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A RANDOMIZED CONTROLLED TRIAL TO REDUCE LIFESTYLE RELATED RISK FACTORS FOR NON-COMMUNICABLE DISEASES THROUGH FUNERAL SOCIETIES IN SRI LANKA

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ABSTRACT

A cluster randomized controlled trial was conducted to change diet, physical activity, smoking and alcohol consumption among participants through funeral societies in the Western Province .Twenty one administrative subdivisions in the Ragama area were randomized into intervention and control groups. Ten administrative subdivisions in the North Western Province were selected as an additional control group. The primary outcome was change in the proportion of individuals who consumed 5 servings or more of fruits and vegetables per day. The study showed only a modest, not significant increase in the proportion of people consuming 5 servings of fruits and vegetables or more per day. Of the secondary outcomes assessed, their intake of green leaves and mean MET minutes spent on leisure activities increased significantly more in the intervention group than in the control groups, but the differences were small. To effectively reduce non-communicable diseases (NCD) in Sri Lanka, community-based organizations could be utilized to deliver prevention programs.

Keywords: Community-based organization, funeral society, non-communicable diseases, randomized controlled trial, Sri Lanka

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INTRODUCTION

Sri Lanka is currently experiencing demographic changes leading to an increase in non-communicable diseases (NCDs)(Sri Lanka Department of Health, 2012). NCDs now account for 85percent of the disease burden in Sri Lanka (Engelgau et al, 2010).

In response, the Sri Lankan Ministry of Healthcare and Nutrition has established the Directorate for Non-Communicable Diseases. In 2007, this Directorate conducted a survey among people aged 15-64 years, which showed that 25% of the study population was overweight or obese. In addition, 11.5% were current daily smokers and 82.4% ate less than 5 servings of fruits and vegetables per day. Twenty five percent of the study population had a low level of physical activity with <600 metabolic equivalent task (MET) minutes/week (Sri Lanka Directorate Of Non Communicable Diseases, 2008).

Lifestyle modifications are key to the prevention of NCDs. The main risk factors associated with NCDs include an unhealthy diet, physical inactivity, tobacco use and harmful use of alcohol. Significant successes have been realized with lifestyle modifications addressing these risk factors in several studies in various populations(Hu et al, 2011; Simoes et al, 2009).The population strategy is the attempt to control the determinants of incidence, to lower the mean level of risk factors, and to shift the whole distribution of exposure in a favorable direction(Rose, 2001).

Although public health programs and policy are often defined at regional and national levels, the community is where prevention and intervention activities actually take place(MacQueen et al, 2001).Community-based lifestyle intervention programs are recommended by World Health Organization to curb the growing threat of NCD(World Health Organization, 2008).

When implementing community-based lifestyle intervention programs, community-based organizations (CBOs), which are not-for-profit nongovernmental, civil society and grassroots organizations are important stakeholders and have been increasingly called upon to use research evidence to inform their advocacy, program planning, and service delivery efforts(Wilson et al, 2010).Experience from HIV/AIDS prevention programs has demonstrated that CBOs can successfully reach out to the most -at- risk populations. The utilization of CBOs has also

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been recommended for NCD prevention and treatment (Lamptey et al, 2011).

In the US, community interventions aimed at reducing NCDs in minority groups have successfully delivered their programs through CBOs such as the Young Women's Christian Association (YWCA) and churches (Dodani, 2011; King, 2007).

Sri Lanka as a developing nation needs to identify feasible and cost effective measures to control the growing epidemic of NCDs and experience gained in more developed countries may be of value in this regard (Sarrafzadegan et al, 2006).

Sri Lanka has numerous CBOs at the village level (Leitan, 2010). However, there is lack of research on whether the use of CBOs for delivering interventions to reduce NCD risk factors is effective. In Sri Lanka, funeral societies are common CBOs that are found in many villages and they organize and take part in many health-related activities.

Funeral societies in Sri Lanka evolved from facilitating gatherings following death or bereavement of a family member. These societies provide financial and other services to the family of the deceased and incorporate a number of social services into their mandates. Today these societies take initiatives to uplift the status of the community including organization of free health clinics, distribution of free spectacles and many other social and health activities. The societies are formed by the community itself with an elected committee and families are enrolled as members. Some of the societies are even registered with the government civil administration system. These societies provide a promising context for successful community-based health promotion, especially as the capacity of communities to mobilize and address community issues is increasingly recognized and utilized.

