PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Living with Dementia in Aotearoa (LiDiA): A cross-sectional feasibility study protocol for a multi-ethnic dementia prevalence study in Aotearoa/New Zealand.
AUTHORS	Martinez-Ruiz, Adrian; Yates, Susan; Cheung, Gary; Dudley, Makarena; Krishnamurthi, Rita; Fa'alau, Fuafiva; Roberts, Mary; Taufa, Seini; Fa'alili-Fidow, Jacinta; Rivera-Rodriguez, Claudia; Kautoke, Staverton; Ma'u, Etuini; Kerse, Ngaire; Cullum, Sarah

VERSION 1 – REVIEW

REVIEWER	Canevelli, Marco Sapienza Univ Rome
REVIEW RETURNED	09-Dec-2020

GENERAL COMMENTS	In the present article, the Authors describe the rationale and methodology of a validity and feasibility studies aimed at informing a future dementia prevalence study In New Zealand. Specifically, the validity study will consist in the translation, cultural adaptation, and validation of the 10/66 dementia assessment protocol for use in the main ethnic groups living in the country. The feasibility study aims at exploring the feasibility of adopting the culturally adapted 10/66 protocol as a research tool in these communities. The topic addressed by the paper is of relevant interest. The manuscript is well written, well organized, and easy to follow. Some minor issues should be addressed by the Authors to further improve the article: - The 10/66 dementia assessment protocol has originally been validated for people older than 65 years. Therefore, its adoption in prevalence studies may result in the exclusion from the estimates of early-onset dementia cases. As acknowledged by the Authors themselves, dementia can occur at younger ages in some ethnic groups. This may be not captured by the adopted criteria. - The AD, LBD, and FTD diagnostic criteria indicated in the Methods section are not updated. More recent (and accurate) versions of these criteria are now available and should preferentially be used. - The Authors should better specify how the amount of 30 participants with dementia in each ethnic group was arrived at. - Page 4, line 51-56: the reported percentages should be carefully checked. - The Authors should better explain why they will not consider people with dementia living in nursing homes. This may lead to underestimate the real dimension of the problem in the country.

	- The main limitations of the study protocol should be better clarified. Accordingly, a risk analysis (mentioning the main expected problems and their potential solutions) should be provided. - It should be interesting to mention if a similar methodology has already been adopted in other world countries to provide robust and culturally sensitive estimates of dementia prevalence at the national level.

REVIEWER	Honda, Takanori Kyushu University
REVIEW RETURNED	06-Jan-2021

GENERAL COMMENTS	In this study protocol paper, the authors presented a study protocol for a development of modified dementia assessment tools and for a feasibility study for a future study to estimate prevalence of dementia in the NZ population. This is a well-considered protocol. I would like to suggest this protocol is acceptable for publication after only minor clarifications. The authors considered participants were eligible if they self-identify as Māori, Samoan, Tongan or Fijian-Indian. Many of them can speak English. Will the authors collect information on whether the language is their mother tongue and whether they generally use their language in daily life? Please clarify the procedure if the participants (both dementia and non-dementia subjects) were bilingual. Feasibility study will be carried out in South Auckland. Please discuss about the applicability, or potential issues if any, of the estimation procedure to other less ethnically-diverse regions for the full dementia prevalence survey. Will the authors collect information on residents' awareness and interest of the study after raising awareness? Information on how much people aware of or interest in the study in each community may enhance effective recruitment.

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1
Dr. Marco Canevelli, Sapienza University Rome

In the present article, the Authors describe the rationale and methodology of a validity and feasibility studies aimed at informing a future dementia prevalence study In New Zealand. Specifically, the validity study will consist in the translation, cultural adaptation, and validation of the 10/66 dementia assessment protocol for use in the main ethnic groups living in the country. The feasibility study aims at exploring the feasibility of adopting the culturally adapted 10/66 protocol as a research tool in these communities. The topic addressed by the paper is of relevant interest. The manuscript is well written, well organized, and easy to follow. Some minor issues should be addressed by the Authors to further improve the article:

1. The 10/66 dementia assessment protocol has originally been validated for people older than 65 years. Therefore, its adoption in prevalence studies may result in the exclusion from the estimates of early-onset dementia cases. As acknowledged by the Authors themselves, dementia can occur at younger ages in some ethnic groups. This may be not captured by the adopted criteria.

