

Protocol

Estimating the effectiveness of nurse led community mental health outreach program on health-related quality of life of elderly at community areas, Chittoor, Andhra Pradesh: a mixed methods approach

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ABSTRACT

Background: India's ageing population faces rising health issues and reduced family support, with old-age homes being culturally less accepted. The nurse led community mental health outreach program (NL-CoMHOP) uses social prescribing to provide affordable, community-based care. Managed by nurses, it improves health, quality of life (QoL), and reduces loneliness for elderly living at home, while easing family burden. This study will evaluate NL-CoMHOP's effectiveness and estimates its costs, aligning with National Mental Health Program's (NMHPs) vision.

Methods: This mixed-methods study (QUAN+qual) adopts an open-label randomized controlled trial with concurrent triangulation in community areas of Chittoor district, Andhra Pradesh. Eligible elderly (≥ 60 years, residents ≥ 5 years) will be randomly recruited, excluding those needing emergency care or with acute psychosis. Total 162 participants will be enrolled. Over 6 months, the NL-CoMHOP will deliver individualized physical, psychological, social, and spiritual activities using local resources.

Conclusions: The NL-CoMHOP, a newer concept and an intermediary solution for the elderly to improve their health-related QoL (HRQoL).

Trial registration: CTRI/2025/06/089067 dated 18/06/2025 under clinical trials registry-India.

Keywords: Social prescription, Geriatric, Aged, Quality of life, Mental health services, Community health nursing

INTRODUCTION

Ageing is inevitable. Healthy aging with good mental health and well-being is as important in older age as at any other time of life. The population of elderly was 8.6% in 2011 (104 million) across the nation, making India the second largest country with 106 million elderly (2015) and it is projected that by 2050 the elderly population will

increase to 19%, making it necessary to understand the age-related challenges and preventive measures so that we can place a person on a path to healthy ageing.^{1,2}

The elderly experience a significant ongoing loss in capacities and a decline in functional ability, and face conditions like bereavement, a drop in socioeconomic status with retirement etc., which act as stressors leading to necessitating long-term care.^{3,4}

LASI data as presented in the 2017–2018 national report and other published articles confirm that the prevalence of chronic diseases increases with age, with a higher prevalence among older adults (aged 60 years and above) compared to those in the 45 to 59 year age group. There is a prevalence of undiagnosed and under diagnosed diseases, such as hypertension, diabetes and vision impairment. Noncommunicable diseases are the major cause of hospitalization among older adults, yet health insurance coverage among this cohort is only around 20%. Gender differences in the health, social and economic wellbeing of older adults are prominent; some diseases such as heart disease, stroke, diabetes mellitus, chronic lung disease and neurological problems are higher among men, while women are more likely to be diagnosed with hypertension, anemia, bronchitis, depression, alzheimers disease and dementia, any bone or joint disease, and cancer. The data reveal other disparities as well: place of residence, caste, religion, education and income have a considerable effect on the wellbeing of older adults. A large proportion of older adults are working in the informal sector and, thus, ineligible to receive a pension when they retire or stop working, which exacerbates the problem of consumption outpacing production for this group. In a telling snapshot of the situation, only around 50% of older adults are ‘highly satisfied’ with their lives.²

The overall HRQoL was higher in those living in homes for the elderly than in those living in the community. However, the domains of physical and emotional were better for elderly living in the community. In the community, these elderly perform social obligations; hence, these domains were higher among community dwellers. Evidence indicates the importance of a more conducive environment for the elderly. Provision of a better and conducive environment may be one option for relative betterment of the QoL of the elderly, particularly those who are socially and economically deprived. Since emotional health (mental health) is as important as physical condition, rejuvenation of the traditional norms and values is equally important during this transition period of shifting values vs. priorities.

Mental health problems are common among seniors, which is one of the neglected areas. Approximately 15% of adults aged 60 and over suffer from a mental disorder. Indian studies have reported that individuals of nuclear families are more susceptible to developing psychological problems than those of joint families because of breakdown in the traditional support system.⁵⁻⁸

India is a country where old age is considered as a sum total of one’s lived experiences and is called a golden age and the elderly receive natural and automatic support in the form of family system. Double income, small homes and the nuclear family system have disrupted the traditional concept of the family system and now children are failing to give personal attention to their parents beyond their control.

Due to lack of family support, it is becoming inevitable to welcome old-age homes. Research studies revealed that the elderly living in old-age homes had a higher QoL than family setup. But, Indian society is still not well prepared to accept the old-age homes concept due to traditional mindset and cultural ethics.⁹

There is a felt need to develop a multidisciplinary and multi-sectoral approach to incorporate geriatric mental health into primary health care while elderly receive all the benefits of old-age home while retaining family association. Studies indicate that social prescribing may be effective in improving health and well-being, as well as being cost-effective by reducing demand on the health sector. An innovative newer model-social prescribing, comprises professionals and general staff from several relevant sectors, by means of which health-care workers will connect the elderly to a range of nonclinical services in the community to improve the health and well-being of the old-age people. Social prescribing is not an intervention by itself, but rather a pathway that helps to address the patient’s needs.

