PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Long-term effectiveness of the community-based Complete Health Improvement Program (CHIP) lifestyle intervention: a cohort study
AUTHORS	Kent, Lillian; Morton, Darren; Hurlow, Trevor; Rankin, Paul; Hanna, Althea; Diehl, Hans

VERSION 1 - REVIEW

REVIEWER	Rene Pols Flinders University, Psychiatry
REVIEW RETURNED	19-Sep-2013

GENERAL COMMENTS	This is a very good clinical study that shows a powerful effect on 106 of the original 284 subjects, many of whom after a 30 day intervention by trained volunteeers have maintained risk factor reduction when they serve as their own controls. Unfortunately this good outcome for these subjects cannot be said to have occurred for the cohort as a whole. This needs to be made clear. It is extremely difficult to follow up a cohort over time and this group have done better than many. In table 1 it would be good to show outcomes at endpoint also. I note in tables 3 & 4 there are varying numbers with missing data. With repeated measures statistical imputation of missing values can be achieved and it would be worthwhile to seek advice from a statistician familiar with mixed modelling techniques to assist with this. I note tables 3 & 4 do not fit well on the page and in table 4 there are multiple variables expressed in mm of Hg - clearly inappropriate typo. Clinically and economically this seems a worthwhile approach using volunteers as for 37% of subject significant change from baseline has remained significantly sustained but at a lower level. Is a booster programme needed? If so when?

REVIEWER	Caroline S. Blackwell Wake Forest School of Medicine United States of America
REVIEW RETURNED	30-Sep-2013

GENERAL COMMENTS	The topic addressed in this manuscript is certainly a timely one. Cost-effective and proven lifestyle interventions to address chronic diseases are needed across the world. There are a few things that need to be addressed to make this manuscript ready for publication. First, additional information needs to be provided on the

	Methods of recruiting and enrolling participants in this follow-up study and about the informed consent process. Second, the authors should clearly state how the 108 participants at follow-up relate with regard to lifestyle behaviors/ compliance and the original CHIP population. While the research objective addressed is an important one, there are several key issues with this manuscript. First, it would be helpful to know more about how participants were recruited to participate in the follow-up visit. Why were only 106 of the original 284 willing to participate? Were they approached only in writing or were phone calls made too? Was the possibility of this additional follow-up visit discussed at the conclusion of their original participation? There is also no information on regulatory review or informed consent provided in the manuscript. While the statistical analyses performed were interesting, it would be of more interest to readers to see the data in Table 1 presented as the number and percentage of males, females, racial groups, etc. that attended follow-up visits versus those that did not. The current table totals percentages in columns, and it might be better to total it in rows. It would also be helpful to see more information describing the 106 participants that attended the follow-up visit in the context of the original 248 population. Were these 106 attendees fairly representative of the wider study population with regard to attendance at the monthly support meetings or self-reported lifestyle compliance? To better understand the relationship between these variables and long term changes in weight, BMI, and other markers, it is important to clearly define how representative this population was, and although this is addressed to some degree in the Limitations section, it would be more helpful earlier in the paper. Also, Tables 3 and 4 are a bit cluttered and hard to read. Please consider stream-lining for ease of interpretation.

VERSION 1 – AUTHOR RESPONSE

Responses to Reviewers comments
Reviewer: Rene Pols
This is a good study and follow up of a cohort tracked for between 3 and 5 years. As with all such follow up studies the sample size and remainder of the cohort is much less than desired.
1. The methodology of the follow up process has not been described. The following text has been added to the methods section: Lines 145-158 “All 323 individuals, who had previously completed the CHIP intervention, were invited, by letter, to participate in a follow-up study, irrespective of their outcomes at 30 days. The letter included information detailing the intent of the study, as well as a complimentary follow-up medical assessment and a form for the participant to provide informed consent. Though the purpose of the study was to look at the long-term effects of the program (3+yrs) it was considered ethical to offer a follow-up health check to all the participants. Of the 192 that replied (59% response rate), 142 consented to participate; 50 did not. On the designated day for the study, 130 returned for the follow-up assessment. Of these 130 individuals, 106 (age = 64.9±7.4 years, range 42-87 years) who had completed the intervention three or more years previously (mean = 49.2±10.4 months, range = 3-5 years) were included in this study. As 284 of the original cohort of 323 participants had completed the intervention three or more years previously, the response rate for this study was 37%. “

