

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Indigenous health worker support for patients with poorly controlled type 2 diabetes: study protocol for a cluster randomised controlled trial of the Mana Tū programme
AUTHORS	Selak, Vanessa; Stewart, Tereki; Jiang, Yannan; Reid, Jennifer; Tane, Taria; Carswell, Peter; Harwood, Matire

VERSION 1 – REVIEW

REVIEWER	Sathish Thirunavukkarasu Nanyang Technological University, Singapore
REVIEW RETURNED	17-Apr-2018

GENERAL COMMENTS	<p>The study protocol paper by Selak et al describes an important piece of work related to the management of type 2 diabetes among indigenous populations in New Zealand. The paper is very well written, and I have only a few clarifications and suggestions for improvement.</p> <ol style="list-style-type: none">1. In methods section, please justify the need for a cluster RCT for this study.2. Do you have plans to perform a cost-effectiveness analysis?3. Page 5, line 46: Authors say that the consent for participating in the trial will not be obtained as the risk of participation is low. Even if the risk is going to be low (the case in most studies of this kind), written informed consent should be obtained from all the participants.4. Please include a figure showing the trial profile.5. Please describe what is usual care.6. Is there a theory behind the intervention? or a needs assessment study was done to inform the development of the intervention program? Please specify.7. In statistical methods, please specify the subgroups that you are planning to analyse.8. In statistical methods, please specify how you will handle the missing data?9. Did you account for loss to follow-up in sample size calculation?10. Why diet and physical activity data are not being collected?11. What is the current status of the trial?
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REVIEWER	Tim Johansson Paracelsus Medizinische Privatuniversität, Institute of general practice, family medicine and preventive medicine
REVIEW RETURNED	26-Apr-2018

GENERAL COMMENTS	Dear authors, dear editor,
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	<p>this study protocol titled „Indigenous health worker support for patients with poorly controlled type 2 diabetes: study protocol for a cluster randomised controlled trial of the Mana Tū programme” aim to determine the effectiveness of the Mana Tu programme in improving glycaemic control. In summary this study protocol is very interesting and important. The selection of study design (cluster RCT) is very appropriate. Still, some minor and major concerns need to be clarified:</p> <p>Please include dates of the study A study protocol should not include a conclusion</p> <p>Background Prevalence and incidence of T2DM and complications in the Maori population</p> <p>Intervention and controls Description of intervention must be improved. For readers, it is very hard to understand the Mana Tu programme. Table 1 and figure 1 should be updated. What is the actual intervention? I strongly recommend to use the MRC guidance on how to evaluate complex interventions You should use the term case manager to describe a component and not Kai Manaaki. In it present form, you get the feeling that Kai Manaaki is the intervention. Please define usual care</p> <p>Recruitment Selection of GPs and recruitment area is unclear (why 10 practices?) Will all eligible patients be invited to participate? Do you aim to recruit a representative study population? It seems, that the case manager can select study participant. Please specify the recruitment strategy. Can you run this trial without patient informed consent?</p> <p>Outcome assessment, data quality, outcome measurements Why do you not use a case report form? Is the quality of data, practice electronic medical record good enough? Who will monitor and assure high quality of data (reporting)? It is not clear how is responsible for the outcome assessment There are so many components in the Mana Tu programme. You have decided to select HbA1c as primary outcome measure. Is this surrogate parameter the most appropriate outcome for this kind of intervention? Do you not think that this intervention will affect other patient related outcomes such as health related quality of life and depression. Please define hospitalisations (all, elective, non-elective), lengths of hospital. Have you planned some kind of cost analysis?</p> <p>For further information please see comments in the separate manuscript (attachment)</p> <p>- The reviewer provided a marked copy with additional comments. Please contact the publisher for full details.</p>
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REVIEWER	Ha Nguyen
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	University of South Australia, Australia, University of Sydney, Australia
REVIEW RETURNED	15-May-2018