The objective of this study was to evaluate the effects of a lifestyle modification program targeting 25-60 year old adults delivered through funeral societies in Ragama, Sri Lanka. Out comes (change from baseline in diet, physical activity, smoking and alcohol use) were assessed six months after the start of the program. Compared to the national survey in 2007 (Sri Lanka Directorate Of Non Communicable Diseases, 2008), in which 19.6% of the males and 30.4% of females aged 15-64 years were found to be overweight or obese, as many as 51.5% of males and 66.0% of females were overweight or obese in the preliminary analysis of the Ragama Health Study (Pathmeswaran, et al, 2009).Ragama is

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therefore identified as a high-risk area for NCD in the report.

MATERIALS AND METHODS

The study was conducted in the Ragama Medical Officer of Health (MOH) area, which is located in the Western Province, and the Wennappuwa MOH area in the North Western Province. The Ragama MOH area has 21 Grama Niladhari (GN) divisions (smallest unit in the country's administrative structure with an average population of 1500 people) and these were the units used for cluster randomization. We randomized 10 GN divisions into study group and 11 into control group (figure 1). An additional control group with 10 GN divisions was selected from Wennappuwa MOH to assess the extent to which there was any local "contamination" from intervention to control groups in Ragama. The participants were selected randomly using Winpepi version 11.0 (Abrahamson, 2010) from the voters' list of the respective MOH areas. Those eligible were 25-60 year olds included in the voters' list with no documented acute illness or disability at the time of enrolment. Pregnant women were excluded. The participants were invited to take part in the study by research assistants who contacted them through the Grama Niladhari (Village officer) of the divisions.

In each GN division in the intervention group, one funeral society was selected to reach the community participants. In GN divisions where there was more than one funeral society, the society registered with the government was selected to carry out the intervention. If all or none were registered, the society with the highest number of members was selected.

The calculated sample size for the comparison between Ragama intervention group and the Ragama control group was 220 participants in each with 90% power and significance of 0.05 to detect a difference of 20% in the outcome: change in the proportion of people consuming 5 combined servings of fruit and vegetables per day (Lock et al,2005; Te Velde et al, 2008). As there were no data available to calculate the intra cluster coefficient for consumption of 5 combined servings of fruit and vegetables per day, the design effect of 2 was used in the sample size calculation, with an additional 10% added to compensate for attrition of subjects. In addition, 220 participants were included from Wennappuwa.