Lines 175-179: “The follow-up study was not planned at the time the participants enrolled in their respective CHIP programs and so participants were not advised of this eventuality. Invitations were extended to all participants to attend the follow-up study, regardless of whether or not they chose to attend the monthly support meetings.“
2. This limitation is not in the abstract and limits its balance even though it is a good effort at follow up -37%. The following text has been added to lines 15, 16 of the Participants section of the abstract: “….37% of the original cohort ….”
3. The study design is not able to answer the claim i.e. that the intervention is efficacious to 4 year follow up. Certainly for the 106 subjects followed this is so, but for the cohort as a whole it is clearly uncertain. This needs to be made clear. The following text has been added to line 41 of the Conclusion in the Abstract “….returned for follow-up assessment and ….”
Lines 428-430 of the discussion: ”The results of this analysis are therefore applicable to those participants who attended the long-term assessment and are not generalisable to the original cohort.”
Lines 437-441 ” It is likely that some of the 121 participants who did not respond to the invitation could not be contacted as they were no longer residing in the area or were not available at the time of retesting, or chose not to respond. Some of those choosing not to return may have done so because they had not been compliant to the CHIP principles.”
4. The presentation in table 1 it would be useful to see the changes at baseline, 30 day and follow up. Table 1 has been revised and follow-up data has been added. Lines 227-233 were also added to the results section “All biometrics significantly increased from program completion to follow-up (Table 1). However, weight was the only biometric in which a net improvement was sustained in the long-term. Participants were able to maintain an average 1.6% decrease in body weight over the long term compared to the weight with which the program was commenced. On the other hand, following program completion, SBP increased resulting in a net 4.2% increase from baseline to follow-up.”
5. Tables 3 and 4 did not fit on my screen. Please advise if this needs reformatting for final publication.
6. I note the missing data and I wonder if a mixed methods approach to statistical analysis that allows for missing values may be able to better assess the outcomes statistically. There was no missing data in the results that were presented for the 106 participants. Table 2 (previously Table 3), shows results for participants who had normal levels at baseline and those with elevated levels. For each biometric the total of the normal and elevated is 106. The title for Table 2 also states n=106. In line 259 “ For all…” has been added to the results section to clarify this. Similarly for Table 3 (previously Table 4), which shows the data for participants who reported being compliant (71) to CHIP principles but split by baseline normal or elevated risk levels. 71 participants reported being compliant, the other 35 did not, which accounts for the full complement of 106 who returned for follow-up. The title for Table 3 also states n=71.
7. The limitations are all those of an incomplete cohort at 3-5 years. It is a good study - better than many but the conclusions cannot be applied to the original cohort, only those that presented for follow up and as such the dilution and regression back to the mean over time can actually be seen as evident in both tables 3&4 as the degrees of significance are less and there has been increases in the changes (deterioration) achieved at 30 days for numbers of variables in both tables. This needs further discussion. Statistical review would be helpful. Please see comments for item 6 as there was no missing data.
8. This is a very good clinical study that shows a powerful effect on 106 of the original 284 subjects, many of whom after a 30 day intervention by trained volunteers have maintained risk factor reduction when they serve as their own controls. Unfortunately this good outcome for these subjects cannot be said to have occurred for the cohort as a whole. This needs to be made clear. Please see comments for item 3.
9. It is extremely difficult to follow up a cohort over time and this group have done better than many. In table 1 it would be good to show outcomes at endpoint also. Please see item 4.
10. I note in tables 3 & 4 there are varying numbers with missing data. With repeated measures statistical imputation of missing values can be achieved and it would be worthwhile to seek advice