GENERAL COMMENTS	<p>Thank you for giving me the opportunity to review this research protocol. It is well written and structured. I highly recommended the protocol to be published with some minor clarifications below:</p> <ul style="list-style-type: none"> • This is a planned study and ethical approval has been obtained. It is recommended by the journal to include dates of the study. • In the Introduction, it would be more convincing if there are some descriptions on the usual care (which was commented by the authors as the “established best practice for diabetes”), how it is compared to the proposed Mana Tū Programme, and the rationales making the Mana Tū Programme superior than the “usual care”. • Given the study has been given ethical approval and consent for participation in the trial will not be obtained, I’m not sure whether participants in the intervention arm would have the right to withdraw from trial in case they might find it uncomfortable. A further note about this would be useful. • The sample size calculation was well explained. However, there seems to be no consideration of potential loss to follow-up.
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VERSION 1 – AUTHOR RESPONSE

Reviewer(s)' Comments to Author:

Reviewer: 1

Reviewer Name: Sathish Thirunavukkarasu

Institution and Country: Nanyang Technological University, Singapore

Please state any competing interests: None declared

Please leave your comments for the authors below

The study protocol paper by Selak et al describes an important piece of work related to the management of type 2 diabetes among indigenous populations in New Zealand. The paper is very well written, and I have only a few clarifications and suggestions for improvement.

Thank you

1. In methods section, please justify the need for a cluster RCT for this study.

Added under trial design section (p5)

2. Do you have plans to perform a cost-effectiveness analysis?

This is planned and has now been added in the discussion (p13)

3. Page 5, line 46: Authors say that the consent for participating in the trial will not be obtained as the risk of participation is low. Even if the risk is going to be low (the case in most studies of this kind), written informed consent should be obtained from all the participants.

We agree and have modified the trial to ensure that written informed consent is obtained from all participants (p 7)

4. Please include a figure showing the trial profile.

Added (Figure 2. Trial flow diagram).

5. Please describe what is usual care.

We have clarified that the comparator in this trial is a 12 month waiting list for the intervention, and have used this instead of usual care throughout the document. We have noted (on p8) that "both groups of practices will continue to provide usual care to all of their patients for the management of diabetes according to relevant guidelines, including regular monitoring of HbA1c, blood pressure and lipid levels"

6. Is there a theory behind the intervention? or a needs assessment study was done to inform the development of the intervention program? Please specify.

Requested information added in introduction (p4)

7. In statistical methods, please specify the subgroups that you are planning to analyse.

Requested information added to statistical methods (p10)

8. In statistical methods, please specify how you will handle the missing data?

Requested information added to statistical methods (p10)

9. Did you account for loss to follow-up in sample size calculation?

Please see addition to statistical methods regarding loss to follow up and missing data (p11).

10. Why diet and physical activity data are not being collected?

These data are not routinely collected electronically in a format that enables reliable extraction therefore we will be unable to provide data on diet and physical activity in all participants.

11. What is the current status of the trial?

10 practices have agreed to participate in the trial and to date 135 participants have been enrolled

Reviewer: 2

Reviewer Name: Tim Johansson

Institution and Country: Institute of general practice, family medicine and preventive medicine.

Paracelsus Medical University

Strubergasse 21, A-5020 Salzburg, Austria

Please state any competing interests: None declared

Please leave your comments for the authors below

Dear authors, dear editor,

this study protocol titled „Indigenous health worker support for patients with poorly controlled type 2 diabetes: study protocol for a cluster randomised controlled trial of the Mana Tū programme” aim to determine the effectiveness of the Mana Tu programme in improving glycaemic control. In summary this study protocol is very interesting and important. The selection of study design (cluster RCT) is very appropriate. Still, some minor and major concerns need to be clarified:

Thank you

Please include dates of the study

Requested information added to trial design (p5)

A study protocol should not include a conclusion

Removed as requested

Background

Prevalence and incidence of T2DM and complications in the Maori population

Added to the introduction (p4)

Intervention and controls

Description of intervention must be improved. For readers, it is very hard to understand the Mana Tu programme. Table 1 and figure 1 should be updated. What is the actual intervention?