It is a holistic approach to health care, while promoting community-based integrated de-medicalized care for the elderly at an easily accessible and affordable level. There is a large body of evidence behind the impact of various non-pharmacological interventions (NPIs) for different conditions in older adults.

The NL-CoMHOP which is developed from the concept of social prescribing, a newer concept and an intermediary solution for the elderly who prefer to stay in their own homes. It is an effort by a nursing officer working in community areas to provide services, support or awareness to the elderly population to promote their HRQoL.

It is a healthy way of engaging the elderly during the day time when their family members have gone to their work; is a solution for those who are deprived of family relationships due to their stay in old age homes as well as for those who were neglected due to the busy schedules of family members.

Impact on NMHP

It is not possible to facilitate additional settings to ensure mental health care provision in community since our country is still developing and budget allocation on health needs by the government is far away from the demand. Hence, NMHP aimed to integrate mental health care into general health care to ensure mental health care provision to all needy. NL-CoMHOP is one such solution to meet the aim of NMHP. Implementing the ‘NL-CoMHOP for the elderly’ helps in ensuring quality life (psychological, physical, social, spiritual) for the elderly, develops productive work culture among them, gives meaning to life and, on the other hand, decreases the burden on family care givers. Hence, this study is planned to estimate the effectiveness of NL-CoMHOP on HRQoL of elderly aged

60 years and above in community areas of Chittoor district, Andhra Pradesh.

Objectives

Objectives were to estimate the effectiveness of NL-CoMHOP on HRQoL of elderly aged 60 years and above living in community areas of Chittoor district, A.P. and to identify the facilitators and barriers of implementing NL-CoMHOP on HRQoL of elderly.

Besides, economic evaluation (cost effectiveness and Cost utility) of NL-CoMHOP on HRQoL of elderly (cost benefit and the cost utility analysis) will also be performed.

METHODS

Research approach

Mixed methods research approach. The study will be a quantitatively driven qualitative study (QUAN+qual).

Research design

The quantitative part of the study will be conducted through an open label Randomized Control Trial and the qualitative part will be conducted by concurrent triangulation design.

Setting of the study

The study is planned to be conducted in community areas of Chittoor district, preferably health care centers and attached sub-centers (health and wellness centers).

Study period

Total study period is 18 months from August 2025 to January 2027.

Sampling unit

Sampling unit is wards in Chittoor corporation.

Sampling strategy

Samples will be selected by multistage random sampling technique. There are an estimated 50 wards in Chittoor corporation. Each ward is expected to have 10-20 units based on population size covered. Initially, we will select two wards which contains approx. 40 units, randomly. From selected 2 wards, 1 will be allocated into intervention arm and other into control arm by applying simple random technique. After making a list of all units in wards, 2 units will be randomly selected from respective arms. Sample frame of all eligible participants within those units of will be made and sample will be recruited into respective arms randomly from sample frame (Figure 1).

