Identification, Prevention, and Management of Dependence among Frail Older People in Low Resourced Primary Health Care Setting

Thiyagarajan, Jotheeswaran Amuthavalli

Awarding institution:
King's College London

The copyright of this thesis rests with the author and no quotation from it or information derived from it may be published without proper acknowledgement.

END USER LICENCE AGREEMENT

Unless another licence is stated on the immediately following page this work is licensed under a Creative Commons Attribution-NonCommercial-NoDerivatives 4.0 International licence. https://creativecommons.org/licenses/by-nc-nd/4.0/

You are free to copy, distribute and transmit the work

Under the following conditions:

• Attribution: You must attribute the work in the manner specified by the author (but not in any way that suggests that they endorse you or your use of the work).
• Non Commercial: You may not use this work for commercial purposes.
• No Derivative Works - You may not alter, transform, or build upon this work.

Any of these conditions can be waived if you receive permission from the author. Your fair dealings and other rights are in no way affected by the above.

Take down policy

If you believe that this document breaches copyright please contact librarypure@kcl.ac.uk providing details, and we will remove access to the work immediately and investigate your claim.
Identification, Prevention, and Management of Dependence among Frail Older People in Low Resourced Primary Health Care Setting

Thesis submitted for the degree of Doctor of Philosophy in Epidemiology to the King’s College London

By

Jotheeswaran Amuthavalli Thiyagarajan
Centre for Global Mental Health
Health Service and Population Research Department
Institute of Psychiatry
King’s College London, UK

September, 2013
SUMMARY OF CONTENTS

This PhD thesis is about the identification, prevention, and management of dependence among frail or dependent older people in low resourced health care settings in low and middle-income countries (LAMICs). The thesis comprises; an overview of the literature (Chapter one); a thematically linked series of studies (Chapters two to seven) each with their own background literature, research methods, results, and discussion sections; a protocol describing future research plans (Chapter eight), and an overarching summary of results and discussion of implications (Chapter nine).

Chapter one comprises an overview review of the literature. The first section is an overview of background issues relevant to my research; the societal impact of population ageing and the epidemiological transition in low and middle income countries; the impact of the developing epidemic of chronic disease among older people; the neglected issue of dependence; and the potential relevance of frailty as a target for health care intervention. In the second section I review the barriers and obstacles to providing age-appropriate healthcare at the primary attention level, linked to the perceived function, systems, structures and resources available in low and middle-income countries. I conclude with a review of models for the development of evidence-based complex interventions, and how these could be applied to the specific context of the development of a home-based package of assessment and intervention to be delivered by non-specialist community health workers (CHWs) in resource poor low and middle income country settings. I conclude by describing the aims and objectives of my research, and the research activities that I carried out in pursuit of these objectives.

Chapter two: Frailty has been little studied in low and middle-income countries. Predictive validity is established through consistent prediction of adverse health outcomes. Chapter two describes a secondary data analysis of longitudinal population-based study data from 10/66 Dementia Research Group studies in Latin America, China and India, to test associations of two widely-used frailty definitions (Fried and Strawbridge) and their individual frailty indicators (gait slowing, fatigue, weight loss, undernutrition, cognitive and sensory impairment) and the onset of dependence and mortality.
Chapter three: Lack of help seeking is an important barrier to access to care by frail dependent older people. Chapter three describes the results of a formal evaluation of the effectiveness of case finding by community health workers in Goa, India. After brief training, 10 CHWs each identified 15 ‘frail or dependent older people’. Those 150 older people were then reassessed in a clinical assessment performed by a primary care doctor using the EASY-Care geriatric assessment to establish if those identified were indeed frail and/ or dependent, with unmet needs for health care intervention.

Chapter four: Simple home-based interventions might be provided by CHWs, when guided by identification of health problems at the level of impairments, rather than underlying diagnoses. Chapter four describes the development and validation of a simple structured assessment (called COPE-Care for Older PEople) designed to assist CHWs to detect specific impairments to inform home-based intervention. The validation of the COPE assessment tool was carried out in the same sample of 150 older people described in Chapter three.

Chapter five: describes the formal process of clinical guideline development established by the World Health Organization to ensure improved transparency, and a sound evidence basis for recommendations. The process is described both according to its generic features, and with respect to their application to the development of the WHO-COPE guideline for the prevention and management of dependence among older people in resource poor settings. The methodology applied for developing WHO-COPE intervention guide, the strengths and limitation of the approach, and challenges for implementing the guideline recommendation in low and middle-income countries were discussed in the chapter.

Chapter six: describes the systematic review I performed to synthesize evidence on the benefit of nutritional interventions for undernourished frail or dependent older people, and the process for translation of evidence into draft guidelines, as an example of the work that I have conducted across the domains covered in the WHO-COPE guideline.
Chapter seven: Full implementation of WHO-COPE guidelines in a country such as India would require some changes in the policies, structures and working practices of health systems and services. To understand opportunities and challenges involved in integrating the WHO-COPE intervention guide for frail older people in these and similar health care settings, I conducted a qualitative study with non-specialist health professionals, and frail older people and family caregivers in Goa, India.

Chapter eight describes a protocol developed for a Phase II trial to test the feasibility, acceptability, potential efficacy, and fidelity of interventions for nutrition and physical exercise, when administered at home by CHWs working in the Goa primary health care service. Ethical approval and funding has been obtained for this work, which will start at the end of 2013. Such evidence will be required for each of the evidence-based guidelines, before the WHO-COPE intervention guide is assembled into a seamless package of assessment, intervention and care addressing each of the common impairments experienced by frail, dependent older people.

Chapter nine summarizes the main findings from each of the study components described in Chapters two to eight, highlighting the strengths and weaknesses of the research procedures. The implications of the findings, as a whole, are assessed and discussed, with respect to policy, practice, and future research priorities.
STATEMENT OF PhD CANDIDATE’S CONTRIBUTION TO WORK

The overall plan of the COPE (Care for Older PEople) programme is to develop and evaluate a package of care, comprising home assessment and evidence-based clinical guidelines, for the prevention and management of dependence among frail older people in Low and Middle Income Countries. It is intended that the package of care be administered by community health workers, linked to primary care. The idea for this intervention approach emerged from discussions that I had with my supervisor, Prof Martin Prince, at the end of my Wellcome Trust Master’s level fellowship. We developed this idea into an application for a Public Health Foundation for India four year PhD fellowship, which I was awarded. In the early period of my PhD fellowship, my supervisor and I made links with Dr John Beard, Director of the Department for Ageing and Life course at the World Health Organization, Geneva, and we entered into an agreement to work together on developing the COPE guidelines as an official WHO clinical guideline.

I have made a substantial contribution to the WHO-COPE guideline development process. This has included designing the guideline development process, and drafting the application to the body at WHO Geneva charged with providing formal approval for these arrangements, identifying suitable experts for the consensus groups, drafting scoping questions, conducting and writing up systematic reviews, convening consensus group meetings and teleconferences, and drafting final recommendations.

Chapter two – While preparing the PhD upgrade research proposal, I developed the idea of testing frailty definitions and performed an initial analysis using the 10/66 Dementia Research Group data set from India dataset that I had collected in my previous Wellcome Trust Master’s Training Fellowship project. Prof.Martin Prince recommended instead for me to use the full 10/66 Dementia Research Group incidence data set, and suggested a revised analysis plan. I conducted all of the data analyses, and produced the first full draft under his guidance. This chapter comprises a manuscript that we will shortly submit for consideration for publication,
Chapters three and four comprise the formative field research in Goa, India, assessing the feasibility of using community health workers to identify frail and dependent older people and assess underlying impairments. I conducted the literature search for simple assessments that can be administered by non-specialist health workers in low resourced health care settings and developed the first draft of COPE assessment package. I negotiated all of the discussions with Goa primary care providers for collaboration and permission to conduct the research. I designed and conducted the training programmes, and was responsible for every aspect of implementation of the field research, which I coordinated and supervised locally in Goa. I conducted the analyses and drafted the paper under the supervision of Prof. Martin Prince.

For the qualitative study on exploring opportunities for integrating continuum of care for older people (Chapter 7) I designed the study, and developed the topic guide, and case vignettes, with some further input from my supervisor after my initial draft. While I had originally intended to conduct some of the qualitative interviews myself, most community health workers were unable to express themselves freely in English; therefore I hired an external qualitative researcher and also a research assistant, who could conduct the qualitative interview in the local language (Konkani) and transcribe and translate this into English I performed the data analysis using Nvivo software and produced initial results with themes and quotes. Simultaneously, Prof. Martin Prince reviewed the transcripts and analysed independently and additional quotes were suggested and added. I wrote the first draft of the paper presented in the chapter.

Chapter eight – Phase II trial protocols – I wrote the first draft of a protocol for a non-randomised (Phase II) trial to test the feasibility, acceptability, efficacy, and fidelity of individual intervention components (nutritional and physical exercise intervention) consistent with recommendations of the WHO Guideline Development Group. I drafted this, initially, as an application for ethical approval from King’s College Research Ethics Committee. Approval was recently granted in London and Goa, and I have worked with my supervisor to develop this into a full trial protocol. The feasibility study will be carried out in primary health care setting in India between 15th Oct 2013 and 1st Jan 2014.
ABSTRACT

Background: Numbers of dependent older people will increase in low and middle-income countries (LMIC) with population ageing. Healthcare services do not meet their needs, and little attention has been given to developing age-appropriate services. Research described in this thesis is formative to development of World Health Organization (WHO)-COPE clinical intervention guidelines for prevention/management of dependence among older people in LMIC.

Method: Predictive validity of frailty indicators was tested by analysing 10/66 Dementia Research Group population-based cohort study data from Latin America, China, and India. Field research was conducted in Goa to train Community Health Workers (CHWs) for case-identification and assessment of frail/dependent older people. Case-identification and impairment classifications were compared with local clinician judgment. Clinical intervention guidelines were developed using WHO methodology (scoping questions/systematic reviews/expert consensus). Qualitative interviews in Goa with CHWs, doctors, and dependent older people and their carers assessed implementation issues for WHO-COE guidelines.

Results: Frailty indicators (weight loss, inactivity, exhaustion, slow gait speed, undernutrition, cognitive and sensory impairments) are consistent predictors of dependence and mortality. Goan CHWs accurately identified older people with multimorbidity, impairments, polymedication, disability and dependence. Agreement with clinicians for specific impairments was moderate, but the COPE assessment positive predictive value was high. It identified those with more pronounced disability. Systematic reviews found moderate quality evidence (from developed countries) for effectiveness of interventions for frail/dependent older people; e.g. exercise, nutritional supplementation/dietary advice, and prompted voiding for incontinence. Consensus guidelines are drafted for most intervention domains. Frail/dependent older people receive little attention in Goan primary healthcare. Home-based assessment and management was endorsed by healthcare professionals, but role definitions, referral options, limited knowledge and skills constituted important obstacles.

Discussion: WHO-COE assessment and multi-component intervention may address the needs of frail/dependent older people. However, feasibility, acceptability, fidelity, and effectiveness should be evaluated when administered by CHWs in the community.
ACKNOWLEDGEMENTS

I am very grateful to my mentor, Prof Martin Prince, for his guidance, comments and support throughout this PhD journey.

I also thank Prof. Vikram Patel and Dr. Amit Dias, for their support for carrying out field research project in Goa, India.

I would like extend my gratitude to primary health doctors, community health worker, and elderly people and their family members participated in my study.

Finally, I thank my mother and wife, without their support and understanding; I could not have finished this PhD.
<table>
<thead>
<tr>
<th>Table of content</th>
<th>Page no</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Summary of contents</strong></td>
<td>2</td>
</tr>
<tr>
<td><strong>Statement of PhD candidate’s contribution to work</strong></td>
<td>5</td>
</tr>
<tr>
<td><strong>Abstract</strong></td>
<td>7</td>
</tr>
<tr>
<td><strong>Acknowledgement</strong></td>
<td>8</td>
</tr>
<tr>
<td><strong>Chapter one: Background</strong></td>
<td>14</td>
</tr>
<tr>
<td>1.1 Demographic and Epidemiological Transition</td>
<td>14</td>
</tr>
<tr>
<td>1.2 Accompanying Social and Economic Transitions</td>
<td>16</td>
</tr>
<tr>
<td>1.3 Burden of chronic diseases among older people in low and middle income countries</td>
<td>19</td>
</tr>
<tr>
<td>1.4 Dependence among older people: a neglected public health problem</td>
<td>23</td>
</tr>
<tr>
<td>1.4.1 Definition</td>
<td>23</td>
</tr>
<tr>
<td>1.4.2 Prevalence and distribution</td>
<td>23</td>
</tr>
<tr>
<td>1.4.3 Consequences of dependence</td>
<td>25</td>
</tr>
<tr>
<td>1.4.4 Long term care systems for older care dependent people</td>
<td>26</td>
</tr>
<tr>
<td>1.5 What are the implications for age-appropriate health and social care in low and middle-income countries experiencing rapid population ageing?</td>
<td>27</td>
</tr>
<tr>
<td>1.6 Frailty and its relevance to the development of interventions to prevent or mitigate dependence among older people</td>
<td>27</td>
</tr>
<tr>
<td>1.7. Resources limitations in primary health care systems in low and middle income countries, and their relevance to the development and delivery of interventions to frail dependent older people</td>
<td>29</td>
</tr>
<tr>
<td>1.7.1 The problem</td>
<td>30</td>
</tr>
<tr>
<td>1.7.2 Reasons for optimism</td>
<td>31</td>
</tr>
<tr>
<td>1.7.3 Primary health care in the Indian context</td>
<td>32</td>
</tr>
<tr>
<td>1.8 Models for community intervention among frail and dependent older people</td>
<td>33</td>
</tr>
<tr>
<td>1.8.1 Model for complex intervention development and evaluation</td>
<td>34</td>
</tr>
<tr>
<td>1.8.2 Applying the MRC complex interventions framework to the development and evaluation of a community-based intervention for frail dependent older people</td>
<td>36</td>
</tr>
</tbody>
</table>
Chapter two: Frailty and the prediction of dependence and mortality in low and middle income countries – a 10/66 population-based cohort study

2.1 Background
2.2 Method
2.3 Results
2.4 Discussion
2.5 Bibliography

Chapter three: Validity of community case finding method and EASY Care assessment for primary health care clinicians in low resourced health care settings

3.1 Background
3.2 Method
3.3 Results
3.4 Discussion
3.5 Bibliography

Chapter four: Identifying common impairments in frail and dependent older people: The COPE assessment for non-specialised health workers in low resource primary health care settings

4.1 Background
4.2 Method
4.3 Results
4.4 Discussion
4.5 Bibliography

Chapter five: Evidence-Based Intervention Guide for Prevention and Management of Dependency among frail dependent older people in Low- and Middle Income Countries: Summary of WHO-COPE (Care for Older PEople) Recommendations

5.1 Background
5.2 WHO-COPE Guideline development process
5.3 Strength and limitations of the process 151
5.4 Implementation (evidence-based recommendation for practice) 152
5.5 Bibliography 159

Chapter six: Does nutritional intervention produce any therapeutic benefit for undernourished dependent older people? A systematic review and meta-analysis

6.1 Background 162
6.2 Method 163
6.3 Results 166
6.4 Discussion 179
6.5 Bibliography 183

Chapter seven: Integrating chronic disease care at primary health care for frail older people: Opportunities and Challenges

7.1 Background 195
7.2 Method 196
7.3 Results 199
7.4 Discussion 210
7.5 Bibliography 213

Chapter eight: WHO-COPE: Feasibility Study Protocol

8.1 Objectives 215
8.2 Method 215
8.3 Nutrition intervention 216
8.3.1 Outcome measure of nutrition intervention 217
8.4 Physical exercise training 218
8.5 Outcome measure of physical exercise training 220
8.6 Generic outcomes (relevant for both intervention) 221
8.7 Informed consent process 223
Chapter nine: Discussion

9.1 Is frailty a useful concept for low resourced health care settings in LAMICs? 226

9.2 Is it efficacious to employ existing community health workers for identification of frail older people and diagnose the impairments at primary health care level? 227

9.3 Is there any evidence to support the effectiveness of strategies for the prevention and management of dependence among frail older people? 230

9.4 Is it viable to integrate home-based care for frail dependent older people in low resourced health care settings? 232

9.5 Implications regarding future research 234

9.6 Implications for practice and policy in LAMICs 237

9.7 Bibliography 240
CHAPTER ONE
CHAPTER ONE:

1. BACKGROUND

1.1 Demographic and Epidemiological Transition

The shift from high to low fertility and mortality is known as the demographic transition. Since the 19th century, fertility and mortality rates have changed remarkably in Low and Middle Income Countries (LAMICs). Between 1970 and 2010, the total fertility rate per woman had decline from 5.3 to 2.6, which was below the population replacement. Consecutively, mortality rate had declined for both men and women in all age groups and resulted in increased life expectancy at birth in most LAMICs. An average life expectancy at birth is projected to rise from 66 years in 2005-2010 to 74 years in 2045-2050 and to 80 years in 2095-2100, while in high income countries the increase is expected to be from 77 years to 83 years by 2050 and to 88 years in 2100. Largely as a result of increased longevity, the proportion of older people in LAMICs is currently increasing at a rate of 3% per year. Thus, in India, by 2050 the proportion of those aged over 65 years will have increased from 5% to 14% of the total population, and the proportion of those aged over 80 years will rise from 1% to 3%, amounting to 44.2 million people.

The epidemiologic transition, which accompanies the demographic transition, refers to a progressive shift in the source of the burden of disease, away from maternal, child and communicable disorders, to chronic non-communicable disease. In the final stage of the epidemiologic transition, the stage of degenerative and man-made disease, attention shifts to chronic diseases and their prevention and control. Many personal factors; mainly behaviour and lifestyle issues such as sedentary life style, high dietary consumption of salt, fat and sugars, smoking and alcohol use; increased the occurrence of certain chronic diseases particularly cardiovascular diseases, cancers, diabetes and obesity. Chronic diseases are now the leading cause of death worldwide in all world regions, with most of the burden experienced in developing countries. Current trends in epidemiological and demographic transition in high income countries suggest that these are still progressing beyond population equilibrium, leading to “ageing and shrinking of population” characterised by birth rates below the population replacement level, an ageing population with many more older people dependent on a diminishing working
population for their economic and health care support, and medically, greater dependence on advanced technological devices and procedures to diagnose and treat diseases.\textsuperscript{6}

Increased life expectancy will influence the occurrence of chronic diseases.\textsuperscript{7} Future forecasts suggest that age-dependent chronic (non-communicable) diseases such as ischaemic heart disease, cancer, stroke, arthritis, chronic obstructive pulmonary disease, dementia, depression and other mental disorders are likely to increase in absolute numbers. These transitions are already well under way in middle-income countries, and are gathering pace in many low income countries, including some of the poorest regions in sub Saharan Africa and Asia. An important public health concern for ageing populations is whether increase in life expectancy will be accompanied by morbidity, disability, and dependence. Two opposing theories have been proposed.\textsuperscript{8} The expansion of morbidity theory assumes that increases in life expectancy arise from reduction in the fatality rate of chronic diseases rather than from a decline in the incidence of these diseases.\textsuperscript{9, 10} Thus increases in longevity should go hand in hand with an increasing number of years spent in poor health and disability. In contrast, compression of morbidity theory proposes that the onset of the chronic diseases will be postponed, but the average maximum life span will not exceed 85 years.\textsuperscript{11} In this case, morbidity will then be compressed into a short period of time at the end of life. Researchers suggest that an appropriate method to understand trends in morbidity and mortality at the population level, and in the health of ageing populations would be to investigate healthy life expectancy.\textsuperscript{12, 13}

Healthy life expectancy is the number of years that a person at a given age can expect to live in good health taking into account age-specific mortality, morbidity, and functional health status. However, drawing conclusions on compression or expansion of morbidity on the basis of health expectancies depend on how these terms are defined. The recent Global Burden of Disease review attempted projections of future trends in compression or expansion of morbidity.\textsuperscript{14} The review data supports expansion of morbidity, assuming that expansion in morbidity is an increase in the absolute number of years lost to disability as life expectancy increases. At the age 50 years, each year of gain in life expectancy corresponded to only minimal gains in healthy life expectancy.\textsuperscript{14} Therefore, projected gains in longevity will be accompanied by disability, dependence, and higher use of health services.\textsuperscript{8}
The implications are challenging for LAMICs, where health systems have limited human resource and capacity to address the care needs of an ageing population. In many developing countries, population ageing is portrayed as burden to health care and economic growth. However, these concerns regarding population ageing as an impediment to economic growth may be overblown, with increases in labour force participation rates expected for various reasons, including a likely boost of lower fertility to female labour force participation. It is widely assumed that the likelihood of older people participating in labour force decreases after 50 years of age. Older people tend to rely on their savings made during the productive lives for income in older age, resulting in dissaving and reduced stock assets. In many developing countries, pension coverage is low, and income security is shaky, leading to high rates of poverty among older people. Many older people who lack formal social security are likely to continue in the labour market. In a national representative survey conducted in India, older people who receive no pension or had not made provisions for regular income after retirement were more likely to be economically active compared to their counterparts (25% in urban and 41% in rural settings). Chronic diseases and disability evidently have a profound effect on older people’s engagement in the labour force – hence in the aforementioned India national survey, each unit increase in the number of chronic diseases or impairments was found to reduce the likelihood of remaining economically active by 0.7 times.

1.2 Accompanying Social and Economic Transitions:

In parallel to epidemiological transition, India and other developing countries are also experiencing social, cultural and economic changes. The key factors include: changes in family structures, urbanisation, and increased female participation in the labour market. Transitions in these key domains pose numerous challenges for organising health and social care for older people. The implications of these transitions on care needs of older people is discussed below in the India context, circumstances may vary in other countries and cultures.

In traditional Indian society, the joint family is a social security system that guarantees basic needs to all family members: the orphans, the disabled, older persons, the widows as well as temporarily unemployed members of the family. In a joint family, as many
as three generations or more (including all brothers and sisters and their families) live together and shared a common kitchen, property and income. The family structure is patriarchal – the oldest male member controlling all social and economic affairs. Correspondingly, the senior female member exercises authority in all household matters and influences general matters as well. Everyone earns according to his or her capacity and everyone receives according to his or her needs. Economic transactions are made between families and not between individuals. The joint family owns land in common and all income is pooled. The son inherits his father’s occupation, ensuring continuity, and customarily the expertise and knowledge of each generation is passed on to the next, which places great importance on older persons in the society. However, these traditional arrangements have been progressively eroded with educational development and technical change linked to the process of urbanization. In the modern society, older people are less likely to be consulted by their children for advice, and loss of status is likely to influence the quality of life and mental health.

Indian society is now undergoing rapid transformation under the impact of industrialization and urbanization with profound effects on the structure and function of family systems. Economic transactions are now between individuals. Individual jobs and earnings give rise to income differentials within the family. Push factors such as population pressure and pull factors such as wider economic opportunities and modern communication cause young people to migrate, especially from rural to urban areas. Work places not always being close to home, family togetherness is disrupted and family ties loosened due to distance. Differences of economic power create sharper disagreements, causing tensions in the family, and eroding the familial authority system and respect for tradition. Improved education and economic development, is promoting individualism and rational questioning of authority. Nuclear households, characterized by individuality, independence, and desire for privacy are gradually replacing the joint family system, which emphasizes the family as a unit and demands deference to age and authority. On the other hand, children who migrate often find it difficult to cope with city life and elect to leave their old parents in the village, causing problems of loneliness and lack of care givers for the old parents. Thus older people cannot depend on their children for financial support, therefore many continue to work at a reduced pace despite functional disability.
In India, the changing role of women in the family and their increased participation in the labour market is likely to impact negatively on the care arrangements of older family members. While many working couples find that the presence of parents in the home provides emotional bonding and is of great help in caring for the young children, high costs of living, and expenditure on health care make it harder for children to have parents live with them. The National Policy on Older Persons acknowledges that due to shortage of space in dwellings in urban areas and high rents, migrants prefer to leave their parents in their communities of origin. Changing roles and expectations of women, their concepts of privacy and space, desire not to be encumbered by caring responsibilities of old people for long periods, career ambitions, and employment outside the home all imply a considerably reduced availability for caregiving. Thus, younger family members (mainly children) can no longer be relied upon as comprehensive providers of physical and health care needs of older people.

Currently there is a big vacuum with respect to institutions and policies to address these challenges in India - less than 10% of the Indian population currently has health insurance (either public or private) and 90% of older people have no pension. In addition, in many developing countries like India there is no formal well established social security system to support older people. Therefore the vast majority of older people rely on their children for health and social care needs. This situation is summarised by the old age dependency ratio, defined as the number of people aged 65+ for every 100 people in the age group of 15-64. In India, the old age dependency ratio is expected to double between 2010 and 2050, from 8 to 20 per 100 people. A similar pattern is expected in some western European countries, such as Italy and Spain, affected by a very low fertility rates and high life expectancy. With large increases in the numbers of dependent people, the dependency ratio will increase from 8% to 14% in China (to 16% in Hong Kong) and from 9% to over 12% in India. The dependency ratio is controversial since many carers are themselves over the age of 60, or children, hence those that need care are not always dependent upon working age adults. Also, while the dependency ratio is intended to be an index of the impact of dependence upon the productive economy, many dependent people continue to work or make other valuable contributions to their families and society.
1.3 Burden of Chronic Disease among Older People in Low and Middle Income Countries (LAMICs)

According to the Global Burden of Disease estimates for 2004, 16.8% of the total disease burden (451 million of the 2,680 million DALYs) is attributable to conditions among those aged 60 years and over - 44.5% of the burden in high income countries (HIC), 23.1% in middle income (MIC) and 9.3% in low income countries (LIC). Among the condition clusters (Figure 1), the leading contributors globally to disease burden among older people are CVDs (157.4 million DALYs, accounting for 34.9% of the total burden among those aged 60 and over), malignant neoplasms (65.3, 14.5%), sense organ diseases (43.9, 9.7%), respiratory diseases (41.0, 9.1%), neuropsychiatric conditions (31.0, 6.9%), infectious and parasitic diseases (18.7, 4.1%), respiratory infections (17.4, 3.9%), digestive diseases (15.2, 3.4%), diabetes mellitus (13.9, 3.1%), unintentional injuries (13.0, 2.9%) and musculoskeletal diseases (12.1, 2.7%). The rank order of the contribution of these conditions does not vary greatly by country income level, but infectious and parasitic diseases make a more prominent contribution in LIC (7.7% of all DALYs in this age group), while in HIC neuropsychiatric conditions (13.9%, 3rd in rank) and musculoskeletal diseases (4.7%, 6th in rank) make a more prominent contribution. The per capita disease burden is higher among older people in LIC (872 DALYs per 1000) than in MIC (667 DALYs per 1000) and HIC (447 DALYs per 1000) accounted for by the greater burden per head of population arising from CVD, sensory, respiratory and infectious disorders in LIC (Figure 2).
Figure 1: Leading contributors to burden of disease among people aged 60 years and over in 2004 - DALYs (million) by cause and World Bank income status
India, in common with other middle income countries, is now well-advanced through the demographic and health transitions.\textsuperscript{3, 6} Data from the World Health Survey in India indicates that more than half of Indians aged 60 to 69 years reported having at least one chronic disease, with multimorbidity becoming progressively more common in older age groups (see Figure 3).
Figure 3: Distribution of chronic diseases by age group for India

Data source: Secondary data analysis was performed using World Health Survey India data presented in the Lancet paper.\textsuperscript{35}
1.4 Dependence among older people: a neglected public health problem

1.4.1 Definition

Dependence is defined as ‘the need for frequent human help or care beyond that habitually required by a healthy adult’. The most prominent factor that contributes to dependence among older people is age dependent chronic diseases.

1.4.2 Prevalence and distribution

The global distribution of dependence was recently estimated for the year 2001, with projections through to 2050, using data on patterns of morbidity from the 2004 update of the Global Burden of Disease study and United Nations population projections. Dependence was inferred from the prevalence of disabling chronic conditions, assuming that there is close relationship between the two. The prevalence of dependence and numbers affected were estimated for eight world regions as defined by the World Bank database; Established Market Economies, the former Socialist economies of Europe, sub-Saharan Africa, Latin America and the Caribbean, the Middle-Eastern crescent, China, India, and ‘other Asia and Islands’.

The total population prevalence of dependence ranged from 4.7% in Established Market Economies, Latin America and Caribbean and Middle-East Crescent, to 5.6% in China, 5.5% in India, and 5.3% in Former Socialist Economies of Europe. In 2010, 65% of dependent people were to be found living in the least developed regions (China, other Asia, India and Sub-Saharan Africa) rising to 69% by 2050. In absolute numbers, worldwide 349 million people are estimated to be needing care and support, of whom 18 million (5% of the total) are children aged under 15, and 101 million (29% of the total) older adults aged 60 years and over. As a result of demographic and epidemiological transitions, marked increase in prevalence of dependence is expected in Low and Middle Income countries. In 2050, while numbers of dependent people are expected to increase by 31% in the Established Market Economies, the numbers will increase by up to 70% in China and 100% in India, Latin America and Caribbean, Middle-East Crescent and other Asia and Islands. The proportions of dependent persons who are aged 60 and over is expected to increase markedly between 2000 and 2050, with this shift being more prominent in low and middle income countries than in high income countries. Over this period the numbers of dependent older people are forecast...
to quadruple in most LMICs, while numbers of dependent younger people in those regions remain relatively stable. By 2050 it is predicted that there will be 613 million dependent people worldwide of whom 277 million (45% of the total) would be aged 60 and over. Therefore dependence is increasingly becoming concentrated in low and middle income countries; while in all world regions it is rapidly becoming a problem that is mainly associated with older people and ageing processes, particularly chronic disease morbidity.