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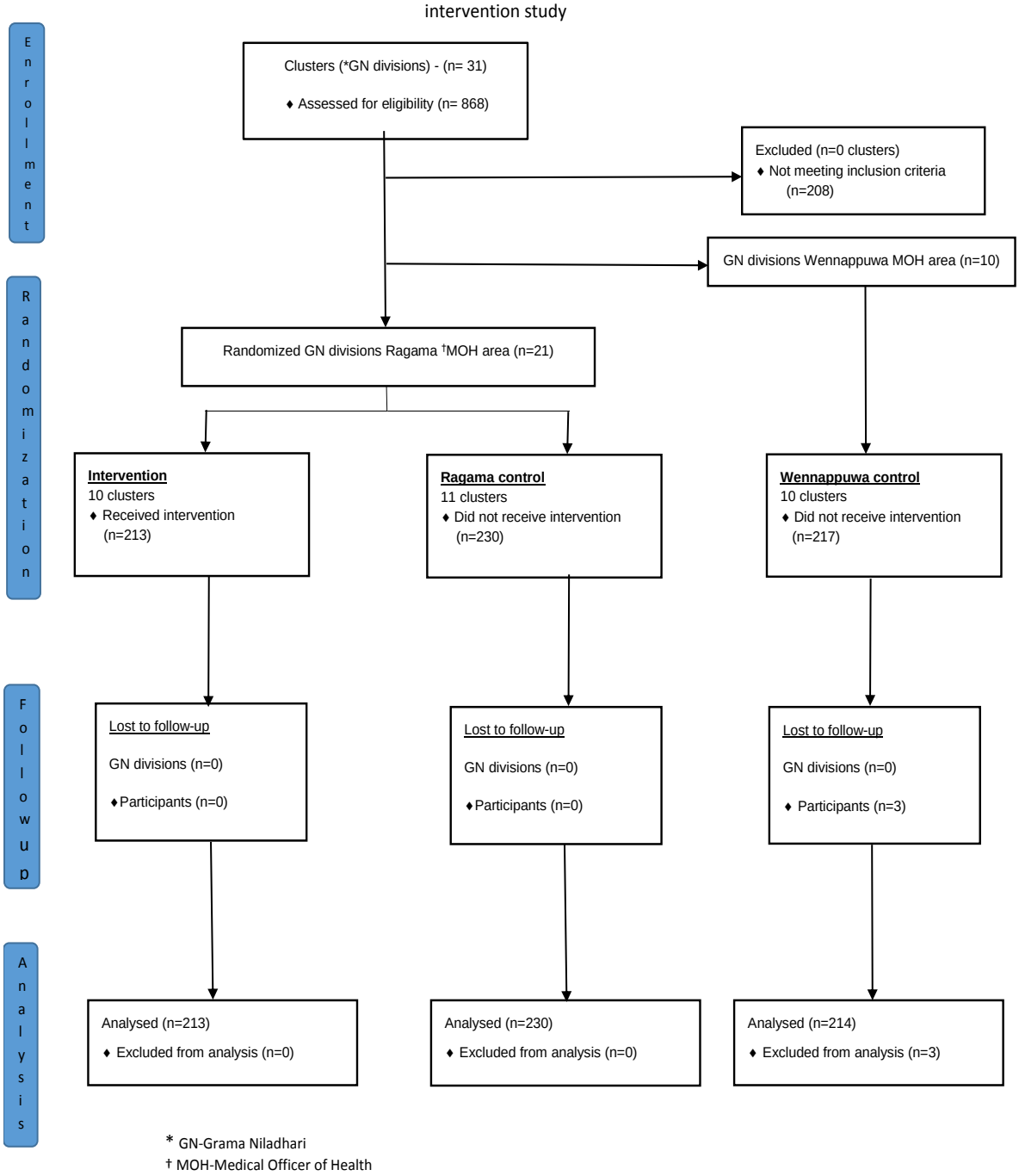
Figure 1 CONSORT flow diagram displaying clusters and subjects recruited into the community based intervention study



* GN-Grama Niladhari
† MOH-Medical Officer of Health

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INTERVENTION

The lifestyle modification program was carried out for six months from April to September 2010 in the 10 GN divisions selected as the intervention group in Ragama. The intervention was focused on modifying the behavior of the individual and the community in relation to Non communicable diseases. The targeted lifestyle characteristics were diet, exercise, smoking and alcohol consumption, and the intervention was designed to help participants to start and maintain healthy lifestyle behaviors. The lifestyle modification program included monthly workshops, with an interactive session where goal setting, self-management, strategies to enhance self-efficacy and relapse prevention strategies were discussed and the progress of the individual lifestyle modification reviewed. The workshops also included an exercise session of 30 minute duration by a certified instructor. The selected exercises included components for endurance, strength, balance, and flexibility. Dissemination of information to the participants and the community was done through handbills and digital presentations and provision of supportive tools (lifestyle log, body mass index guide, information sheets) through the funeral societies. Social Marketing principles ("The Basics of Social Marketing, How to use marketing to change behavior," 1997)were used to design the lifestyle modification program. The intervention is summarized graphically in figure 2 (Perera et al, 2007).

Focus group discussion was conducted with funeral society members and community members to obtain an understanding of the behaviors related to NCDs, to identify possible activities and to get the community's views on the feasibility of an intervention. Society members were actively involved in the design, planning and delivery of the intervention. There were no financial incentives for their involvement. They helped organize group discussions, health education and exercise sessions and meetings with the community. Community centers available to the society were utilized. Members distributed leaflets and health education material to the participants in the community. Healthy refreshments were provided by the society. Their monthly meetings were utilized as educational or exercise sessions and to deliver health messages through leaflets and audio visual materials. Their public announcement systems were used to make the community aware of the intervention. The societies also printed notices and banners announcing the dates and times of

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the workshops and some of the tools for lifestyle modification (lifestyle log).