Response: Thank you for raising this important issue. Although we suspect there is a higher proportion of dementia presented at a younger age in Maori and Pacific people (aged 55 to 64) compared to NZ Europeans, the sample size calculation showed that we would have to interview twice as many participants to identify sufficient cases in that age group in the community. Unfortunately, we had insufficient funding to include the 55-64 age group in our study. Thus, we have decided to investigate the prevalence of dementia in the 65+ first, and then we will aim to conduct a separate future study in people aged 55-64. We have therefore acknowledged this issue as a limitation of our study as follow:

Changes within the text:
Page 21, lines 27-34: ….. (iii) Another limitation is that we will only include people aged 65 years or over. Future studies, including people with younger onset dementia, particularly from the ethnic groups that have shown to be at a higher risk of developing dementia at a younger age (such as Maori and Pacific People), will be needed to clarify this issue.

2. The AD, LBD, and FTD diagnostic criteria indicated in the Methods section are not updated. More recent (and accurate) versions of these criteria are now available and should preferentially be used.

Response: Thank you for your comment. As suggested, we have updated the dementia diagnostic criteria bibliography within the manuscript text and in the reference list as follows:

Changes within the text:
Page 11, lines 10-15: …. The clinical diagnoses will be made by a multidisciplinary team of dementia specialists at the memory service, guided by standard clinical criteria, including NIA-AA criteria for Alzheimer's disease dementia (33), NINCDS-AIREN criteria for vascular dementia (34), criteria for Lewy Body dementia (35), and the criteria for Frontotemporal dementias (36))…….

Changes within the reference list:
33. Jack CR, Jr., Bennett DA, Blennow K, Carrillo MC, Dunn B, Haeberlein SB, et al. NIA-AA Research Framework: Toward a biological definition of Alzheimer's disease. Alzheimers Dement. 2018;14(4):535-62.
35. McKeith IG, Boeve BF, Dickson DW, Halliday G, Taylor JP, Weintraub D, et al. Diagnosis and management of dementia with Lewy bodies: Fourth consensus report of the DLB Consortium. Neurology. 2017;89(1):88-100.
36. Neary D, Snowden JS, Gustafson L, Passant U, Stuss D, Black S, et al. Frontotemporal lobar degeneration: a consensus on clinical diagnostic criteria. Neurology. 1998;51(6):1546-54.

3. The Authors should better specify how the amount of 30 participants with dementia in each ethnic group was arrived at.

Response: Thank you for raising this important issue. As a convenience sample, we judged that 30 people per group were the number of people we would be able to recruit from the memory service for each ethnic group; it also aligns with the recommended sample sizes between 24 and 50 for pilot

studies (References 41-43). We have therefore acknowledged this issue as a limitation of our study as follow:

Changes within the text:
Page 21, lines 8-20: There are some limitations that need to be acknowledged: (i) the sampling methodology was based on convenience sampling. Although sample sizes between 24 and 50 have been recommended for pilot studies (41-43) and convenience sampling may provide accurate correlations and rich qualitative information, it will not offer generalisable results to the overall NZ population. However, this study will lay the foundations for a future national prevalence study representing all the ethnic groups included in our research.

Changes within the reference list:
41. Sim J, Lewis M. The size of a pilot study for a clinical trial should be calculated in relation to considerations of precision and efficiency. J Clin Epidemiol. 2012;65(3):301-8.
42. Julious SA. Sample size of 12 per group rule of thumb for a pilot study. Pharmaceutical Statistics. 2005;4(4):287-91.
43. Browne RH. On the use of a pilot sample for sample size determination. Stat Med. 1995;14(17):1933-40.