Epidemiological studies on care dependence are very limited in low and middle-income countries. Population-based studies from high-income countries indicate a prevalence of dependence among older people ranging between 12 and 17%. The variation in the prevalence is mainly due to the differing definitions of dependence applied in these studies. The 10/66 Dementia Research Group population-based survey provided estimations of the prevalence of dependence among older people aged 65 years in eight MICs, these include, Cuba, Dominican Republic, Puerto Rico, Venezuela, Peru, Mexico, China and India (MICs). Dependence in this study was measured more directly using a series of open-ended questions to a key informant (a family member or co-resident who knows the older person well) on need for care. Based on the informant report, older people were classified by the interviewer as no care required, care needed occasionally (‘some care’), or care needed much of the time (at least daily – ‘much care’). According to these measures, the crude prevalence of dependence varied from 2.9% in urban India to 15.7% in urban China. The prevalence was particularly high in rural Nigeria, where 24.3% needed care and 7.8% needed much care. Other than in India, the reported prevalence was lower in rural sites compared to urban areas. The prevalence of dependence nearly doubled with every five-year increase in age, and was generally lower in men than in women, particularly in older age groups (meta-analysed Prevalence Ratio 0.83, 0.75-0.95). Older people with better education tended to have a lower prevalence of dependence (prevalence ratio 0.89, 95% CI 0.84-0.94). The observed differences in the prevalence of dependence among eight MICs were mainly due to differences in the prevalence of underlying chronic diseases rather than demographic factors. The reported prevalence of dependence in the 10/66 studies
tended to be lower than that previously reported in high income country surveys. Lower prevalence in MICs could have been explained by a) an under ascertainment of dependence among older people living with their families who routinely provide high level of care and support for elderly, b) high mortality rate and short survival of older people who develop needs for care, c) lower prevalence of chronic diseases that contribute to disability and dependence.33

The 10/66 study conducted in MICs also investigated the independent contribution of chronic diseases and impairments to both disability and dependence among community dwelling older people.48, 49 After controlling for demographic factors (age, gender, marital status, education and all other health conditions), dementia, limb paralysis or weakness, stroke, depression, eyesight problems and arthritis were each independently associated with dependence, but the association with dementia was much the strongest. A similar trend was observed in the analysis on the same data set, performed using a similar approach to understand the independent contribution of chronic diseases and impairment to disability.49

1.4.3 Consequences of dependence

Dependence is a double burden – it has a profound impact on dependent older persons and also upon their families. The perceived quality of life and mental health of dependent older people is strongly associated with the level of dependence in his or her activities of daily living (ADL).50 Studies have also found strong associations between an older person’s dependence level in ADL and caregiving strain.51, 52 As a result of overwhelming caregiving activities, many caregivers experience psychological problems and poor quality of life. Studies from HICs have found strong inverse associations between an older person’s needs for care and the quality of life among family caregivers.53-55, a similar association also having been observed in a study from China.56 The 10/66 Dementia Research population based studies in Latin America, India and China confirmed strong associations between health status of the index older person (specifically depression, dementia, stroke, and physical impairments) and psychological morbidity among the co-resident key informants.57 Thus living with an older person with a disabling chronic disease seemed to be an important determinant of
co-residents’ mental health, with some, but by no means all of this effect mediated through disability and needs for care.

1.4.4 Long-term care systems for older care dependent people

In dependent older people, chronic diseases in general, and multimorbidity in particular are very common, and correlated with high levels of health service utilization and out of pocket expenditure on health.\textsuperscript{47} Out of pocket expenditure (OOP) on health has strong link with poverty, and for households just above the poverty line even a small expenditure of OOP payments will drop them below the poverty line.\textsuperscript{58, 59} Furthermore, the direct and indirect influence of dependence on families and family caregivers is daunting. In many LAMICs, older people are indivisible from their families. As a result, many family members had to cut from work to care for dependent older person in the family.\textsuperscript{60}

Formal long term care and support provided through residential care or home based community care programmes have for the most part not yet been developed in LAMICs.\textsuperscript{61} In most high income countries a range of long term care services are available to supplement or substitute the unpaid contributions of family caregivers. These include; intensive institutional care (long term hospitalisation and nursing homes); less intensive institutional care (residential homes, short stay or respite care, sheltered housing); community services (day centres and nurse visits); home care (home help, cash benefits for carers, support groups for carers). According to a recent Organisation for Economic Co-operation and Development (OECD) report, one in five users of long term care services are less than 65 years, while around half of all users are aged over 80 years. Between half and three quarters of all formal long term care is provided in home settings, with a substantial share arising from care needs of older people with dementia.\textsuperscript{62} A key recommendation from the OECD report was for the need to provide more support for family caregivers, given that high intensity caregiving is associated with a reduction in labour supply for paid work, a higher risk of poverty, and a 20% higher prevalence of mental health problems among family carers than for non-carers. Bolstering informal care is beneficial for care dependent older people, who generally prefer to be looked after by family and friends. And it is beneficial for public
finances, because it involves far less public expenditure for a given amount of care than if this was provided in the formal sector. In the absence of formal support in LAMICs, it is crucially important to encourage and support the continuation of informal support received by care dependent older people from family, relatives, and friends as unpaid carers.

1.5 What are the implications for age-appropriate health and social care in low and middle-income countries experiencing rapid population ageing?

The epidemic of chronic diseases is now very much on the development agenda, and the link to population ageing is well understood; however, until now discussions have largely focussed on the prevention of premature mortality, rather than addressing the inevitable increased demand for age-appropriate health and social care among older people, arising from the rising prevalence of age-associated chronic disease morbidity, disability and dependence. Interventions that delay the onset of dependence among frail older people, that reduce needs for care among older people who are already dependent, or that mitigate the impact of care provision should also be prioritised. Research evidence suggests two main risk markers for targeting efforts to improve the health of older people at risk of dependence: frailty (defined and described in the following section) and chronic diseases.

1.6 Frailty and its relevance to the development of interventions to prevent or mitigate dependence among older people

Frailty is a geriatric syndrome encapsulating age related decrements in organ-based and physiological system functioning that collectively confer an increased vulnerability to stressors and hence an increased risk of adverse health outcomes, and loss of functional independence among older adults. In general frailty is reported to be progressive and the syndrome is seen as a complex interaction between several factors including but not limited to ageing, inflammatory processes, chronic diseases, nutritional adequacy, cumulative negative environmental impact, genetics and lifestyle choices. Although frailty is clearly associated with increasing age, not all old people are frail. It is generally considered that frailty, unlike the ageing process, is in part reversible and amenable to interventions. The concept of frailty is increasingly proposed as an
objective clinical syndrome, with criteria for ‘diagnosis’. However, there is limited consensus as to the definition of frailty. In the earlier gerontology literature, frailty was used to describe older people with disability, dependence, ‘failure to thrive’ or being at risk of institutionalization, and near the end of life. Strawbridge and colleague assumed frailty to be a multi-dimensional concept, proposing that it could be diagnosed if two or more impairments were detected in the following four domains: nutrition, physical functioning, cognitive, and sensory function. Subsequently, Fried and colleagues proposed a ‘physical frailty’ phenotype with five indicators; weight loss; subjective exhaustion; weakness (reduced grip strength); gait speed slowing; and decline in physical activity. Both Strawbridge and Fried conceived frailty as a precursor to disability and dependence, triggered by an event or stressor that may lead to an older person progressing from a ‘pre-frail’ to frail state. Another contemporary frailty model was developed by Rockwood and colleagues, which implicitly applied a broader definition by incorporating impairments, morbidities, disability, and dependence as indicators of frailty. The original frailty index developed by this group had 70 items in its fixed set of variables, designed as continuous measure of accumulation of deficits. A short version of the index (20 items) was also investigated recently. The rational for inclusion of items into the index is based on four principles; a) that each of the health deficits should progress with age, b) that the prevalence of each should be at least 1%, c) that the deficits should be related to adverse outcomes, and d) that the set of items should collectively cover diverse organ systems. Although the frailty index is at times dichotomized in research studies to mirror dichotomous conditions, its major strength is embedded in the continuous nature of the scale. However, frailty index is difficult to administer on first contact with an older person because it can only be generated after, or in parallel with a comprehensive geriatric assessment. Therefore it may have a limited application in fledgling low resourced health care settings.

Two physical changes associated with ageing are considered by many to be core to the syndrome: loss of muscle mass and strength. The European Working Group on Sarcopenia in Older People defined sarcopenia as a syndrome characterised by progressive and generalised loss of skeletal muscle mass and strength conferring a risk of adverse outcomes. Sarcopenia is a multifactorial process that may be associated with changes in endocrine function (decreases of testosterone, estrogens and growth
hormones), physical inactivity, chronic illness (increase of cytokines) and inadequate nutrition. There is a growing consensus on other indicators of frailty including age-associated declines in endurance, balance, walking performance, physical activity, cognition and mood.\textsuperscript{70}

Estimates of the prevalence of frailty are highly variable, reflecting, to a large extent the lack of consensus regarding the definition of the syndrome, and the wide variation in criteria and assessment tools used in different studies. The prevalence of frailty ranges from 6.5\% to 20\% in community dwelling older people and from 33\% to 88\% in clinical populations.\textsuperscript{86} The predictive validity of the frailty syndrome for adverse health outcomes and increasing needs for care is, nevertheless, clearly established in cohort studies conducted in high income countries, although indicators linked to different domains of frailty seem to have variable predictive characteristics.\textsuperscript{87,88}

Recently, efforts were made to develop a better consensus on the definition of frailty, and its assessment using Delphi consensus method with experts in the field.\textsuperscript{89} None of the existing operational definitions of frailty were considered to be completely satisfactory. Some important advances were made, including consensus around; the need to define frailty as distinct from disability and needs for care; the high likelihood that frailty was a multidimensional construct; the necessity to include biomarkers as more direct and objective assessments of frailty domains, but no consensus on which specific biomarkers to include. A paucity of data from primary research was reported to be one of the reasons for inability to arrive at consensus. This is particularly true for low and middle income countries, where very little descriptive research, including research to test the relevance of the construct, has been carried out to date.

1.7. Resource limitations in primary health care systems in low and middle income countries, and their relevance to the development and delivery of interventions to frail dependent older people

In India, as in other rapidly developing middle income countries, chronic diseases among older people, and their long-term care needs are under prioritized with respect to research, policy and practice. While cancer and heart disease contribute mainly to mortality, much of the burden from other chronic diseases (stroke, dementia and mental
disorders) arises from years lived with disability. However, research suggests that the process of ageing is heterogeneous with much inter-individual variability. Therefore there may be scope for primary and secondary preventive interventions to reduce the incidence of disability and dependence, as well as interventions to promote the health of those older people who are already dependent, and to support their caregivers, hence mitigating the impact of dependence. Thus, chronic illness among older people could be better managed if such interventions proved to be efficacious, and could feasibly be made available, at low cost, through primary health care. Vertical single disease-focused programmes for older people, which might be appropriate for acute conditions, are likely to be inefficient, unaffordable and unsustainable in low income country settings. Therefore, there is a pressing need to develop new integrated models of care for primary health care systems to address the care needs of dependent older people, and support their families to optimise informal care arrangements. Given the frailty of many older people there is a need for outreach, assessing and managing patients in their own homes. However, healthcare systems and services in LMICs are often relatively unsuited to the needs of their ageing populations.

1.7.1. The problem

Traditionally, in low and many middle income countries, primary health care has been orientated to deliver a preventive and curative care model addressing the major disease burdens pre-demographic and epidemiologic transition – communicable, maternal and childhood conditions. With the coming chronic disease epidemic, a paradigm shift has been called for, from preoccupation with simple curative interventions to chronic disease management, long-term support and care at primary health care level. However, there is a widely held view that while primary health care may succeed in reducing burden in young and middle aged populations, their capacity to address long term care needs of older people is doubtful, mainly because

a) they are mostly clinic-based with little or no outreach activities, ill suited to the needs of older people among whom there is a significant prevalence of long-term disability and dependence,
b) their main focus is still on the detection and treatment of acute health conditions, with little knowledge and skills, and insufficient systems for the delivery of continuing chronic disease care.

c) complex comorbidity between physical, mental and cognitive disorders is much more common in older people than younger adults, requiring sensitive case management with coordination, and a holistic, patient-centred approach to care.

d) older people often have deficient social protection (no income, no pension, family not always available to support and provide care), which in the context of poor health and needs for care can lead to significant disadvantage.

The primary health care system in low and middle income countries is known to fall victim to the inverse care law: those most in need of care have least access.\textsuperscript{94} In many LAMICs, delivery of effective treatment at primary health care is further compromised by underfunding.\textsuperscript{65} Primary care health workers are already overburdened with many responsibilities, and lack supervision and specialist support after training. The detection and control of hypertension could be considered to be an important indicator of effectiveness of primary care for older people; data from the 10/66 Dementia Research Group’s baseline population-based surveys shows this to be clearly deficient in most LAMIC regions, particularly in the sites in India and rural China.\textsuperscript{95}

\subsection*{1.7.2 Reasons for optimism}
Without doubt, primary health care in low and middle-income countries is providing an essential health service. Although progress towards achievement of Alma Ata objectives has fallen short of expectations, the 30 years old declaration on “health for all” is still relevant for many developing countries, and renewed global interest in strengthening the capacity of primary health care to tackle chronic diseases is a promising development.\textsuperscript{96} The epidemiological transition in LAMICs has transformed thinking from the original concept of primary care as the first level care to an integrated continuum of chronic disease care and support.\textsuperscript{97} Although there are many shortcomings in scaling up services for older people in primary health care, there remain many advantages. For example, primary care remains the main entry point (first contact with health system) for many people. It has played a vital role in the delivery of prevention
and care interventions for communicable diseases such as tuberculosis, HIV, malaria. Building on this success, primary care could also play a key role in addressing the care needs of frail dependent older people. Nevertheless, the existing primary health care model requires reorientation. The progress made in developing countries in the area of managing chronic infectious diseases such as tuberculosis and HIV is proof of principle that a reorientation is possible for horizontal care and continuum of care. However, there are persisting problems such as the overall quality of health care and the lack of human resource that need to addressed at policy level for more effective management of the coming epidemic of chronic diseases among ageing populations.

1.7.3 Primary health care in the Indian context

In India, primary health care services are provided through a network of community health centres (CHC), primary health centres (PHC), and health sub-centres (HSC). These cater to a population of 80,000-120,000; 20,000-30,000; and 3000-5000, respectively, in geographically accessible areas; different norms apply for mountainous terrain and tribal areas. However, according to a recent survey of health facilities the average population served at the three facility levels was greater than that designated, 128,186, 49,193 and 8,372 respectively. Health Sub-Centres (HSC) is the first point of contact with the public health care system. For most rural and sub-urban populations, this is the nearest and most accessible public health facility. Health Sub-Centres are required to provide a range of preventive, curative, and referral services to the local population. The HSC norm is to have one female health worker/ Auxiliary Nurse Midwife (ANM) and one male health worker, known as Multi-Purpose Workers. Some HSCs also have a voluntary worker to assist the ANM.

A key component of any public health system’s capacity to deliver services is human resources. As in many developing countries, the Indian public health system faces several challenges, most prominent among them the ability to deploy and sustain the required number and skill mix of staff across the entire health system. Moreover, there is also an inequality in human resource provision, and services provided in India’s primary health care system between rich and poor areas and among states of the country. The generally low healthcare resource and inequality in provision of preventive and curative services do lead to poor access to basic health services for the
disadvantaged sections of the population, mainly people in low socioeconomic groups. Because poor people tend to use the government health services more than the affluent population, but also lack access to basic health services in government health settings, this may force many to seek health services from the private sectors despite financial barriers. Household survey data suggest that 85% of all visits for health care in rural areas, even by the poorest people, are to private practitioners.\textsuperscript{105} In turn, this may have a direct impact on health spending and household economic productivity, and those who are unable to afford private health care may refrain from seeking health care. In India only 15% of people have health insurance (primarily through their employers), and the share of out-of-pocket health expenditure exceeds 70% of total health spending.\textsuperscript{106} Thus, access to care is strongly determined by economic status.

Unfortunately, the specific needs of frail and dependent older people are often forgotten in the development of national policies, such as the Government of India National Rural Health Mission.\textsuperscript{107} In India 79% of older people live in rural areas. The National Rural Health Mission was developed to improve the health status of deprived rural population in the country by supporting community health volunteers, but to date the programme is largely focused only on maternal and child health.

1.8 Models for community intervention among frail and dependent older people

The 10/66 Dementia Research Group dementia caregiver training, education and support intervention, ‘Helping Carers to Care’ has been tested in randomised controlled trials in community settings in India, Russia and Peru, in which contexts it has been shown to be feasible and effective in reducing carer strain.\textsuperscript{108,109} This evidence has been incorporated into a more broadly based ‘package of care’ for dementia, addressing case-finding in the community, making a diagnosis, attending to physical comorbidity, and supporting and training caregivers.\textsuperscript{110} This evidence was later used to develop a WHO clinical guideline for dementia management by non-specialists in resource poor settings, as part of the WHO Mental Health Global Action Plan (MHGAP)\textsuperscript{111} dementia was one of seven priority mental and neurological conditions targeted for attention. However, while dementia and cognitive impairment make the largest single contribution to dependence among older people, such a vertical condition specific approach is unlikely to be attractive to policymakers, particularly in low income and rural settings where
dementia awareness is low, and population ageing not yet so advanced as to create a critical mass leading to advocacy and demand for services. Frailty and dependence may be more appropriate targets in such settings. Packages of care for frail dependent older people could be constructed at community level that address relevant impairments (mobility, behaviour, cognitive, nutrition, incontinence, falls) across underlying health conditions (dementia, stroke, heart disease, Parkinson’s disease, arthritis). Among the advantages of this approach is that:

1. horizontal programs are more likely to be adopted and used by hard pressed primary care services, than would be the case with single condition ‘vertical’ programs
2. the appropriate identification of dependent and/or frail older people may be a less challenging task for non-specialist health care workers than arriving at clinical diagnoses. Impairments may be relatively simply identified and assessed at the syndromal level
3. Comorbidity between diagnoses, and impairments, is relatively common, and most closely characterises frailty and dependence

More basic research is needed to construct evidence-based packages of care for frail and dependent older people that could then be formally evaluated in the public healthcare system in India.

1.8.1 Model for complex intervention development and evaluation

There are many challenges in the design, evaluation and delivery of interventions in this area, mainly due to their complexity. Complex interventions are composed of a number of elements and in this case focus on a variety of interrelated levels: the patient as an individual, their families and carers, health professionals and the organisation that offers health services to the community, in a context that is characterised by community health workers work overload and lack of time. In 2000, the Medical Research Council (MRC) of the United Kingdom defined a theoretical and methodological framework for the design and evaluation of this type of complex intervention in the clinical context (MRC 2000), updated in 2008 (MRC 2008). This framework consists of concurrent qualitative and quantitative techniques that could be executed in a sequential or iterative manner:
a) Preclinical or theoretical phase: The first step is to identify the evidence that the intervention might have the desired effect and review the theoretical basis for an intervention. This may lead to changes in the hypothesis, and improved specification of potentially active ingredients. The establishment of theoretical fundamentals and identification of the active components of interventions in the evidence base is the main focus of the preclinical phase;

b) Phase modelling phase or I: The second step in evaluating a complex intervention is to develop an understanding of each component of intervention and its possible effects on specific outcomes. This involves delineating an intervention’s components and how they inter-relate, and how active components of a complex package may relate to either surrogate or final outcomes. This may also include consulting experts in the field, qualitative interviews, focus groups, preliminary surveys, case studies, or small observational studies. Defining the intervention components, identification of potential barriers to change, and of the mechanisms through which interventions should operate would be main activities in the modelling or Phase I.

c) Phase II or exploratory trial:
The third step is evaluating complex interventions in the field; this is often a crucial stage prior to a definitive RCT. In Phase II, all the evidence gathered in the preclinical phase and phase I is brought together, culminating in a test of the feasibility of delivering the intervention and acceptability to providers, patients and family members. Different versions of the intervention may need to be tested or the intervention may have to be adapted to achieve optimal effectiveness—for example, if the proposed intensity and duration of the intervention are found to be unacceptable to participants. In Phase II, it may be appropriate to experiment the intervention, varying different components to see what effect each has on the intervention as a whole. The researcher’s ability to fully control the intervention in different settings can be established. Further, evidence can be obtained to support the theoretically expected intervention effect, to identify an appropriate control group, outcome measures, sample size estimation for a main trial, and other requirements of such a trial. Phase II trials may need to be adaptive and incremental in nature, modifying and evolving over time in the light of findings, although there may also be circumstances where Phase II trials need to be more precise and consistent about the intervention to inform key decisions
for a definitive trial. The main activity during this phase is defining the intervention design, its acceptability and feasibility, the fidelity of administration, the suitability of outcome assessments, and the possible effect sizes.\textsuperscript{113}

d) Phase III or definitive randomised controlled trial, to enable the controlled experimental evaluation of the intervention;

e) Phase IV or long-term implementation phase under real-world conditions.

Several projects have successfully applied the MRC framework for the design and evaluation of complex interventions.\textsuperscript{113} The MRC framework is strongly recommended as a tool for researchers in the design, planning and evaluation of innovative interventions to improve health.

1.8.2 Applying the MRC complex interventions framework to the development and evaluation of a community-based intervention for frail dependent older people

Implementing the MRC complex intervention framework for developing and evaluating an intervention for the prevention and management of dependence among frail and/ or dependent older people, by non-specialists in low resourced health care settings poses many challenges. These include:

- Defining an appropriate target population and identifying key indicators is crucially important. Frailty is still an evolving area of research and no consensus has been reached on frailty definitions. It is still unclear whether frailty indicators are strong predictors of adverse health outcomes, including the onset of dependence and mortality among older people in LAMICs.

- In the preclinical stage it is suggested that the first step for intervention development is to identify the evidence for an intervention that might have the desired effect. Intervention studies in this area are rarely conducted in low and middle-income countries and generalising evidence from high income countries may not be appropriate.

- In the modelling stages it is suggested that an understanding of the context in which the intervention was developed is necessary for further development of the
intervention. For example, non-specialist health care workers in the Indian context often have very limited knowledge, skills and experience for managing older people and they are heavy burdened with other routine work reflecting the current system of priorities. Therefore it still unclear whether or not non-specialist workers can be trained to identify older people who are frail, and/ or have needs for care, and can assess their specific impairments in such a way as to inform the delivery of a set of appropriate interventions at the primary health care level.

These feasibility issues are important to address in the early stages of intervention development.

1.9 Aims and objectives

My overall aim is to work on the development of a multi-component (complex) intervention package for use by non-specialist health workers for prevention and management of dependence among frail dependent older people in low resourced health care settings and to carry out initial preparatory work for a definitive randomized controlled trial. However before evaluating the intervention in the real world settings, the following research questions require convincing answers:

1. Among older people in low and middle-income countries, which impairments are common, burdensome, and associated with adverse health outcomes including the onset of dependence and mortality? Can these impairments be considered to form part of a frailty syndrome?

2. Can non-specialist health workers be trained, effectively and efficiently to identify older people who are frail and dependent or both, and are the characteristics of those individuals (high levels of multimorbidity, multipharmacy, disability and needs for care) similar to those seen in high-income countries?

3. Can non-specialist health workers correctly identify specific frailty impairments among older people whom they have identified as frail or dependent, in such a way as could be used to inform the selection of appropriate interventions?

4. Is there evidence for the effectiveness of interventions addressing impairments when applied to frail or dependent older people? Is the evidence generated in, or at least
relevant to resource poor low and middle-income country settings? Could the interventions feasibly be administered by non-specialist health care workers, and in the home setting?

5. Is it feasible to integrate a continuum of care for frail older people in low resourced health care settings, using a home-based outreach model, based upon task-shifting or task-sharing with community health workers? What are the challenges involved?

To address these questions, I aimed to conduct the following research activities

1. A secondary data analysis of longitudinal data from the baseline and incidence phases of the 10/66 Dementia Research Group population-based surveys conducted in Latin America, India and China. This would allow me to assess the prevalence of frailty indicators, and their association with the onset of dependence, and mortality.

2. Development of an evidence-based guideline for clinical intervention by non-specialist health care workers, under the auspices of, and in collaboration with the World Health Organization’s Department of Ageing and Life course.

3. Formative research in Goa, South India to:
   a. develop a brief training programme for non-specialist healthcare workers on the identification of frail dependent older people, and on the use of specially developed comprehensive geriatric assessment tool
   b. evaluate the effectiveness of the resulting community case-finding, and assessment of impairments among older frail and dependent people
   c. evaluate through a qualitative study the experiences, opinions, attitudes and beliefs among care dependent older people, their family caregivers, and professional primary health care providers, regarding the current function of the Goan primary health care system with respect to the care needs of older people, and the potential scope for reorientation to a more age-appropriate model of care.
4. The development of plans to begin to implement and evaluate evidence-based packages of care administered at home by community health workers, in the form of a detailed protocol for a Phase II trial in Goa of nutritional and exercise interventions to address undernutrition and mobility impairment respectively.

1.10 Bibliography


42. Bond J, Carstairs V. Services for elderly: a survey of the characteristics and needs of a population of 5000 older people. London, 1982 HMSO.


86. van Iersel MB, Rikkert MG. Frailty criteria give heterogeneous results when applied in clinical practice. *Journal of the American Geriatric Society* 2006; 54(4).


99. WHO. Country Health System Profile-India. 2007.


CHAPTER TWO
CHAPTER TWO:

Frailty and the prediction of dependence and mortality in low and middle-income countries – a 10/66 population-based cohort study

2.1 BACKGROUND

Most definitions of frailty share two core features; firstly, an underlying progressive age-related decline in physiologic systems, with large individual variation, and second a consequent decreased functional reserve capacity, conferring vulnerability for failure in the face of environmental stressors.¹ Sustained interest in the construct stems mainly from its predictive validity, confirmed through increased risks of adverse health and social outcomes for older people – morbidity, hospitalization, falls and fractures, disability, dependence, institutionalization and death.²⁻⁵ The process of becoming frail may be delayed, slowed, or even partly reversed by interventions targeted early in the process of functional decline.⁶ Trials of complex interventions, designed to promote independence in moderately frail older people have shown potential benefits.⁷⁻⁹ These are important findings with global implications. Demographic ageing is proceeding apace in all world regions, but the populations of many low, and particularly middle income countries are ageing more rapidly than any country in the past; two-thirds of the world’s older people live in low and middle income countries, rising to 80 % by 2050.¹⁰ While morbidities mediate the relationship between population ageing and societal costs, the relationships with chronological age are variable, and potentially amenable to influence from public health, health and social care interventions.¹¹

A clearer understanding of the nature of the frailty construct, and its relations to adverse outcomes is necessary to inform and prioritise intervention strategies. Dissatisfaction has been expressed with current models of frailty and approaches to measurement, with at least seventeen different conceptual definitions proposed.¹²⁻¹⁵ As originally defined by Fried and colleagues, frailty was a unidimensional, largely physical construct identified by the presence of three or more of five indicators - exhaustion, weight loss, weak grip strength, slow walking speed and low energy expenditure. Others have proposed widening the scope to include, for example, cognitive or sensory domains.¹⁶,¹⁷ Incorporating diseases and disability has been particularly controversial;⁴ if frailty
represents an underlying vulnerability, then disease and disability may be among the predicted outcomes rather than part of the construct itself. ‘Frailty indices’ neglect this distinction, assessing age-dependent accumulation of a wide range of health indicators; symptoms, signs, conditions, diseases and disabilities.\textsuperscript{18,19}

In summary, it is unclear whether frailty is best considered to be a unidimensional or multidimensional construct. Its boundaries remain unclear, with tentative evidence to support the inclusion of cognitive ageing as a relevant aspect of frailty. We therefore set out to test, empirically, the utility of two widely applied frailty constructs, the Fried physical frailty phenotype and the multi-dimensional frailty model proposed by Strawbridge and colleagues based on deficiencies in physical, nutritive, cognitive, and sensory domains of functioning.\textsuperscript{16,19} We had three questions. Are older people defined as frail according to these paradigms at higher risk of dependence and death, even after controlling for major chronic diseases and disability? Does the aggregate of the individual indicators provide a better prediction of these outcomes (judged by population attributable fraction derived from multivariable models) than the dichotomised or ordinal frailty scores? Are different frailty indicators differentially associated with the incidence of dependence and mortality? We addressed these questions in a large population-based cohort study in seven low and middle-income countries, in which settings little previous research into frailty had been conducted.

\textbf{2.2 METHOD}

\textbf{Settings and study design}

The 10/66 Dementia Research Group’s (10/66 DRG) population-based studies of ageing and dementia in LMIC comprised baseline surveys of all older people aged 65 years and over living in geographically defined catchment areas in seven countries, with a follow-up three to five years later. For the current analyses this comprises urban and rural sites in China, Mexico and Peru, and urban sites in Cuba, Dominican Republic, Venezuela and India. Baseline population-based surveys were carried out, between 2003 and 2007 and incidence wave follow-up assessments between 2008 and 2010. For India, the follow-up comprised a mortality sweep only. The design of the baseline and follow-up phases of the 10/66 DRG research program have been described in detail elsewhere.\textsuperscript{20} Here we will describe aspects directly relevant to the analyses presented in this paper.
Exposures - Frailty

Frailty indicators: We assessed seven indicators of frailty: exhaustion, weight loss, slow walking speed, low energy expenditure (physical inactivity), undernutrition, cognitive and sensory impairment. These were operationalized as follows

1. Exhaustion: assessed using a single item (Q.48.1) from the Geriatric Mental Status examination. Participants who reported feeling worn out or exhausted were considered to have this frailty.21

2. Weight loss: Self-reported weight loss was assessed using a single item from the Geriatric Mental State (Q53.1) “Have you lost any weight in the last three months?”. Those reporting weight loss of 10lbs (4.5kg) or more in last three months were considered to have this frailty.21

3. Slow walking speed: assessed using a standard timed walking test in which the participant was asked to walk five metres at usual speed, turn, and return to the starting point. Those taking 16 seconds or longer to complete the task were considered to have a slow walking speed.

4. Low energy expenditure: In response to the question “Taking into account both work and leisure, would you say that you are; very, fairly, not very or not at all physically active?”. Those that rated themselves not at all physical active were considered physically inactive.

5. Undernutrition: assessed through the measurement of mid-upper arm circumference (MUAC); those with MUAC <22cms were considered to be frail. This cut-point is used in the Mini Nutritional Assessment (MNA) ® to identify the most severe level of undernutrition according to this index.22

6. Cognitive impairment: Cognitive function was assessed using the Community Screening Instrument for Dementia (CSI-D) COGSCORE, which tests multiple domains of cognitive function, and has been found to have robust cross-cultural measurement properties in the 10/66 study sites.23 Frailty was defined according to the higher of two possible cut-points (29.5, for ‘possible dementia’) in order to identify cognitive impairment beyond dementia.23

7. Sensory impairment: Sensory impairment was assessed according to self-report (from two separate items) of having ‘eyesight problems’ or ‘hearing problems or deafness’, which interfered with activities to at least some extent.
Frailty phenotypes

Physical frailty model (Fried): This definition provides a specific list of five measurable items to identify frailty (exhaustion, weight loss, weak grip strength, slow walking speed and low energy expenditure). Individuals are identified as frail if they meet three or more of the five criteria, as intermediate if they meet one or two, and as non-frail if they met none of the five criteria. We applied our exhaustion, weight loss, slow walking speed and low energy expenditure indicators. Since hand grip strength was not measured we considered participants as frail if they fulfilled two or more of the four frailty indicators. Multi-dimensional frailty (Strawbridge): The original model in the Alameda County study (ACS) consisted of 16 self-reported items grouped into four domains of functioning (physical, nutrition, cognitive and sensory). The physical functioning domain included dizziness, loss of balance, weakness in the arms and weakness in the legs. The nutritive functioning domain included loss of appetite and unexplained weight loss. The cognitive functioning domain included memory and attention difficulties. The sensory functioning domain included vision and hearing difficulties in different situations. Participants were classified as frail if they had difficulties in two or more domains. We applied our slow walking speed, undernutrition, cognitive impairment and sensory impairment indicators.