Figure 2 Graphical overview of the design and implementation of the intervention

Timeline	Intervention group	Control groups
Baseline assessment	a b	a b
Design of the intervention	c	
1st Month	d f g h i	i
2nd Month	e f	
3rd Month	e f	
4th Month	e f	
5th Month	e f	
6th Month	e f	
End of 6 months	Measurement of outcomes-post intervention survey	

a Questionnaires
b Anthropometric data sheet
c Focus group discussion
d Lecture on NCDs
e Group interactive session (1hour)
f Exercise session (1/2 hour)
g Printed information, BMI guide and lifestyle diary
h Booklet and compact disc on yoga exercises
i Handbill on NCD Prevention

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EVALUATION

An interviewer-administered questionnaire, a Food Frequency Questionnaire (FFQ) and the International Physical Activity Questionnaire (IPAQ) were used to collect baseline and post-intervention data on socio-demographics and economic data, alcohol use and smoking, diet and physical activity.

Data analysis

The primary comparison of outcomes was between the intervention group and the control group in Ragama. Comparison of the same outcomes between the intervention and Wennappuwa control group was also conducted to control for contamination.

The primary outcome evaluated in the study was change in the proportion of participants who consumed 5 servings or more of fruits and vegetables per day. Secondary outcomes include change in the consumption of green leaves; deep fried, commercially baked foods and roti; and sugar and sweetened beverages, change in Metabolic Equivalent Task (MET) minutes spent in work, transport, domestic and leisure (moderate and vigorous) domains and change in the smoking and alcohol consumption.

The physical activity outcomes are presented as mean change from the baseline survey levels, while the dietary intake outcomes are presented as change in proportions. Significance of difference in means and proportions was assessed by multivariable analysis adjusting for age, gender, marital status, religion, income, education level and baseline values and analyzed adjusting for clustering by GN divisions.

Analysis of data was done using SPSS (Version 20.0. Armonk, NY: IBM Corp.).

Ethical clearance for the study was obtained from the Ethics Committee of Faculty of Medicine, University of Kelaniya. The study was registered in ClinicalTrials.gov (ClinicalTrials.gov Identifier: NCT01174381).

RESULTS

Out of the total sample of 660, there were 213 participants in the intervention group, 230inthe Ragama control and 217 in the Wennappuwa control group at baseline. By the time of 6 months post- intervention survey, 3 participants had been lost to follow up in Wennappuwa.

Table 1 describes the socio demographic characteristics of participants in the intervention and control groups. In Ragama

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intervention and control groups the baseline demographics of the participants were similar. Participants from the Wennappuwa control group were comparatively similar to those in Ragama in basic socio demographic characteristics. There were statistically significant differences in the age groups (X2 =14.1, p=0.02), religion (Fisher's exact =139.3, p<0.001) and ethnicity (X2 =8.6, p=0.01) between intervention and Wennappuwa control group.

Baseline mean body mass index (BMI) in the intervention group was 23.81kgm-2(95%CI 23.31-24.30) while mean BMI in the Ragama and Wennappuwa controls was 23.87(95%CI 23.38-24.36) and 24.54(95%CI 24.01-25.07) respectively. There was no statistically significant difference in mean baseline BMI between the 3 groups.

The changes in outcome in diet and physical activity following the intervention are shown in Tables 2 and 3, respectively. In the intervention group, the proportion meeting their fruit and vegetable consumption goals increased by 1.9% from baseline to follow-up. This change was not significantly different from the change in the control groups (0% and 0.9%, respectively). There was a significantly greater increase in the intake of green leaves among the participants in the intervention group than in the control groups (p<.01). The intervention group showed a significantly greater increase of mean MET minutes of21.81 (95% CI, -3 to 47.81; p<.01) spent on leisure (moderate and vigorous) activities compared to controls in whom the mean increased by 3.57(95% CI,-0.47 to 7.65) in Ragama control group and 3.92(95% CI, -14.29 to 6.41) in Wennappuwa. There was a significantly greater decrease in mean sitting time in the intervention group by -30.04 (95% CI, -51.40 to -8.82) compared to -0.22 (95% CI,-7.34 to 6.78) in the Ragama control group and -2.80 (95% CI, -20.52 to 14.91) in the Wennappuwa control group(p<.01).None of the current smokers (38.2% in the intervention group) quit or reduced smoking. Out of the 15% respondents who consumed alcohol 5-6 days a week, only one reduced alcohol consumption in the intervention group.