from a statistician familiar with mixed modelling techniques to assist with this. Please see comments for item 6 as there was no missing data.
11. I note tables 3 & 4 do not fit well on the page and in table 4 there are multiple variables expressed in mm of Hg - clearly inappropriate typo. mmol/l added as appropriate.
12. Clinically and economically this seems a worthwhile approach using volunteers as for 37% of subject significant change from baseline has remained significantly sustained but at a lower level. Is a booster programme needed? If so when? Lines 172-175 were added to the methods “Following completion of the program, a monthly support group was offered to the participants to reinforce lifestyle behaviour changes, and build a network of support and ongoing education, although it was not considered part of the intervention.”
Reviewer: Caroline S Blackwell
The topic addressed in this manuscript is certainly a timely one. Cost-effective and proven lifestyle interventions to address chronic diseases are needed across the world. There are a few things that need to be addressed to make this manuscript ready for publication.
1. First, additional information needs to be provided on the Methods of recruiting and enrolling participants in this follow-up study and about the informed consent process. Please see our comments which address item 1 for the previous reviewer.
2. Second, the authors should clearly state how the 108 participants at follow-up relate with regard to lifestyle behaviors/ compliance and the original CHIP population. Please see item 1.
3. While the research objective addressed is an important one, there are several key issues with this manuscript. First, it would be helpful to know more about how participants were recruited to participate in the follow-up visit. Why were only 106 of the original 284 willing to participate? Were they approached only in writing or were phone calls made too? Was the possibility of this additional follow-up visit discussed at the conclusion of their original participation? There is also no information on regulatory review or informed consent provided in the manuscript. Please see item 1 additions that address all these issues.
4. While the statistical analyses performed were interesting, it would be of more interest to readers to see the data in Table 1 presented as the number and percentage of males, females, racial groups, etc. that attended follow-up visits versus those that did not. The following demographic information is available for this study and is found in Lines 242-246: “There were no significant differences between the participants who did and did not undergo the 3-5 year follow-up testing in baseline age (60.6 versus 58.4 years, p=0.07), gender (35.2% versus 34.6% men, p=0.92), marital status (90% versus 80% married, p=0.18), smoking status (70.3% versus 68.8%, p=0.28). “
5. The current table totals percentages in columns, and it might be better to total it in rows. It would also be helpful to see more information describing the 106 participants that attended the follow-up visit in the context of the original 284 population. Please see table 2.
6. Were these 106 attendees fairly representative of the wider study population with regard to attendance at the monthly support meetings or self-reported lifestyle compliance? No information is available on self-reported compliance for those that did not attend the follow-up assessment. Lines 440-441 have been added to the discussion “Some of those choosing not to return may have done so because they had not been compliant to the CHIP principles.”
7. To better understand the relationship between these variables and long term changes in weight, BMI, and other markers, it is important to clearly define how representative this population was, and although this is addressed to some degree in the Limitations section, it would be more helpful earlier in the paper. We believe lines 242-255 covers this point “There were no significant differences between the participants who did and did not undergo the 3-5 year follow-up testing in baseline age (60.6 versus 58.4 years, p=0.07), gender (35.2% versus 34.6% men, p=0.92), marital status (90% versus 80% married, p=0.18), smoking status (70.3% versus 68.8%, p=0.28). Table 1 also shows baseline characteristics of participants who did and did not attend the 3-5 year follow-up testing. There were no significant differences between the participants who did and did not undergo follow-up testing in SBP, DBP, TC, LDL and HDL. Individuals who did not attend the follow-up had significantly higher BMI, TG and FPG at program entry. There were also no significant differences between those

who did and who did not attend follow-up in 30-day levels of SBP, DBP, TC, LDL and FPG (Table 1). However, there were no significant differences in the amount of change experienced in any of the biometrics during the 30-day intervention, even for the biometrics that were different between the groups at baseline"
8. Also, Tables 3 and 4 are a bit cluttered and hard to read. Please consider stream-lining for ease of interpretation. Please see item 5 for previous reviewer

VERSION 2 – REVIEW

REVIEWER	Rene Pols Flinders University, Psychiatry
REVIEW RETURNED	21-Oct-2013

GENERAL COMMENTS	The revised paper is a much improved version, particularly the wording in respect of the results, the limitations and the format of the tables. It is worthy of publication as it stands