4. Page , line 51-56: the reported percentages should be carefully checked.

Response: Thank you for your suggestions. We have clarified within the text why the reported percentages sum up more than 100 percent. The text has been amended as follow:

Changes within the text:
Page 6, lines 19-24: …According to the 2018 NZ census, approximately 70% of the people in the total population self-identified as NZ-Europeans, 17% as Māori, 15% as Asians, 8% as Pacific people, 2% as Middle Eastern/Latin American/African, and 1% as other (9). However, the 2018 NZ census also included those who identify with more than one ethnicity; thus, the proportion sum is higher than 100 percent.

5. The Authors should better explain why they will not consider people with dementia living in nursing homes. This may lead to underestimate the real dimension of the problem in the country.

Response: Thank you for your comments. We have updated the text to explain why we have excluded people from long term care facilities and retirement villages, and it has been added as a limitation of the study. Briefly, long term care facilities and retirement villages will be excluded from our study as it may introduce result bias (since their overall dementia prevalence, sociodemographic and general health status may differ from those in the community) in our relatively small sample study. However, we intend to conduct a future study using the Long-Term Care Facility version of the International Residential Assessment Instrument (interRAI). interRAI routinely collects information on dementia diagnosis and is mandated by the Ministry of Health to be completed with every long term care facility residents every 6 months. We also have planned to conduct a dementia prevalence study in long term care facilities using the 10/66 instruments (reference standard) and compare the results against interRAI data to assess their utility for ongoing dementia surveillance.

Changes within the text:
Page 15, lines 43-48: The exclusion criteria are participants unable to identify a friend or family member to complete the informant schedule, and people living in long term care facilities and retirement villages (since their overall dementia prevalence, sociodemographic and general health

status may differ from those in the community, and thus it might introduce results bias in our relatively small community sample).

Page 21, lines 34-55: …..(iv) The feasibility phase will only include people recruited from the community. Consequently, people living in long-term care facilities and retirement villages will be excluded from our study. However, we intend to conduct a future study using the Long-Term Care Facility version of the International Residential Assessment Instrument (interRAI) (44). interRAI routinely collects information on dementia diagnosis and is mandated by the Ministry of Health to be completed with every long term care facility residents every 6 months. . We also have planned to conduct a dementia prevalence study in long term care facilities using the 10/66 instruments (reference standard) and compare the results against interRAI data to assess their utility for ongoing dementia surveillance.

Changes within the reference list:
44. Hirdes JP, Ljunggren G, Morris JN, Frijters DHM, Finne Soveri H, Gray L, et al. Reliability of the interRAI suite of assessment instruments: a 12-country study of an integrated health information system. BMC Health Services Research. 2008;8(1):277.

6. The main limitations of the study protocol should be better clarified. Accordingly, a risk analysis (mentioning the main expected problems and their potential solutions) should be provided.

Response: Thank you for your valuable suggestion. We have included at the end of the discussion a section where the study limitations are discussed and possible solutions are proposed.