In secondary analyses of those who were part of the intervention group, assessing the relationship between participation in the workshops and diet, 79 (37%) participants attended 4-6 workshops and, 116(55%) did not attend any workshops. Sixteen (7.5%) participants attended 1-3 workshops. Among those who attended 4-6 workshops, there was a net increase of 18.8% in the intake of green leaves, compared to a 4.9% increase among those who did not attend any

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workshops. This difference was statistically significant (X2=10.14, p<0.01).There were no significant differences by participation for the other dietary primary outcomes. Change in mean physical activity levels in leisure domain (primary outcome) were greater among participants who attended 4-6 workshops than among those with zero participation in the intervention group (figure 3), but this difference was also not statistically significant. The change in mean physical activity in work, transport and domestic domains were greater among participants who attended 4-6 workshops, but again these differences were not statistically significant.

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Table 1. Distribution of baseline characteristics of participants in a community-based lifestyle modification intervention study in Western and North Western Sri Lanka

	Intervention (n=213)		Ragama Control (n=230)		Wennappuwa Control (n=217)	
	n	%	n	%	n	%
Gender						
Female	122	(57.3)	123	(53.5)	118	(54.1)
Age categories(years)						
25-30	48	(22.5)	58	(25.2)	50	(23.0)
31-40	61	(28.6)	91	(39.6)	76	(35.0)
41-50	67	(31.5)	42	(18.3)	46	(21.3)
51-60	37	(17.4)	39	(16.9)	45	(20.7)
Marital Status						
Unmarried	29	(13.6)	28	(56.1)	22	(10.1)
Married	179	(84.0)	199	(41.3)	193	(88.8)
Widowed	4	(1.9)	3	(2.6)	1	(0.5)
Other	1	(0.5)	0	(0)	1	(0.5)
Ethnicity						
Sinhalese	206	(96.7)	218	(94.8)	216	(99.5)
Other (Tamil, Burgher, Muslim)	5	(3.3)	8	(5.2)	1	(0.5)
Religion						
Buddhist	159	(74.6)	129	(56.1)	47	(21.6)
Roman Catholic	51	(23.9)	95	(41.3)	165	(75.7)
Other	3	(1.4)	6	(2.6)	5	(2.7)
Education level						
None/primary	13	(6.1)	9	(3.9)	22	(10.1)
Secondary	196	(92.0)	211	(91.7)	192	(88.5)
Tertiary	4	(1.9)	10	(4.3)	3	(1.4)
Income[*†]						
Rs 4999 or less	22	(10.3)	29	(12.6)	17	(7.8)
Rs 5000-9999	30	(14.1)	36	(15.7)	29	(13.4)
Rs 10000-49999	150	(70.4)	162	(70.4)	161	(74.2)
Rs 50000 or more	9	(4.2)	2	(0.9)	10	(4.6)
Employment						
Professionals/semi professionals	31	(14.6)	50	(21.7)	29	(13.4)
Other skilled workers						
Unskilled workers	37	(17.4)	43	(18.7)	36	(16.6)
Other	17	(8.0)	22	(9.6)	33	(15.2)
Unemployed	24	(11.3)	19	(8.3)	22	(10.1)
	104	(48.8)	96	(41.7)	97	(44.7)

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Table 2. Change in healthy intake of selected food groups among participants in a community-based lifestyle modification intervention study in Western and North Western Sri Lanka. Proportion of participants with healthy in take at baseline and proportion change at follow-up are shown for both control and intervention groups. The results of the logistic regression analysis showing the effects of the intervention by groups are also show.

	Intervention n=213		Control Ragama n=230		Control Wennappuwa n=217		Multiple regression: p[a]	
	Baseline n (%)	Change n (%)	Baseline n (%)	Change n (%)	Baseline n (%)	Change n (%)	I versus R	I versus W
Fruits and Vegetables[a]	104 (48.8)	4(1.9)	80(34.8)	0(0)	73(34.1)	2(0.9)	0.99	0.5
Green leaves*	62 (29.1)	22 (10.3)	68(29.6)	5(2.1)	81(37.4)	3(1.4)	0.002	0.004
Deep fried foods, commercially baked foods and roti†	198 (93.0)	2 (0.9)	218(94.8)	0 (0)	206(96.30	0(0)	0.99	1.0
Sugar and sweetened beverages†	86 (40.4)	7 (3.2)	122(53.0)	8(3.4)	92(43.0)	1(0.4)	0.92	0.04

Adjusted for age, gender, marital status, religion, income, education level and baseline values

***Healthy intake -5-6 times a week, once a day or more than once a day; aHealthy intake –at least 5 servings per day; † Healthy intake - 2-4 times a week, once a week or less than once a week**

I - Intervention group: R-Ragama control group: W- Wennappuwa control group

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Table 3. Change in Physical activity (metabolic equivalent (MET) minutes) among participants in a community-based lifestyle modification intervention study in Western and North Western Provinces in Sri Lanka. Mean MET minutes at baseline and mean change at follow-up are shown for both control and intervention groups. The results of the multiple regression analysis showing the effects of the intervention by group is also shown.

