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Evaluation of an active focused intervention on the quality of life among elderly individuals in the slum areas of Thane district in India: An experimental field-based randomized clinical trial

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ABSTRACT

Background: Care-giving to elderly population is challenging impacting their quality of life (QoL). We carried out the present study evaluating the influence of an intervention targeting this population in improving their QoL.

Materials and Methods : A community-based randomized clinical trial was undertaken targeting the elderly population residing in an urban slum area after evaluating the baseline QoL using pre-validated questionnaire from World Health Organization (WHO QOL-BREF). Intervention involving mainly the interaction with elderly population in facilitating their interaction with the health care providers, and social clubs was carried out in the intervention group. Control group of participants was provided the usual standard of care without any active intervention.

Results: Eight-hundred and fifty-two were included (study group: 426 and control group: 426) with a large-majority in the age range of 60-69 years. Most of the participants were educated, housewives, economically dependent on their family members, with a monthly income ranging between 5001 and 10000 rupees. The demographic characteristics were comparable between the intervention and control groups except for the concomitant diseases that were significantly more in the intervention group. Baseline mean WHO QOL-BREF scores were 40.04 and 45.2 in the intervention and control groups, respectively. Post-intervention, the QoL scores were significantly ($p < 0.05$) greater in the intervention group. Those between 60 and 69 years, male gender, those independant on their family members, and healthy individuals had significantly greater QoL scores post-intervention.

Conclusion: We observed that our intervention had significant beneficial effects in improving the QoL among the elderly individuals residing in an urban slum area. We have also identified certain sub-groups of individuals with a greater response. There is an urgent need for evaluating the utility of our intervention using a randomized study.

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1. Background

Demographic transition, improvement in the healthcare services, and advancement in the medical sciences contributed to increased prevalence of elderly population. In 2012 the elderly population in the world was 11% of the total population, which is expected to increase to 22% by 2050.[1] Elderly population pose a lot of challenges particularly they are neglected by their family members, lack of social security, and lack of emotional, physical and

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financial support.[2] As per the 2014 report on "Elderly abuse in India", 50% of elderly people reported of having been abused by their family members.[3] A paradigm shift has happened in India where the traditional values particularly taking care of elderly at home has been abandoned due to rapid industrialization, urbanization and globalization. The elderly who have always been the support to their family until then, start feeling neglected, and start craving for love at this stage of their life leading to deterioration in the physical strength, poor financial condition, and consequently poor quality of life (QoL).[4] As expected, there is a steady rise in the old age dependency ratio (estimated as ratio of population above 60 years old to that of 15-59 years) was observed to be 0.14, and the old age economic dependency ratio was observed as 0.23.[5] This was reiterated by World Health Organization (WHO) that has stated that as people across the world live longer, increased risk/prevalence of chronic illness, and compromised well-being were observed as major challenges in the contemporary world.[6] Hence, we carried out the present study with the primary objective of assessing the impact of the special intervention on the QoL of elderly individuals residing in an urban slum area in a metropolitan city in India and to correlate the QOL with various socio-demographic factors.

2. Materials and Methods

2.1. Study design and ethics

The present study was a prospective study carried out in a slum area (Mira) in Mumbai, a metropolitan city in India. We used epidemiological two groups pre- and post-intervention test research design. The key epidemiological and health indicators of the Mira area are listed in Table 1. We carried out the study after obtaining approval from the Institutional Ethics Committee and consent from the study participants between January 2016 and November 2017. The study was carried out in adherence to the latest Declaration of Helsinki guidelines.

2.2. Study procedure

Those aged 60 years and above residing in the above-mentioned area for at least six months were included in this study after obtaining their consents. Those who were either bedridden or with serious illness were excluded. Following details were collected from the study participants: age, sex, education, occupation, monthly income, family background, beneficiary of any social security scheme, and concomitant disorders. The interventional group was provided a special attention that included the following:

1. Providing health check-up for two times at stipulated intervals with multi-disciplinary team and the required medicines,
2. Personalized counselling and referral to a specialist wherever necessary,
3. Facilitating the formation of area-wise clubs/social gatherings with identification of their team leaders and organizing meetings at least once a week; and liaison with community-based and non-governmental organizations.
4. Providing health education on geriatric care to the study participants and their family members and organizing orientation sessions addressing domestic violence, and
5. Distributing the information brochures regarding various social security measures.