Changes within the text:
Page 21, lines 8-60 and Page 22, lines 3-20:
There are some limitations that need to be acknowledged: (i) the sampling methodology was based on convenience sampling. Although sample sizes between 24 and 50 have been recommended for pilot studies (41-43) and convenience sampling may provide accurate correlations and rich qualitative information, it will not offer generalisable results to the overall NZ population. However, this study will lay the foundations for a future national prevalence study representing all the ethnic groups included in our research. (ii) Not all ethnic minorities in New Zealand will be included in this phase of the study; other ethnic groups will need to be included in future studies, for example, people from other Pacific Islands, Middle Easterners, Latin American, and Africans. (iii) Another limitation is that we will only include people aged 65 years or over. Future studies, including people with younger onset dementia, particularly from the ethnic groups that have shown to be at a higher risk of developing dementia at a younger age (such as Maori and Pacific People), will be needed to clarify this issue (iv) The feasibility phase will only include people recruited from the community. Consequently, people living in long-term care facilities and retirement villages will be excluded from our study. However, we intend to conduct a future study using the Long-Term Care Facility version of the International Residential Assessment Instrument (interRAI) (44). interRAI routinely collects information on dementia diagnosis and is mandated by the Ministry of Health to be completed with every long term care facility residents every 6 months. We also have planned to conduct a dementia prevalence study in long term care facilities using the 10/66 instruments (reference standard) and compare the results against interRAI data to assess their utility for ongoing dementia surveillance. (v) Finally, our study will be carried out in a multi-ethnic urban area. Nevertheless, in less ethnically diverse regions, it may be more challenging to recruit bilingual interviewers for ethnic minorities other than Maori. It would mean looking for alternatives to recruit interviewers for these populations—for example, mobilizing bilingual interviewers from one location to another, which will increase the study costs but present more accurate results. Additionally, in rural areas is likely that different engaging strategies will have to be

sought. For example, disseminating the study in a rural population might require other engaging methods (such as face-to-face) compared to the methods used in urban areas. Also, due to cultural factors, the participation and declining rates might be different from less to more ethnically diverse areas and from rural to urban areas. A specific engaging method will have tested for these areas.

7. It should be interesting to mention if a similar methodology has already been adopted in other world countries to provide robust and culturally sensitive estimates of dementia prevalence at the national level.

Response: Thank you for your comments. We have updated the introduction to reflect studies with similar methodology.

Changes within the text:
Page 5, lines 35-60: Other studies have included multi-ethnic samples (6). For example, a study conducted in Singapore used the 10/66 assessment protocol (7) to calculate the prevalence of dementia among their population (6). It included a sample of 2,565 subjects aged 60 years and over who speak Chinese, Malay, Tamil, or other dialects (Hokkien, Cantonese, and Teochew). The instrument was first translated and adapted into those languages that had not been translated before and subsequently applied. The results showed an overall dementia rate of 10% using the 10/66 diagnostic algorithm (6). Interestingly they also found that the Indian population had a lower probability of having dementia compared to the Chinese-speaking population (6). These results demonstrate how the prevalence and aetiologies may vary in different populations. Therefore, careful assessment of each population is essential to establish both the prevalence of dementia and community-specific risk factors related to it.

Changes within the reference list:
6. Subramaniam M, Chong SA, Vaingankar JA, Abdin E, Chua BY, Chua HC, et al. Prevalence of Dementia in People Aged 60 Years and Above: Results from the WiSE Study. J Alzheimers Dis. 2015;45(4):1127-38.

Reviewer: 2
Dr. Takanori Honda, Kyushu University

In this study protocol paper, the authors presented a study protocol for a development of modified dementia assessment tools and for a feasibility study for a future study to estimate prevalence of dementia in the NZ population. This is a well-considered protocol. I would like to suggest this protocol is acceptable for publication after only minor clarifications.

1. The authors considered participants were eligible if they self-identify as Māori, Samoan, Tongan or Fijian-Indian. Many of them can speak English. Will the authors collect information on whether the language is their mother tongue and whether they generally use their language in daily life? Please clarify the procedure if the participants (both dementia and non-dementia subjects) were bilingual.

Response: Thank you for your comments and raising this important issue. To clarify this, we have included information about languages spoken in South Auckland and the percentage of people by ethnic group in this area who were not able to speak English. This issue might be explained since a lot of older people who migrated to NZ following their adult children in the last 20 years; therefore, many have no need to learn English prior to immigration. Also, they often live in close-knit communities, speaking their mother tongue in everyday life and hence usually there is no need to learn English after their arrival in NZ. Also, we want to acknowledge that cultural appropriateness is very important for engagement in our study, thus the importance of speak and

communicate with them in their own language. Since the interviewers will be bilingual, the participants will be able to decide in which language they prefer the interview to take place following cultural appropriateness.