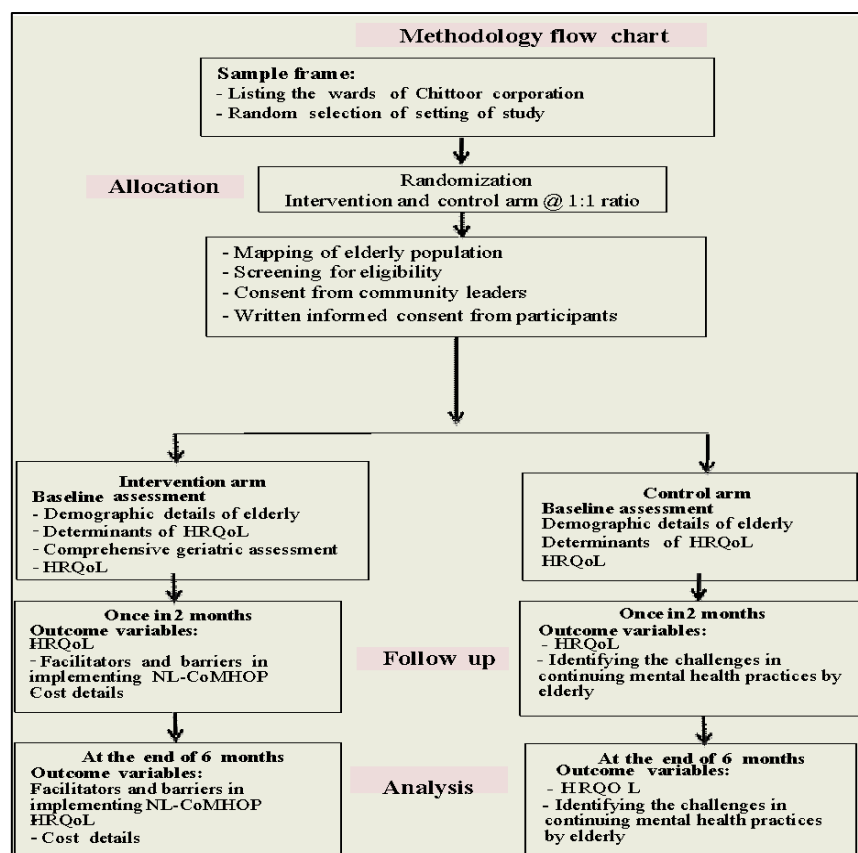


Figure 1: CONSORT flow chart for the trial NL-CoMHOP.

Population and sampling

The sample under the study are elderly people aged 60 years and above residing in Chittoor district, A.P. India.

Inclusion criteria

The study includes elderly people-aged 60 years and above, both genders, residing in community areas, Chittoor district, Andhra Pradesh and permanent residence of Chittoor who were staying for the past 5 years.

Exclusion criteria

Study excludes elderly people-in need of emergency geriatric management and with acute psychotic symptoms.

Sample size

Assuming a true difference in means between the test and the reference group of 6 (i.e. 53-47) units, a pooled standard deviation of 7 units and a design effect (DEFF) of 1.2, the study would require a sample size of 81 for each group (equal group) i.e. a total sample size of 162, to achieve a power of 80% and a level of significance of 5%, for declaring that the intervention is superior to the control arm outcome at 3 units (σ 7 units) margin of superiority (assuming that a larger mean is desirable). Sample size for IDI will be determined based on point of data saturation.^{16,19,20}

Tools and techniques

The study will collect the demographic details and details of determinants of QoL of the elderly (Gender, age, working status, education, living status, community, livelihood, spouse status, relative status, head of house hold, possession of property, decision making role, perceived disease status, marital and economic status) and also short form 36 (SF-36) questionnaire will be used to assess the HRQoL. An in-depth interview guide (IDI guide) will be developed to collect information about facilitators and barriers and also HRQoL data qualitatively.¹⁴⁻¹⁶ Both qualitative and quantitative data

will be concurrently collected and analysed. Cost incurred in implementing the intervention at the community level will also be reported concurrently.

Intervention

Proposed intervention under study is 'NL-CoMHOP'.

Details of intervention

Upon selecting the eligible settings randomly, mapping of the elderly will be done in the selected settings and categorised them into bed bound, restricted mobilization and mobile elderly. On the other hand, available resources (human and service) will be identified. The elderly will be either visited at their doorsteps or called for a common place and a geriatric assessment will be performed. Based on the health problems identified, they will be directed to health care services (if needed) and all of them will be enrolled in nurse led mental health outreach program where person-centered individualised mental health care services will be provided, which includes physical, psychological, social and spiritual practices for six months. First half of first month will be introduced with measures to promote physical activities, second half with psychological activities like relaxation and reminiscence. Second month first half with social activities and second half will be introduced with spiritual activities. All these activities will be continued till the end of 6 months (Table 1).

At every step of mental health service provision, identified resources will be utilized (Volunteers, NGO members etc.). All these practices will be directed towards promoting HRQoL among the elderly. Control arm participants will be given same but delayed intervention if the intervention is found to be effective, after the end line data collection is done. Intervention will be implemented by the study principal investigator with the help of Department of Nursing, Apollo College of Nursing, Chittoor. Training will be given on implementation of intervention to those whoever involves in implementation by the PI using uniform intervention guide.

Table 1: Implementation plan for intervention.

Nurse led mental health interventions	1 st month		2 nd month		3 rd month		4 th month		5 th month		6 th month	
	I	II	I	II	I	II	I	II	I	II	I	II
	half	half	half	half	half	half	half	half	half	half	half	half
Monitoring of intervention	Researcher		Researcher and volunteers									
Physical activities												
Life style modification: Diet, exercises												
Sleep hygiene												
Self-care practices												
Promoting peer relationship												
Psychological												
Relaxation practices: Breathing, loosening exercises, art, play, yoga, meditation												
Reminiscence therapy												

Continued.