More details about the intervention are provided in the Electronic Supplementary File.

The investigator team approached the study site for obtaining permission and consent from the study participants during the first two visits. From the third visit, the special intervention package was carried out in the intervention group at various stages. During the initial stages, clubs (20 subjects in 1 club) were formed (overall 21 clubs were formed) and the club meetings were facilitated with a total of 12 meetings organized. In the third stage, health checkup camps, and referrals were done. The forth session was the orientation session to the study participants in which orientation to CBOs/SHGs/NGOs (3 times) was provided on topics related to domestic violence, social security, and legal provisions. The fifth session was on the health education on geriatric care to the study participants and their family members that was associated with distribution of brochures. After the fifth session, monitoring and supervision was done in the intervention group every fortnightly. The control group was not provided any of the active intervention other than the standard of care. A pre-validated WHOQoL-BREF questionnaire was used for assessing the QoL that consisted of 26 test items structured under four domains namely, physical, psychological, social and environmental. Raw scores were calculated and were transformed using the following formula: {(actual raw score – least possible raw score)/possible raw score range} X 100. The scale was administered baseline, and after 18 months of providing the intervention.

3. Statistical Analysis

Descriptive statistics were used for representing demographic variables. Numerical variables were tested for their distributions and non-parametric tests were used. The categorical variables were evaluated using Chi-square or Fisher exact probability test. The sample size was calculated with the following estimates: alpha error - 5%, power - 80%, mean difference - 59.2, standard deviation of 11.87, and anticipated drop-out of 20%, and was observed to be 426

Table 1: Key epidemiological and health indicators of the Mira region.

Parameters		**Estimates**
Total population		814655
Total numbers of primary health centres		9
Total numbers of population above 60 years		45497
Slum pockets affiliated to Nursing college for teaching training purpose (Names and individual populations)		Penkarpada-97000 [study area] Kashigoan-78000 [control area]
Health infrastructure (Public & private sectors)	Tertiary level	Public sector-1 Private sector- 5
	Secondary level	Public sector-1 Private sector- 135
	Primary level	Public sector-9 Private sector-10
Crude birth rate		15.1/1000 population
Crude death rate		5.48/1000 live births
Infant mortality rate		12.9/1000 live births

Table 2: Demographic characteristics of study participants.

Variables	**Study group [n (%)]**	**Control group [n (%)]**
Age group (Years)		
60 – 69	330 (77.46)	345 (80.98)
70 – 79	78(18.31)	65(15.26)
80 & above	18 (4.23)	16(3.76)
Gender		
Female	272(63.85)	248(58.22)
Education		
Non formal	167(39.20)	260(61.03)
Primary	75(17.61)	51(11.98)
Secondary	160(37.56)	105(24.65)
Higher secondary	17(3.99)	6(1.41)
Graduate & above	7(1.64)	4(0.93)
Occupation		
Employed	86(20.19)	175(41.07)
Housewife	241(56.57)	177(41.55)
Unemployed	99(23.24)	74(17.38)
Marital status		
Married	298(69.95)	310(72.77)
Widow/widower	120(28.18)	108(25.35)
Single	3(0.70)	8(1.88)
Divorced	5(1.17)	0
Family income (Rs)		
<5000	48(11.27)	108(25.35)
5001-10000	224(52.58)	191(44.83)
10001-15000	95(22.30)	75(17.61)
>15000		59(13.85)
Dependent on family member		
Yes	336(78.87)	262(61.50)

Table 3: Health care factors among the study population.

Health care factors		Study group [n (%)]	Control group [n (%)]	p-values
Hospital facility available	Government	64(15.02)	123(28.87)	<0.0001
	Private	326(76.53)	284(66.66)	
	Both	36(8.45)	19(4.47)	
Accessibility (min)	<30	336(78.87)	334(78.41)	0.87
	30 & above	90(21.13)	92(21.59)	
Health Insurance	Yes	2(0.47)	8(1.87)	0.064
	No	424(99.53)	418(98.13)	

Table 4: Comparison ofQoL scores in the intervention and control groups.