	Intervention (n=207*)		Control Ragama (n=219*)		Control Wennappuwa (n=216*)		Multiple regression: P‡	
	Baseline Mean (SE)	Mean Change (95% CI)	Baseline Mean (SE)	Mean Change (95% CI)	Baseline Mean (SE)	Mean Change (95% CI)	I versus R	I versus W
Work	1806.08(332.48)	2.63 (-12.59 to 17.73)	1581.95 (300.74)	1.72(-17.51 to 21.44)	1134.86 (232.35)	-1.38 (-4.12 to 1.34)	0.76	0.7
Transport	757.6 (119.93)	3.83 (-12.66 to 20.33)	590.42 (83.95	4.31 (0.04 to 8.58)	323.17 (38.54)	3.28(-4.35 to 10.86)	0.93	0.63
Domestic	1797.37 (179.91)	12.94 (-30.96 to 56.53)	2212.59 (193.1	3.07 (-8.26 to 14.82)	895.08 (93.33)	5.18 (-9.51 to 19.91)	0.87	0.83
Leisure	177.06 (41.97)	21.81 (-3 to 47.81)	295.71 (52.08)	3.57 (-0.47 to 7.65)	170.56 (57.10)	- 3.92 (-14.29 to 6.41)	0.007	0.001
Sitting time	380.38 (15.01)	-30.04(-51.40 to -8.82)	396.94 (15.65)	-0.22 (-7.34 to 6.78)	346.61 (14.69)	-2.80 (-20.52 to 14.91)	0.001	0.001

Excluding outliers (Sum of time spent in walking, moderate and vigorous activities > 960 minutes)

‡ Adjusted for age, gender, marital status, religion, income, education level and baseline PA activity levels

Categorical variables: =<41 years (for age); male (for gender); others (for ethnicity); =>Rs10000 (for income): secondary or tertiary (for education)

CI -Confidence Interval: SE- Standard Error: I - Intervention group: R-Ragama control group: W- Wennappuwa control group

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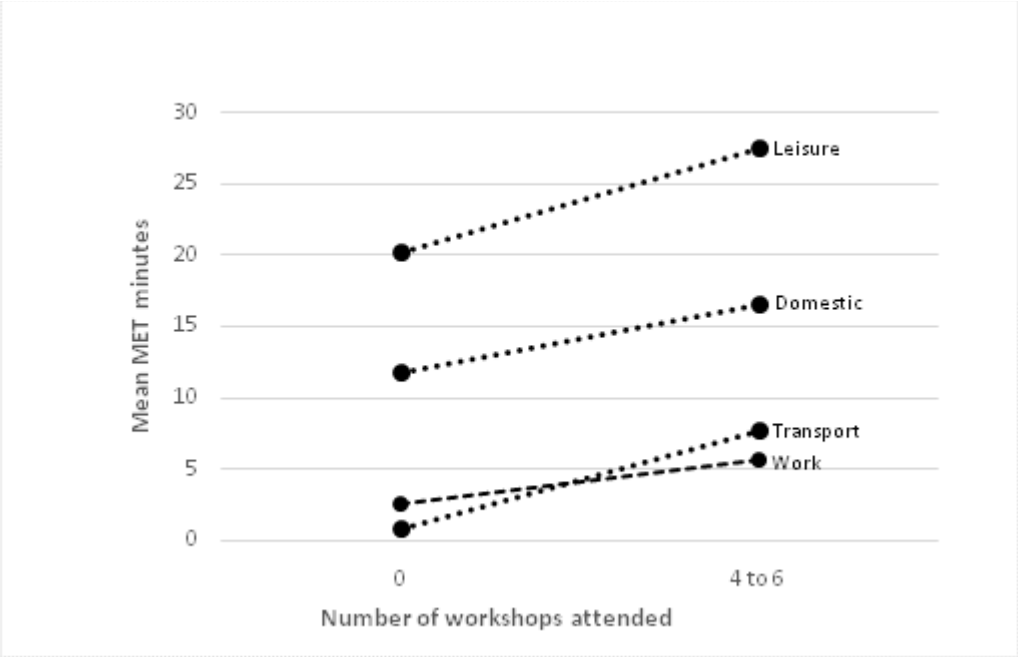
Figure 3. Association of physical activity with workshop participation in intervention group. Change in mean MET minutes of activity by workshop attendance by domain in shown.



