to provide phone numbers of a willing third party who lived nearby.”

Participants with very high BP had a different follow-up but were they still included in the study? This should be mentioned. Was it the i/e crierias from the start?

I have now put a sentence in clarifying that they were only managed by physicians until their blood pressure was more stable, and they were returned to community care.

The intervention should be clearly identified in a separate section. Part of it is actually with the participants. Treatment is mentioned (line 6 page 5) but the guidelines are presented in a separate section. A table could be added. Was treatment provided (free medication or did the patient payed for the medication)? This is not mentioned and it could make an important difference for patient’s enrollment. If we are to accept that “this” intervention works, we need to be able to grasp exactly on what the intervention is for reproducibility purpose and how much of it we need to get these resultats. Did everyone receive the daily reminders? Weekly tips etc? The treatment goal should be stated first when the intervention is described.

We had discussed this in the introduction, but have now moved this from the introduction into the intervention section of the methods where it may be clearer. We had written : “All patients enrolled in ComHIP receive SMS daily for medication reminders, weekly for health education, and upon need for appointment and screening reminders”.

We also added the statement:

In Ghana, there is a system of National Health Insurance, and every Ghanaian is required to enroll in. The Scheme provides select medications at no cost for anyone who has a valid National Health Insurance card. Although the NHIS does not attempt to treat all diseases suffered by insured members, over 95% of disease conditions that afflict us are covered by the NHIS. Services can be accessed at accredited health facilities.

The pharmacotherapy is based on risk assessment (line 12 page 5) and risk assessment is also mentioned in other parts of the document. Please state what tool was used for the evaluation. Reference?

We have now included the clinical guidelines as an appendix.

Which levels were used to decide on monotherapy or multiple drug therapy? P5 line line 15: who reviewed and adjusted therapy? Was this “q three months review” intended for all? What if the patient only came at 6 months or 12 months? The intensity of follow-up needed for this type of intervention is an important issue so what was planned is interesting to not but what appended during the trial should also be described? The result section should also identified which patient received which intervention (or part of).

We have now included the clinical guidelines as supplementary material

Variables

Main outcome: add mm Hg beside 140/90

Thank you for noticing! This has been fixed.

In this section, it says that appointments at 6 months and 12 months were used but later it says around 6 and 12 (+ - a few months). This should be clarify and stated in the same manner.

This has been amended.

Other outcomes are mentioned (secondary outcomes) in the abstract but not mentioned again in this section (knowledge of risk factors)

Thank you, this has now been amended.

Statistical methods Review the description of education (4 categories mentioned but more are used in the Table 1. Please review the use of capital (or non capital letters in the Table 1) e.g. Primary, secondary etc.

Thank you, this has now been amended

Results

The characteristics of the participants enrolled but that did not come back should be presented in the Table one (n=712). How similar? Different are they from the participants?

Thank you for this comment. However, we think that this can be clearly seen in the table, by looking at the characteristics of people that stayed in.

Table 1

Treatment section: Change “no treatment” for diagnosed but no treatment Please state which BMI scale was used (normal is between X and X) – when results about this are mentioned, it should be written normal weight not normal.

These have now been changed.

Table 3 page 12:

The second and third line with 552 et 338 should be better described. Those numbers include the same patients. It should say (on the left) with at least one six months visit and with at least one 12 months. As it is, we tend to add 552, 338 and 712 (non participant) and it doesn’t add up to 1339. Maybe these two categories should not be used at all? What would they represent in the clinical setting? The patients that do only one of the two visits and the ones that do both could be different?

there are 552 patients that have a six month visit, and 338 patients that have a 12 month visit. Because the cohort had such low retention, we are trying to present the results in a useful but transparent way, thus we are showing the relationship between remaining in the cohort for 6 months and 12 months and reduction in blood pressure. We think that showing it in the manner suggested by the reviewer would actually result in less information. I have tried to elaborate a bit more in the text to try and make this clearer.

Table 4 stages described in the text should have same terminology stge I, II or II vs mild moderate, severe.

This has now been amended.

Table 5 angiotensin should read ACE inhibitor

This has now been amended

Secondary outcomes mentioned in the abstract are not presented in the result section neither is it discussed (awareness of risk factors)?

With apologies, this has been added in

Summary of results

Presenting the follow-up at 6 and 12 months with 338 patients for 12 months is misleading. Only 263 had both 6 and 12 months follow up which represents 20%.

I have added in that only 20% had both a 6 and 12 month appointment.

Comparison with other studies

Results and lost to follow up are compared which is interesting but the interventions are not discussed. What was more efficient? What is (are) the intervention (s) that work(s)?

This was not a study testing different interventions, all patients were given the same package of interventions. This was a study testing the success of a model of care, (ie having nurses screen and provide community based management) to decrease blood pressure. I have amended the text in a few areas to refer to the package of interventions to make this more clear.

Reviewer: 2

Reviewer Name: Lesli Skolarus

1. Information on how the primary outcome was assessed would be helpful? Who took the blood pressures? How many blood pressures were taken? Were they to be taken at a scheduled clinical appointment? Or at a research visit?
We have now added more information in the “intervention” section, and included clinical guidelines.

2. The authors recommend staff incentives as a way to increase participant retention. I am wondering if participant incentives were used to facilitate retention? For example, to help pay for childcare or transportation to assess outcomes?
We did not give any participant incentives.

3. How was the cloud based health records linked to SMS used to capture clinic visits? Other than the time where the system was down, was this system used to assess the visit coutcome?

We have now added some information on this in the text in the “intervention” section.

4. How was hypertensive awareness assessed?
In the variables section I have added the sentence “defined as having knowledge of a previous diagnosis of hypertension”

5. I was surprised that most of the participants were aware of their hypertension and taking medications. How would the authors recommend reaching a population without a diagnosis of hypertension and less controlled at baseline?

The reason that this population was used was that this was an attempt to achieve greater hypertension control in the community, by bringing greater access to community based hypertension care. For this reason, we did not think it was ethical to deny patients care, just because they were already being treated. From a research standpoint, it may have been more interesting to only include

less controlled patients, but from an ethical/implementation standpoint, we wanted to include all patients. This was an interesting finding in our study, and future research may want to concentrate on more difficult to access patients. We have added a statement at the end of our discussion.

VERSION 2 – REVIEW

REVIEWER	Lyne Cloutier Université du Québec à Trois-Rivières
REVIEW RETURNED	28-Jan-2019

GENERAL COMMENTS	All comments presented for the first revision were addressed to my satisfaction.