Covariates - measures of socio-demographic circumstances, morbidity and disability

Age, sex and educational level were important determinants of mortality and dependence in our LMIC sites. Participants’ ages were established during the baseline interview, from stated age, official documentation, informant report, and, in the case of discrepancy, age according to an event calendar. We also recorded the participant’s gender and educational level (none; some but did not complete primary; completed primary; completed secondary; tertiary).

We summarised the impact of physical, mental and cognitive health through measurement and control for stroke, physical impairments, dementia and depression; conditions previously shown to make a substantial contribution to disability and dependence. These were assessed as follows:
1. Dementia diagnosed according to the cross-culturally developed, calibrated and validated 10/66 dementia diagnosis algorithm, on the basis of cognitive testing, clinical mental state interview and informant interview.\textsuperscript{23}

2. Self-reported stroke, confirmed by the interviewer as having characteristic symptoms lasting for more than 24 hours.\textsuperscript{28}

3. Number of self-reported limiting physical impairments from a list of nine (arthritis or rheumatism; persistent cough; breathlessness, difficulty breathing or asthma; high blood pressure; heart trouble or angina; stomach or intestine problems; faints or blackouts; paralysis, weakness or loss of one leg or arm; skin disorders such as pressure sores, leg ulcers or severe burns).

4. ICD-10 depressive episode (mild, moderate or severe), derived using a computerised algorithm applied to a structured clinical interview, the Geriatric Mental State.\textsuperscript{25}

Disability was assessed as activity limitation and participation restriction measured by the WHODAS 2.0 scale, developed by the World Health Organization as a culture-fair assessment tool for use in cross-cultural comparative epidemiological and health services research.\textsuperscript{29} We had previously demonstrated measurement invariance across the sites included in our survey.

**Outcomes**

In the incidence wave we sought to trace and re-interview all baseline survey participants. We first called on their residence at baseline, revisiting on up to four occasions. Where the participant was no longer resident we sought information regarding their vital status (if known) and/or current residence, assisted by having recorded at baseline, the names and addresses of three non-coresident friends or family members. Where participants had moved away, we sought to re-interview them, even if they had moved out of the original catchment area, by telephone if necessary. Where a participant had died, we recorded date of death, and completed a verbal autopsy interview with a suitable key informant.

Dependence (needs for care) was identified through a series of open-ended questions to a key informant: Who shares the home? What kind of help does the participant need inside and outside of the home? Who, in the family, is available to care? What help do you provide? Do you help to organise care? Is there anyone else in the family who is more involved in helping? What do they do? What about friends and neighbours, what
do they do? The interviewer then coded whether the participant required no care, care some of the time, or care much of the time.\textsuperscript{30} The same approach was used at baseline and follow-up surveys. Those with no needs for care at baseline were considered to be at risk for the incidence of dependence, and those among them who were rated as needing care some of the time or much of the time at follow-up were considered to have incident dependence.

Analysis
All data was double entered into EPIDATA software and data analysis was performed using STATA version 10. We describe the principal characteristics of the mortality cohort (the whole baseline survey sample, at risk for mortality), and the dependence cohort (those with no needs for care at baseline, hence at risk for the onset of dependence). Person-years risk for the onset of dependence was calculated as the interval between baseline and follow-up assessment, or the mid-point of this interval for those who developed dependence. We used Poisson regression to estimate incidence rate ratios (IRR) for associations with incident dependence. We used Cox’s proportional hazards regression to estimate hazard ratios for associations with mortality. Survival times were censored on the date of death, or the date of follow-up for those who were re-interviewed, or the median date of follow-up interview in that site for those refusing interview. We first assessed the association between the dichotomized frailty syndromes, defined according to Fried and Strawbridge criteria and both outcomes, controlling incrementally for age, sex and education (model 1), these factors plus health conditions (dementia, depression, number of physical impairments and stroke – model 2), and all of these factors plus disability (model 3). We ran the models in each site, and then used a fixed or random effects meta-analysis to combine them. Higgins I\textsuperscript{2} was computed, estimating the proportion of between-site variability in the estimates accounted for by heterogeneity, as opposed to sampling error; up to 40\% heterogeneity is conventionally considered negligible, while up to 60\% may reflect moderate heterogeneity.\textsuperscript{31} For Model 2 (controlling for age, sex, education and health conditions, but not disability) we used the Stata alogit command to calculate population attributable fractions (PAF \% with 95\% confidence intervals) for the contribution of Fried and Strawbridge syndromes to the incidence of dependence and mortality, comparing the dichotomised frailty syndrome with two alternative approaches; either using the number of indicators (0,1,2,3, or 4) as an ordinal scale, or the aggregate effect
of the four individual indicators. We also estimated the aggregate effect of all seven frailty indicators entered simultaneously. The STATA aflogit command estimates the individual and combined attributable fractions robustly from within the Poisson regression framework. Population attributable fractions represent the proportion of the incidence of the outcome that could theoretically be avoided if the exposure could be removed from the population, assuming causal relationships estimated free of confounding. Finally we estimated and compared the effects of each of the seven individual frailty indicators for associations with incident dependence (pooled meta-analysed IRR) and mortality (pooled meta-analysed HR) controlling as per model 2 above for demographic variables and health conditions.

2.3 RESULTS

Mean age of the participants at baseline ranged from 71.4 (6.1) in urban India to 75.4 (7.6) in Dominican Republic. The mortality cohort comprised 13,924 individuals at baseline. Vital status was ascertained at follow-up in 88.9% (n=12,373) ranging from 74.4% to 100% by site. Median years of follow-up ranged from 2.8 to 5.0 years, because of the variation among sites in the period in which the baseline surveys were conducted; overall 47,439 person years of mortality follow-up were accumulated. Mortality rates ranged from 27.3 per 1000 person years (urban Peru) to 70.0 per 1000 person years in urban India. The dependence cohort comprised 11,251 individuals, with no needs for care at baseline; 7,910 (70.3%) were successfully reinterviewed (64.6% to 77.4% by site). Deaths accounted for 1,510 (13.4%), 724 (6.4%) refused, and 1,116 (9.9%) could not be contacted. The incidence of dependence ranged from 22.3/1000 (rural China) to 50.0/1000 person years (urban China). In the full baseline sample (mortality cohort) the prevalence of frailty was 17.5% according to Fried criteria and 29.1% according to Strawbridge criteria. There was considerable variation among sites, with the highest prevalence observed in Dominican Republic (34.6% Fried and 47.8% Strawbridge) and the lowest in urban China (7.8% Fried and 11.3% Strawbridge). Prevalence of frailty according to Strawbridge criteria was generally higher than those for Fried. Among those without needs for care at baseline (the dependence cohort), the prevalence of frailty was somewhat lower, 13.5% according to Fried criteria, and 22.5% according to Strawbridge criteria (Table 1).
Table 1: Cohort characteristics

<table>
<thead>
<tr>
<th></th>
<th>Cuba</th>
<th>Dominica Republic</th>
<th>Peru (urban)</th>
<th>Peru (rural)</th>
<th>Venezuela</th>
<th>Mexico (urban)</th>
<th>Mexico (rural)</th>
<th>China (urban)</th>
<th>China (rural)</th>
<th>India (urban)</th>
<th>All centres combined</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MORTALITY COHORT</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Baseline sample (alive at baseline)</td>
<td>2813</td>
<td>2011</td>
<td>1381</td>
<td>552</td>
<td>1997</td>
<td>1003</td>
<td>1000</td>
<td>1160</td>
<td>1002</td>
<td>1005</td>
<td>13924</td>
</tr>
<tr>
<td>Vital status determined (% of baseline sample)</td>
<td>2637 (93.7%)</td>
<td>1706 (84.8%)</td>
<td>1245 (90.2%)</td>
<td>507 (91.8%)</td>
<td>1697 (84.5%)</td>
<td>909 (90.6%)</td>
<td>933 (93.3%)</td>
<td>989 (85.2%)</td>
<td>1002 (100.0%)</td>
<td>748 (74.4%)</td>
<td>12373 (88.9%)</td>
</tr>
<tr>
<td>Deaths (% of those with vital status determined)</td>
<td>609 (23.1%)</td>
<td>467 (27.4%)</td>
<td>98 (7.9%)</td>
<td>54 (10.6%)</td>
<td>200 (11.8%)</td>
<td>99 (10.9%)</td>
<td>110 (11.8%)</td>
<td>224 (22.6%)</td>
<td>291 (29.0%)</td>
<td>154 (20.6%)</td>
<td>2306 (18.6%)</td>
</tr>
<tr>
<td>Person years of follow-up</td>
<td>10852.5</td>
<td>7448.6</td>
<td>3592.7</td>
<td>1764.1</td>
<td>7031.1</td>
<td>2689.3</td>
<td>4630.6</td>
<td>4563.3</td>
<td>2198.7</td>
<td>47437.9</td>
<td></td>
</tr>
<tr>
<td>Mortality rate (per 1000 person years)</td>
<td>56.1 (51.8-60.7)</td>
<td>62.7 (57.2-68.6)</td>
<td>27.3 (22.3-33.1)</td>
<td>30.6 (23.2-39.6)</td>
<td>28.4 (24.7-32.6)</td>
<td>37.1 (30.3-45.0)</td>
<td>40.9 (33.8-49.1)</td>
<td>48.4 (42.3-55.0)</td>
<td>63.8 (56.8-71.4)</td>
<td>70.0 (59.6-81.8)</td>
<td>56.1 (51.8-60.7)</td>
</tr>
<tr>
<td>Median years of follow-up (25th and 75th centile)</td>
<td>4.2 (3.5-5.0)</td>
<td>5.0 (3.6-5.1)</td>
<td>2.8 (2.4-3.4)</td>
<td>3.7 (3.6-3.8)</td>
<td>4.2 (4.0-4.8)</td>
<td>3.0 (2.9-3.2)</td>
<td>3.0 (2.9-3.1)</td>
<td>4.9 (4.6-5.3)</td>
<td>4.9 (4.4-5.2)</td>
<td>2.9 (2.5-3.6)</td>
<td>3.9 (3.0-4.9)</td>
</tr>
<tr>
<td>Mean age at baseline (SD)</td>
<td>75.2 (7.1)</td>
<td>75.4 (7.6)</td>
<td>75.0 (7.4)</td>
<td>74.1 (7.3)</td>
<td>72.3 (6.8)</td>
<td>74.4 (6.6)</td>
<td>74.1 (6.6)</td>
<td>74.1 (6.3)</td>
<td>72.4 (6.0)</td>
<td>71.4 (6.1)</td>
<td>74.1 (7.0)</td>
</tr>
<tr>
<td>Female sex (%)</td>
<td>1714 (65.0%)</td>
<td>1130 (66.3%)</td>
<td>805 (64.7%)</td>
<td>270 (53.2%)</td>
<td>1072 (63.2%)</td>
<td>605 (66.5%)</td>
<td>569 (60.9%)</td>
<td>560 (56.6%)</td>
<td>556 (55.5%)</td>
<td>422 (57.2%)</td>
<td>7703 (62.3%)</td>
</tr>
<tr>
<td>Did not complete primary education (%)</td>
<td>661 (25.1%)</td>
<td>1211 (71.7%)</td>
<td>114 (9.2%)</td>
<td>206 (41.3%)</td>
<td>499 (30.0%)</td>
<td>530 (58.4%)</td>
<td>787 (84.2%)</td>
<td>346 (35.0%)</td>
<td>693 (69.2%)</td>
<td>492 (66.0%)</td>
<td>5539 (45.1%)</td>
</tr>
<tr>
<td></td>
<td>Fried</td>
<td>Strawbridge</td>
<td>DEPENDENCE COHORT</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>----------------</td>
<td>-------------</td>
<td>-------------</td>
<td>-------------------</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>554 (21.0%)</td>
<td>591 (34.6%)</td>
<td>2225 (74.7%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>591 (25.9%)</td>
<td>323 (21.0%)</td>
<td>1770 (64.6%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>87 (11.0%)</td>
<td>354 (25.9%)</td>
<td>2054 (66.6%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>92 (10.1%)</td>
<td>130 (25.9%)</td>
<td>1246 (66.6%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>79 (8.5%)</td>
<td>340 (25.9%)</td>
<td>1754 (66.6%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>77 (7.8%)</td>
<td>208 (25.9%)</td>
<td>889 (66.6%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>87 (8.7%)</td>
<td>338 (25.9%)</td>
<td>918 (66.6%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>85 (11.4%)</td>
<td>112 (25.9%)</td>
<td>977 (66.6%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2162 (17.5%)</td>
<td>225 (25.9%)</td>
<td>948 (66.6%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Baseline sample (no needs for care at baseline)  
Re-interviewed (% of baseline sample)  
Incident dependence (% of those re-interviewed)  
Person years of follow-up  
Incidence rate (per 1000 person years)  
Median years of follow-up (25th and 75th centile)  
Mean age at baseline (SD)  
Female sex (%)  
Did not complete primary education (%)
<table>
<thead>
<tr>
<th></th>
<th>Fried</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>258 (15.5%)</td>
<td>347 (30.3%)</td>
<td>185 (22.3%)</td>
<td>58 (14.5%)</td>
<td>89 (7.7%)</td>
<td>57 (8.3%)</td>
<td>37 (5.6%)</td>
<td>5 (0.7%)</td>
<td>33 (4.7%)</td>
<td>-</td>
<td>1069 (13.5%)</td>
</tr>
<tr>
<td>Strawbridge</td>
<td>397 (23.9%)</td>
<td>457 (39.9%)</td>
<td>181 (21.8%)</td>
<td>84 (21.1%)</td>
<td>182 (15.8%)</td>
<td>121 (17.6%)</td>
<td>221 (33.3%)</td>
<td>23 (3.4%)</td>
<td>115 (16.5%)</td>
<td>-</td>
<td>1781 (22.5%)</td>
</tr>
</tbody>
</table>
The meta-analysed effects of frailty on the incidence of dependence and mortality are presented in (Table 2). Both the Fried and the Strawbridge dichotomous frailty definitions independently predicted the onset of dependence and mortality. Effect sizes were progressively attenuated after controlling sequentially for demographic factors, chronic health conditions and disability, but remained statistically significant. The heterogeneity among sites in the estimates of association are minimal to moderate throughout, and only those for the association between frailty according to the Strawbridge criteria and mortality are statistically significant.

### Table 2: Meta-analysed effects of dichotomous frailty indicators (Fried and Strawbridge) on the incidence of dependence and mortality, controlling sequentially for health conditions and disability

<table>
<thead>
<tr>
<th></th>
<th>Model 1 (age, sex and education)</th>
<th>Model 2 (model 1 + health conditions(^1))</th>
<th>Model 3 (model 2 + disability(^2))</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fried</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dependence (IRR(^3))</td>
<td>F(^3)=1.77 (1.53-2.04)</td>
<td>F=1.43 (1.24-1.64)</td>
<td>F=1.28 (1.10-1.48)</td>
</tr>
<tr>
<td>Heterogeneity</td>
<td>Cochrane’s Q 14.1, 8 df, p=0.08, Higgins I(^2) 43 (0-74)</td>
<td>Cochrane’s Q 13.9, 8 df, p=0.09, Higgins I(^2) 42 (0-73)</td>
<td>Cochrane’s Q 10.0, 8 df, p=0.27, Higgins I(^2) 20 (0-61)</td>
</tr>
<tr>
<td>Mortality (HR(^5))</td>
<td>F=1.89 (1.72-2.08), R(^\delta)=1.97 (1.68-2.31)</td>
<td>F=1.51 (1.36-1.68)</td>
<td>F=1.18 (1.06-1.33)</td>
</tr>
<tr>
<td>Heterogeneity</td>
<td>Cochrane’s Q 20.1, 9 df, p=0.02, Higgins I(^2) 55 (9-78)</td>
<td>Cochrane’s Q 15.0, 9 df, p=0.09, Higgins I(^2) 40 (0-71)</td>
<td>Cochrane’s Q 10.8, 9 df, p=0.29, Higgins I(^2) 16 (0-58)</td>
</tr>
<tr>
<td><strong>Strawbridge</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dependence (IRR)</td>
<td>F=2.15 (1.88-2.46)</td>
<td>F=1.46 (1.27-1.68)</td>
<td>F=1.36 (1.18-1.57)</td>
</tr>
<tr>
<td>Heterogeneity</td>
<td>Cochrane’s Q 2.9, 8 df p=0.95, Higgins I(^2) 0 (0-65)</td>
<td>Cochrane’s Q 6.1, 8 df p=0.64, Higgins I(^2) 0 (0-65)</td>
<td>Cochrane’s Q 3.5, 8 df p=0.90, Higgins I(^2) 0 (0-65)</td>
</tr>
<tr>
<td>Mortality (HR)</td>
<td>F=1.96 (1.78-2.15), R=1.94 (1.66-2.28)</td>
<td>F=1.54 (1.39-1.71), R=1.53 (1.29-1.81)</td>
<td>F=1.38 (1.24-1.54), R=1.36 (1.14-1.62)</td>
</tr>
<tr>
<td>Heterogeneity</td>
<td>Cochrane’s Q 21.1, 9 df, p=0.01, Higgins I(^2) 57 (14-79)</td>
<td>Cochrane’s Q 19.7, 9 df, p=0.02, Higgins I(^2) 54 (7-78)</td>
<td>Cochrane’s Q 19.8, 9 df, p=0.02, Higgins I(^2) 55 (8-78)</td>
</tr>
</tbody>
</table>

1. 10/66 or DSM-IV dementia diagnosis, ICD-10 depression, number of physical impairments and stroke; 2. WHODAS 2.0 Disability Assessment Scale; 3. IRR = Incidence rate ratio; 4. F = Pooled fixed effect; 5. HR = Hazard ratio; 6. R = Pooled random effect (estimated only in the presence of statistically significant heterogeneity)
Next, we compared the Fried and Strawbridge frailty phenotypes as dichotomised syndromes, ordinal scales (0,1,2,3,4) and as the aggregate of their individual indicators, with respect to the PAFs for their independent contribution to the onset of dependence (table 3) and mortality (table 4). For both outcomes, the contribution of ordinal scale and the aggregate of the individual indicators of frailty consistently exceeded those for the dichotomous definition, and the aggregate contribution of the individual indicators generally exceeded that of the ordinal scale. For the Fried model, the PAFs for dependence for the dichotomous definition range from 3.1% to 26.7% (weighted mean 9.5%), for the ordinal scale from 3.3% to 43.4% (weighted mean 18.6%), and for the individual indicators from 3.6% to 62.1% (weighted mean 23.2%). For the Strawbridge model, the PAFs for dependence for the dichotomous definition range from 7.0% to 31.0% (weighted mean 18.0%), for the ordinal scale from 5.5% to 47.7% (weighted mean 31.3%), and for the individual indicators from 15.2% to 58.3% (weighted mean 36.9%). The PAFs for mortality for the dichotomous definition of the Fried frailty criteria range from 0.8% to 18.9% (weighted mean 10.5%), for the ordinal scale from 0.6% to 40.3% (weighted mean 20.9%), and for the individual indicators from 8.9% to 46.5% (weighted mean 25.1%). For the Strawbridge model, the PAF for dependence for the dichotomous definition range from 5.3% to 42.2% (weighted mean 19.6%), for the ordinal scale from 4.3% to 49.8% (weighted mean 28.3%), and for the individual indicators from 7.7% to 56.2% (weighted mean 33.4%). In general, the aggregate effect of all seven indicators exceeded that for any of the Fried or Strawbridge operationalisations with a weighted mean PAF of 41.8% for dependence and 38.3% for mortality.
Table 3: Population attributable fractions (% with 95% confidence intervals) for the independent contribution of frailty to the incidence of dependence, when operationalized as dichotomous categories, ordinal scales or individual indicators

<table>
<thead>
<tr>
<th></th>
<th>Fried</th>
<th></th>
<th>Strawbridge</th>
<th></th>
<th>Individual indicators from both frailty paradigms</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Dichotomous</td>
<td>Ordinal scale</td>
<td>Individual indicators</td>
<td>Dichotomous</td>
</tr>
<tr>
<td>Cuba</td>
<td>10.3</td>
<td>(2.9-17.2)</td>
<td>27.0 (15.2-37.2)</td>
<td>28.0 (16.4-38.1)</td>
<td>23.5 (10.7-34.5)</td>
</tr>
<tr>
<td>Dominican Republic</td>
<td>3.1</td>
<td>(0.0-8.6)</td>
<td>3.3 (0.0-15.3)</td>
<td>3.6 (0.0-8.3)</td>
<td>7.6 (0.0-18.4)</td>
</tr>
<tr>
<td>Peru (urban)</td>
<td>9.4</td>
<td>(0.0-20.1)</td>
<td>11.1 (0.0-29.2)</td>
<td>17.8 (0.0-39.4)</td>
<td>31.0 (4.2-50.3)</td>
</tr>
<tr>
<td>Peru (rural)</td>
<td>26.7</td>
<td>(2.3-45.2)</td>
<td>43.4 (0.0-68.8)</td>
<td>62.1 (0.0-86.7)</td>
<td>22.9 (0.0-48.5)</td>
</tr>
<tr>
<td>Venezuela</td>
<td>15.5</td>
<td>(3.9-25.7)</td>
<td>30.8 (12.7-45.1)</td>
<td>30.4 (10.1-46.1)</td>
<td>21.5 (6.1-34.4)</td>
</tr>
<tr>
<td>Mexico (urban)</td>
<td>5.9</td>
<td>(0.0-18.5)</td>
<td>16.2 (0.0-40.0)</td>
<td>24.8 (0.0-49.9)</td>
<td>17.0 (0.0-35.2)</td>
</tr>
<tr>
<td>Mexico (rural)</td>
<td>11.1</td>
<td>(0.0-23.3)</td>
<td>13.0 (0.0-32.7)</td>
<td>27.0 (0.0-47.0)</td>
<td>7.0 (0.0-25.0)</td>
</tr>
<tr>
<td>China (urban)</td>
<td>10.5</td>
<td>(0.0-33.2)</td>
<td>24.6 (0.0-46.4)</td>
<td>26.1 (0.0-47.5)</td>
<td>14.4 (0.0-34.9)</td>
</tr>
<tr>
<td>China (rural)</td>
<td>Inverse association</td>
<td>Inverse association</td>
<td>8.1 (0.0-43.8)</td>
<td>13.0 (0.0-37.6)</td>
<td>5.7 (0.0-43.3)</td>
</tr>
<tr>
<td>Weighted mean</td>
<td>9.5</td>
<td>18.6</td>
<td>23.2</td>
<td>18.0</td>
<td>31.3</td>
</tr>
</tbody>
</table>

(continued on next page)
Table 4: Population attributable fractions (% with 95% confidence intervals) for the independent contribution of frailty to the incidence of mortality, when operationalised as dichotomous categories, ordinal scales or individual indicators

<table>
<thead>
<tr>
<th></th>
<th>Fried</th>
<th>Strawbridge</th>
<th>Individual indicators from both frailty paradigms</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Dichotomous</td>
<td>Ordinal scale</td>
<td>Individual indicators</td>
</tr>
<tr>
<td>Cuba</td>
<td>8.8 (6.5-11.0)</td>
<td>16.5 (12.0-20.8)</td>
<td>13.6 (8.1-18.7)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>20.1 (15.5-24.4)</td>
<td>30.2 (24.3-35.6)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>30.4 (24.0-36.2)</td>
<td>29.8 (22.8-36.1)</td>
</tr>
<tr>
<td>Dominican Republic</td>
<td>5.4 (2.3-7.7)</td>
<td>17.8 (12.4-22.8)</td>
<td>20.5 (14.9-25.7)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>13.1 (8.6-17.5)</td>
<td>21.8 (14.4-28.6)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>30.0 (23.4-36.0)</td>
<td>33.5 (27.2-39.3)</td>
</tr>
<tr>
<td>Peru (urban)</td>
<td>13.6 (4.9-21.6)</td>
<td>26.0 (11.9-37.9)</td>
<td>40.0 (22.2-53.8)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>42.2 (22.5-56.9)</td>
<td>49.8 (28.7-64.6)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>56.2 (38.9-68.6)</td>
<td>56.7 (39.5-69.0)</td>
</tr>
<tr>
<td>Peru (rural)</td>
<td>0.8 (0.0-10.1)</td>
<td>0.6 (0.0-19.7)</td>
<td>13.6 (0.0-30.1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>27.5 (5.5-44.4)</td>
<td>29.2 (0.0-52.7)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>34.5 (7.1-53.9)</td>
<td>34.9 (3.8-55.9)</td>
</tr>
<tr>
<td>Venezuela</td>
<td>17.5 (11.2-23.4)</td>
<td>32.5 (23.0-40.8)</td>
<td>38.1 (24.5-49.3)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>21.9 (12.4-30.4)</td>
<td>41.8 (29.3-52.1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>51.6 (37.8-62.3)</td>
<td>55.0 (41.3-65.6)</td>
</tr>
<tr>
<td>Mexico (urban)</td>
<td>12.8 (2.9-21.7)</td>
<td>20.3 (0.0-36.8)</td>
<td>8.9 (0.2-16.8)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>15.7 (0.7-28.4)</td>
<td>29.2 (4.1-47.7)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>22.3 (0.0-44.9)</td>
<td>24.1 (1.8-41.4)</td>
</tr>
<tr>
<td>Mexico (rural)</td>
<td>18.9 (9.4-27.4)</td>
<td>40.3 (25.8-52.0)</td>
<td>46.5 (32.3-57.8)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>10.9 (0.0-23.6)</td>
<td>16.4 (0.0-33.9)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>36.3 (17.3-50.9)</td>
<td>49.0 (35.1-59.9)</td>
</tr>
<tr>
<td>China (urban)</td>
<td>14.5 (10.4-18.4)</td>
<td>30.7 (24.6-36.2)</td>
<td>31.7 (25.1-37.8)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5.3 (0.0-12.2)</td>
<td>17.1 (6.8-26.2)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>26.4 (16.3-35.3)</td>
<td>36.1 (26.1-44.8)</td>
</tr>
<tr>
<td>China (rural)</td>
<td>3.4 (1.7-5.1)</td>
<td>5.9 (0.5-11.0)</td>
<td>25.7 (14.5-35.3)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No association</td>
<td>4.3 (0.0-10.5)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7.7 (1.4-13.6)</td>
<td>33.8 (18.9-46.0)</td>
</tr>
<tr>
<td>India (urban)</td>
<td>5.4 (0.1-10.4)</td>
<td>6.6 (0.0-17.1)</td>
<td>13.8 (4.9-21.9)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>19.7 (11.7-27.0)</td>
<td>30.0 (18.0-40.3)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>25.1 (9.6-37.9)</td>
<td>25.3 (10.4-37.7)</td>
</tr>
<tr>
<td>Weighted mean</td>
<td>10.5</td>
<td>20.9</td>
<td>25.1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>19.6</td>
<td>28.3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>33.4</td>
<td>38.3</td>
</tr>
</tbody>
</table>
In table 5, the independent associations between individual frailty indicators (from both frailty paradigms) and incident dependence and mortality are presented. Data from all sites were combined together and meta-analysed to estimate pooled effect sizes for incidence rate ratio (IRR) for dependence and hazard ratio (HR) for mortality. After controlling for demographic factors and chronic health conditions, weight loss, underactivity, slow walking speed, and cognitive impairment were associated with both outcomes. Undernutrition (arm circumference) was particularly strongly associated with mortality, but was not associated with incident dependence. Conversely, sensory impairment was weakly associated with onset of dependence, but was not associated with mortality. Exhaustion was associated with neither outcome. Heterogeneity in the effect sizes among sites was negligible to moderate, and only statistically significant for the associations between slow walking speed and cognitive impairment with incident dependence, and for the association of weight loss with mortality.
<table>
<thead>
<tr>
<th>Frailty indicator</th>
<th>Associations with incident dependence</th>
<th>Associations with mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mutually adjusted (^1) pooled effect size (IRR (^2))</td>
<td>Mutually adjusted (^1) pooled effect size (HR (^3))</td>
</tr>
<tr>
<td><strong>Exhaustion</strong></td>
<td>(F=1.03 ) (0.90-1.17)</td>
<td>(F=1.00 ) (0.90-1.12)</td>
</tr>
<tr>
<td></td>
<td>(Cochrane’s Q 8.6, 8 \ df, )</td>
<td>(Cochrane’s Q 10.4, 9 \ df, )</td>
</tr>
<tr>
<td></td>
<td>(p=0.37 )</td>
<td>(p=0.32 )</td>
</tr>
<tr>
<td></td>
<td>(Higgins I^2 7 ) (0-67)</td>
<td>(Higgins I^2 13 ) (0-55)</td>
</tr>
<tr>
<td><strong>Weight loss</strong></td>
<td>(F=1.31 ) (1.06-1.61)</td>
<td>(F=1.40 ) (1.19-1.64)</td>
</tr>
<tr>
<td></td>
<td>(Cochrane’s Q 8.4, 6 \ df, )</td>
<td>(Cochrane’s Q 17.7, 9 \ df, )</td>
</tr>
<tr>
<td></td>
<td>(p=0.21 )</td>
<td>(p=0.04 )</td>
</tr>
<tr>
<td></td>
<td>(Higgins I^2 28 ) (0-69)</td>
<td>(Higgins I^2 49 ) (0-75)</td>
</tr>
<tr>
<td><strong>Under activity</strong></td>
<td>(F=1.35 ) (1.10-1.67)</td>
<td>(F=1.53 ) (1.32-1.88)</td>
</tr>
<tr>
<td></td>
<td>(Cochrane’s Q 11.8, 8 \ df, )</td>
<td>(Cochrane’s Q 12.8, 9 \ df, )</td>
</tr>
<tr>
<td></td>
<td>(p=0.16 )</td>
<td>(p=0.17 )</td>
</tr>
<tr>
<td></td>
<td>(Higgins I^2 32 ) (0-69)</td>
<td>(Higgins I^2 30 ) (0-66)</td>
</tr>
<tr>
<td><strong>Slow walking speed</strong></td>
<td>(F=1.28 ) (1.12-1.47)</td>
<td>(F=1.36 ) (1.21-1.51)</td>
</tr>
<tr>
<td></td>
<td>(R=1.30 ) (1.05-1.61)</td>
<td>(Cochrane’s Q 14.7, 9 \ df, )</td>
</tr>
<tr>
<td></td>
<td>(Cochrane’s Q 17.0, 8 \ df, )</td>
<td>(p=0.10 )</td>
</tr>
<tr>
<td></td>
<td>(p=0.03 )</td>
<td>(Higgins I^2 39 ) (0-71)</td>
</tr>
<tr>
<td></td>
<td>(Higgins I^2 53 ) (0-78)</td>
<td></td>
</tr>
<tr>
<td><strong>Sensory impairment</strong></td>
<td>(F=1.14 ) (1.01-1.29)</td>
<td>(F=1.03 ) (0.93-1.14)</td>
</tr>
<tr>
<td></td>
<td>(Cochrane’s Q 7.2, 8 \ df, )</td>
<td>(Cochrane’s Q 6.9, 9 \ df, )</td>
</tr>
<tr>
<td></td>
<td>(p=0.52 )</td>
<td>(p=0.65 )</td>
</tr>
<tr>
<td></td>
<td>(Higgins I^2 0 ) (0-65)</td>
<td>(Higgins I^2 0 ) (0-62)</td>
</tr>
<tr>
<td><strong>Cognitive impairment</strong></td>
<td>(F=1.53 ) (1.30-1.79)</td>
<td>(F=1.38 ) (1.23-1.54)</td>
</tr>
<tr>
<td></td>
<td>(R=1.48 ) (1.16-1.90)</td>
<td>(Cochrane’s Q 15.1, 9 \ df, )</td>
</tr>
<tr>
<td></td>
<td>(Cochrane’s Q 16.9, 8 \ df, )</td>
<td>(p=0.09 )</td>
</tr>
<tr>
<td></td>
<td>(p=0.03 )</td>
<td>(Higgins I^2 40 ) (0-71)</td>
</tr>
<tr>
<td></td>
<td>(Higgins I^2 53 ) (0-78)</td>
<td></td>
</tr>
<tr>
<td><strong>Undernutrition (arm circumference &lt; 22cms)</strong></td>
<td>(F=1.11 ) (0.89-1.38)</td>
<td>(F=1.72 ) (1.47-2.01)</td>
</tr>
<tr>
<td></td>
<td>(Cochrane’s Q 10.4, 6 \ df, )</td>
<td>(Cochrane’s Q 9.2, 9 \ df, )</td>
</tr>
<tr>
<td></td>
<td>(p=0.11 )</td>
<td>(p=0.41 )</td>
</tr>
<tr>
<td></td>
<td>(Higgins I^2 42 ) (0-76)</td>
<td>(3 ) (0-63)</td>
</tr>
</tbody>
</table>

1. The effect of each frailty indicator is adjusted for all of the others, in models also controlling for age group, sex, level of education, and health conditions (10/66 or DSM-IV dementia diagnosis, ICD-10 depression, number of physical impairments and stroke)
2. IRR = Incidence rate ratio; 3. HR = Hazard ratio; 4. F = Pooled fixed effect
5. R = Pooled random effect (estimated only in the presence of statistically significant heterogeneity)
2.4 DISCUSSION

We have found, in a large population-based cohort study in seven low and middle income countries, that both the Fried and Strawbridge frailty syndromes predict the onset of dependence and mortality, even after adjusting for chronic diseases and baseline WHODAS II disability score.(Table 2) However, analysis of population attributable fractions suggests that treating the number of underlying frailty indicators as ordinal scales, and, to an even greater extent, considering the aggregate effect of individual frailty indicators, provides a better overall prediction of risk of experiencing these adverse outcomes. Combining the seven indicators underlying both syndromes provided the best overall prediction. While some of these seven indicators (weight loss, under activity, slow walking speed and cognitive impairment) predicted both dependence and mortality, undernutrition predicted mortality only, and sensory impairment dependence only. Self-reported exhaustion predicted neither outcome.