DISCUSSION

The study showed only a modest, not significant increase in the proportion of people consuming 5 servings of fruits and vegetables or more per day. Of the secondary outcomes assessed, their intake of green leaves and mean MET minutes spent on leisure activities increased significantly more in the intervention group than in the control groups, but the differences were small. The changes observed in physical activity, dietary intake and alcohol use in this study are comparable to those from other studies that demonstrate modest improvements in behavior following a lifestyle intervention program (Mohan et al, 2006; Pazoki et al, 2007).

Community-based studies conducted in Iran, Brazil, Mauritius and China have demonstrated that although it is possible to change the dietary habits and physical activity levels in the population through interventions targeting lifestyle (Dowes et al, 1995; Lv et al, 2014; Sarrafzadeg an et al, 2006; Simoes et al, 2009) results from large-scale, community-based prevention trials indicate that, in general, these programs produce only modest effects in changing population risk behaviors. A number of reasons for the lack of strong evidence has been highlighted in a systemic literature review (Merzel and D'Afflitti, 2003).These

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reasons include methodological limitations, influence of secular trends, smaller than expected effect sizes, limitations of interventions and limitations of theory.

The short duration of the lifestyle modification program, limited access to resources and facilities for physical activity, time constraints participants may have faced and availability of healthy food choices are all possible reasons why the intervention failed to show more significant improvements in diet and physical activity outcomes.

There was no significant change in smoking and alcohol use following the intervention in the present study. The result was not unanticipated in that there was limited focus on these behaviors in our study - even large community trials conducted for many years have shown very small reduction in smoking and alcohol use (Gnich et al, 2002).

Reduction in sitting time did show a statistically significant difference between intervention and control areas ($p<0.001$).The sitting time question in the IPAQ long version is an additional indicator variable to assess sedentary behavior. Sedentary behavior refers to a group of behaviors that occur whilst sitting or lying down while awake and typically require very low energy expenditure. There is growing evidence that sedentary behavior may be adversely associated with chronic disease in adults and risk factors for chronic disease in children and adolescents (British Heart Foundation National Centre (BHFNC), 2012).

While the effects were small, considering the relatively short duration of the intervention and limited resources used in the implementation, these changes are still promising for future prevention programs for NCDs. The study demonstrates that funeral societies can be used successfully to deliver interventions to reduce NCD risk factors in the community, which could impact on the population level.

Strengths of this study include use of a cluster randomized control design, the support of the funeral societies, the inclusion of an additional control area from a separate province to assess potential contamination between the primary intervention and control areas and low numbers lost to follow up.

The main limitation of the study is that the assessment of the outcomes were measured through self-reported change in diet, physical activity, alcohol use and smoking, and some ascertainment bias may therefore be present. Although administered by trained data collectors, the questionnaires like lymay not be very accurate in measuring

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the outcomes, especially the IPAQ (Bauman et al, 2009).There may have been differential recall bias. The participants in the intervention group would be more likely to remember and report behavior changes following the intervention than those in the control groups.

The short intervention period of 6 months is another limitation as it is difficult to make any reliable and valid evaluation of impact of behavioral intervention on outcomes.

Also, a relatively large number of participants failed to attend any of the interactive workshops and exercise sessions which were part of the intervention. In fact, only 44% of the participants in the intervention area attended at least one workshop. However, all participants in the intervention area were provided with the educational materials and instructions for lifestyle modification on the first day of contact and monthly reminders were sent through society members.

The results were not adjusted for multiple comparisons, so the effects that are marginally significant should be interpreted with caution to avoid type 1 errors.

CONCLUSION

Our study demonstrates that funeral societies provide a promising vehicle to mobilize and address community for successful community-based health promotion. Although there were some positive changes in diet and physical activity seen in this study, these changes were modest. To achieve success, a lifestyle modification program through funeral societies should be more intensive, and conducted as a long term intervention.

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