I strongly recommend to use the MRC guidance on how to evaluate complex interventions

You should use the term case manager to describe a component and not Kai Manaaki. In its present form, you get the feeling that Kai Manaaki is the intervention.

We have enhanced the description of the intervention by describing the development of and theory behind the intervention (introduction, p4 and Fig 1 framework for change) and providing more detail (including an additional diagram – Figure 4) to describe the intervention in more detail (p7-8).

Please define usual care

Please see response above

Recruitment

Selection of GPs and recruitment area is unclear (why 10 practices?)

We have now noted in the introduction (p4) that the National Hauora Coalition (a Maori-led Primary Health Organisation) had 33 affiliated general practices.

We have already noted under study setting (p5) that the programme will be implemented in general practices affiliated with that Primary Health Organisation.

We have now added that the rationale for this is the study “will utilise routinely collected electronic data and such data are already provided to the NHC by these practices using established and secure methods that protect patient confidentiality” (p5)

We have now noted under sample size (p9) that the number of general practices required and participants per practice were informed by estimates of the number of potentially eligible patients within each of the Primary Health Organisations 33 practices.

We have already noted under general practice eligibility (p5) that “Practices will be approached in descending order according to their number of potentially eligible patients, until there are a sufficient number of practices enrolled in the trial”

Will all eligible patients be invited to participate?

No. As noted on p7 (under the section “Participant consent)

“After the practice has been randomised (irrespective of the treatment arm), the Network hub will assign a Kai Manaaki to the practice. The Kai Manaaki will approach all eligible patients referred to the network hub, to discuss the trial and Mana Tū with them. Eligible patients who provide written informed consent to participation in the trial and the Mana Tū programme (either delivered then or in 12 months’ time) will be included in the trial. Once the Kai Manaaki has identified 40 trial participants, no further participants will be sought to ensure that the case load of the Kai Manaaki is manageable.”

Do you aim to recruit a representative study population? It seems, that the case manager can select study participant. Please specify the recruitment strategy.

As described on p6 under Patient Eligibility:

“Potentially eligible patients will be identified centrally using data from electronic practice records that are already provided to the National Hauora Coalition. Each participating practice will review the eligibility of their patients for the trial, and will refer all eligible patients to the Mana Tū programme network hub (National Hauora Coalition).”

As noted above, on p7 (under the section “Participant consent),
“After the practice has been randomised (irrespective of the treatment arm), the Network hub will assign a Kai Manaaki to the practice. The Kai Manaaki will approach all eligible patients referred to the network hub, to discuss the trial and Mana Tū with them. Eligible patients who provide written informed consent to participation in the trial and the Mana Tū programme (either delivered then or in 12 months’ time) will be included in the trial. Once the Kai Manaaki has identified 40 trial participants, no further participants will be sought to ensure that the case load of the Kai Manaaki is manageable.”

Can you run this trial without patient informed consent?

Please see response to Reviewer 1

Outcome assessment, data quality, outcome measurements

Why do you not use a case report form?

Is the quality of data, practice electronic medical record good enough?

Who will monitor and assure high quality of data (reporting)?

It is not clear how is responsible for the outcome assessment

As noted in the discussion (p11):

“One of the major disadvantages of conducting randomised controlled trials is their cost – particularly for recruitment and data collection. This trial has been designed to leverage off, and to be as integrated as possible, with existing infrastructure, which will minimise the associated costs for recruitment and data collection. For example, once ethics approval has been obtained, potentially eligible patients can be identified by the Primary Health Organisation / network hub, and their baseline and follow up data obtained, using routinely collected electronic practice data to which the Primary Health Organisation / network hub already has access.”

We have added (to the randomisation and blinding section, p7) the following:

“data from community laboratories (including HbA1c) is sent electronically and entered automatically into the electronic medical record”

We have noted (under the intervention and control arm section) that “both groups of practices will continue to provide usual care to all of their patients for the management of diabetes according to relevant guidelines, including regular monitoring of be encouraged to ensure that patients HbA1c, blood pressure and lipid levels”

There are so many components in the Mana Tu programme. You have decided to select HbA1c as primary outcome measure. Is this surrogate parameter the most appropriate outcome for this kind of intervention?