The analyses were conducted on large population-based samples in Latin America, India and China, hence allowing us to assess the consistency or cultural specificity of the observed associations. The study design was prospective, limiting information bias, with modest attrition. Measurement error will have occurred, but, if random, the effect will have been systematically to underestimate the effect of frailty exposures on mortality and dependence. We studied a wide range of frailty indicators comprising most of those included in the most widely used frailty phenotypes. Walking speed, undernutrition and cognitive impairment were measured objectively, an advantage over some other studies that relied entirely on self-report. Visual and auditory impairment probably would also have been more accurately and appropriately assessed by objective testing. Hand grip strength was not measured in our surveys, hence we could only make an approximation to the Fried criteria. In other longitudinal studies the association between hand grip strength and adverse outcomes was attenuated when adjusted for other frailty indicators and potential confounders. We were able to control fairly comprehensively for physical, mental and cognitive disorders that are the major predictors of mortality and dependence, and for disability, hence precisely estimating the independent contribution of frailty to those outcomes.
Our findings regarding the predictive validity of the two frailty models are partly consistent with other studies. In a four-year prospective community-based cohort study in three French cities the Fried frailty phenotype was associated with an increased incidence of disability, independent of cognitive impairment. In the 12 country Survey of Health and Retirement in Europe (SHARE) those meeting Fried frailty criteria had nearly a five times higher odds of death compared to non-frail individuals. Most frailty studies have been conducted in developed countries. Two prospective studies from China, and one from Mexico have demonstrated prospective associations between frailty indices (a composite of indicators of physical impairment, chronic disease diagnoses, activity limitation and disability) and mortality. The justification for considering frailty as a unitary construct (‘frailty’ rather than ‘frailties’) seems not previously to have been subjected to critical empirical examination. Our finding, that slow gait speed, low physical inactivity, weight loss, and cognitive impairment were associated both with mortality and dependence, but that self-reported exhaustion was associated with neither outcome replicates precisely a finding from an earlier north American cohort study. Variable predictive associations among frailty indicators explain our finding that the overall prediction of mortality and dependence is significantly reduced when the information from the various indicators is summarised as a dichotomous syndrome. The implicit assumption, that these are all indicators of a unidimensional latent trait is challenged by our finding that the prediction provided by the aggregate of individual indicators exceeds that when the indicators are summed to form an ordinal scale.

The measurement models for the Fried and Strawbridge phenotypes are psychometrically naïve, and further empirical work on the construct validity of these and other approaches to assessing frailty should be a priority for future research. However, even at this early stage in the conceptualisation and measurement of frailty, it seems clear that information regarding variation in patterns of age-related change in physiologic and organ/ system function may help to stratify risk for dependence and death, over and above any prediction provided by clinical diagnoses and disability. These are key outcomes in monitoring the public health response to the challenges of
global population ageing, in particular the holy grail of compression of morbidity. Frailty indicators may assist in developing and targeting effective primary and secondary prevention strategies to delay or prevent the onset of dependence, and in providing holistic, coordinated care for older people with complex multimorbidities, particularly at the primary care level.\textsuperscript{39} Evidence presented here supports the argument that frailty is likely to be a multidimensional construct, and that we need therefore to consider ‘frailties’ in different organ-based and physiological systems, and their individual and joint impacts on functional decline, loss of independence and survival. There are likely to be benefits in moving beyond the Fried physical frailty phenotype to consider at least the effects of chronic undernutrition, sensory and cognitive impairment. A broader range of frailty indicators may cluster into meaningful sub-domains of frailty with common underlying patho-physiological mechanisms.\textsuperscript{40} It is likely that more objective measurement of frailty indicators (including underlying physiological biomarkers) may provide better risk stratification. A better understanding of the frailty phenotypes and the pathways to adverse outcomes could inform simple multi-dimensional assessment and multi-component intervention strategies with considerable potential to add life to years as well as years to life.\textsuperscript{41} Such approaches may have particular value in resource poor low and middle-income country settings, where population ageing is proceeding most rapidly, dependence is already highly prevalent\textsuperscript{27} and where numbers of dependent older people are forecast to quadruple between 2000 and 2050.\textsuperscript{42}
2.5 BIBLIOGRAPHY


17. Avila-Funes JA, Pina-Escudero SD, Aguilar-Navarro S, Gutierrez-Robledo LM, Ruiz-Arregui L, Amieva H. Cognitive impairment and low physical activity are the


CHAPTER THREE
CHAPTER THREE:

Validity of community case finding method and EASY Care assessment for primary health care clinicians in low resourced health care settings

3.1 BACKGROUND:

Driven by population ageing, the numbers of dependent older people in India are forecast to increase from 15.5 million in 2010 to 49.7 million by 2050. This trebling of numbers, an increase of 34.2 million, accounts for the bulk of the 49.7 million increase (from 63.6 million to 113.3 million) in the total numbers of dependent persons over this period. This unprecedented increase in the numbers of dependent older people will markedly increase the need for medical and social care.\(^1\) \(^2\) Findings from the 10/66 Dementia Research Group surveys in India and other low and middle income country settings indicated a relatively high level of utilization of health services in the urban and rural settings in Tamil Nadu, South India.\(^3\) However, government primary care services were little used, with a predilection instead for hospital outpatient and private health care, and hence a relatively high proportion of consultations for which out-of-pocket payments were incurred. The high cost of services coupled with low flexibility of payment options, and negative cultural perceptions regarding the benefits of medical intervention for older people have been reported as primary determinants of health service utilization among older people.\(^4\)

Limitations in physical mobility, linked to ageing and chronic disease will tend to exclude frail older people from access to low cost, affordable basic health care.\(^3\) \(^5\) In India, the coverage of specialist geriatric care services is very limited, mainly to large cities.\(^6\) Even when made available and affordable, lack of community outreach resulted in very small proportion of older people being aware of such services or using them.\(^7\) \(^8\) Community services provided by primary health care could have much to offer frail and dependent older people and their families, particularly if assessments and interventions could be conducted at home (see Chapters three and seven). However, the first step, to circumvent limited access, and low levels of help-seeking, would be case-finding in the community.
In a study conducted nearly 15 years ago in Goa, it was established through qualitative research that primary care doctors had good technical knowledge of dementia, but reported rarely if ever seeing cases in their primary healthcare clinics. However, the CHWs who visited every home in the local community as part of their health promotion and disease prevention work (principally orientated to maternal and child health), reported seeing many such cases, and recognized the high burden that it caused to families. Their knowledge of the condition was, however, very limited, tending, in common with others in the community, to see the problem as a normal part of ageing rather than a medical condition. The 10/66 Dementia Research Group in Kerala, South India subsequently developed a half day training program for CHWs providing them with basic information regarding the onset and course and typical features of dementia. CHWs, thus trained, then returned to their communities charged with identifying cases among the households that they served. Of the 1979 persons aged 60 and over 51 (2.6%) were identified as having possible dementia, of whom 33 (65%) were confirmed by clinician diagnosis, the others having other functional or organic mental disorders with considerable unmet needs. A similar study conducted in a rural town in Brazil reported similar case-finding effectiveness, with 2% of those aged 65 and over identified by CHWs, 63% of whom were confirmed by clinician interview finding method. Based on this model, I hypothesized that CHWs could be trained accurately to identify frail or dependent older people, using their knowledge and past observations of the older residents in the community in which they worked, sensitized by the training process. This could then be a cost-effective process of identifying those to whom further, more detailed and comprehensive home-based assessment could be offered. CHWs, as the interface between the community and primary and secondary health care facilities, are ideally placed to identify those at need, conduct basic assessments, and refer or deliver simple interventions at community level.

The aim of this study was first to develop a brief training programme to help CHWs identify older people who were frail, dependent, or both. The feasibility of this approach would then be tested in the communities where the trained CHWs worked, and the validity of their judgments tested against a clinical assessment conducted by a local physician, informed by the Easy-Care geriatric assessment. Specifically, I hypothesized that those identified would have a high prevalence of multi-morbidity,
multiple impairments, polymedication, a high risk of falls, marked limitation in activities of daily living, and high needs for care. Given the salience of the Easy-Care independence score and risk of falls scale to establishing the criterion of functional limitation and dependence, I also took this opportunity to assess the internal construct validity (hierarchical and classical scaling properties) of these measures.

3.2 METHOD:

Ten community health workers (CHWs) working in six sub-centres of the Corlim Primary Health Centre, Goa, India, were trained in the identification of frail dependent older people in the community. All had completed Auxiliary Nurse-Midwife (ANM) training and were currently employed by Directorate of Health Service, Goa. Based on constructive learning principles, a three hour training programme was developed. After the training, each CHW was asked to identify up to 15 older people who they considered to be frail or dependent. For the clinical examination, three doctors (two primary health care physicians and a private doctor) administered the Easy-Care geriatric assessment tool.

Outline of training programme organised for CHWs:

Two facilitators conducted the three-hour training programme, delivered as part of the monthly CHW meeting at the primary health centre in Corlim. The first part of the training programme comprised a brief introduction to the public health relevance of population ageing, age related changes in organ systems, common chronic diseases, and the contribution of common impairments to disability and dependence. In the second part of the interactive training section we provided case vignettes of frail older people with problems including undernutrition, mobility impairment, urinary incontinence, cognitive and behavioural impairments, and risk of falls. After presenting each case vignette open ended questions were asked to stimulate discussion: what are his/her main problems?; do his /her problems require health care support?; have you met such older people in the community?; what features enable you to identify them? Any misconceptions and doubts at this stage were clarified by the facilitator. Peer learning was initiated by encouraging trainees to share their experiences from the field with older people who had similar characteristics.
Orientation training for doctors on Easy-Care assessment:

The three doctors were given orientation on the use of the Easy-Care assessment, mainly regarding its purpose, and scoring procedures for the items and sub scales. This tool provides assessors with a pre-defined list of closed and open-ended questions in modular format. Assessment domains cover contact information; service user’s perspective of current needs; clinical background including vision, hearing, communication, depression; activities of daily living, personal care and continence; memory and cognitive functioning; safety and support and health behaviors in relation to tobacco and alcohol consumption, exercise and screening. Easy-Care has been tested for practicability and validity for contact and overview assessments in primary care. Doctors were also encouraged to perform additional clinical examinations as necessary to confirm the presence or absence of impairments.

Easy-Care measure of Activities of Daily Living (ADL), Instrumental Activities of Daily Living (IADL), and independence scale:

The Easy-Care independence scale was originally developed from Duke OARS IADL Scale. It consists of 18 items ascertaining limitations in ADL and IADL. The weighted items include: use of telephone, keeping up appearance, dressing, bath, housework, preparing meals, feeding, taking medications, incontinence, ability to use the toilet, transfer from bed to chair, mobility inside the home, managing stairs, mobility outside home, ability to shop, use of public services, and managing finance. The total score ranges from 0 to 100, with higher scores denoting greater degrees of dependence and needs for care.
**Easy-Care risk of falls:** EASY-Care risk of falls scale consists of eight items; difficulty with vision, difficulty in transferring, problem with feet, one or more falls in the past year, housebound, safety risks inside and outside of the home, and excess intake of alcohol. Each item was coded as 0 and 1, with higher scores indicating greater risk of falls.\(^{16}\)

**Multi-morbidity:** Clinicians recorded diagnosed morbidities based on medical records (where available) and self-reported information from the older person and family caregiver.

**Clinician ratings of impairment:** At the end of the EASY-Care assessment, the clinicians were asked to code the presence or absence, to a clinically significant degree, of impairments in nutrition, mobility, vision, hearing, continence, cognition, mood and behavior. The primary purpose of this assessment was to assess the concurrent (construct) validity of the structured comprehensive geriatric assessment administered by the CHW (see Chapter four).

**Statistical analysis:**

Descriptive analysis was conducted to provide a detailed description of demographic circumstances, morbidity, functional status (impairments, ADL and IADL disabilities) and needs for care of the older people identified by the CHWs as frail or dependent. For the EASY-Care independence and falls risk subscales internal consistency (Cronbach’s alpha) was calculated using SPSS 21.0\(^{17}\). A Mokken model was applied to investigate hierarchical scaling properties using STATA 11.0 after downloading the LoevH add-on program from [http://www.anaqol.org](http://www.anaqol.org). Mokken scaling involves the application of a non-parametric item response model\(^{18}\) to measure the hierarchical properties of items in a scale, assessing if the items can be ordered by degree of difficulty, such that any individual who endorses a particular item will also endorse all the items ranked lower in difficulty. Three basic assumptions are required for a monotone homogeneity model (MHM): 1) unidimensionality (one latent variable summarises the variation in the item scores in the questionnaire), 2) local independence (after conditioning on the position on the latent trait, the item scores are statistically independent), and 3) monotonicity (for all
items the probability of a positive response increases monotonically with increasing values of the latent trait). These assumptions being met, an individual’s position on the latent trait can conveniently be estimated as the rank of the highest item in the hierarchy that they endorse, or their total number of positive responses.\textsuperscript{19}

Double monotonicity models (DMM) require in addition that for any value of the latent trait, the probability of a positive response decrease with the difficulty of the item. This means that the order of item difficulties remains invariant over all values of the latent trait and thus, that the item response function curves do not intersect.\textsuperscript{20, 21} To assess single monotonicity, we estimated Loevinger coefficients for each item (Hi) and for the whole scale (H), where values between 0.3 and 0.4 suggest weak scalability, values between 0.4 and 0.5 moderate, and values above 0.5 strong scalability. We also tested formally for violations of monotonicity (using the Stata loevh monotonicity command) and non-intersection (using the Stata loevh nipmatrix command) between pairs of items (minimum violation 0.03, alpha=0.05), using overall criteria values as an indication of the likelihood of assumption violation; ≤40 ‘satisfactory’, 40 to 79 ‘questionable violation’, 80 and over ‘strongly suggesting an assumption violation’.\textsuperscript{22}

3.3 RESULTS:

Trained community health workers identified n=152 older people as frail or dependent, or both. Two of these older persons were not available for clinician reassessment due to hospital admission. The mean age of the participants was 73.6 years (SD 7.6). Most were women (72%), and 118 (78%) had no education. Forty-eight (31%) were still married and 102 (67%) widowed. Only four (3%) were living alone, while 121 (80%) lived with children and/ or children-in-law. Nine (6%) were in paid full- or part-time employment. The very large majority, 141 (94%), indicated that they did receive care and support, 12 of whom also reported providing care for someone else. Restricted mobility was a common feature; only 15 participants (10.1%) were mobile outside of the home without assistance, while 24 (16.1%) were housebound. Only six older people reported that they could access local health services (pharmacy or primary health care centre ‘with no difficulty’, 118 (78.7%) required some help, and 26 (17.3%) could not access these services (Table 1).
Table – 1 Demographic characteristic of frail dependent older people

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Total =150  n(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age mean (SD)</td>
<td>73.6 (7.9)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>43 (28.3%)</td>
</tr>
<tr>
<td>Female</td>
<td>109 (71.7%)</td>
</tr>
<tr>
<td>Education</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>118 (77.6%)</td>
</tr>
<tr>
<td>Primary level</td>
<td>30 (19.7%)</td>
</tr>
<tr>
<td>Secondary /higher degree</td>
<td>4 (2.6%)</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
</tr>
<tr>
<td>Never married</td>
<td>1 (0.7%)</td>
</tr>
<tr>
<td>Married</td>
<td>48 (31.6%)</td>
</tr>
<tr>
<td>Widowed</td>
<td>102 (67.1%)</td>
</tr>
<tr>
<td>Divorced/separated</td>
<td>1 (0.7%)</td>
</tr>
<tr>
<td>Occupation</td>
<td></td>
</tr>
<tr>
<td>Paid work (full/part time)</td>
<td>9 (5.9%)</td>
</tr>
<tr>
<td>Retired/ ‘unemployed’</td>
<td>122 (80.3%)</td>
</tr>
<tr>
<td>Housewife (full time)</td>
<td>21 (13.8%)</td>
</tr>
<tr>
<td>Living arrangements</td>
<td></td>
</tr>
<tr>
<td>Living alone</td>
<td>4 (2.6%)</td>
</tr>
<tr>
<td>With spouse</td>
<td>15 (9.9%)</td>
</tr>
<tr>
<td>With son/daughter</td>
<td>34 (22.4%)</td>
</tr>
<tr>
<td>Son/daughter-in-law</td>
<td>87 (57.2%)</td>
</tr>
<tr>
<td>With sibling/other relatives</td>
<td>12 (7.9%)</td>
</tr>
</tbody>
</table>
Health and morbidity profile of the participants: Self-rated health was positive (good or very good) for only 17 participants (11.3%), 103 (68.7%) rated their health as fair and 30 (19.7%) as poor. Multi-morbidities were very common, more than 50% of the older people reported (or were recorded as) having more than one medical condition (Table 2). Hypertension (57%) was the most common condition (Figure 1), followed by diabetes (26%), arthritis (20%), chronic obstructive pulmonary disease (COPD) (19%), ischemic heart disease (IHD) (18%) and cardiovascular disease (15%). Neurological and mental disorders were rarely reported or diagnosed. Only six participants (4%) were known to have dementia. The same numbers were identified with mental disorder, five with Parkinson’s disease (3%), and five with seizures. Cataract had previously been identified in only seven participants, five of whom had been operated. Polymedication was common; only 31% of older people were free of medication and nearly 42% were found to be taking three or more medications on a daily basis, with 13% taking six or more medications. Forty-eight percent reported that they had been admitted to hospital in the last five years.
Figure 1: Prevalence of diagnosed or reported medical conditions

[Bar chart showing the prevalence of various medical conditions, with diabetes being the most prevalent.]
Table 2: Morbidity profile of frail older people

<table>
<thead>
<tr>
<th>Health status</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of medical illnesses</td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>16 (10.5%)</td>
</tr>
<tr>
<td>1</td>
<td>47 (30.9%)</td>
</tr>
<tr>
<td>2</td>
<td>43 (28.3%)</td>
</tr>
<tr>
<td>3</td>
<td>26 (17.1%)</td>
</tr>
<tr>
<td>4 or more</td>
<td>20 (13.2%)</td>
</tr>
<tr>
<td>Number of Impairments</td>
<td></td>
</tr>
<tr>
<td>0-1</td>
<td>2 (1.3%)</td>
</tr>
<tr>
<td>2-3</td>
<td>23 (15.1%)</td>
</tr>
<tr>
<td>4-5</td>
<td>33 (21.8%)</td>
</tr>
<tr>
<td>6 or more</td>
<td>94 (61.8%)</td>
</tr>
<tr>
<td>Number of falls in the last 12 months †</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>49 (33.1%)</td>
</tr>
<tr>
<td>One</td>
<td>54 (36.5%)</td>
</tr>
<tr>
<td>Two or more</td>
<td>45 (30.4%)</td>
</tr>
<tr>
<td>Risk of falls score &gt;3</td>
<td>109 (73.1%)</td>
</tr>
<tr>
<td>Hospital admission one or more times in the last 5 years</td>
<td>72 (48%)</td>
</tr>
<tr>
<td>Polymedication</td>
<td></td>
</tr>
<tr>
<td>No medications</td>
<td>47 (30.9%)</td>
</tr>
<tr>
<td>1 or 2 medications</td>
<td>41 (27.0%)</td>
</tr>
<tr>
<td>3 to 5 medications</td>
<td>44 (28.9%)</td>
</tr>
<tr>
<td>6 or more</td>
<td>20 (13.2%)</td>
</tr>
</tbody>
</table>

*mv=11; † mv=12

A high prevalence of impairments was reported from the clinician assessment. According to clinician rating, 65.3% were undernourished, 91.3% of had mobility impairment, 98.7% were judged to have vision impairment, 66.0% hearing impairment, 78.4% cognitive impairment, 82.0% depression, 56.0% behavioral problems, and 35.3% incontinence (Figure 2). Nearly two-thirds (61.8%) of the older persons were rated by the clinicians as having six or more clinically significant impairments. Two-thirds (66.9%) reported having fallen at least once in the last year, and according to the EASY-Care falls risk score, 73.1% were at significant risk of falls.
Figure 2 Prevalence of impairment according to clinician judgment
Disability and dependence measures:

A higher score on the EASY-Care independence scale indicated a high need for care among the older people identified by the CHWs as frail or dependent. The independence scale was positively skewed, with a mean of 37.9, but a median of 34, and an interquartile range (25th centile, 75th centile) of 25.0 to 44.2. The self-reported IADL and ADL disability scales were also positively skewed, with a relatively high distribution of scores (Table 3).

**Figure 3 Distribution of EASY-Care Independence scale scores**
Table 3: Global health outcomes measures (ADL, IADL, dependence measure)

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>ADL</th>
<th>IADL</th>
<th>Independence (weighted score)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean ( SD)</td>
<td>10.2 (3.2)</td>
<td>15.4 (2.2)</td>
<td>37.9 (18.8)</td>
</tr>
<tr>
<td>Score range</td>
<td>7 - 20</td>
<td>14-17</td>
<td>6 – 97</td>
</tr>
<tr>
<td>minimum-maximum</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>25th percentile</td>
<td>7.0</td>
<td>14.0</td>
<td>25.0</td>
</tr>
<tr>
<td>Median</td>
<td>10.0</td>
<td>15.5</td>
<td>34.0</td>
</tr>
<tr>
<td>75th percentile</td>
<td>11</td>
<td>17.0</td>
<td>44.2</td>
</tr>
</tbody>
</table>

ADL- Activities of daily living; IADL- Instrumental Activities of Daily Living

**Mokken analysis for independence scale:**

Item and scale Loevinger H coefficients were estimated using a polytomous Mokken analysis. There was robust evidence that the EASY-Care independence scale and its constituent items conformed to a ‘strong’ Mokken scale (Table 4). The coefficient H values for individual items exceeded 0.47 (range 0.47 to 0.68) other than two items; unable to use telephone (0.27) and unable to manage finances (-0.13). The overall scale H coefficient was 0.50. There were no statistically significant violations of monotonicity assumptions. However, there were a number of statistically significant violations with respect to non-intersection (double monotonicity). Of these, only those for ‘unable to do housework’, ‘confined to bed’, and ‘unable to manage finances’ were associated with criteria values >80, strongly suggesting an assumption violation. Internal consistency of the items (Cronbach’s alpha) was 0.88, providing further evidence of unidimensionality.
<table>
<thead>
<tr>
<th>Items</th>
<th>Mean score</th>
<th>Loevinger H coefficient</th>
<th>Non-intersection (Pmatrices curve)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unable to use telephone</td>
<td>2.3</td>
<td>0.27</td>
<td>78</td>
</tr>
<tr>
<td>Needs help with keeping up appearance</td>
<td>1.1</td>
<td>0.57</td>
<td>19</td>
</tr>
<tr>
<td>Unable to dress</td>
<td>1.2</td>
<td>0.67</td>
<td>47</td>
</tr>
<tr>
<td>Unable to bath</td>
<td>1.2</td>
<td>0.63</td>
<td>65</td>
</tr>
<tr>
<td>Unable to do housework</td>
<td>2.4</td>
<td>0.55</td>
<td>90</td>
</tr>
<tr>
<td>Unable to prepare meals</td>
<td>2.6</td>
<td>0.47</td>
<td>64</td>
</tr>
<tr>
<td>Unable to feed</td>
<td>1.3</td>
<td>0.47</td>
<td>61</td>
</tr>
<tr>
<td>Unable to take medicines</td>
<td>1.4</td>
<td>0.47</td>
<td>63</td>
</tr>
<tr>
<td>Frequent accidents of bladder</td>
<td>1.3</td>
<td>0.55</td>
<td>67</td>
</tr>
<tr>
<td>Frequent accidents of bowels</td>
<td>1.2</td>
<td>0.63</td>
<td>49</td>
</tr>
<tr>
<td>Unable to use toilet</td>
<td>1.3</td>
<td>0.68</td>
<td>64</td>
</tr>
<tr>
<td>Unable to move from bed to chair</td>
<td>1.3</td>
<td>0.53</td>
<td>69</td>
</tr>
<tr>
<td>Confined to bed</td>
<td>1.6</td>
<td>0.50</td>
<td>92</td>
</tr>
<tr>
<td>Unable to manage stairs</td>
<td>2.2</td>
<td>0.48</td>
<td>53</td>
</tr>
<tr>
<td>Unable to walk outside</td>
<td>2.0</td>
<td>0.52</td>
<td>37</td>
</tr>
<tr>
<td>Unable to shop</td>
<td>2.8</td>
<td>0.49</td>
<td>16</td>
</tr>
<tr>
<td>Unable to get public services</td>
<td>2.1</td>
<td>0.51</td>
<td>38</td>
</tr>
<tr>
<td>Unable to manage finances</td>
<td>1.6</td>
<td>-0.13</td>
<td>186</td>
</tr>
<tr>
<td>Overall scale Loevinger’s H coefficient</td>
<td>0.50</td>
<td>0.61</td>
<td></td>
</tr>
<tr>
<td><strong>Cronbach’s Alpha (internal consistency of the items)</strong></td>
<td><strong>0.88</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Mokken analysis for risk of falls scale:

The Loevinger H coefficient for the eight items in the EASY-Care risk of falls scale ranged between 0.12 and 0.37, and the Loevinger H coefficient for the scale was 0.14, which indicated that this was not a hierarchical scale. Internal consistency was also low (Cronbach’s alpha 0.38) (Table 5). There was therefore no evidence that the selected items formed a measurement scale. However, there was a strong association between risk of falls score (excluding the item referring to the number of falls in the last 12 months) and number of reported falls in the previous 12 months (linear ANOVA, $F=23.7$, 1 degree of freedom, $p<0.001$).

Table 5: Polytomous Mokken analysis with EASY care assessment risk of fall scale

<table>
<thead>
<tr>
<th>Items</th>
<th>Loevinger H coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Has difficulty with vision</td>
<td>0.37</td>
</tr>
<tr>
<td>Difficulty when transferring</td>
<td>0.17</td>
</tr>
<tr>
<td>Need for help with feeding</td>
<td>0.29</td>
</tr>
<tr>
<td>Problems with feet</td>
<td>0.15</td>
</tr>
<tr>
<td>One or more falls in the past year</td>
<td>0.17</td>
</tr>
<tr>
<td>Is housebound</td>
<td>0.12</td>
</tr>
<tr>
<td>Not safe outside house</td>
<td>0.04</td>
</tr>
<tr>
<td>Excess alcohol intake</td>
<td>0.01</td>
</tr>
<tr>
<td>Overall scale coefficient</td>
<td>0.14</td>
</tr>
<tr>
<td>Cronbach’s Alpha (internal consistency of the items)</td>
<td>0.38</td>
</tr>
</tbody>
</table>
3.4 DISCUSSION

In this study, I established that a brief training for CHWs can be effective in identifying frail dependent older people with reasonable accuracy. I also found that the EASY-Care independence scale has strong construct validity and robust scaling properties in the Goan cultural setting, hence establishing this as a useful indicator of disability and needs for care.