Changes within the text:
Page 6, lines 24-40: ….Also in urban areas of NZ, there are many diverse communities in which many different languages are spoken and a large proportion of the people are not able to speak English as reported in the Counties Manakau Population Census (10) (Table 1). This might be explained by recent New Zealannd immigration policy when many older people from these ethnic groups emigrated to NZ following their adult children in the last 20 years, therefore many have had no need to learn English prior to immigration. Also, they often live in close-knit communities, speaking their mother tongue in everyday life and hence usually there is no need to learn English after their arrival in NZ.

Page 6, lines 42-56

Table 1. Language indicator for the Counties Manakau population Census in people aged 65 years and over.

Ethnic group	% of people who are not able to speak English	% people who are able to speak their own language
Chinese	64	90[a]
Indian	37	56[b] – 85[c]
Samoan	35	97
Tongan	44	92

[a] Corresponds to the total of people able to speak a Sinitic language
[b] Corresponds to people who are able to speak Hindi.
[c] Corresponds to people who are able to speak Indian languages other than Hindi.
Totals do not add to hundred percent as people might be included in one or more category, and not all categories included in the report were described in this table.

Page 13, lines 31-43: The GMS will assess will assess if the participant was not interviewed in their mother language or if the participant was using an unclear dialect or accent. We presume that some of the participants will be to some extent bilingual, however, this will depend on the characteristics of their life history and other socio-culturral factors. Since the interviewers will be bilingual, the participants will be able to decide in which language they prefer the interview to take place.

Changes within the reference list:
10. Winnard D, Lee M, Macleod G. Demographic Profile: 2013 Census, Population of Counties Manukau.: Counties Manakau Health; 2015.

2. Feasibility study will be carried out in South Auckland. Please discuss about the applicability, or potential issues if any, of the estimation procedure to other less ethnically-diverse regions for the full dementia prevalence survey.

Response: Thank you for your comments. We include the following sections in the manuscripts for your consideration.

Changes within the text:
Page 21, lines 55-60 and Page 22, lines 3-20: v) Finally, our study will be carried out in a multi-ethnic urban area. Nevertheless, in less ethnically diverse regions, it may be more challenging to recruit bilingual interviewers for ethnic minorities other than Maori or NZ Europeans. It would mean

looking for alternatives to recruit interviewers for the Tongan, Samoan, Indian, Fijian-Indian and Chinese groups—for example, mobilizing bilingual interviewers from one location to another, which will increase the study costs but present more accurate results. Additionally, in rural areas is likely that different engaging strategies will have to be sought. For example, disseminating the study in a rural population might require other engaging methods (such as face-to-face) compared to the methods used in urban areas. Similarly, due to cultural factors, the participation and declining rates might be different from less to more ethnically diverse areas and from rural to urban areas. A specific engaging method will have to tested for these areas.

3. Will the authors collect information on residents' awareness and interest of the study after raising awareness? Information on how much people aware of or interest in the study in each community may enhance effective recruitment.

Response: Thank you for your comments and suggestions. We have included the following text in the manuscripts to clarify the point and for your consideration.

Changes within the text:
Page 17, lines 10-15: ……We will also send information about the study by post to all potential households in the chosen locations. Subsequently, we will ask study participants to feedback if/how they knew about the study beforehand, informing our launch strategy for the full study.....

We look forward to hearing from you in due time regarding our submission and to respond to any further questions and comments you may have.

VERSION 2 – REVIEW

REVIEWER	Canevelli, Marco Sapienza Univ Rome
REVIEW RETURNED	27-Mar-2021

GENERAL COMMENTS	The authors have successfully addressed all the points raised. The manuscript has relevantly improved through the review process.

REVIEWER	Honda, Takanori Kyushu University
REVIEW RETURNED	25-Mar-2021

GENERAL COMMENTS	The authors addressed all of the comments that I have raised. I have no further comments. I hope your study will be successfully completed.