QOL domain score	Pre test		Post test		Wilcoxon Z Value	P Value
	Mean	SD	Mean	SD		
Intervention group						
Physical	41.08	12.01	59.85	7.64	16.99	<0.0001
Psychological	41.46	11.94	69.53	9.47	17.24	<0.0001
Social	36.51	14.98	60.37	11.44	17.07	<0.0001
Environmental	41.11	10.27	61.94	6.46	17.04	<0.0001
Control group						
Physical	48.28	8.09	48.54	8.94	0.66	0.51
Psychological	46.07	9.59	46.43	9.76	0.79	0.43
Social	42.94	11.83	43.29	11.57	1.24	0.22
Environmental	43.43	8.48	43.67	8.76	0.96	0.34

Table 5: Comparison ofQoL scores between the intervention and control groups.

QOL domain score	Study group (n=426)		Control group (n=426)		MW test Z Value	P Value
	Mean	SD	Mean	SD		
			Pre-test			
Physical	41.08	12.01	48.28	8.09	10.05	<0.0001
Psychological	41.46	11.94	46.07	9.59	5.89	<0.0001
Social	36.51	14.98	42.94	11.83	7.25	<0.0001
Environmental	41.11	10.27	43.43	8.48	4.48	<0.0001
			Post-test			
Physical	59.85	7.64	48.54	8.94	16.06	<0.0001
Psychological	69.53	9.47	46.43	9.76	22.08	<0.0001
Social	60.37	11.44	43.29	11.57	16.76	<0.0001
Environmental	61.94	6.46	43.67	8.76	21.77	<0.0001

per group. P-values of < 0.05 were considered significant. SPSS version 22 was used for statistical analysis.

All parameters are expressed in numbers (n) unless specified otherwise.

4. Results

4.1. Demographics

Mean ages of study participants were 64.87 and 64 years in the intervention and control groups. A summary of the demographic characteristics of the study population is listed in Table 2 wherein majority of them were in the age group of 60-69 years, without formal education, housewives, and economically dependent on their family members. Regarding the health care factors, only the availability of hospital facility was significantly different between the groups with more participants in the intervention group availing private hospitals/clinics and majority did not have any health insurance (Table 3). Significantly more participants in the interventional group were had at least one concomitant disorder (intervention group: 311, 73%; control group: 281, 65.97%).

4.2. WHO QoL-BREF scores

Internal consistencies as evaluated by Cronbach's alpha ranged between 0.64 and 0.75, thus demonstrating a good reliability. The QoL scores across all domains were significantly greater post-intervention in the intervention group but not in the control group (Table 4). At baseline, baseline QoL scores were significantly ($p = 0.001$) lower in the intervention group (Table 5). Post-intervention (at 18^{th} month) QoL scores were significantly greater in the

Table 6: Distribution of variables between the groups.

Variables		Study group	Control group	P-values
Age categories				
60 – 69 years		330	345	
70 – 79 years		78	65	0.44
80 years & above		18	16	
Gender				
Male		154	178	0.09
Female		272	248	
Education				
Illiterate		167	260	
Primary		75	51	
Secondary		160	105	0.0001*
Higher secondary		17	6	
Graduate & above		7	4	
Occupation				
Employed/pensioner		168	223	0.0001*
Unemployed		258	203	
Marital status				
Married		298	310	
Widow/widower		120	108	0.04*
Single		3	8	
Divorced		5	0	
Family income (INR)				
<5000		48	108	
5001-10000		224	191	0.0001*
10001-15000		95	75	
>15000		59	52	
Self earning				
Yes		108	182	0.0001*
No		318	244	
Dependent on family member				
Yes		336	262	0.0001*
No		90	164	
Health care factors				
Hospital facility available	Government Private Both	64 326 36	123 284 19	0.0001*
Accessibility (min)	<30 30 & above	336 90	334 92	0.87
Health Insurance	Yes No	2 424	8 418	0.064
Concomitant illnesses				
Diabetes		88	65	0.039*
Hypertension		130	90	0.0016*
Heart Disease		34	8	0.0001*
Stroke		9	3	0.08
Respiratory disorders		16	30	0.033*
Urinary disorders		2	1	0.56
Arthritis		22	59	0.0001*
Cancer		5	1	0.10
Musculo skeletal diseases		91	90	0.93
Cataract		56	4	0.0001*
Other Illness		88	87	0.93

Table 7: Key studies evaluating theQoL in elderly individuals.