Were the older people identified by community health workers frail?
Multimorbidity and multiple impairments are reported to be common characteristics of frail older people. In this study, 58.6% of older people identified by community health workers had already been identified with two or more diagnosed morbidities, which is consistent with earlier reports of multimorbidity. This is likely to be a marked underestimate, given that lack of awareness and low access to health services will have led to under reporting and under diagnosis. The low prevalence of dementia is particularly striking given the high prevalence of significant cognitive impairment according to clinician judgment. Multiple impairments including those in the domains of nutrition, mobility, sensory function, cognition, mood and behavior also characterize frail older persons, and predict subsequent adverse health outcome. Three-quarters of the older people identified by the CHWs had more than five impairments. Frailty limits older people’s capacity to their environmental challenges, and independence is often compromised due to low physical or cognitive capacity to carry out daily activities. Therefore, limitation in ADL and IADL are commonly measured in studies to identify frailty in older people. The mean EASY-Care independence score in my sample (37.9) can be compared with that from an ambulatory sample of older primary care attendees in Kuala Lumpur, Malaysia (5.1) signifying a group with distinctively high levels of disability and needs for care. Falls in older people are recognized as an important indicator of frailty. Nearly 73% of the identified older people were rated by EASY-Care of being at elevated risk for falls, and two-thirds of participants had had at least one fall in the last year. Polymedication, which is common in frail older people and strongly associated with risk of falls, was also highly prevalent among identified older people in this study.
Do the EASY-Care independence and risk of falls sub-scales have robust measurement properties?

A scale is unidimensional if all the items of the scale measure one common latent variable. Hierarchical scales have particularly desirable measurement properties in terms of precision and measurement efficiency. The EASY-Care independence scale is highly internally consistent, and is a strong hierarchical scale, hence providing strong evidence for unidimensionality. Two items in the scale (unable to use telephone, or manage finances) had much lower item Loevinger H coefficients than others. This is partly due to cultural appropriateness of the items in the scale. In India, it is common for older people to transfer financial management responsibilities to co-resident children after retirement. In such a context the question of inability to manage finances may be irrelevant, or at least less reliably discriminating than in other cultures were older people retain this role and responsibility other than in the context of incapacity. Likewise, telephone use is uncommon among older people particularly since telecommunications are generally conducted via personal mobile phones rather than fixed landlines. The unidimensionality of the independence scale can be improved if these two items are dropped. The strong performance of the EASY-Care independence scale is encouraging, since this will be a useful confirmatory indicator of disability and needs for care in other linked studies. By contrast, the items included in the risk of falls scale do not in fact conform to a unidimensional scale, and the measurement properties of the summed scale are therefore unclear. Nevertheless, there is some empirical evidence for their association with risk for falls and interventions targeting these items may prevent subsequent falls in older people.33

This study has several limitations. The clinician assessment cannot be considered as a ‘gold standard’ since the doctors carrying out the assessments were non-specialists. They did not have the time or the equipment to carry out a rigorous examination. Nevertheless, the structured EASY-Care assessment, coupled with physical examination, and access to previous medical notes should have ascertained many of the
morbidities, impairments and activity limitations among the older participants. It is likely that morbidities were underestimated, given the unreliability of recorded diagnoses and self-report in settings where help seeking may be uncommon. The discrepancy between known diagnoses, and the much higher prevalence of relevant impairments suggests much potential under-identification and unmet need. While the results of this study suggest that those identified by the CHWs do indeed possess many of the characteristics usually associated with frailty and needs for care (hence a high positive predictive value for the CHW identification) I did not assess the health profile of any older people considered by the CHWs who were not felt to be frail or dependent. Hence the sensitivity of the case-finding methodology is unknown. Since we did not, due to budget limitations, ask the CHWs systematically to screen all older people living in households within their catchment areas, but rather requested them to stop when they had identified the target 15 frail or dependent older people, I was not able to estimate the population prevalence of frailty/dependence among older people according to CHW identification, which information would have been valuable in considering the cost and resource implications of such a case-finding methodology. A full screen of an entire catchment area, coupled with a community survey to validate this would also permit assessment of the equity of the case-finding procedure, specifically any biases associated with, for example, age, gender, educational level, or co-residential status. Finally, since I did not elicit information on recent health service utilization, specifically attendance at primary care, I was not able to establish the incremental benefit of community case-finding, over and above that of using enhanced assessment procedures among those who did happen to attend primary care facilities. However, 17% reported that they could not access primary care services, and 79% could only do so with help.

Given the modest cost of the training procedure, and the high yield of valid cases delivered by the CHWs based simply on their knowledge of the local population, it is likely that this would be a cost-effective approach for identifying frail or dependent older people in the community. Prior to this study, there has been a paucity of evidence on possibilities of training and engaging existing non-specialist health professionals for identification and management of older people in need for care. In the last few years, the health of the ageing population in India has become a prioritized concern, and there is an increased commitment to improve health and social care for older people through
existing health care systems. In 2012, India signed the Yogyakarta declaration on ‘Ageing and Health’, the Ministry of Health committed to strengthen the primary health care system to address the health needs of the older population including in-service training of health professionals.\textsuperscript{34} In 2011, India developed a national programme for health care of older people through community-based primary health care.\textsuperscript{35} However, the proposed strategies have not been successfully implemented and the objectives not achieved through the existing primary health care system.\textsuperscript{36, 37} The clinic-based model of care with little or no outreach activities is a significant obstacle to be overcome, together with the primary focus upon the identification and treatment of acute conditions.\textsuperscript{38} This study suggests that non-specialist CHWs can play a useful role in case identification. Given that referral up to primary health care remains problematic, the next step would be to demonstrate that the same CHWs could conduct comprehensive structured assessments in the community, in such a way as to identify and distinguish between common impairments, hence informing the delivery of simple evidence-based home interventions for, for example, undernutrition, mobility impairment, incontinence, cognitive impairment, depression. Family caregivers might also be advised and supported. Other interventions, for example refraction to provide glasses, or surgery for cataract would still require referral, but this could now be targeted on those most at need, and lack of help-seeking might not constitute a barrier to care. Beyond the ability of CHWs to conduct more detailed assessments, and evaluation of the feasibility and effectiveness of any home-based interventions that were subsequently delivered, it would be important to assess the readiness of the health system, the CHWs, and the potential users of such home-based services, to embrace the necessary system change, comprising task-shifting from non-specialist doctors in primary care to CHWs, and assessment and care provided in the community rather than the primary care facility. These considerations informed the next two studies described in this dissertation.
3.5 BIBLIOGRAPHY


30. Valarmathi M; Ee Ming Khoo. Validity and Reliability of the Easy-Care Standard 2010 Questionnaire in Assessing Elderly People Attending A Primary Care Clinic. 1st Asia Pacific Clinical Epidemiology & Evidence-Based Medicine Conference. Kuala Lumpur 2012.


37. GoI. Indian Public Health Standards(IPHS), Guidelines for Sub-Centres Revised In: Directorate General of Health Services MoHFW, editor. New Delhi, India: Government of India (GoI); 2012.

CHAPTER FOUR
CHAPTER FOUR:

Identifying common impairments in frail and dependent older people: The COPE assessment for non-specialised health workers in low resource primary health care settings

4.1 BACKGROUND:

More than chronic diseases, impairments in mobility, nutrition, vision, hearing, cognition, mood, and behaviour are strongly linked with years lived with disability, and dependence.¹⁻⁴ A recent systematic review concluded that interventions targeting particular risk factors or functional difficulties may be more effective than disease specific interventions at primary health care level.⁵ Identifying impairments that limit older people’s functional capacity, and treating them irrespective of underlying cause will be a key challenge for low resourced health care settings.

In India, as with many other low and middle-income countries (LAMIC), the primary health care system is the core of the government’s provision for the population’s basic health care needs. However, studies conducted in LAMIC indicate highly variable levels of utilization of government primary health care services among older people, with an apparent preference for private doctor and hospital outpatient services in India and some Latin American countries.⁶ The current system of public health care is acknowledged to be limited, in that it is mostly clinic-based with little or no outreach, focuses upon the detection and treatment of acute illnesses, and fails to provide coordinated continuing care to those with chronic conditions.⁷ ⁸ In India, it is not considered part of the primary health care physician’s role to make home visits to assess and treat those who cannot access health facilities.⁹ A cadre of Auxiliary Nurse Midwives (ANM) often referred to as community health workers (CHW) was introduced 50 years ago to increase the coverage of basic health care at the community level, and improve equity.¹⁰ CHWs undergo training focused mainly upon midwifery and maternal and child health, for nine or 24 months. Their key role is to supplement the contributions made by doctors and other higher trained personnel in promoting preventive and curative health activities. CHWs have become key workers at the interface of primary health care services and the community, and their effectiveness is
reflected in secular reductions in maternal and child mortality. Only recently has interest shifted to the potential to engage CHWs in the task of controlling chronic non-communicable diseases. As the only branch of primary care offering outreach into the community, and with a family and household orientation to their work, CHWs are in principle ideally situated to implement age-appropriate care for older people; case-finding (identifying frail or dependent older people in the community, who have not sought help at the health facility), and home-based assessment and intervention to treat or mitigate the effect of impairments arising from chronic disease.

We have already demonstrated that, after three hours training, CHWs working in the Goa State health service could accurately identify frail, dependent or frail and dependent older people (see Chapter three). The next step was to develop and evaluate a simple structured assessment that would enable CHWs to identify specific impairments at the level that could inform targeted evidence-based intervention. In support of this approach, a review conducted with studies of high income countries reported that preventive home visits undertaken based on comprehensive geriatric assessment can reduce the functional decline in older people. Although there has been increased recognition for the value of comprehensive assessments, less effort had been taken to validate the assessments that can be used by non-specialised community health workers in resource poor settings.

The scope of the assessment was determined by a concurrent World Health Organization program to develop evidence-based guidelines for the prevention and management of dependence by non-specialist health workers; covering nutrition, mobility, falls, cognition, mood and behaviour, sensory impairment, and incontinence. It was assumed that CHWs would lack prior experience in assessing older people, and hence structured assessments with objective tests would be required, rather than the exercise of clinical judgment. Scoping the literature failed to identify any comprehensive multi-dimensional assessment that was simple, fully structured and capable of identifying and distinguishing between specific impairments. Existing comprehensive assessment tools recommended for use in older people, for example the EASY-Care, the Duke Older Americans Resources and Services (OARS) Multidimensional Functional Assessment Questionnaire, WONCA were either generic and/or they required specialised clinical knowledge for administration and interpretation.
The aim of the current study was therefore to develop a comprehensive assessment tool for community health workers working in the primary health care system, to assess the feasibility and acceptability of this approach through qualitative interviews with community health workers (CHWs), and to explore the concurrent validity against clinical assessments carried out by physicians working in the same local public health system. It would not be appropriate to consider such assessments as a ‘gold standard criterion’ given that these doctors were non-specialists, lacking the time or equipment for a rigorous comprehensive clinical examination. The aim was, rather, to assess pragmatically whether those identified by the CHWs would be likely to be confirmed as cases for intervention by local clinicians.

4.2 METHOD

Design: Older people identified by CHWs as frail, or dependent, or frail and dependent, were assessed at home by the CHW using the COPE assessment tool (see below for details), generating information on impairments in nutrition, mobility, vision, hearing, continence, cognition, mood and behaviour. After an interval of up to two weeks, they were re-assessed by local physicians who reached a clinical judgment regarding the presence or absence of the same impairments based upon clinical examination guided by the EASY-Care assessment tool.20

Development and structure of COPE assessment

Rapid review was conducted to select appropriate assessments for undernutrition, mobility and strength impairments, visual and hearing impairments, and cognition, mood and behavioural impairments. The selection of measurements was based on the following criteria: a) they should be simple, quick, and easy to administer in a primary health care facility, or the older person’s own home, b) they should be capable of being administered by non-specialist health workers with suitable training c) they should have good sensitivity, specificity and positive predictive value for identification of the target impairment. The full COPE assessment tool comprises; Section 1 - demographic information; Section 2 - assessments for specific impairments; Section 3 – a brief interview with co-resident or primary caregiver; Section 4 – a summary of findings and action plans for management or referral. The time taken to administer the full COPE
assessment ranges from 30 to 45 minutes. The following description focuses upon Section 2, the assessment of impairments

**Assessments of mobility:**

A ten metre walk test, and the chair stand test were used to identify mobility impairment. Both are well suited to standardised evaluation of older people at community level by non-specialist health workers, being quick to administer, inexpensive, and a reliable measure of frailty with respect to physical functioning.\(^{21-24}\) The walking test, used successfully in the 10/66 Dementia Research Group population-based studies in LAMICs, involves the participant being timed walking five metres (indicated by a piece of string), turning and returning to the starting point; with time taken to turn taken into account, a cut off of more than 15 seconds to complete the test was considered to reflect limited mobility (<1.2 metres per second).\(^{25,26}\) Although often considered to be a good proxy measure of sarcopaenia (loss of muscle mass and strength) gait speed will also reflect impairments in the function of joints, central and peripheral nervous system. The ‘30 second chair stand’ test assesses proximal lower limb strength, and has also been used in LAMICs.\(^{27}\) The person being assessed is asked to stand upright from a chair with their arms folded across their chest, then to sit down again and then to repeat the action at their own pace. The test score is the number of times they rise to a full stand from the seated position within 30 seconds. A cut-off of fewer than seven stands in 30 seconds was recommended for detecting older people with, or at risk of, lower limb strength impairment.\(^{28}\) Fewer than 14 stands predicted falls in a study conducted among community-dwelling older people in Japan.\(^{29}\) The main limitations are that the score may be influenced by the height of the chair, leading to problems with standardisation when used in the community, and that a high proportion of frail participants may be unable to perform the task, leading to floor effects.
Assessment of nutritional status:

The mini-nutritional assessment (MNA-SF®) is a short form version of the original 18 item MNA full version, comprising six items that best discriminated between malnourished, at risk, and normal older people; decline in food intake; weight loss in the last three months; mobility limitation; psychological stress or acute diseases in the past three months; neurological problems (dementia and depression); and body mass index (BMI). BMI, requiring accurate assessment of height and weight, is time-consuming and difficult to measure in the community, particularly in bed- or chair-bound older people. In the revised MNA, calf-circumference was substituted for BMI, with good criterion and predictive validity. The MNA short form has a maximum score of 14 points, with risk of malnutrition increasing with lower scores. Respondents are classified as well nourished (a score of 12–14), at-risk for malnutrition (8–11), or malnourished (0–7).

Assessment for incontinence:

Incontinence was identified from the interview conducted with family caregivers, specifically the question ‘Does he/ she have difficulty using the toilet? Does he/ she wet or soil herself?’. Responses to this question were coded as no problems; occasional urinary incontinence; frequent urinary incontinence; or double incontinence. Those with incontinence of either bladder, or bowel were identified as having continence problems.

Assessment of visual impairment:

The Snellen ‘tumbling E’ chart has been used in population-based studies to identify visual impairment in older people in India. Although developed for use in children, it has a general application for low literacy groups, and has been used and validated in many developing countries, for age groups ranging from four to 90 years. This test was considered suitable for primary health care in low resource settings, since it is an easy to administer and education-free assessment. According to the World Health Organisation, visual impairment is defined as a best-corrected visual acuity of less than 6/18 in the better-seeing eye.
Assessment of hearing impairment:
The whisper voice test was administered to identify hearing impairment. The examiner stands behind the seated older person and enunciates three random numbers (for example, 2-6-9) at four decreasing levels of loudness: a conversational voice at six inches and two feet from the ear and then a whispered voice at the same distances. Tests were presented to each ear, masking the other by rubbing the tragus. If correct, the examiner proceeds to the next level of difficulty, if incorrect, the test is repeated using different numbers. A pass at each level is achieved if the three numbers are repeated correctly or if at least three out of six numbers are repeated correctly over two sets. Failing the whisper voice test at two feet implies a 30 dB hearing loss, likely to have a significant impact on communication. Sensitivity and specificity against audiometry ranges from 90% to 100% and 80% to 87% respectively, with little difference when administered by experienced and inexperienced examiners. However, studies validating the whisper voice test were conducted in hospital or institutional settings, exclusively in high income countries.

Assessment of cognition:
The Community Screening Instrument for Dementia (CSI-D) was extensively validated against clinician dementia diagnosis (DSM-IV dementia) in 26 centres in Latin America, India and SE Asia. It combines culture and education-fair cognitive testing of the participant and an informant interview enquiring after the participant’s daily functioning and general health, into a single predictive algorithm. The Brief version of CSI-D (administered in around five minutes) was developed using item response theory for item reduction, the intention being to make the assessment brief enough to be used as a screening assessment by non-specialist health workers in low resource primary care settings. The brief version comprises seven cognitive test items for the older person and six informant report items for family or primary caregiver. Lower scores in the cognitive test and higher scores in the informant reports indicate cognitive impairment. To calculate the total score, the informant score is subtracted from the cognitive score, giving a possible range of -6 to +9 with a cut-off of less than five reported to have 97.3% sensitivity and 90.5% specificity in detecting older people with dementia, based on research data from community surveys. It has not previously been used by non-specialist health workers in low resource settings.
Assessment of mood:

The Geriatric Depression Scale was originally devised with 30 items specifically for use in older populations\(^47\), and has been used successfully in an illiterate older Indian population.\(^48\) A 15 item short version is more widely used, but is still time-consuming to administer. An eight item version, the GDS-8 has been developed in the Netherlands for brevity and ease of use in nursing home residents. The GDS-8 has good psychometric properties; it is internally consistent (alpha=0.80) and against clinician interviews yielded a sensitivity of 96.3% for major depression and 83% for minor depression with specificity of 71.7% at a cut-off point of 2/3.\(^49\) The GDS-8 item short version has not been validated in community settings.

Assessment of behaviour:

The brief form of the Neuropsychiatric Inventory (NPI-Q) consists of questions covering 12 common behavioural and psychological symptoms: delusions, hallucinations, agitation/aggression, depression, anxiety, elation/euphoria, apathy, disinhibition, irritability/lability, aberrant motor activity, sleep and night time behaviours, appetite change and eating behaviour.\(^50\) Where the behaviour or symptom is present, it is rated by the carer on a six point scale (0-5) for the distress it occasions them. The total NPI-Q distress scores is the sum of the 12 individual domain scores, with a maximum possible score of 60. NPI-Q has shown to have adequate test-retest and inter-rater reliability as well as good concurrent validity.\(^51\) We considered presence of behavioural problems only if it was rated by the caregivers as causing distress.

Training CHW for COPE assessment:

Training for administration of the COPE assessment was conducted by two facilitators for ten Community Health Workers (CHWs) currently working in Sub-Health Centres of Corlim Primary Health Centre, Goa, India. The training involved a) brief introduction to common problems associated with ageing and age dependent chronic diseases and need for care in frail and or dependent older people. b) a detailed description of each impairment and the COPE assessment methods. c) general rules for identifying
impairments, emphasizing the use of the specified test cutpoints, but recommending procedures for exercising judgment when the relevant test was difficult or impossible to administer. d) Role play: Facilitators demonstrated the correct method of performing the assessment in older people’s home. Precaution and safety measures were clearly flagged. After each assessment demonstration, the facilitators invited CHWs to demonstrate how they would perform the assessment with the facilitator acting as the older person. Other trainees observed the role-play and commented on their colleague’s performance. e) At the end, the facilitator summarised the section with all key points and health workers were also given time to clarify their doubts. In addition facilitators asked a set of specific questions to check whether participants have understood the assessment procedure and general rule for diagnosis. f) Post training (on job supervision): Each CHW was requested to identify an older person for whom they believed a COPE assessment would be indicated. These supervised assessments were observed by the facilitator who noted any deviations from assessment protocol, which were then communicated to the CHW for improvement. Any doubts or questions raised by the CHW were also clarified at this stage.

**Clinician assessment**

Clinician assessments were guided by the EASY-Care Standard 2010 assessment comprising brief questionnaires and single items derived from established instruments, including the Barthel index, the Duke OARS IADL scale, the SF-36, questions on cognitive function, the four-item geriatric depression scale, and questions from the World Health Organisation 11 countries social and medical survey instrument. The EASY-Care assessment, as a package, had shown content, discriminant, and cross culturally validity. Forty-nine checklist items are clustered into seven groups; seeing, hearing and communicating; looking after yourself; getting around; your safety; your accommodation and finance; staying healthy; and your mental health and wellbeing. The assessment can be used by a suitably trained clinician to identify and prioritise management of unmet needs. Based on 18 ADL and IADL items, EASY-Care also generates summary scores for ‘independence’ (higher scores indicating needs for care and support), risk of breakdown in care and risk of falls. We have demonstrated that the independence score scale has excellent core psychometric properties, with high
internal consistency, and strong hierarchical scale properties (see Chapter three). Although the 49 checklist items are structured and quite well operationalised, other than the three assessment scales, identification of unmet needs and development of management plans requires the exercise of clinical judgment, hence the choice of this assessment for the clinician validation rather than the CHW test assessment. EASY-Care assessment was supplemented by clinical assessments routinely used by local clinicians (see Table 1). To match the CHW COPE assessment, clinical judgment was then applied, based upon the entirety of available evidence to identify impairments in nutrition, mobility, vision, hearing, continence, cognition, mood and behaviour.

**Qualitative interview with CHWs:**

The purpose of the qualitative study was to elicit information regarding CHW’s experiences and opinions about the administration of the COPE structured assessment, and also to understand its possible utility for routine primary health care practice. A research assistant trained in qualitative interviewing, conducted individual in-depth interviews with ten CHWs who had administered the COPE assessment for frail dependent older people, and had provided informed consent to participate in the qualitative study. All qualitative interviews were conducted in sub-health centres, and the duration of each interview ranged between 45 and 90 mins. Interviews were mainly conducted in Konkani (Goan local language). All interviews were recorded using digital voice recorder, transcribed and translated in to English before thematic analysis was carried out.
<table>
<thead>
<tr>
<th>Impairments</th>
<th>COPE</th>
<th>COPE criterion</th>
<th>Clinical examination¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mobility</td>
<td>Ten metre walking test</td>
<td>Complete the walking test in &gt; 15 seconds, and/ or &lt;7 chair stands in 30 seconds, or could not participate in the tasks because of severely restricted mobility.</td>
<td>Neurological examination, including power in major muscle groups. ADL difficulties. EASY-Care checklist: Can you move yourself from bed to chair? Can you get around indoors? Can you manage stairs? Can you walk outside?</td>
</tr>
<tr>
<td>Vision</td>
<td>Snellen ‘tumbling E’ visual acuity chart</td>
<td>Visual acuity &lt;6/18 in one or both eyes, or CHW impression of visual impairment for those not able to complete test</td>
<td>Counting fingers, hand motion, light perception. EASY-Care checklist: Can you see (with glasses if worn?)</td>
</tr>
<tr>
<td><strong>Hearing</strong></td>
<td>Whisper voice test</td>
<td>Failed whisper voice test at 2 feet</td>
<td>Weber and Rinne tests. Vestibular function. EASY-Care checklist: Can you hear (with hearing aid if worn)?</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td><strong>Continence</strong></td>
<td>Single item from informant CSI-D ‘Does she have difficulty using the toilet? Does she wet of soil herself?’</td>
<td>Coded 0. No problems 1. Occasionally wets bed 2. Frequently wets bed 3. Double incontinence</td>
<td>EASY-Care checklist: Do you have accidents with your bladder? Do you have accidents with your bowels?</td>
</tr>
<tr>
<td><strong>Cognition</strong></td>
<td>Brief Community Screening Instrument for Dementia (CSI-D)</td>
<td>Combined score of &lt;5</td>
<td>CNS Higher Functions; mental status examination; family history, medical history (underlying mental health conditions), addictions.</td>
</tr>
<tr>
<td><strong>Mood</strong></td>
<td>Eight item Geriatric Depression Scale (GDS-8)</td>
<td>GDS score of &gt;=3, or (for those not able to respond), informant report of depressed mood (NPI-Q q.4)</td>
<td>EASY-Care checklist: Do you have any concerns about memory loss or forgetfulness? Do you feel lonely? Have you suffered from any recent loss or bereavement?</td>
</tr>
</tbody>
</table>
| **Behaviour** | 12 item Neuropsychiatric Inventory (NPI-Q) | One or more behavioural or psychological symptoms causing caregiver at least some distress | In the past month…
Have you had any trouble sleeping? Have you had bodily pain? Have you often been bothered by feeling down, depressed or hopeless? Have you often been bothered by having little interest or pleasure in doing things? |

1. **For clinician assessment, the criterion was ‘clinical judgment’ in all cases**
Statistical analysis:

All analysis was carried out using STATA version 11. The proportion of older people considered, according to the CHW COPE assessments, to have impairments in nutrition, mobility, vision, hearing, continence, cognition, mood and behaviour, was described, and the independent effects of age (per year) and gender (male versus female) assessed using Poisson regression to generate prevalence ratios. The prevalence of each impairment according to CHW assessment was compared with that from clinician assessment using clinical judgment. The agreement between CHW assessment and clinician judgment was assessed using the % of overall agreement, and Cohen’s kappa. The sensitivity, specificity, positive and negative predictive values of the CHW assessment were estimated using the clinician judgment as the external reference criterion. The construct (concurrent) validity of the CHW COPE assessments was assessed by;

1) comparing mean EASY-Care independence scores for those identified as impaired in the CHW COPE assessment (‘true positives’ and ‘false positives’ combined) with those who were identified as impaired only according to clinician judgment (‘false negatives’) and those identified as impaired according to neither criteria (‘true negatives’), using one way ANOVA and Scheffe tests for statistical significance accounting for multiple sub-group comparisons. 2) assessing the correlations between number of impairments identified by CHW COPE assessment, needs for care assessed by CHW, numbers of impairments identified by clinician judgment, and EASY-Care independence scores.

3) using multiple linear regression to assess the independent individual and collective contribution of a) CHW identified impairments and b) clinician judgment identified impairments to the percentage of variance in EASY-Care independence scores, having controlled for age and gender.
4.3 RESULTS

The ten trained community health workers (CHWs) consulted the sub-health centre case registry to identify people aged 60 years and over, and reviewed the family record, and their own recollections of family visits to identify those who, on the basis of their training, could be considered to be frail and/ or dependent (See Chapter three). The 159 so identified were approached by the CHWs for informed consent. Seven refused to participate and two other frail older people completed COPE assessment but could not participate in clinician assessment due to hospitalisation. The COPE assessment was administered by CHWs for all frail dependent older people in their own home. Subsequently, the clinician made a home visit to conduct the clinical examination as possible; however, for three frail dependent older people the clinical examination was performed at the primary health care facility.

Characteristics of the study participants: The mean age of the participants was 73.6 years (SD 7.6). Most were women (72%), and 118 (78%) had no education. Forty-eight (31%) were still married and 102 (67%) widowed. Only four (3%) were living alone, while 121 (80%) lived with children and/ or children-in-law. Nine (6%) were in paid full- or part-time employment. The very large majority, 141 (94%), indicated that they did receive care and support, 12 of whom also reported providing care for someone else.

Distribution of impairments as assessed by the CHW using the COPE assessment
Valid data was obtained for most participants for most of the assessments. However, mainly because of severe mobility impairment, 27 (17.8%) could not attempt the chair-stand test, and 21 (13.8%) could not attempt the walking test. Mainly because of cognitive impairment, 19 could not be tested for visual acuity, eight (5.3%) for hearing, and 12 (7.9%) could not provide meaningful responses for the Geriatric Depression Scale. According to data collected by the CHWs in their structured assessments, the most common impairment was mobility (n=124, 81.6%), followed by hearing (104, 68.4%), mood (91, 60.7%), nutrition (82, 53.9%), behaviour (73, 48.0%), vision (66, 45.8%), cognition (58, 38.2%) and continence (34, 22.4%). Among those identified with visual impairment, 16 were considered by CHWs to have refractable errors (corrected by pinhole) and 40 unrefractable errors. Among those identified with
incontinence, 21 had occasional urinary incontinence, six frequent urinary incontinence, and seven faecal incontinence. The commonest behavioural disturbances reported to be distressing by the carer were appetite and eating problems (n=29), agitation or aggression (n=25), sleep disturbance (n=23), depression (n=23), irritability (n=20) and apathy (n=19).