We have selected this outcome measure for the trial as it is routinely available electronically for participants in both the intervention and control groups. We have now expanded the paper to include the other ways in which the programme will be evaluated (p13)

Do you not think that this intervention will affect other patient related outcomes such as health related quality of life and depression.

We agree that these are important outcomes that could be affected. However, we have very limited funding and are restricted to using data that are routinely available electronically for the both the intervention and control groups for the trial.

As noted on p10 (under Outcomes):

“The Mana Tū programme includes a range of initial assessments (Appendix), which will be monitored over time as part of the programme, but data from these assessments are not able to be collected from participants waiting for Mana Tū due to funding constraints, and therefore will not be considered as part of the trial. Data from these assessments will be used in other (concurrent) evaluations of the Mana Tū programme.”

We have now noted at the end of the discussion (p13):

“At the same time as the cluster randomised controlled trial, the Mana Tū Programme will also be evaluated using four additional studies, some of which will use data collected as part of the assessments included within the Mana Tū Programme (Appendix). One of these studies will investigate the cost-effectiveness of Mana Tū. The other three studies are qualitative: one will explore how the implementation process affects implementation outcomes, one will investigate the impact of the initiative on patients and health care providers and the final study will identify success factors to support upscaling of the intervention if it is found to be acceptable to whanau and health care providers, effective and cost-effective.”

Please define hospitalisations (all, elective, non-elective), lengths of hospital.

Added to outcomes section (p10).

Have you planned some kind of cost analysis?

Please see response to reviewer 1

For further information please see comments in the separate manuscript (attachment)

Additional suggestions from separate manuscript:

- Report HbAc1 in % (as well as mmol/mol): *Done*
- Could not find trial on trial register: *Corrected*
- Please specify mana tu assessment – *Added (Appendix)*
- What if patient has several measurements in window (under outcomes) – *Added (outcomes, p10)*

Best regards
Tim Johansson

Reviewer: 3
Reviewer Name: Ha Nguyen
Institution and Country: University of South Australia, Australia
University of Sydney, Australia
Please state any competing interests: None declared

Please leave your comments for the authors below

Thank you for giving me the opportunity to review this research protocol. It is well written and structured. I highly recommended the protocol to be published with some minor clarifications below:

Thank you

- This is a planned study and ethical approval has been obtained. It is recommended by the journal to include dates of the study.

Please see response to reviewer 2

- In the Introduction, it would be more convincing if there are some descriptions on the usual care (which was commented by the authors as the “established best practice for diabetes”), how it is compared to the proposed Mana Tū Programme, and the rationales making the Mana Tū Programme superior than the “usual care”.

Please see response to Reviewer 1

- Given the study has been given ethical approval and consent for participation in the trial will not be obtained, I’m not sure whether participants in the intervention arm would have the right to withdraw from trial in case they might find it uncomfortable. A further note about this would be useful.

Please see response to Reviewer 1 re: consent

- The sample size calculation was well explained. However, there seems to be no consideration of potential loss to follow-up.

Please see response to reviewer 1

VERSION 2 – REVIEW

REVIEWER	Sathish Thirunavukkarasu Nanyang Technological University, Singapore
REVIEW RETURNED	30-Jul-2018

GENERAL COMMENTS	Thank you for addressing all my comments satisfactorily. Just one minor suggestion for consideration. I suggest you use the term 'usual care' instead of '12-month wait list for the programme' throughout the manuscript, and just explain what the usual care is.
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REVIEWER	Ha Nguyen University of South Australia, Australia, University of Sydney, Australia
REVIEW RETURNED	26-Jul-2018

GENERAL COMMENTS	I greatly appreciate authors' efforts to response to reviewers' comments. I'm happy with the revision of the manuscript and recommend for publication.
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