				WHOQOL Domain(Mean)			
Author	**Place**	**Year**	**Sample Size**	**Physical**	**Psychological**	**Social**	**Environmental**
Present study	Thane, India	2019	852	48.28	46.07	42.94	43.43
Kumar et al.[7]	Delhi, India	2014	273	37.3	45.13	28.47	37.76
Hariprasad et al.[8]	Bangalore, India	2013	120	52.21	55.73	55.42	68.74
Mudey et al.[9]	Wardha, India	2011	400	50.97	51.14	59.39	60.28
Farajzadeh et al.[10]	Iran	2016	425	65	58.68	64.36	65.86
Barua et al.[11]	Manipal, India	2007	70	51.2	51.3	55.9	57.1
Paul et al.[12]	Vellore, India	2017	140	37.4	35.7	36.2	37.5
Varun et al.[13]	Haridwar, India	2017	35	52.6	57.2	47.5	65.9

intervention group compared but not in the control group (Table 5). Literacy, occupation, marital status, monthly income, self earning status, family dependence, access to private hospitals, and concomitant illnesses such as diabetes mellitus, hypertension, ischemic heart disease, respiratory disorders, arthritis, and cataract were the factors significantly different between the groups (Table 6).

5. Discussion

5.1. Statement of key findings

The present study evaluated the QoL and the determining factors in elderly individuals living in a metropolitan city in India. Additionally, a special intervention was provided and its effect on QoL was assessed in comparison to the control group that did not receive the intervention. The QoL scores across all domains were significantly greater post-intervention in the intervention group but not in the control group. Literacy, occupation, marital status, monthly income, self earning status, family dependence, access to private hospitals, and concomitant illnesses such as diabetes mellitus, hypertension, ischemic heart disease, respiratory disorders, arthritis, and cataract were the factors significantly different between the groups.

5.2. Comparison with other studies

The current study assessed the effect of specially devised intervention package on quality of life among senior citizens. The results showed a statistically significant difference between pre intervention and post intervention score of WHO physical, psychological, environmental and social quality of life score in the study group. This confirmed that the difference in pre intervention and post-test mean score of WHO quality of life score in the study group is a real difference and not by chance. This supports the effectiveness of the intervention package in improving the score of quality of life (all four domains) of senior citizens in the study group. We observed that the intervention group had significantly greater QoL compared to control group. Key studies addressing a similar hypothesis are summarized in Table 7 Although the findings were similar to several other studies, those carried out in Iran and in another metropolitan city (Bangalore) revealed a slightly better QoL. Various interventions have been explored for improving the QoL of elderly individuals. A study conducted in Japan by Kamegaya et al. through a randomized controlled trial has shown that a twelve-week physical and leisure activity programtin improving the cognitive function in community-dwelling elderly subjects.[14] Hariprasad et al. in 2013 evaluated the effects of yoga intervention on quality of life and sleep in the elderly after a period of six month.[8] The authors in that study observed a significant improvement in the QoL across all domains and sleep. Similarly, Kumar et al. in 2014 through a randomized controlled trial have shown that a novel occupational therapy could improve the QoL of elderly following five weeks of intervention.[15] We observed that with an advancing age the score of the QOL decrease significantly in all domains in all domains. Contrary to the present study, Kumar P et al.[7] who have evaluated the elderly living in an urban area in 2013 observed that older age was associated with a poor QoL. This possibly could be attributed to the differences in the physical, psychological and social changes and due to altered immunity amongst the elderly.[16]

5.3. Strengths and limitations

The sample size was sufficiently large (and adequate) compared to several previous studies leading to a better confidence on the obtained results. However, the study is limited in not having a long term follow up with the study participants, and there was no follow up to evaluate the changes in QoL.

6. Conclusion

The present study estimated the QoL amongst elderly individuals living in a metropolitan city in Indian subcontinent. We have also observed that a special intervention package resulted in improvement of physical, psychological, social and environmental domains of QoL in the elderly population. Certain factors were also identified to be significantly associated with the QoL that needs to be

validated in prospective studies.

7. Source of Funding

None.

8. Conflict of Interest

None.

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