Only two older people were rated as having no impairments; 28 (18.4%) had one or two impairments, 55 (38.2%) had three or four impairments, and 67 (44.1%) had five or more. Most (82.8%) were assessed by the CHW as having needs for care; 72 (47.4%) were identified as needing occasional care, and 54 (35.5%) as needing care much of the time. The independent effects of age and gender on the prevalence of the impairments is described in Table 2 and (age only) in Figure 1. While the prevalence of all impairments other than depression, mobility and undernutrition increased monotonically with increasing age, only the effect of age on the prevalence of cognitive impairment was statistically significant. There were no differences in the prevalence of impairment with gender.
Table 2: Independent effects (Prevalence Ratios) of age and sex on the prevalence of common impairments, as assessed by Community Health Workers

<table>
<thead>
<tr>
<th>Impairment</th>
<th>Effect of age (in years, controlling for sex)</th>
<th>Effect of sex (men compared with women, controlling for age)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nutrition impairment</td>
<td>1.01 (0.98-1.04)</td>
<td>1.11 (0.68-1.83)</td>
</tr>
<tr>
<td>Mobility impairment</td>
<td>1.00 (0.96-1.03)</td>
<td>0.87 (0.49-1.57)</td>
</tr>
<tr>
<td>Vision impairment</td>
<td>1.02 (0.99-1.05)</td>
<td>0.91 (0.54-1.55)</td>
</tr>
<tr>
<td>Hearing impairment</td>
<td>1.01 (0.99-1.04)</td>
<td>1.41 (0.88-2.28)</td>
</tr>
<tr>
<td>Incontinence</td>
<td>1.05 (1.00-1.10)</td>
<td>0.58 (0.29-1.17)</td>
</tr>
<tr>
<td>Cognitive impairment</td>
<td>1.04 (1.01-1.07)</td>
<td>1.39 (0.76-2.56)</td>
</tr>
<tr>
<td>Depression</td>
<td>0.99 (0.97-1.02)</td>
<td>1.01 (0.63-1.62)</td>
</tr>
<tr>
<td>Behavioural impairment</td>
<td>1.01 (0.99-1.04)</td>
<td>1.27 (0.74-2.17)</td>
</tr>
</tbody>
</table>
Figure 1: Prevalence of impairments (as identified by the community health worker, using the COPE assessment), by age

Agreement between CHWs COPE assessment and clinician diagnosis:

The agreement between the CHW identification of impairment, and the rating of the clinician assessor is summarised in Table 3. The agreement was generally modest; kappa between 0.20 and 0.41 for undernutrition, incontinence, depression and impairments in hearing and behaviour, 0.14 for mobility, 0.12 for cognitive impairment, and -0.02 for vision impairment. Other than hearing impairment, the prevalence of each impairment was always higher according to the judgment of the clinician. While overall agreement proportions were generally high, ‘false negatives’ (clinician +/ CHW -) were more numerous than ‘false positives’ (clinician -/ CHW +). This was particularly striking for visual impairment, where according to the clinicians 98.7% were impaired but according to the CHW assessment only 45.8%, cognitive impairment (78.4% versus 38.2%) and depression (82.0% versus 59.9%). The overall pattern was therefore one of moderate sensitivity and specificity for each of the assessments, with a generally high positive predictive value (exceeding 78.0% for all assessments), and low negative predictive value. For those CHW administered COPE assessments that generated continuously distributed scores, the area under the ROC curve (AUROC) suggested
only moderate discriminability with respect to the relevant impairment according to clinician judgment with AUROC close to 0.70 for most tests, but somewhat lower for mobility (walking test, AUROC 0.63; chair stand test, AUROC 0.65).
Table 3: Validity of COPE community health workers assessment against clinical diagnosis as external reference criterion

<table>
<thead>
<tr>
<th>Impairments</th>
<th>Prevalence according to COPE assessment and clinician</th>
<th>Agreement between COPE assessment and clinician (CHW first)</th>
<th>Indicators of agreement</th>
<th>Validity coefficients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CHW/COPE</td>
<td>Clinician judgment</td>
<td>+/- +/- +/- +/-</td>
<td>% overall agreement</td>
</tr>
<tr>
<td>Nutrition</td>
<td>82 (53.9%)</td>
<td>98 (65.3%) MV=2</td>
<td>64 18 34 34</td>
<td>65.3%</td>
</tr>
<tr>
<td>Mobility</td>
<td>124 (81.6%)</td>
<td>137 (91.3%) MV=2</td>
<td>113 8 24 5</td>
<td>91.3%</td>
</tr>
<tr>
<td>Vision</td>
<td>66 (45.8%) MV=8</td>
<td>148 (98.7%) MV=2</td>
<td>64 1 76 1</td>
<td>45.8%</td>
</tr>
<tr>
<td>Hearing</td>
<td>104 (68.4%) MV=8</td>
<td>99 (66.0%) MV=2</td>
<td>77 26 15 24</td>
<td>71.1%</td>
</tr>
<tr>
<td>Continence</td>
<td>34 (22.4%) MV=1</td>
<td>53 (34.9%) MV=2</td>
<td>25 8 29 88</td>
<td>75.2%</td>
</tr>
<tr>
<td>Category</td>
<td>N (Percentage)</td>
<td>Mean</td>
<td>Median</td>
<td>Mode</td>
</tr>
<tr>
<td>------------</td>
<td>----------------</td>
<td>------</td>
<td>--------</td>
<td>------</td>
</tr>
<tr>
<td>Cognition</td>
<td>58 (38.2%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>116 (78.4%)</td>
<td>7</td>
<td>67</td>
<td>25</td>
</tr>
<tr>
<td>Mood</td>
<td>91 (59.9%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>81 (56.0%)</td>
<td>17</td>
<td>32</td>
<td>46</td>
</tr>
<tr>
<td>Behaviour</td>
<td>73 (48.0%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>72.2%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>59.0%</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Concurrent validity of COPE assessment:

The continuously distributed COPE assessments for impairment in cognition, nutrition, mobility and behaviour correlated statistically significantly, but moderately (correlation coefficient 0.21 to 0.47) with the EASY-Care independence score (Table 4). Correlations with the GDS-8 depression score and the number of hearing tests passed (from 0 to 4) in the best or worst ear, were negligible or low, and not statistically significant. The numbers of impairments identified by the CHW-administered COPE assessment and by clinician judgment correlated moderately (Kendall’s Tau-B +0.38, p<0.001). The Kendall’s Tau-B correlation between numbers of impairments according to CHW/COPE and the EASY-Care independence score was +0.31 (p<0.001), and with intervals of care assessed by the CHW was +0.25 (p<0.001).

Table 4 : Criterion validity (Area under ROC curve, against clinician judgment) and concurrent validity (correlation with EASY-Care independence score)

<table>
<thead>
<tr>
<th>Impairment</th>
<th>Test</th>
<th>Criterion validity</th>
<th>b) Concurrent validity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Area under ROC curve, against clinician judgment</td>
<td>Correlation with EASY CARE independence score</td>
</tr>
<tr>
<td>Cognition</td>
<td>Brief cognitive score</td>
<td>0.71 (0.61-0.80)</td>
<td>-0.47, p&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>Combined score</td>
<td>0.68 (0.58-0.78)</td>
<td>-0.48, p&lt;0.001</td>
</tr>
<tr>
<td>Nutrition</td>
<td>MNA—SF score</td>
<td>0.70 (0.62-0.79)</td>
<td>-0.34, p&lt;0.001</td>
</tr>
<tr>
<td>Mobility</td>
<td>Gait speed</td>
<td>0.63 (0.45-0.80)</td>
<td>-0.21, p=0.02</td>
</tr>
<tr>
<td></td>
<td>Chair stand</td>
<td>0.65 (0.48-0.83)</td>
<td>-0.38, p&lt;0.001</td>
</tr>
<tr>
<td>Depression</td>
<td>GDS-8</td>
<td>0.73 (0.64-0.80)</td>
<td>0.04, p=0.66</td>
</tr>
</tbody>
</table>
### Behaviour

<table>
<thead>
<tr>
<th></th>
<th>NPI severity score</th>
<th>NPI distress score</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.72 (0.64-0.80)</td>
<td>0.21</td>
</tr>
<tr>
<td></td>
<td>0.69 (0.60-0.77)</td>
<td>0.28, p=0.001</td>
</tr>
</tbody>
</table>

### Hearing

<table>
<thead>
<tr>
<th></th>
<th>Best ear</th>
<th>Worst ear</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.71 (0.62-0.80)</td>
<td>0.71 (0.63-0.80)</td>
</tr>
<tr>
<td></td>
<td>-0.14, p=0.10</td>
<td>-0.12, p=0.16</td>
</tr>
</tbody>
</table>

### Post hoc analysis

Given the under-identification of impairments by the COPE tool as administered by the CHWs (or, alternatively, the over-identification of impairments by the clinician unstructured assessment), we carried out a post-hoc analysis to compare the EASY-CARE independence scale score among three groups:

1) those who screened positive using the COPE (true positives and false positives),

2) those who were identified with impairment by the clinician, but not by COPE (false negatives),

3) those identified as negative by CHW and clinician (true negatives).

For all impairments other than hearing impairment and depression, those identified by the COPE as impaired (Group 1) had higher independence scale scores (suggesting greater needs for care) than did those identified by the clinician but not confirmed by COPE (Group 2) (Table 5). For nutrition, vision, incontinence and cognitive impairment the difference in mean dependence score between these sub-groups was statistically significant.
Table 5 Mean EASY-Care independence scores for those identified as impaired by CHW administered COPE assessment (Group 1), compared to those identified as impaired by clinician judgment but not by CHW/COPE (Group 2) and those identified by neither assessor (Group 3)

<table>
<thead>
<tr>
<th>Impairment</th>
<th>Group 1 CHW COPE+</th>
<th>Group 2 Clinician +/- CHW COPE-</th>
<th>Group 3 Both -</th>
<th>1 vs 3&lt;sup&gt;1&lt;/sup&gt;</th>
<th>1 vs 2&lt;sup&gt;1&lt;/sup&gt;</th>
<th>2 vs 3&lt;sup&gt;1&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nutrition</td>
<td>43.8 (21.4)</td>
<td>34.6 (12.3)</td>
<td>26.9 (10.5)</td>
<td>16.9, p&lt;0.001</td>
<td>9.2, p=0.04</td>
<td>7.7, p=0.20</td>
</tr>
<tr>
<td>Mobility</td>
<td>39.3 (19.0)</td>
<td>33.3 (17.8)</td>
<td>23.0 (15.2)</td>
<td>16.3, p=0.16</td>
<td>6.0, p=0.76</td>
<td>10.3, p=0.53</td>
</tr>
<tr>
<td>Vision</td>
<td>40.7 (21.6)</td>
<td>33.1 (13.0)</td>
<td>-</td>
<td>-</td>
<td>7.6, p=0.02</td>
<td>-</td>
</tr>
<tr>
<td>Hearing</td>
<td>36.3 (15.4)</td>
<td>40.3 (24.2)</td>
<td>29.9 (2.5)</td>
<td>6.4, p=0.21</td>
<td>-3.9, p=0.68</td>
<td>10.4, p=0.15</td>
</tr>
<tr>
<td>Continence</td>
<td>56.5 (25.5)</td>
<td>43.7 (15.2)</td>
<td>29.1 (9.4)</td>
<td>27.4, p&lt;0.001</td>
<td>12.8, p=0.006</td>
<td>14.6, p&lt;0.001</td>
</tr>
<tr>
<td>Cognition</td>
<td>48.8 (22.0)</td>
<td>32.1 (13.0)</td>
<td>28.0 (11.8)</td>
<td>20.8, p&lt;0.001</td>
<td>16.6, p&lt;0.001</td>
<td>4.1, p=0.58</td>
</tr>
<tr>
<td>Mood</td>
<td>38.4 (19.6)</td>
<td>39.5 (19.4)</td>
<td>30.6 (11.4)</td>
<td>7.9, p=0.29</td>
<td>-1.1, p=0.95</td>
<td>8.9, p=0.26</td>
</tr>
<tr>
<td>Behaviour</td>
<td>42.6 (22.1)</td>
<td>39.1 (17.8)</td>
<td>29.6 (9.6)</td>
<td>12.9, p=0.01</td>
<td>3.5, p=0.66</td>
<td>9.4, p=0.08</td>
</tr>
</tbody>
</table>

1. Scheffe test for mean difference with multiple sub-group comparisons
2. Could not be computed as only one participant in this sub-group
Finally, in a multivariable model, controlling for age and gender, neither vision nor depression made a statistically significant contribution to EASY-Care independence scores, whether assessed by CHW-administered COPE, or clinician judgment (Table 6). The contribution to the variance made by nutrition, mobility and cognition impairment was greater for CHW/COPE assessed impairment than for clinician judgment, while the reverse was true for impairment in hearing and behaviour.

Table 6: Independent, individual and collective contribution of impairments ascertained through CHW administered COPE and clinician judgment to the variance (eta squared %) in EASY-Care independence score

<table>
<thead>
<tr>
<th>Impairment</th>
<th>Mean difference (95% confidence intervals) and variance explained (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CHW COPE assessment</td>
</tr>
<tr>
<td>Nutrition</td>
<td>-6.3 (-11.4 to -1.2) 4.5%</td>
</tr>
<tr>
<td>Mobility</td>
<td>-7.8 (-14.2 to -1.4) 4.3%</td>
</tr>
<tr>
<td>Hearing</td>
<td>-0.8 (-6.6 to 5.0) 0.1%</td>
</tr>
<tr>
<td>Vision</td>
<td>-0.6 (-5.6 to 4.4) (0.4%)</td>
</tr>
<tr>
<td>Mood</td>
<td>1.2 (-3.9 to 6.4) (0.2%)</td>
</tr>
<tr>
<td>Behaviour</td>
<td>-2.7 (-7.8 to 2.5) 0.8%</td>
</tr>
<tr>
<td>Cognition</td>
<td>-9.6 (-15.3 to -4.0) 8.2%</td>
</tr>
<tr>
<td>Total</td>
<td>17.8%</td>
</tr>
</tbody>
</table>
Qualitative data on COPE assessment: community health workers (CHWs)

The COPE assessment package was generally perceived as easy to administer, with CHWs reporting that they gained knowledge, experience and confidence through training.

“COPE assessment was designed in a very simple way; therefore we had no difficulty in using it. We had used it at ground level and it wasn't expensive also. Tomorrow if anyone require assessment, most of the things are ready to administer”. Respondent - A

“It was not easy in the beginning. You came with us and taught us properly. We also came to know about our mistakes. After that it was easy with the rest of the patients”. Respondent- B.

The CHWs felt empowered to conduct assessments of older people, and discriminate between different types of impairment that might require intervention

“We got to learn a lot of new thing from it, which we were not doing in our routine work. Mostly we refer older patients to the doctors. But in this we were playing the role of a doctor and assessing older patient, it was interesting and we were curious to identify their problems”. Respondent - D.

“The COPE tool given to us was very easy and we were doing it as if we were the doctor. After administering the test at home we came to know what exactly their problems is like their vision power, can or cannot hear or to what extent they are depressed or cannot remember, or having incontinence”. Respondent -E

“We are able to distinguish between their problems. Sometimes what happens, older people experience psychological problem and they don’t eat well and may be become undernourished. In such cases, we could not understand whether it was psychological or nutrition problem? But now we can separate the nutrition and psychological problems, and refer them as per their need”. Respondent – F.
In their view this could increase the efficiency of the care provided, both in improving identification and generating more accurate referrals.

“The skills have developed and now the job is also getting done in a better way - Therefore I am interested. Earlier if anyone was telling us that they cannot see - we simply ask them to go to the PHC (Primary Health Centre). Now we feel good to look at their problem, we tell them let us go inside (home) and do the test”. Respondent - B.

“If the tools were not there we would refer them to the doctor directly and we would not be able to tell their exact problem to them and their family. Now if they tell us that they cannot see or hear or they cannot remember or have incontinence - we can do these tests with them and tell them and their family that these specific problems. Moreover, according to the test results we can refer them to PHC or GMC for hearing and vision”. Respondent - E

“But now, since we know we have the training and assessment tool in our hand, we can use them and assess the older person. Even if nothing could be done at our level, we could at least refer them to appropriate service. In this regard the COPE assessment tool was useful to find out what exactly the problem is and then refer them accordingly”. Respondent - A

“Only when we identify the real problems of older people, we would be able to refer them to the specialist doctor. In case if we don’t have any idea about their problems, it not easy to refer them”. Respondent - F

We see a group (dependent older people) in whom even the conditions that are treatable were not treated at home. Mainly because assessments were not done properly” Respondent - A

After knowing his/her history, we can tell the doctor about older person problems. Because when they go to the OPD, the doctor does not have so much time to assess everything. So sometimes it is neglected because the doctor is busy”. Respondent - F
However, several of the CHWs were of the view that the involvement of doctors was crucial, to validate their findings, and to recommend and implement treatment. One CHW mentioned that a doctor’s involvement would increase cooperation from older people and family members.

“We only do the identification, but the treatment part which is very important. We cannot give treatment. Finally, for any treatment you need the doctor, therefore doctors visit is important”. Respondent - F

“The doctors should assess them and give treatment or solution to the identified problems. Otherwise there is no benefit from our assessment”. Respondent - B

“Yes, I feel so. Because at times we may be making some mistake. Until the doctor confirm, the older patients do not get agree 100 percent”. Respondent - G

“We used to do this whisper voice test, some older people complain about pain in their ears or some other problems for which doctor is needed”. Respondent - A

The assessment was generally perceived as acceptable to the older people and their family members, in part because this showed that the service was interested in their problems. Benefit might come simply from improved knowledge and understanding. However, some CHWs did experience difficulty in convincing some older people of the possible benefits of assessment, given their fatalistic view of their health status.

“They really felt that we will get some information about their sickness through assessment. And they came to know what difficulties and problems they had, which satisfied them”. Respondent - H

“Somebody was concerned about their health. So older people and as well as the family members were genuinely showed good interest”. Respondent-A

“Few of the family members were becoming more excited. All the tests are happening by sitting at home, they felt good. Many even asked us, “When will you come back again?” Respondent- D

“Most of the family members, as well as, older people who were not able to perform their daily activities were willingly participated. Because they knew that
something is been assessed and they would benefit by at least knowing what are their problems”. Respondent – A

“Most of the older patients were agreed for assessment and okay with it. But few directly say “No, we don’t require, what are you going to do? We are like this for so many years. You just come for one day, there is not going to be any change at all”. Respondent - A

Some health workers mentioned that the caregiver part of the COPE assessment helped family members to reorient the care needs of older person.

“Even family members felt that what they were doing for the older person was less than what is required. So, with the help of COPE we increased the knowledge of family members regarding care needs of older person”. Respondent - D

“Older people do not know that they have disease, and their caregivers are less aware of older person’s problems. Through the assessment, they came to know about what can happen if these problems become more severe?” Respondent - C

Opinion was divided among CHWs as to whether the COPE assessment could be routinely incorporated in their daily work. Some felt that was both feasible and necessary. Others expressed concern about the time to administer the COPE assessment, and the impact that this might have on their other work

“We did not have any concerns about the time. In the beginning we felt that this is going to take a lot of time and we have our other targets too. But later in the field it became a usual thing and perfect for us, so there was no big problem - It was easy to use it”. Respondent - E

“There was no problem about the time. Whatever required has to be done and should be done correctly. For that reason we would take whatever time that was required. So that we get the correct answer from older patients and family members”. Respondent - D
“Not that easy I would say. Tools were very good - they are simple to be understood by the old people. But then administration taking bit longer time. It be may be because, older people have difficulties in hearing, walking, and their age. So it wasn’t that easy to administrate I would say. Generally, other works takes lesser time - suppose we attend to two to three older people then most of our time for the day will be consumed”. Respondent-A

“We had to take a little trouble since it was extra work. Mainly because it required 30 to 45 minutes with one older patient, and to complete the work we had to go early to the field and work till lunch time”. Respondent- E

“Only the thing we have heavy work load. Nowadays, time available to do the work is not sufficient. Therefore additional work is impossible. We only have morning hours for field visits; we have to complete all our work with that time”. Respondent - C

Several CHWs had already begun to use the COPE assessment outside of the confines of the research evaluation

“Now I have included it in my daily field work. So now both are going on side by side. So now I don’t think I have to specially to assess older people”. Respondent - F

“We use it in our practice and we can also use it in future. Whenever we go to houses, we will use it”. Respondent - B

“As I said, besides our other duty, when we are in the field and meet anyone older person, we can assess by taking out some time. Otherwise after completing other duties, we can do the assessment”. Respondent -D

“I am ready to do the administration because I did not have any problem. All older people welcomed me because they will get some benefit this work. So I am ready to it in the future”. Respondent - H

The main difficulties experienced in using the COPE tool were that organisation was required to carry out the caregiver assessment, and sometimes a second visit was required for that purpose. Some tests, particularly the five metre walk test and the visual
acuity test were difficult to perform in some households because of cramped space and/or poor lighting. The visual acuity test was difficult to explain to participants with cognitive impairment, and some health workers expressed a need for additional training to identify vision problems in older people with dementia. Some CHWs commented that a second assistant might be required with very frail older people when no family caregiver was at hand.

4.4 DISCUSSION

The first objective of this study was to examine the acceptability and utility of comprehensive COPE assessment developed for non-specialist community health workers in identifying specific impairments in frail older people at primary health care level. Our second objective was to explore the concurrent validity of COPE assessment against clinical assessments carried out by physicians working in the same local public health system.

The strengths of this study included, first, a clear brief for the development of a comprehensive geriatric assessment tool for use in resource poor settings by suitably trained CHWs, with little or no assumed relevant clinical experience or knowledge. The pragmatic study design assessed how the structured assessment might work in real world primary care settings, and how the results of the assessment might converge with those of clinicians working in the same settings. The clinicians conducted an independent assessment and were completely masked from the CHW COPE assessment results. The clinician assessment may have been adversely affected by the doctors’ non-specialist background, the short time available for the assessment, and the lack of equipment (for, for example audiometry or visual acuity testing). For all these reasons, the clinician judgment certainly cannot be considered to represent a ‘gold standard’ and we have carried out a construct validation rather than a criterion validation of the COPE assessment. It would be possible, perhaps desirable, to carry out a more detailed criterion validation of the COPE in the future. However, evidence, mainly from high income countries, already supports criterion validity for most of the components.
Arguably, the convergence with local clinician opinion may be most relevant to considering its utility and acceptability within the local health system.

Most CHWs reported that the COPE assessment was relatively easy to administer, and appreciated the empowerment that the training and tool gave them to conduct competent assessments of older people and identify specific problems. Some spoke of the potential advantages in terms of increasing the coverage and efficiency of care provided for older people, and in orientating family carers to the care needs of frail older people. Regarding the feasibility of administering COPE assessment as part of their routine work, many of the CHWs talked of this as a necessary development and expressed willingness to use this in the future. However, there were concerns regarding the time taken to administer the assessment, and its impact on their current workload. These views are likely coloured by the fact that attending to the needs of older people is currently neither part of their role, nor on the priority healthcare agenda of the primary health care or sub-centre system. Therefore, spending time with older people is considered as additional responsibility.

There was only a moderate agreement between the CHW COPE assessment and the clinician judgment for some of the impairments; nutrition, continence, mood, hearing and behaviour; and low agreement for mobility, cognition and vision impairments. On closer inspection of the data, this was mainly accounted for by the generally higher prevalence of all of the impairments other than hearing impairment, according to clinician judgment compared with the findings from the structured COPE assessment. Impairments identified by COPE were generally confirmed by the clinicians, reflected in the high positive predictive values for the COPE assessment (72.2% to 98.5%). However, particularly for vision, cognition and mood impairment, many more participants were considered by the clinician to have the impairment, reflected in the large discrepancy in prevalence, the low sensitivity of the COPE assessment, and the low levels of agreement. Since we lack an independent gold standard assessment, it is impossible to be sure whether this represents under-recognition by the COPE, or over-diagnosis by the clinician assessor, or both. In the 10/66 Dementia Research Group’s population-based surveys in Latin America, India and China, the prevalence of dementia among care dependent participants was a little under or a little over 50% in
most sites. This is closer to the COPE estimate of 38% with cognitive impairment than the clinician estimate of 78%. There are no suitable external comparators for the prevalence of low mood and visual impairment among care dependent older people. The level of disability/ needs for care among those identified by COPE was generally higher than that for those additionally identified by the clinicians but not confirmed by COPE. This difference was both particularly striking and statistically significant for nutrition, cognition and vision impairments, suggesting that COPE might be more conservative than clinician judgment and more effective at targeting those with more severe impairment. This may be because the CHW COPE assessment comprised objective tests with clear operationalisation, whereas clinician relied upon global clinical impression.

Reassuringly, COPE assessed impairments were generally correlated with (continuous test scores) or associated with EASY-Care independence scores. The lack of any crude or adjusted association between mood impairment and disability, whether mood was assessed by COPE or clinician judgment, is surprising. It may be that in this sample of older people with extensive multimorbidity and quite intensive needs for care, the impact of other conditions and impairments predominates. Whether assessed by COPE or clinician judgment, impairments in nutrition, mobility, hearing, vision, mood, behaviour and cognition collectively accounted for just under 20% of the variance in the independence score, with the largest contributions coming from cognition/ behaviour, consistent with other reports of the dominant effect of disorders of the brain and mind on disability and dependence.

In low resourced primary health care, it is rare for clinicians to visit patients in the community, and this is even considered undesirable. Physical mobility impairment and lack of transportation limits the scope for frail dependent older people to visit the primary health care facilities for assessment and treatment. Community health workers (who are currently the interface between the community and primary health care facility) could bridge this divide by performing home based assessments, consulting doctors or initiating referral where necessary, and implementing some indicated evidence-based interventions themselves, in the patient’s own home. This kind of collaborative working model is already in practice for improving maternal and child health, but its potential is rarely considered for managing dependent older people. The
evidence presented here suggests that the COPE assessment is a useful tool for identifying specific impairments linked to needs for home care and support. The high positive predictive value of the CHW identification using the COPE assessment tool suggests that local physicians could have confidence in the accuracy of the CHW assessments, whether in authorising them to initiate interventions based upon their findings, or in accepting referrals arising from these assessments.

Some needs for refinement were noted in the course of this pilot evaluation of the COPE assessment. A portable light source and a mirror could facilitate the administration of the Snellen chart vision test, where space is cramped and lighting inadequate. Vision testing should be extended to include near vision testing (reading), since unlike refraction errors (which would require optometry and a prescription for glasses or cataract surgery), hyperopia can be corrected by low cost magnifying lens glasses, which could be dispensed by the CHW. Pain is a common and burdensome impairment, which is not yet assessed as part of COPE, and may be a relevant co-factor in other impairments. Pain management may be challenging unless prescribing restrictions that pertain in many health systems, including that in Goa, are eased. More information would be required to plan interventions; for example a dietary assessment for nutritional intervention, and assessment of pain, recent fractures, and safety aspects prior to exercise interventions to improve mobility. However, such additional assessments could be conducted as part of the intervention, after screening using COPE. The next step would be to evaluate the COPE for cost-effectiveness, in the context of a cluster randomised controlled trial of a complex intervention comprising screening and intervention with evidence-based packages of care.
4.5 BIBLIOGRAPHY


12. GoI. Indian Public Health Standards(IPHS) Guidelines for Sub-Centres Revised In: Directorate General of Health Services MoHFW, editor. New Delhi, India: Government of India(GoI); 2012.


30. Rubenstein LZ, Harker JO, Salva A, Guigoz Y, Vellas B. Screening for undernutrition in geriatric practice: developing the short-form mini-nutritional


61. StataCorp. Stata Statistical Software: Release 11.: College Station, TX: StataCorp LP; 2009.


CHAPTER FIVE
CHAPTER FIVE:

Evidence-Based Intervention Guide for Prevention and Management of Dependency among frail dependent older people in Low and Middle Income Countries: Summary of WHO-COPE (Care for Older PEople) Recommendations

5.1 BACKGROUND:

The demographic transition in Low and Middle Income Countries is expected to result in an increase in the proportion of care dependent older people.\(^1\) There is evidence that the age-specific prevalence of dependence (needs for care) among older people is already nearly as high in low and middle-income countries (5-12% of those aged 65 and over) as in high-income countries. Numbers affected are set to rise rapidly, with the demographic and health transitions. By 2050 a fourfold increase is anticipated among older people, while numbers among younger people remain stable. Hence, disability and dependence will become increasingly concentrated among older people.\(^2,3\)

The implications of dependence are expected at all levels of society. However, there are, currently, particular problems with the identification and management of care dependent older people at primary health care level. Therefore there is an increasing need to develop evidence based intervention guidelines for non-specialist health workers on simple home-based assessments and interventions for frail, dependent older people and advice and support to their family carers. The rationale for the development of this package of care includes: a) dependence among older people is associated with multiple comorbidities of physical, mental and, particularly, cognitive disorders, b) dependence is strongly associated with economic disadvantage, low socioeconomic position acting as a risk factor for the multiple chronic diseases leading to disability and needs for care, and economic hardship arising from catastrophic health care spending, and carers giving up or cutting back on work to care, c) there is widespread recognition that community health services do not meet the needs of older people in general, and that services for frail dependent older people are particularly limited. The focus on acute ‘treatable’ conditions, the lack of outreach and continuing care excludes many older people from receiving appropriate assistance. A paradigm shift has been called for
towards chronic disease management, long term support and care, d) packages of care for individual chronic diseases (e.g. dementia, stroke, heart disease, arthritis) are likely to be difficult to implement, and inefficient given the multiple co morbidities that afflict this vulnerable group of older people, e) community interventions for frail dependent older people can instead be structured horizontally, targeting relevant impairments that are common across many underlying chronic diseases – e.g. immobility, under nutrition, confusion, depression, incontinence, falls, blindness and deafness – and providing appropriate advice and support to carers.

The work outlined in this chapter was a first systematic attempt to bring together all of the evidence and knowledge pertaining to a) valid and feasible assessments, allowing non-specialists to identify those with needs for care, and accurately to identify the nature and degree of associated impairments and b) effective interventions that would be feasible for use in the community, by non-specialists. The evidence on assessment and intervention will be integrated into a single package of care, comprising an ‘intervention guide’ management algorithm, and accompanying training materials. The proposed guideline will make recommendations for the identification and treatment/management of common ‘geriatric conditions’, including undernutrition, immobility, incontinence, cognitive impairment, behavioural impairment, visual and hearing impairment, and associated caregiver burden. However, evidence for identification and management by non-specialist health care workers is scant, particularly in low and middle-income countries. Our expert consensus group (covering all WHO regions, and all targeted domains) carefully reviewed the systematically documented evidence. Consensus agreement was made based on strength of evidence, feasibility and generalizability of the evidence.

5.2 WHO-COPE GUIDELINE DEVELOPMENT PROCESS:

The detail of WHO guideline development process is presented in figure 1. The central aim throughout the process of guideline development is to maintain transparency and reduce personal judgement. In brief, the key components of WHO-COPE guideline development process include; 1) priority setting, and choice of the topic for
development of WHO guideline, 2) group composition and consultation, 3) declaration and avoidance of conflict of interest, 4) managing the expert group for the process of developing guideline, 5) explicit definition of the scoping questions and eligibility criteria, 6) identification of important outcomes, 7) decision on the type of study designs suitable for the questions considered, 8) identification of evidence (from systematic reviews), 9) the grading, synthesis and presentation of evidence, 10) specification and integration of values and preferences, 11) making judgements about desirable and undesirable effects, 12) taking account of cost, 13) drafting final recommendations and defining the strength of those recommendations (strong/ conditional/ weak). After establishing an external review committee, an application justifying the need for developing intervention guidelines, and the methodology of guideline development was submitted to WHO Guideline Review Committee (GRC), and initial approval was obtained before contacting the expert members.

5.2.1 Declaration and management of conflict of interest:
All members agreeing to participate were requested to complete a Declaration of interest (DoI) form. The conflict of interest statements expressed by group members were reviewed by Dr. John Beard (Chair) and Prof. Martin Prince (Co-chair) before finalising the group composition. Any member who declared interests that were relevant to the review of evidence and recommendation of guideline were discussed with WHO guideline review committee or legal counsel to decide whether they could participate in the guideline development. All Declarations of interest by the participants of guideline development work were circulated electronically to all other expert group members. At each review meeting (teleconference), members were requested to provide a verbal summary of their written declaration of interest. During the face-to-face consultation, the Chair and Co-Chair of guideline steering committee will present the Declarations for the group to review and revise as necessary. If any member who declared interests with significant potential for conflict will only be allowed to act as an observer during the final consensus meeting for drafting guideline recommendations. The decisions made for such exclusions will be clearly documented. To date, no significant conflicts of interest have been identified. A summary of conflicts of interest declarations will be included in the actual official guideline document when published. In the event that no conflict was declared, this information would also be published.
5.2.2 Formulation of foreground question:
The foreground questions formulated for conducting systematic reviews are presented in table 1. The questions were formulated using PICO framework (P-population, I-intervention, C-comparison group, O-outcomes). The selection of appropriate questions to be addressed in the guideline has major consequences for the scope of the guideline, and also determine the type of information that needs to searched (inclusion and exclusion of data) and synthesised in preparing the evidence for recommendation. The foreground questions of WHO-COPE were clearly defined in advance with consensus agreement from expert members.