Nurse led mental health interventions	1 st month		2 nd month		3 rd month		4 th month		5 th month		6 th month	
	I half	II half	I half	II half	I half	II half	I half	II half	I half	II half	I half	II half
Social activities												
Volunteering services to bed-bound elderly												
Volunteering in social services												
Spiritual												
Spiritual practices based on individual choices												

Data collection

Data will be collected at different time points from the study participants. Demographics and determinants of HRQoL will be collected at baseline. HRQoL, facilitators and barriers in implementing nurse led mental health outreach program will be collected at baseline and every 2 months till 6 months. Cost details will be reported simultaneously (Figure 1).

Expected outcome

Implementing the 'NL-CoMHOP' helps in improving the HRQoL (psychological, physical, social, spiritual) of the elderly, develops productive work culture among them, gives meaning to their lives and, on the other hand decreases burden on family care givers. All this happens by making effective utilization of available resources in community (cost effective) without much investment.

Plan for data analysis and statistical application

The primary outcome variable for assessing the effectiveness of the intervention will be HRQoL. Data will be analyzed using both descriptive and analytical approaches, applying intention-to-treat (ITT) and per-protocol analyses. Contamination between the intervention and control arms will be minimized through rigorous randomization, ensuring adequate geographical separation, and further addressed using contamination-adjusted ITT (CA-ITT), which adjusts ITT estimates for the proportion of participants who actually received the intervention. Missing data will be managed by assigning values to both positive and adverse outcomes to examine differences in results. Subgroup analyses will be conducted based on determinants of HRQoL such as gender, socioeconomic status, family size, type of participation in the intervention, and history of co-morbidities. Univariate statistical tests, including t-tests and one-way ANOVA (based on data distribution), will be used to examine associations between participant characteristics and HRQoL, while paired t-tests will assess treatment outcome differences. Correlation analysis will be used to determine the strength of relationships, and multiple logistic regression will identify independent determinants of HRQoL. Qualitative data will be analyzed using thematic analysis to identify themes and subthemes. In parallel with the RCT, a cost-utility analysis will be conducted to estimate QALY gains over a six-

month time horizon, considering both direct and indirect costs (research, fixed, semi-fixed, and material costs). Cost-effectiveness will be assessed using the Incremental Cost-Effectiveness Ratio (ICER), with willingness-to-pay thresholds based on India's GDP at the time, and sensitivity analyses will be carried out to address uncertainty.

Ethical considerations and quality control measures

Institutional Ethics Committee clearance was obtained for conducting the study (No:IEC-AIMSR/2025/A/39 dated 11/03/2025, Apollo Institute of Medical Sciences and Research, The Apollo Medical College, Chittoor district). Written informed consent will be obtained from all participants. All study-related documents will be preserved in the department under lock and key, and electronic case report forms will be stored on a password-protected computer for a minimum period of five years. The study investigator will undergo ICH-GCP training, and all procedures will adhere to country-specific guidelines and regulations to ensure protection of participants' rights. Standardized and pretested data collection forms, along with detailed interviewer guides, will be used. Questionnaires and other study forms will be translated into local languages and back-translated to ensure accuracy. Furthermore, the study protocol will be pilot tested before full implementation.

Data monitoring

Data monitoring committee will be formed with project investigators, and other study members. This committee will monitor every step of trial implementation, namely recruitment process, collection of data at different time points, perceived risks and measures applied to overcome, data completeness, adverse events during trial conduction, withdrawal of study participants etc.

Harms

There won't be any expected direct physical harm to any participants out of this study participation.

Auditing

Trial will be audited by external agency independent of trial team.

Protocol amendments

Any change in the protocol which do not change the title and objectives and the safety of the participants will be amended with the consensus of trial team. Any change in protocol which will change the title, objectives of the study will be amended after the approval of the institutional ethics committee.

Confidentiality

Researcher will ensure confidentiality of all the participant's information such as eligibility assessment of prospective participants, data with personal identifiers which is collected during the trial. Data will be de-identified with unique identifiers immediately after its collection wherever required.

Declaration of interests

None of the study team members has any financial or non-financial conflict of interest.

Access to data

Data access will be under the control of researcher only. Whatever the information collected under the project will be used only for the purpose of the work mentioned herein above and team members are liable to administrative action in case the data is found to be misused beyond the scope.

Ancillary and post-trial care

Throughout the trial period efforts will be taken to identify the volunteers at the study settings to sustain the intervention. All the cases whoever get referred to a tertiary care facility for treatment will be linked to the staff at PHC or Sub-center for further follow up.

Dissemination policy

Final results of the study will be published in a n open-access journal. The same will be communicated to the stake holders working for elderly including policy bodies. Anonymized data will be shared by the principal investigator only, if there is a reasonable justification.

CONCLUSION

The NL-CoMHOP which is developed from the concept of social prescribing, a newer concept and an intermediary solution for the elderly to improve their HRQoL by keeping the concept of family and relationship with the family intact.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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