5.2.3 Rating relevance of outcomes:
Initially, the key outcomes that are possibly relevant were listed for each foreground question, and circulated to expert sub-groups for comments. The expert members were asked to consider the importance of each outcome from patient and service providers’ perspectives and to rate their relevance as not important, important, very important, or critical for making guideline recommendation. The purpose of this exercise is to identify the outcomes that will be most relevant for making decisions, and to identify the most relevant studies and data for evidence synthesis in drafting the final recommendations (see table 1).

5.2.4 Evidence retrieval, assessment and synthesis:
For drafting guideline recommendation, in consultation with the expert panels, a series of systematic reviews was carried out using EMBASE, Medline and PsyINFO data bases applying Mesh terms where appropriate. The Cochrane Library for existing reviews was searched systematically for each scoping question. In formulating the scoping questions, and conducting the reviews, we were particularly interested in evidence that applied specifically; 1) to older people who were dependent and/or frail, as opposed to older community-dwelling older people in general, 2) interventions applied in community-settings or primary healthcare, by non-specialist health or social
care workers, and 3) trials conducted in low or middle income countries, and/or resource poor settings.

The steps undertaken for retrieval of evidence, assessment, and synthesis were summaries below. **Step one:** We conducted a comprehensive search of Ovid MEDLINE and EMBASE databases for systematic reviews and individual randomised control trials, investigating benefit of intervention/treatment programme for frail and or dependent older people with mobility limitation, under-nutrition, falls, urinary incontinence. Identified studies were then exported to reference manager bibliography software and checks for duplicates were performed. These were screened for relevance by study abstract, and relevant selected studies were then carried forward for full text review. In the full text review, the following information was extracted to summarise the evidence, “year of publication, country, setting intervention delivered to experimental and control groups, duration of intervention, frequency of intervention, sample size and number of participants in each groups, reported adverse events, adherence to treatment, study design, randomisation process, allocation concealment, information on intention to treat analysis, blinding, and baseline difference between experimental and control group”. Studies were generally excluded if they were conducted on unselected populations of older people (unless the evidence-base on frail dependent older people was severely limited). However, it was apparent that search strategies using these terms as inclusion criteria would yield very few results, and would cover only a small proportion of trials giving salient evidence to the scoping question. The issue of the directness or indirectness of the evidence identified (GRADE methodology) is therefore critical. **Step-two:** Relevant reviews and studies with comparable intervention and outcome characteristics were submitted to meta-analysis. Review manager 5 software was used to calculate mean differences (MD) and standardised mean differences (SMD) between intervention and control group. Relative risks or odds ratios were presented for categorical outcomes. **Step-three:** Meta-analysed results were exported to GRADE Profiler software for evidence grading work. Evidence was graded as very low, low, moderate and high, based on limitations of included studies – specifically with respect to inconsistency, indirectness, imprecision and publication bias. **Step-four:** A narrative description of the studies that were included in the analysis was summarised in the text, providing information regarding the participants, the setting,
coverage of evidence (LMIC/HIC), intervention administration (specialist/non-specialist), type of intervention, frequency of intervention, duration of follow-up, reported outcomes, and adverse events. Step-five: Grade tables were exported to a Microsoft Word document and final evidence to recommendation was drafted by comparing the effect of interventions on relevant outcomes, the quality of evidence, the balance between benefit and harm, values and preferences, and resource limitations. Step-six: The final outcome of systematic review, meta-analysis and grading the evidence exercise is to produce a 2x2 table with all outcomes and interventions, which is then discussed with the expert panel for a clear understanding of the implications of this evidence upon the recommendation of feasible intervention approaches. Based on the effect of the intervention on relevant outcomes, and the quality of evidence, ‘zero draft’ recommendations were made. However, after first consultation with external advisory group, necessary modifications were made to reach a draft recommendation based on the experts’ agreed consensus opinion (see table 2).

Figure 1 : WHO Guideline development process
5.3 STRENGTH AND LIMITATIONS OF THE PROCESS:

Developing recommendations is a complex process that involves systematic review and assessment of the quality of evidence and balance of benefits and harms. In addition, explicit consideration of other issues such as value judgments, resource use, and feasibility, which are major considerations, need to be incorporated. Developing WHO-COPE recommendations within this framework highlighted several challenging and critical issues, including difficulties in formulating questions and rating outcomes, potential reproducibility and consistency problems, problems in incorporating observational evidence when evidence in the form of randomized trials was not available, and difficulties in defining how values, preferences, and feasibility issues should be considered, as the methodology for these aspects is much less developed. Moreover, one of the main challenges faced by WHO-COPE GDG was the lack of funding for face-to-face meetings with the expert groups. The entire guideline development process was conducted electronically through email contact and teleconference. Although we tried to set-up online an community using the World Health Organization’s WHO-EZ collab website for working groups, expert group members valued such interaction as not very helpful.

Furthermore, most of the studies presented for drafting recommendation were conducted in high-income countries. For some areas, the conventional way of synthesizing and evaluating the evidence revealed either no relevant studies, or only very poor quality studies, which were considered insufficient to make any recommendation. One of the most challenging aspects of the whole process was generalizing evidence from high-income countries to low resourced health care settings in LAMICs. For example, all intervention trails for managing urinary incontinence (using prompted voiding techniques) comes from high income countries and studies were mainly conducted in residential or long term care settings. Furthermore, interventions in these studies were mainly administered by nurse professionals involved in routine care. Although such studies provided evidence for the cost-effectiveness of these strategies for reducing the incidence of urinary incontinence, generalizing the evidence to LAMICs countries many challenges. Primary caregivers of older people in
LAMICs are generally family members, who might often have other routine family responsibilities, and their ability to delivery such an intervention effectively needs further research. In such instances we took advantage of the GRADE methodology, which clearly recognizes that in addition to the evidence base, other aspects that are expected to inform the recommendations include consideration of values such as protection of human rights, feasibility and resource use, and the knowledge and experience of the GDG experts. As previously noted, the added value of GRADE in these circumstances is that it requires GDG to transparently report that some recommendations are based on strong values and weak evidence.

5.4 IMPLEMENTATION (evidence-based recommendation for practice):

In LAMICs primary health care is the largest health care sector. However, there is a lacunae in the care organised for frail and/or dependent older people. The structural and practical barriers to assuring coverage of, and access to age-appropriate health care have been presented and discussed in previous chapters. Using community health workers (who have frequent contact with older people and their families in the community) provides one window of opportunity to scale up such services. Achieving quality of care requires a greater health system and policy commitment. There are fewer opportunities for primary health care professionals in low resourced setting to access research to improve their evidence-based clinical practise. Even if systematic reviews by Cochrane are made freely available to LAMIC health professionals, translation into clinical practice is not straightforward. The World Health Organization has a strong and authoritative role in providing policy assistance and advice to Ministries of Health in all of its member countries. Therefore, the evidence-based WHO-COPE intervention guide on assessment, clinical decision-making, and administration of intervention at community or primary health care level should add value to the health care provided for older people.

The issue of how guidelines should be implemented to maximise their impact on clinician performance and patient outcomes has rarely been investigated in low resourced primary health care settings in LAMICs. Furthermore, health systems vary greatly among LAMICs in the availability of human resource and capacity, policy and regulations, therefore the WHO-COPE intervention recommendations would need to be
adopted and tailored to each local health system context and effectively integrated into practice. Initial evaluation of the feasibility of administering individual intervention components is well underway in India. Future research should also aim to evaluate the feasibility of implementing the WHO-COPE intervention guide in low resourced health care settings and also evaluate the cost effectiveness of the package of intervention administered at primary health care or community.
Table 1: Scoping questions formulated and agreed by the guideline development group are listed below.

<table>
<thead>
<tr>
<th>Impairments/conditions</th>
<th>Foreground questions</th>
<th>Outcome rated by experts panel as important or crucial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Undernutrition</td>
<td>Q. For frail dependent older people at risk for malnutrition or malnourished living in the community do nutritional interventions such as dietary advice and oral nutrition supplement produce any benefit / harm compared to placebo/control group?</td>
<td>Mortality, weight gain, hand grip strength, hand grip strength, ADL, IADL, Physical function, QoL, compliance, side effect</td>
</tr>
<tr>
<td>Mobility</td>
<td>Q. For frail dependent older people with mobility impairment do physical exercise interventions such as progressive resistance strength training or multicomponent (strength, balance, flexibility, coordination, aerobics) exercises, or other physical exercise interventions produce any benefit / harm compared to control groups?</td>
<td>Main function measure, Main lower limb (LL) strength measure, gait speed (Six-minute walk test), balance, timed walk, timed up-and-go seconds, time to stand from a chair, physical function domain of SF-36, ADL, Co-ordination and functional task, mortality, falls, adverse event during the trial.</td>
</tr>
<tr>
<td>Vision</td>
<td>Q. For frail dependent older people does screening for visual impairment / cataract surgery/ refraction (new glasses)/ referral to specialist services produce any benefits/ harm in the vision related outcomes when compared to placebo/controls?</td>
<td>Improved visual acuity, vision related quality of life, increased physical function</td>
</tr>
<tr>
<td>Impairments/conditions</td>
<td>Foreground questions</td>
<td>Outcome rated by experts panel as important or crucial</td>
</tr>
<tr>
<td>------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Hearing</td>
<td>Q. For frail dependent older people does screening for hearing impairment, ear syringing/ fitting a hearing aid produce any benefits/ harm in hearing related outcomes when compared to placebo/ controls?</td>
<td>† improvement in whispered voice test, improvement in audiometric test score, improvement in social activities, physical function, quality of life.</td>
</tr>
<tr>
<td>Urinary incontinence</td>
<td>Q. For frail dependent older people with urinary incontinence does prompted voiding/ timed voiding/ functional incidental training/ or other physical therapy produce any benefit / harm compared to placebo/ control groups?</td>
<td>UI urgency, frequency, incidence and mean change, change in mean proportion of hourly check for wet, self-initiated toilet, adverse events</td>
</tr>
<tr>
<td>Risk of falls</td>
<td>Q. Do fall prevention interventions such as medication withdrawal, environmental intervention, or other interventions administered for frail dependent older people produce any benefit / harm compared to control group?</td>
<td>Rate of falls, number of falls, hip fractures, fear of falling.</td>
</tr>
<tr>
<td>Cognitive</td>
<td>Q. For frail dependent older people with dementia or cognitive impairment, which cognitive/psychosocial interventions such as cognitive rehabilitation, reality orientation, and reminiscence therapy would produce any benefits/harm compared to placebo/control? *</td>
<td>Cognitive function, functional status, mortality, reduction in symptoms of depression, QoL.</td>
</tr>
<tr>
<td>Impairments/conditions</td>
<td>Foreground questions</td>
<td>Outcome rated by experts panel as important or crucial</td>
</tr>
<tr>
<td>------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>------------------------------------------------------</td>
</tr>
<tr>
<td>Behavioral</td>
<td>Q.1 For frail dependent older people with depression, which pharmacological, psychological and psychosocial interventions, produce any benefits/harm in the specified outcomes when compared to placebo/controls?*</td>
<td>Reduction in challenging behavior (from patient and family caregivers’ perspectives).</td>
</tr>
<tr>
<td></td>
<td>Q.2 For frail dependent older people with behavior disturbance, e.g. agitation, aggression, wandering, which pharmacological, psychological and psychosocial interventions, produce any benefits/harm in the specified outcomes when compared to placebo/controls?**</td>
<td></td>
</tr>
<tr>
<td>Caregivers strain</td>
<td>Q. For caregivers of frail dependent older people, do interventions such as psychoeducation, training of caregivers, psychological interventions, case management, general support, respite, and multicomponent interventions produce any benefits/harm in the specified outcomes when compared to placebo/comparator?***</td>
<td>Carer strain, depression/psychological problems in carers, caregiver’s quality of life,</td>
</tr>
</tbody>
</table>

* This scoping question has already been addressed in the course of the development of the WHO mhGAP evidence based guidelines and intervention guide (depression management section), and the draft guidelines from this exercise will therefore be adopted.

** This scoping question has already been addressed in the course of the development of the WHO mhGAP evidence based guidelines and intervention guide (dementia management section). We will review the wider applicability of the evidence-base to the management of these problems (which are not unique to dementia), and modify the WHO mhGAP draft guidelines accordingly.

*** This scoping question has already been addressed in the course of the development of the WHO mhGAP evidence based guidelines and intervention guide (dementia management section). We reviewed the wider applicability of the evidence-base to the support of carers of frail dependent older people in general (since not all needs for care arise from dementia), and modify the WHO mhGAP draft guidelines accordingly.

Scoping question and relevance of outcome was not discussed with the experts panel.

QoL - Quality of Life; ADL - Activities of Daily Living; IADL - Instrumental Activities of Daily Living
Table 2: **WHO-COPE recommendation for identification and management of under nutrition, mobility, vision, hearing, cognitive and behavioural, urinary incontinence.**

<table>
<thead>
<tr>
<th>Impairment/conditions</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Undernutrition</strong></td>
<td>Dietary advice should be provided as first line of intervention for frail and or dependent older people at risk of malnutrition. For frail dependent older people who are severely undernourished, oral nutrition supplement (with macro and micro ingredients) should be recommended.</td>
</tr>
<tr>
<td><strong>Mobility</strong></td>
<td>Multicomponent exercises including progressive resistance strength, balance, flexibility, and aerobic training should be administered for frail and/ or dependent older people with mobility impairment. However, capacity of these individuals (housebound, chair bound, bed bound) to perform the exercises may vary, therefore non-specialist health workers should be thoroughly trained to assess the capacity and administer tailored physical exercise interventions.</td>
</tr>
<tr>
<td><strong>Vision</strong></td>
<td>Corrective eye glasses should be recommended for frail dependent older people with low vision acuity. Near vision problems are very common, for which non-specialist health workers can effectively distribute magnifying (reading glasses) of appropriate strength to correct near vision problems in the older person’s home. Provision for cataract eye surgery should be recommended for frail dependent older people with cataract. Non-specialist health workers can be trained to identify older people with cataract and low visual acuity; however, referral to PHC or eye clinic would be necessary in the majority of cases to identify cataract that may require for surgical intervention, and diabetic retinopathy (undiagnosed diabetes).</td>
</tr>
<tr>
<td><strong>Hearing</strong></td>
<td>Consultation with expert members for drafting recommendations is in progress.</td>
</tr>
</tbody>
</table>
### Impairment/conditions

<table>
<thead>
<tr>
<th>Impairment/conditions</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Urinary incontinence</strong></td>
<td>Prompted voiding should be recommended for frail and or dependent older people who can not toilet independently, including for those with cognitive impairment. For older people who can reach independently to toilet and with stable cognitive functioning, pelvic floor muscle and bladder training can be administered.</td>
</tr>
<tr>
<td><strong>Risk of fall prevention</strong></td>
<td>Evidence from systematic review showed that for older people at risk of falls, preventive interventions such as medication review by pharmacist, vitamin D + calcium, multidisciplinary team and multi-factor intervention with comprehensive geriatric care were likely to reduce the incidence of falls. However, we will consult the expert group regarding the generalizability and feasibility of delivering these interventions in low resourced non-specialised health care settings.</td>
</tr>
<tr>
<td><strong>Cognitive</strong></td>
<td><strong>Note:</strong> WHO-mhGAP recommendations for management of older people dementia will be revisited. In near future, same experts group members will be contacted for generalising or revising the recommendations for frail and or dependent older people with cognitive impairment.</td>
</tr>
<tr>
<td><strong>Behavioral problems</strong></td>
<td><strong>Note:</strong> WHO-mhGAP recommendation for management of behavioral problems due to dementia, was mainly about caregivers training and support. However, experts group members will be contact again for revising the recommendation for frail and or dependent older people who have no dementia.</td>
</tr>
<tr>
<td><strong>Carer strain</strong></td>
<td>Psychoeducational interventions should be provided to family carers of frail and or dependent older people with dementia. Additional training of carers involving active caregiver participation (role playing/behavioural problem management) may be indicated according to the care needs, mainly for caregivers who are coping with behaviour symptoms.</td>
</tr>
</tbody>
</table>


CHAPTER SIX
CHAPTER SIX:

Does nutritional intervention produce any therapeutic benefit for undernourished dependent older people? A systematic review and meta-analysis

6.1 BACKGROUND:

Undernutrition is an important indicator of frailty. In studies from developing countries prevalence among community dwelling older people ranges between 1.3 % and 47.8 %. These prevalence are somewhat higher than those from high income countries, where a recent systematic review recorded prevalence of 0% to 4.9% in community dwelling older persons (but a much higher prevalence in settings with higher dependency levels; 18.6% to 68.0% for those in acute care; 42% to 47% for subacute care, and 5.7% to 39% for residential care). Observational studies reported strong association between undernutrition and adverse health outcomes including impaired quality of life, functional decline and mortality. In high income countries older people who report (unintentional) weight loss have an increased risk of developing ADL disability. In a three year longitudinal study conducted in China, low BMI was a moderate risk factor for the onset of activities of daily living (ADL) disability and functional decline. Strong cross-sectional associations were observed between nutritional status and functional impairment in rural settings in India and Bangladesh, and indicators of undernutrition have been found to be associated with lower hand grip strength in studies in Malawi, and Rwanda. In a recent review of evidence from high income countries, in three of seven studies malnutrition as significant predictors of mortality among community dwelling older people. In a longitudinal study in south India, smaller mid arm circumference was a strong and independent predictor of mortality among people aged 60 years and over.

The evidence of a high prevalence of undernutrition among community-dwelling older people in low and middle income countries, and an important association with functional impairment and mortality, suggests that this could be a target for community intervention. However, causality is not clearly demonstrated, and the evidence base for the effectiveness of intervention is not clear cut. Recent systematic reviews on oral nutritional supplementation found very few trials from low and middle-income country
settings, and the bulk of the evidence comes from trials conducted in hospitals and nursing homes.\textsuperscript{23, 24} With respect to interventions in the community, no distinction was made between those trials that focused upon frail or dependent older people, and those which included ‘healthy volunteers’ or unselected samples of community residents. Therefore, this review was undertaken to update the evidence base, extending the scope of the review to include other types of nutritional intervention (principally dietary advice and mealtime enhancement strategies), but focusing specifically upon randomised controlled trials that recruited older people who were already frail, or dependent, or both. We were particularly interested in the extent to which the evidence base was applicable to, or could be generalised to low and middle-income country settings.

\textbf{6.2 METHOD:}

\textbf{Criteria for inclusion in the review:}

\textbf{Studies}
This review included randomised controlled trials comprising of the following interventions targeting undernutrition: a) macronutrient oral nutritional supplement with or without micronutrient components; studies in which the nutritional supplementation was restricted to glucose, vitamin, mineral or fatty acid supplementation alone, were excluded, b) dietary education or advice; c) meal time enhancement strategies (feeding assistance or environment modification)

\textbf{Participants}
We included trials that recruited participants aged over 60 years, male and female, meeting commonly used criteria for undernutrition. Trials in which normally nourished individuals were also included were considered eligible if sub-group analyses were reported restricted to those who were undernourished. As there is no consensus on the definition of frailty, we included studies that mentioned they involved frail older people and/ or dependent older people or those with functional limitation. No language restrictions were applied.
Outcome measures

Outcome measures were the following.

- Weight at the end of the trial, or change from baseline to end-point
- Mortality
- Health-related quality of life (e.g. Nottingham Health Profile (NHP), Short form 36 health survey questionnaire (SF-36), Euroqol EQ-5D.
- Disability or functional status: activity of daily living scale and instrumental activities of daily living scale, Barthel index, and functional independence measures.
- Physical functioning: hand grip strength, gait and six minutes walking test, time up to go test, stair climbing test, physical activity rating, number of falls, LASA physical and functional limitation questionnaire, Berg balance scale, Norton activity rating scale.
- Adverse events during the intervention or follow-up period

Search methods for identification of studies

Literature searches (last update: June 2012) were performed in the following databases: Ovid MEDLINE, EMBASE and Cochrane database. MeSH (Medical Subject Heading) was utilised where appropriate terms were available, supplemented with keyword searches to ensure comprehensiveness. Search results were restricted to randomised control trials, and was not limited to language or publication year. To supplement the searches of published researches, experts in the field of nutrition were contact for additional studies if any.

Data collection and analysis

Selection of trials

Included and excluded studies were classified and described according to the Preferred Reporting Items for Systematic reviews and Meta Analysis (PRISMA). We examined all titles and abstracts, and obtained full texts of potentially relevant studies. Two reviewers independently screened the papers and determined whether they fulfilled inclusion criteria. Care was taken to exclude duplicate publications.
Assessment of risk of bias in included studies

The risk of bias in the included studies were assessed using Cochrane guideline on following parameters: Two items assess the strength of the randomization process in preventing selection bias in the assignment of participants to intervention and comparison groups: adequacy of sequence generation and allocation concealment. The third item, masking out assessor, which assesses the influence of performance bias on the study results. The fourth item assesses the likelihood of incomplete data, which raises the possibility of bias in effect estimates.

Data extraction

In the full text review, the following information was extracted to summarize the evidence, “year of publication, country, setting intervention delivered to experimental and control groups, duration of intervention, frequency of intervention, sample size and number of participants in each group, reported adverse events, adherence to treatment, study design, randomization process, allocation concealment, information on intention to treat analysis, blinding, and baseline difference between experimental and control group” . First reviewer (ATJ) independently extracted the data concerning details mentioned above. Second reviewer verified the extracted information. Disagreements were resolved by discussion and consensus with a third member of the review team.

For continuous outcomes, the mean change from baseline to end-point or mean scores at end-point, the standard deviation or standard error of these values, and the number of patients included in each experimental group were extracted. For dichotomous outcomes, the number of participants with relevant outcome and total number of participants in each group were extracted for analysis.

Data analysis:

A double-entry procedure was employed. Data were initially entered and analysed using the Cochrane Collaboration’s Review Manager software version 5, and subsequently entered into a spreadsheet and re-analysed using the ‘metan’ command of STATA 11 version for Mac. Outputs were crosschecked for internal consistency.

For continuous outcomes, when only the standard error was reported, it was converted into standard deviation. When standard deviation and errors were not reported at end-
point, the mean value of known standard deviations was calculated from the group of included studies. Continuous data were analyzed using mean differences or standardized mean differences (when scores from different outcome scales were summarized) and for dichotomous outcomes, the relative risk (RR) was calculated using the random or fixed effects model (with 95% confidence intervals, CI) depending on significant level of heterogeneity.

The heterogeneity around the meta analyzed estimates were calculated using using Higgins $I^2$. This provides an estimate of the percentage of variability due to heterogeneity rather than chance alone. Where the $I^2$ estimate is greater than or equal to 50%, we interpreted this as indicating the presence of high levels of heterogeneity. Visual inspection of funnel plot, for asymmetry, was used to investigate the possibility of publication bias. Findings were summarized in a GRADE table according to the methodology described by the GRADE working group (Note: here we only presented the forest plot as formatting the GRADE table was not feasible for thesis).

6.3 RESULTS:

Characteristics of included studies

The search retrieved 3482 reviews and 2086 clinical trials (Fig.1). After reviewing titles and abstracts 102 trials were considered relevant, but after the full text article review, only 62 studies fully satisfied the inclusion criteria.

Participants:

All included studies either involved frail dependent older people at risk of under nutrition or undernourished. Eight studies mentioned they involved older people with dementia and 13 studies mentioned they involved frail and/ or dependent older people at risk of undernutrition or undernourished. The age of participants ranged from 65 to 99 years, while four studies did not report the age distribution of participants. Women tended to predominate; seven studies recruited only women, two studies recruited only men, and five studies did not report the number of women and men in the study groups.
Settings:
Thirty-two studies were conducted in hospital settings,\textsuperscript{29, 30, 32, 34, 42, 50-53, 55-57, 59-79} 13 studies were conducted in long term care facilities (nursing home or retirement or residential home),\textsuperscript{31, 33, 36, 38, 39, 44, 45, 80-85} and two were conducted in sheltered homes.\textsuperscript{47, 86} Other 12 studies were conducted in community settings\textsuperscript{37, 40, 41, 43, 46, 48, 54, 58, 87-90} and one study was conducted in primary care.\textsuperscript{91}

International coverage:
Just two studies were conducted in middle-income countries; a multi-centre study recruiting study participants from India (as well as in the United Kingdom, Italy, and New Zealand)\textsuperscript{65}, and a study conducted in Brazil.\textsuperscript{32} Fourty studies were conducted in Europe,\textsuperscript{29-31, 33, 38-47, 50-52, 54-57, 60, 62, 64, 66-68, 71-74, 76-79, 83-86, 88, 91} eleven from North America,\textsuperscript{36, 37, 48, 58, 59, 75, 80, 82, 87, 89, 90} four from Australia,\textsuperscript{53, 63, 69, 70} and one each from Hong Kong,\textsuperscript{81} Japan,\textsuperscript{61} and Korea.\textsuperscript{49}

Intervention and comparison groups
ONS was the main intervention component in 54 of the 62 included studies. Of the 54 trials focusing upon ONS, six studies incorporated dietary advice\textsuperscript{33, 58, 73, 76, 79, 89} and one exercise training.\textsuperscript{61} Five of the 61 studies examined the benefit of dietary advice or nutritional education to participants.\textsuperscript{32, 34, 37, 43, 46} One study investigated benefit of mealtime feeding assistance\textsuperscript{82} and one study examined family style mealtimes (environment modification) intervention.\textsuperscript{85} Detail of oral nutritional supplement: 49 of 54 studies of oral nutritional supplement comprised of protein and calorie supplementation. A variety of proprietary brands were used including Ensure, Fortisip, Novasource, Clinutren, Tonexis, Biosorb, Fortimel, Build-Up and Nutribar. One study included ‘non-caloric’ protein supplementation only. For four studies the nutritional intervention was individualised following nutritionist assessment of needs. Of the 49 studies providing protein and calorie supplementation, 31 of the comprehensive protein and calorie supplementation interventions included additional micronutrient supplementation, and 14 did not. In four studies micronutrient composition was not specified. Four were designed be low in fat. The intervention trials were therefore relatively homogenous with respect to the broad nature of the nutritional supplement.
However, there will have been variation in protein/ fat/ carbohydrate composition and calorie value (as well as dose and duration).

The ONS interventions aimed to provide between 97 additional kcal per day up to a maximum of 1200 additional kcal per day. Less than 400 kcal per day was provided in 14 studies, \cite{36, 38, 44, 45, 47, 54, 55, 60, 75, 80, 83, 84, 86, 87} 400 kcal per day or more was provided in 23 studies, \cite{29-31, 33, 38, 39, 48, 49, 51-53, 61, 64-67, 69-71, 74, 77, 78, 88} two studies used ‘non-caloric’ protein supplementation only, \cite{59, 62} and energy supplement was not clearly described or not reported in six studies. \cite{42, 57, 58, 81, 90, 91} Additional protein was between 0.4 g and 62.5 g protein per day, 17 studies administered nutritional supplement with 20 g protein or more per day. \cite{29, 32, 48, 49, 51, 52, 55, 56, 65-67, 69, 71, 74, 78, 83, 88} Fifteen studies used a supplement with at least some micronutrient component (vitamins or minerals, or both). \cite{35, 38, 44-49, 53, 56, 59, 61, 69, 71, 73, 78, 86} Eight studies of factorial design, combined nutritional intervention with physical exercise. \cite{39, 40, 43, 61, 70, 80, 92}

**Comparison groups:** One study did not provide any information about control group intervention. \cite{44} Five studies mentioned that no intervention was administered for comparison groups. \cite{32, 60, 74, 81, 90} In five studies social visits were offered to the control groups \cite{49, 63, 70, 87, 89} and in other two studies nutritional education or dietary advice was offered to the control group. \cite{61, 73} In ten studies, nutrition supplement was compared with usual care. Seven studies provided placebo drink for control group, \cite{35, 38-40, 47, 78, 86} three provided low nutrient placebo drinks. \cite{39, 48, 78} One study provided same amount of vitamin for the control group with no macronutrients. \cite{30} Three other studies provided non-placebo low nutrient drink to the control group \cite{45, 72, 80} and one provided carbonated water. \cite{91}

All studies conducted in hospital settings, provided standard hospital diet and usual care during the hospital stay for the control group, two studies administered standard hospital diet plus additional supplement to control group \cite{53, 76} and one of them provided high protein supplement to the control group. \cite{53} Two studies of dietary advice intervention, provided no intervention to control group \cite{32, 46} one study mentioned that control group received usual care, \cite{34} in one study an exercise intervention was administered to the control group, \cite{37} and in one study the control group
received dietary advice and physical exercise.\textsuperscript{43} One study that tested meal time feeding assistance administered between meal snacks to the control group.\textsuperscript{92}

**Duration of the follow-up:**

Duration of follow-up ranged from 48 hours to 18 months. Three studies followed up the study population 12 months,\textsuperscript{34, 54, 79} and one study had follow up of 18 months.\textsuperscript{48} In 14 studies, length of follow-up was reported as 6 months,\textsuperscript{31, 32, 37, 39, 45, 47, 56, 57, 64, 65, 74, 79, 82, 86} and two studies followed up the study participants for 9 months.\textsuperscript{38, 43} Seven studies reported 3 months follow up data,\textsuperscript{33, 35, 61, 66, 68, 71, 82} and 12 studies reported follow up of 12 weeks or more. Three studies reported 17 weeks follow-up data,\textsuperscript{40, 41, 53} two studies reported 16 weeks follow up data,\textsuperscript{88, 90} and eight studies reported 12 weeks follow up data.\textsuperscript{30, 46, 49, 63, 70, 83, 87, 91} Further 13 studies had length of follow up less than 10 weeks,\textsuperscript{29, 42, 44, 51, 58, 59, 62, 67, 69, 76, 77, 80, 81} seven studies had length of follow up less than a month,\textsuperscript{36, 52, 55, 60, 72, 75, 78} and one study did not report study duration.\textsuperscript{50}

**Effectiveness and acceptance of nutritional intervention versus placebo or usual care**

**Oral nutritional supplement with or without dietary advice:**

**Mortality:**

Thirty-seven studies of oral nutritional supplement with or without dietary advice compared with usual care or low energy supplement reported the number of participants deceased in the intervention and control group, and these studies were pooled together in a meta analysis (see the figure 3). Nine of the studies reported no deaths.\textsuperscript{30, 36, 44, 50, 51, 55, 59, 72, 90} The overall pooled effect was in favour of experimental group, the pooled relative risk for mortality was 0.82 (95% CI 0.69 to 0.98) for the oral supplement compared with control group. There was no significant heterogeneity of effect ($I^2 = 0\%$). In a subgroup analysis, studies conducted in community settings showed no difference in mortality RR 1.14 (95% CI 0.49 to 2.68), while for studies conducted in hospital or long term care settings there was a significantly lower risk of mortality in the
intervention group compared to controls RR 0.81 (95% CI 0.68 to 0.97). No subgroup difference observed.

**Figure 3**: Fixed effects meta-analysis of the effect of oral nutrition supplement v. placebo or usual care controls on incidence of mortality.

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Experimental Events</th>
<th>Control Events</th>
<th>Total Weight</th>
<th>Risk Ratio M–H, Fixed, 95% CI</th>
<th>Risk Ratio M–H, Fixed, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brown et al 1992</td>
<td>0</td>
<td>5</td>
<td>0</td>
<td>Not estimable</td>
<td></td>
</tr>
<tr>
<td>Carlsson et al 2011</td>
<td>2</td>
<td>44</td>
<td>1</td>
<td>41</td>
<td>2.14 (0.20, 22.74)</td>
</tr>
<tr>
<td>Carver et al 1995</td>
<td>0</td>
<td>20</td>
<td>0</td>
<td>Not estimable</td>
<td></td>
</tr>
<tr>
<td>Daniels et al 2003</td>
<td>2</td>
<td>49</td>
<td>2</td>
<td>51</td>
<td>0.8% (0.15, 7.10)</td>
</tr>
<tr>
<td>Deleter et al 1991</td>
<td>0</td>
<td>18</td>
<td>0</td>
<td>Not estimable</td>
<td></td>
</tr>
<tr>
<td>Edington et al 2004</td>
<td>17</td>
<td>51</td>
<td>15</td>
<td>49</td>
<td>6.6% (0.61, 19.93)</td>
</tr>
<tr>
<td>Fialkow et al 1994</td>
<td>1</td>
<td>49</td>
<td>1</td>
<td>51</td>
<td>0.4% (0.07, 16.18)</td>
</tr>
<tr>
<td>FOOD trial 2005</td>
<td>43</td>
<td>156</td>
<td>48</td>
<td>158</td>
<td>20.5% (0.64, 1.28)</td>
</tr>
<tr>
<td>Gamba et al 1988</td>
<td>2</td>
<td>20</td>
<td>7</td>
<td>20</td>
<td>3.0% (0.29, 0.17)</td>
</tr>
<tr>
<td>Gazzotti et al 2003</td>
<td>2</td>
<td>39</td>
<td>2</td>
<td>41</td>
<td>0.8% (0.16, 7.10)</td>
</tr>
<tr>
<td>Gray-Donald et al 1995</td>
<td>3</td>
<td>25</td>
<td>1</td>
<td>25</td>
<td>0.4% (0.33, 26.92)</td>
</tr>
<tr>
<td>Hampson et al 2003</td>
<td>0</td>
<td>36</td>
<td>1</td>
<td>35</td>
<td>0.7% (0.01, 7.70)</td>
</tr>
<tr>
<td>Hanks et al 1996</td>
<td>2</td>
<td>17</td>
<td>4</td>
<td>14</td>
<td>1.9% (0.09, 19.3)</td>
</tr>
<tr>
<td>Hubsch et al 1992</td>
<td>0</td>
<td>16</td>
<td>0</td>
<td>Not estimable</td>
<td></td>
</tr>
<tr>
<td>Kim 2012</td>
<td>1</td>
<td>43</td>
<td>3</td>
<td>44</td>
<td>0.4% (0.12, 7.18)</td>
</tr>
<tr>
<td>Kwok et al 2001</td>
<td>1</td>
<td>28</td>
<td>0</td>
<td>24</td>
<td>0.2% (0.11, 0.60)</td>
</tr>
<tr>
<td>Larsson et al 1990</td>
<td>29</td>
<td>197</td>
<td>55</td>
<td>238</td>
<td>21.4% (0.42, 0.96)</td>
</tr>
<tr>
<td>Lauque et al 2000</td>
<td>0</td>
<td>19</td>
<td>0</td>
<td>22</td>
<td>Not estimable</td>
</tr>
<tr>
<td>Lauque et al 2004</td>
<td>2</td>
<td>46</td>
<td>2</td>
<td>48</td>
<td>0.2% (0.3, 59.18)</td>
</tr>
<tr>
<td>McEvoy et al 1982</td>
<td>0</td>
<td>26</td>
<td>0</td>
<td>25</td>
<td>Not estimable</td>
</tr>
<tr>
<td>McMurdo et al 2009</td>
<td>6</td>
<td>93</td>
<td>6</td>
<td>98</td>
<td>2.5% (0.35, 3.15)</td>
</tr>
<tr>
<td>Miller et al 2006</td>
<td>1</td>
<td>25</td>
<td>0</td>
<td>26</td>
<td>0.2% (0.13, 73.06)</td>
</tr>
<tr>
<td>Neelemaat et al 2012</td>
<td>14</td>
<td>105</td>
<td>11</td>
<td>105</td>
<td>4.7% (0.61, 26.7)</td>
</tr>
<tr>
<td>Ovesen et al 1992</td>
<td>0</td>
<td>17</td>
<td>0</td>
<td>17</td>
<td>Not estimable</td>
</tr>
<tr>
<td>Payette et al 2002</td>
<td>0</td>
<td>43</td>
<td>0</td>
<td>46</td>
<td>Not estimable</td>
</tr>
<tr>
<td>Persson et al 2007</td>
<td>6</td>
<td>51</td>
<td>12</td>
<td>57</td>
<td>4.9% (0.23, 13.8)</td>
</tr>
<tr>
<td>Poter et al 2001</td>
<td>21</td>
<td>186</td>
<td>33</td>
<td>195</td>
<td>13.8% (0.40, 1.11)</td>
</tr>
<tr>
<td>Price et al 2005</td>
<td>3</td>
<td>66</td>
<td>2</td>
<td>58</td>
<td>2.1% (0.16, 2.56)</td>
</tr>
<tr>
<td>Rabadi et al 2008</td>
<td>0</td>
<td>58</td>
<td>0</td>
<td>58</td>
<td>1.1% (0.01, 8.08)</td>
</tr>
<tr>
<td>Rufinacht et al 2010</td>
<td>4</td>
<td>27</td>
<td>0</td>
<td>25</td>
<td>0.4% (0.38, 2.98)</td>
</tr>
<tr>
<td>Salvi et al 2005</td>
<td>5</td>
<td>24</td>
<td>3</td>
<td>29</td>
<td>1.2% (0.54, 2.52)</td>
</tr>
<tr>
<td>Tidermark et al 2004</td>
<td>1</td>
<td>20</td>
<td>1</td>
<td>20</td>
<td>0.4% (0.07, 14.90)</td>
</tr>
<tr>
<td>Vlasing et al 2001</td>
<td>12</td>
<td>275</td>
<td>14</td>
<td>274</td>
<td>6.0% (0.40, 1.81)</td>
</tr>
<tr>
<td>Volkert et al 1996</td>
<td>4</td>
<td>35</td>
<td>8</td>
<td>37</td>
<td>3.3% (0.17, 6.60)</td>
</tr>
<tr>
<td>Wouters et al 2002</td>
<td>1</td>
<td>21</td>
<td>2</td>
<td>23</td>
<td>0.9% (0.05, 5.10)</td>
</tr>
<tr>
<td>Wouters et al 2003</td>
<td>0</td>
<td>52</td>
<td>1</td>
<td>49</td>
<td>0.7% (0.01, 7.54)</td>
</tr>
<tr>
<td>Young et al 2004</td>
<td>0</td>
<td>34</td>
<td>0</td>
<td>34</td>
<td>Not estimable</td>
</tr>
</tbody>
</table>

**Total (95% CI)**: 2036 / 2108 100.0% 0.82 (0.69, 0.98)
Weight gain:

Out of the 61 included studies, mean weight change or percentage of weight change was reported in 54 studies but 13 of these did not provide sufficient information that could be used for meta analysis, therefore these studies were discussed in the narrative review and not included in the meta analysis. Of the remaining 41 studies, 37 tested ONS with or without dietary advice, and these studies were pooled together for meta-analysis. The overall pooled effect favours the oral nutritional intervention group compared to control group, mean difference was 2.12 (95% CI 1.47 to 2.76), P values = <0.001. The heterogeneity was statistically significant P < 0.00001; I² = 93%. Subgroup analysis was performed with studies conducted in community and hospital or long term care settings. Overall pooled mean difference favours intervention group for both the settings. No significant difference between subgroups was observed.

Full text access was unavailable for three of the 13 studies that were not included in the meta analysis, thus reported data was extracted from earlier reviews. Two studies that tested nutritional supplement reported statistical significant difference in weight gain for intervention group compared to control group, as did one other in a post hoc subgroup analysis after omitting the patients in the control group with dietary recording. Two other studies reported weight gain in the intervention group but no statistical test was performed or reported. In three studies there was no statistical difference between groups for weight gain.
Figure 4: Random effects meta-analysis of the effect of oral nutrition supplement v. placebo or usual care controls on weight gain.

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Experimental Mean</th>
<th>Control Mean</th>
<th>Weight</th>
<th>Mean Difference IV, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bonnetoy et al 2003</td>
<td>3.05</td>
<td>5.6</td>
<td>25.5</td>
<td>-0.53</td>
</tr>
<tr>
<td>Bonnetoy et al 2010</td>
<td>-1</td>
<td>0.3</td>
<td>12</td>
<td>0.7</td>
</tr>
<tr>
<td>Brown et al 1992</td>
<td>-2.6</td>
<td>2.3</td>
<td>5</td>
<td>-9.1</td>
</tr>
<tr>
<td>Cameron et al 2011</td>
<td>-0.02</td>
<td>0.28</td>
<td>23</td>
<td>-0.04</td>
</tr>
<tr>
<td>Carlsson et al 2011</td>
<td>-0.2</td>
<td>0.4</td>
<td>47</td>
<td>0.2</td>
</tr>
<tr>
<td>Carver et al 1995</td>
<td>7.5</td>
<td>10</td>
<td>20</td>
<td>1.32</td>
</tr>
<tr>
<td>Daniels et al 2003</td>
<td>-5.45</td>
<td>10</td>
<td>49</td>
<td>-5.75</td>
</tr>
<tr>
<td>De JN, et al 2000</td>
<td>-0.2</td>
<td>1.2</td>
<td>35</td>
<td>-0.3</td>
</tr>
<tr>
<td>Deletter et al 1991</td>
<td>1.96</td>
<td>10</td>
<td>18</td>
<td>0</td>
</tr>
<tr>
<td>Edington et al 2004</td>
<td>3.7</td>
<td>7.32</td>
<td>32</td>
<td>2.59</td>
</tr>
<tr>
<td>Fiaratore et al 1994</td>
<td>1.5</td>
<td>3.4</td>
<td>24</td>
<td>-0.8</td>
</tr>
<tr>
<td>Gariballa et al 1998</td>
<td>0.35</td>
<td>18</td>
<td>10</td>
<td>-1.23</td>
</tr>
<tr>
<td>Gazzotti et al 2003</td>
<td>0.68</td>
<td>7.1</td>
<td>34</td>
<td>-1.73</td>
</tr>
<tr>
<td>Gray-Donald et al 1995</td>
<td>4.38</td>
<td>4.8</td>
<td>22</td>
<td>1.23</td>
</tr>
<tr>
<td>Hampson et al 2003</td>
<td>5.2</td>
<td>5.2</td>
<td>31</td>
<td>0.2</td>
</tr>
<tr>
<td>Hankey et al 1993</td>
<td>2.83</td>
<td>10</td>
<td>7</td>
<td>-0.53</td>
</tr>
<tr>
<td>Hubsch et al 1992</td>
<td>-0.33</td>
<td>10</td>
<td>16</td>
<td>0.33</td>
</tr>
<tr>
<td>Kim et al 2012</td>
<td>2.5</td>
<td>5.7</td>
<td>41</td>
<td>2.8</td>
</tr>
<tr>
<td>Kwok et al 2001</td>
<td>3.37</td>
<td>10</td>
<td>25</td>
<td>-0.7</td>
</tr>
<tr>
<td>Larsson et al 1990</td>
<td>0.05</td>
<td>0.19</td>
<td>59</td>
<td>-1.96</td>
</tr>
<tr>
<td>Lauque et al 2000</td>
<td>2.6</td>
<td>10</td>
<td>13</td>
<td>-2.48</td>
</tr>
<tr>
<td>Lauque et al 2004</td>
<td>2.86</td>
<td>6.1</td>
<td>37</td>
<td>1.22</td>
</tr>
<tr>
<td>McEvoy et al 1982</td>
<td>4.33</td>
<td>4</td>
<td>26</td>
<td>-0.33</td>
</tr>
<tr>
<td>McWhirter et al 1996</td>
<td>2.9</td>
<td>10</td>
<td>35</td>
<td>-2.5</td>
</tr>
<tr>
<td>Payette et al 2002</td>
<td>3.02</td>
<td>3.3</td>
<td>42</td>
<td>0.08</td>
</tr>
<tr>
<td>Persson et al 2007</td>
<td>0.95</td>
<td>4.12</td>
<td>45</td>
<td>-3.09</td>
</tr>
<tr>
<td>Potter et al 2001</td>
<td>1</td>
<td>5.6</td>
<td>142</td>
<td>-1</td>
</tr>
<tr>
<td>Price et al 2005</td>
<td>2.2</td>
<td>10</td>
<td>66</td>
<td>1.6</td>
</tr>
<tr>
<td>Salas et al 2005</td>
<td>4</td>
<td>3.7</td>
<td>15</td>
<td>0.65</td>
</tr>
<tr>
<td>Scarer et al 1990</td>
<td>5</td>
<td>10</td>
<td>47</td>
<td>-1.57</td>
</tr>
<tr>
<td>Smoller et al 2008</td>
<td>3.4</td>
<td>1.7</td>
<td>22</td>
<td>2.7</td>
</tr>
<tr>
<td>Sugawara et al 2010</td>
<td>3</td>
<td>5.4</td>
<td>17</td>
<td>-1.3</td>
</tr>
<tr>
<td>Tidermark et al 2004</td>
<td>-3.39</td>
<td>8.75</td>
<td>18</td>
<td>-2.77</td>
</tr>
<tr>
<td>Vollert et al 1996</td>
<td>8.2</td>
<td>10</td>
<td>7</td>
<td>6.45</td>
</tr>
<tr>
<td>Weekes et al 2009</td>
<td>2.2</td>
<td>0.9</td>
<td>28</td>
<td>-1.7</td>
</tr>
<tr>
<td>Wouters et al 2002</td>
<td>2.71</td>
<td>4.65</td>
<td>19</td>
<td>-1.5</td>
</tr>
<tr>
<td>Wouters et al 2003</td>
<td>2.55</td>
<td>3.71</td>
<td>34</td>
<td>0.49</td>
</tr>
<tr>
<td>Yamaguchi et al 1998</td>
<td>4.8</td>
<td>10</td>
<td>11</td>
<td>-5.3</td>
</tr>
</tbody>
</table>

Total (95% CI) 1167 1166 100.0% 2.12 [1.47, 2.76]
Figure 5: Fixed effects meta-analysis of the effect of oral nutrition supplement v. placebo or usual care controls on the hand grip strength failing to show improvement.

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Experimental Mean (SD)</th>
<th>Control Mean (SD)</th>
<th>Mean Difference IV, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cameron et al 2011</td>
<td>14.8 (5.6) 23</td>
<td>12.4 (5.6) 21</td>
<td>2.40 [-0.91, 5.71]</td>
</tr>
<tr>
<td>Ha Lisa et al 2010</td>
<td>2.3 (3.7) 56</td>
<td>-0.3 (4.9) 65</td>
<td>15.2% 2.60 [1.06, 4.14]</td>
</tr>
<tr>
<td>Kim 2012</td>
<td>15.1 (4.8) 41</td>
<td>16.4 (5.3) 43</td>
<td>12.3% -1.30 [-3.46, 0.86]</td>
</tr>
<tr>
<td>Payette et al 2002</td>
<td>-0.5 (1.3) 42</td>
<td>0.25 (2.75) 41</td>
<td>17.8% -0.75 [-1.71, 0.21]</td>
</tr>
<tr>
<td>Persson et al 2007</td>
<td>19.5 (7.8) 45</td>
<td>17.5 (7) 45</td>
<td>8.9% 2.06 [-1.06, 5.06]</td>
</tr>
<tr>
<td>Price et al 2005</td>
<td>1.89 (10) 66</td>
<td>0.9 (10) 70</td>
<td>8.0% 0.99 [-2.37, 4.35]</td>
</tr>
<tr>
<td>Smoliner et al 2008</td>
<td>13.9 (6.1) 22</td>
<td>12.2 (6.3) 30</td>
<td>7.8% 1.70 [-1.70, 5.10]</td>
</tr>
<tr>
<td>Tiddermark et al 2004</td>
<td>1.28 (3.2) 18</td>
<td>-0.88 (3.5) 17</td>
<td>12.0% 2.16 [-0.07, 4.39]</td>
</tr>
<tr>
<td>Wouters et al 2003</td>
<td>-0.7 (5.83) 34</td>
<td>-0.4 (5.83) 34</td>
<td>9.9% 0.36 [-3.07, 2.47]</td>
</tr>
</tbody>
</table>

Total (95% CI) 347 365 100.0% 0.52 [-0.31, 2.14]

Heterogeneity: Tau² = 1.95; Chi² = 21.58, df = 8 (P = 0.006); I² = 63%
Test for overall effect: Z = 1.47 (P = 0.14)

Figure 6: Fixed effects meta-analysis of the effect of Dietary advice v. no advice or exercise or usual care controls failing to show improvement on weight gain.

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Experimental Mean (SD)</th>
<th>Control Mean (SD)</th>
<th>Mean Difference IV, Fixed, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Berroten et al 2002</td>
<td>158.7 (9.35) 38</td>
<td>159.3 (7.1) 32</td>
<td>-0.60 [-4.46, 3.26]</td>
</tr>
<tr>
<td>Lammers et al 2012</td>
<td>60.1 (16.3) 25</td>
<td>57.1 (9.5) 21</td>
<td>2.2% 3.00 [-2.35, 8.88]</td>
</tr>
<tr>
<td>Rydlewski et al 2003</td>
<td>0.78 (2.1) 22</td>
<td>0.63 (2.5) 19</td>
<td>36.3% 0.15 [-1.28, 1.58]</td>
</tr>
<tr>
<td>Salter et al 2011</td>
<td>0.26 (8.939) 448</td>
<td>0.09 (8.932) 498</td>
<td>56.6% 0.17 [-0.97, 1.31]</td>
</tr>
</tbody>
</table>

Total (95% CI) 533 570 100.0% 0.19 [-0.67, 1.05]

Heterogeneity: Chi² = 1.05, df = 3 (P = 0.79); I² = 0%
Test for overall effect: Z = 0.42 (P = 0.67)
**Functional outcome:**

Outcome related to functional status was reported in 42 included studies, of which 13 studies reported hand grip strength.

29 studies reported functional status related outcomes measured using one of following measurement; activity of daily living scale and instrument activities of daily living scale, Physical Performance (SPPB), Barthel index, gait and 6 minutes walking test, time up to go test, stair climbing test, physical activity rating, general wellbeing questionnaire, number of falls, LASA physical and functional limitation questionnaire, berge balance scale, Norton activity rating scale, and functional independence measure. 23 of 29 studies reported no statistically significant effect of nutritional supplementation on any of functional status outcome.

In mixed groups of elderly people reported that the number of falls was lower among supplemented participants than controls (0% versus 21%; P = 0.05). 87

**Disability/ functional limitation**

Activities of daily living (ADL) were assessed in 12 studies, however, only three studies achieved some statistical significance. Tidermark et al 56 found an improvement at six months (P < 0.05), which did not persist at 12 months. Potter et al 52 reported a significant improvement with supplementation only in a subgroup of very malnourished patients (17 versus 11; P < 0.04). Volkert et al 57 found an improvement in the ADL score from admission to six months only in the subgroup with good acceptance of the ONS (72% versus 39%; P < 0.05). Persson et al 73 reported a significant improvement in ADL measure in the intervention group compared to control group (P<0.05).

Neelemaat et al 71 reported that functional limitations improved significantly more for patients in the intervention group than patients in the control group (P<0.001). Rabadi et al 75 reported statistically significant improvement for functional independence measure in the intensive nutritional supplementation group compared to standard nutritional supplements (P<0.05).
Physical function
Overall physical function: A study reported no statistically significant difference for physical activities. In contrast, other study reported a significant improvement in the activity rating in the supplemented group at eight weeks compared to the control group (P < 0.05) due mainly to improvement in the initially well nourished patients; however, the number of participants studied was not clear. Another study found no difference in level of physical activity in community-living older women with osteoporosis given ONS.

Hand grip strength: No statistically significant effect of supplementation was reported for handgrip strength in 11 of 13 studies. Two studies showed significant improvement in hand grip strength in the intervention group compared to control group. Eight studies provided sufficient data on handgrip strength that could be meta analysed. The overall pooled mean difference for hand grip strength was in favour of intervention group, but with no statistically difference observed (MD 0.92 (95% CI -0.31 to 2.14), P=0.17, I²=63%.

Lower limb strength and mobility: A study measured muscle function and mobility, found a short term improvement in quadriceps muscle power at three months with supplementation (56.8%; P = 0.03) but this was not sustained at nine months. And no statistically significant effect on six meters walk, five time chair rise, or six stair climb at 3 and 6 months. Another study also found no significant effect of supplementation on a timed ‘up and go’ test, although Payette 2004 found a trend towards improvement in this test (P = 0.057). Other study reported no significant effect of the supplement on balance, gait or lower limb strength. One other study also failed to demonstrate any beneficial effect of supplementation on mobility in women with hip fracture. However, one study reported significant improvement in the Short Physical Performance Battery, gait speed, time up to go in the 12 weeks follow-up in the ONS group compared to control group (P=<0.05), but there was no benefit reported for physical function, and one legged stance test. Another study also reported statistically significant improvement for 2-minute and 6-minuted timed walk tests in the intensive nutritional supplementation group compared to standard nutritional supplements (P<0.05). Walking distance and velocity was assessed in one study of patients with Chronic Obstructive Pulmonary Disease, but no statistically significant improvement
with supplementation reported, however a non significant trend towards improvement in 12 minute walking distance after nine weeks in the supplemented group compared to the control group was noted (65 m versus 16 m; P > 0.05).  

**Health-related quality of life:**

Seventeen studies reported health related quality of life outcome. In only two of these studies was there a statistically significant benefit in favour of the ONS intervention group. One study reported nutritional supplementation with low intensity exercise training improved health related QOL in the intervention group compared to control group in the three months follow-up (p =0.02). Other observed improvement in quality of life measure (SF 36) in the nutritional supplement group compared to control group, which received written dietary advice in the leaflet. The reported SF-36 Health Change score was significantly different in the intention-to-treat analysis and at both 6 and 12 months in those who completed the study (p<0.05).

Another study reported SF36 in a subgroup of patients suggesting significant improvement in physical and social score. A study also reported that more women 'felt better’ in the supplemented group (48% versus 20%; P = 0.029). In another study; although, there was no effect on overall EQ5D score or for the visual analogue scale, the supplemented group reported fewer mobility problems at 24 weeks (P = 0.022).

Other study reported a statistically significant difference in change in EQ VAS score between the study groups (P < 0.009). In this study, patients in the intervention had a significant 20% increase in EQ VAS score after three months, compared to no change within the control group.

**Adherence (acceptance of the supplement):**

Twenty-nine of 60 included studies discussed acceptance of nutritional supplement. Reported adherence ranged from 54% to 84 % for ONS. Particular problems with the acceptance of ONS were highlighted in four studies. In a study, 36% of potentially eligible participants refused to participate mainly because they did not wish to take a nutritional supplement; of those that did take part, adherence was realised by 68% of those who agreed to participate. Another study found that 39 out of 197 patients
refused the supplement and were withdrawn. One other study reported poor adherence in both arms (38% in the intervention and 50% in the control arms), further reporting that many participants disliked milk-based drinks. Other reported data from 45% of participants who had poor acceptance of the supplements, but stated that “if taken they were well tolerated”.

Twelve of 29 studies reported acceptance of supplements to be good, compliance reported ranged 54% to 84%. A study reported median percentage of prescribed volume of nutritional supplement consumed daily was 67% in participants who received supplement. Another study reported that oral nutritional support group achieved 80% compliance compared to 96% for telephone counselling by dietician. One other study found no difference in compliance between the intervention and placebo products over six months: 85% (SD 36%) versus 94% (SD 24%) respectively.

Adverse events:
Sixteen studies included systematic reports on adverse events, and/ or withdrawals attributed to side effects. Of these studies, three were conducted in the community, three in nursing homes, and eight in hospital settings. Commonly reported side effects in other studies included gastrointestinal symptoms, nausea, and diarrhoea. Only four of these trials systematically evaluated and compared adverse effects in treatment and control conditions (two in hospital, one in a nursing home and one in the community). Among these, in one of the hospital trial there was a large and statistically significant increase in reporting of GI disturbance in the ONS intervention group 39% vs 14% (p<0.001). In the other hospital, nursing home, and community trials, there were no significant differences in gastrointestinal adverse events between ONS and control conditions. One study measured serum blood urea nitrogen and creatinine clearance, and reported no significant difference between the groups. The other 10 trials assessed (or at least reported) adverse events in ONS groups only. Two of these were conducted in the community, two in nursing homes, and six in hospital. Gastrointestinal adverse events seemed to be more commonly reported in hospital settings (28%; 13%; 24%; 8%; 29%; no report) than in community (7%; 7%) or nursing home settings (8%; 0%).
Dietary advice compared with controls:

Mortality:
Two of the dietary advice studies reported mortality data. One study compared individualised dietary counselling with general advice, and in each study group, one participant deceased in the follow-up. In this study dietician was allowed to prescribe a nutritional supplement, but supplement details was not discussed in the paper. Another study which tested nutritional education with usual care reported high incidence of mortality in the experimental group, 9.5% (43/448) in the intervention group compared to 5.8% in usual care control group.

Weight gain:
Four studies of dietary counselling alone were pooled together in separate analysis, the pooled estimate was not in favour of intervention group. One of these study administered mini nutritional assessment and reported significant improvement in the intervention group compared with controls at the end of follow up (P=0.02), but nutritional education programme did not improve weight or BMI. Another study investigated benefit of nutritional education, reported significant improvement for weight and BMI in the nutritional education group compared to control group.

Nutritional supplement combined with physical exercise training:
A study compared protein supplement plus exercise combined with physical exercise and placebo drink, reported no change in weight and BMI in 3 and 6 months follow-up. Another study reported significant benefit of exercise intervention for functional outcome, but consumption of enriched products did not affect performance, fitness, or disability scores. Three other studies also reported no beneficial interactive effect of exercise combined with nutritional supplement. Other study administered individual nutrition counselling plus physical exercise training and reported no beneficial effect on nutritional outcome for community-dwelling frail elderly people aged 75 and older. A study reported weight loss for the combined nutrition and resistance training intervention was 4.7% compared with 6.3% in those receiving resistance training alone, this difference was statistically significant (P= 0.01), however no difference was observed for functional status and quality of life outcome.
**Feeding assistance:**
A study investigated the benefit of meal time feeding assistance for older people with unintentional weight loss. The study reported significant increasing in weight gain for the group that received mealtime feeding assistance compared to the control group which received between meal snacks. Overall, 56% of participants maintained or gained weight during the intervention compared to 28% in the control group.82

**6.4 DISCUSSION:**

This systematic review found evidence suggesting that there is considerable clinically important difference between nutritional intervention and placebo or usual care targeted on undernutrition in dependent older people. The studies presented predominantly included undernourished older people who are dependent on other for meeting their daily, although very few studies clearly defined this criterion. Nutritional intervention mainly oral nutritional supplement with or without dietary advice significantly reduce the mortality and increase weight gain in the intervention group compare to placebo or usual care controls. Further, nutritional supplementation did not achieve statistically significant benefit on functional outcome (hand grip strength) although over effect were in favour of intervention group. The overall quality of nutrition supplementation studies was moderate. Dietary advice alone did not produce any significant effect on weight change. Meal enhancement strategy such as feeding assistance did show considerable increase in weight gain. However the quality of evidence is low.

Fourteen studies have reported systematically on adverse events, and/ or withdrawals attributed to side effects. Of these studies, three were conducted in the community, three in nursing homes, and eight in hospital settings. Gastrointestinal AEs seemed to be more commonly reported in nutritional supplement groups in hospital settings (28%; 13%; 24%; 8%; 29%; no report) than in community (7%;7%) or nursing home settings (8%;0%). Taken together, the evidence is therefore relatively reassuring regarding adverse event profile for protein and calorie supplementation in community and nursing home settings. The higher prevalence of adverse event in hospital settings may be related to baseline severity of undernutrition, intensity of supplementation, comorbid acute illness, or, possibly increased monitoring of adverse events.
**Limitations**: Our systematic literature search was limited to only electronic data bases, grey literature are under represented in this review. Almost of the trials included were conducted in high income countries, translating the evidence to low and middle income countries is limited.

**Clinical implications**: Undernutrition is key indicators that is strongly linked up to frailty, dependent, and premature mortality. Evidence synthesized here suggested that nutritional supplement should be considered for treating undernourished dependent older people.

**Research Implication**: The cost effectiveness of nutritional intervention is still unclear as there are no studies that investigated cost benefit for nutritional intervention mainly supplementation. Future trials should explicitly investigate the cost benefit of nutritional intervention. Furthermore, evidence of nutritional intervention was limited to high income countries, future work should involve frail and dependent older people from low and middle income countries. Taken together, the evidence is therefore relatively reassuring regarding adverse event profile for protein and calorie supplementation in community and nursing home settings. The higher prevalence of AEs in hospital settings may be related to baseline severity of undernutrition, intensity of supplementation, comorbid acute illness, or, possibly increased monitoring of AEs.
Fig. 1 Flow of information through the different study phases according to the Preferred Reporting Items for System reviews and Meta-analyses (PRISMA).
Figure 2: Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

- **Allocation concealment (selection bias)**
- **Blinding of outcome assessment (detection bias)**
- **Incomplete outcome data (attrition bias)**

Legend:
- Low risk of bias
- Unclear risk of bias
- High risk of bias
6.5 BIBLIOGRAPHY


43. Lammes E, Rydwik E, Akner G. Effects of nutritional intervention and physical training on energy intake, resting metabolic rate and body composition in frail elderly. a


68. Ha L, Hauge T, Spenning AB, Iversen PO. Individual, nutritional support prevents undernutrition, increases muscle strength and improves QoL among elderly at

69. Hankins C. Dietary supplementation with sustagen in elderly patients with fractured neck of femur [Ph.D]. Sydney: Sydney University; 1996.


85. Nijs KA, de Graaf C, Kok FJ, van Staveren WA. Effect of family style mealtimes on quality of life, physical performance, and body weight of nursing home


91. Scorer H. The effect of nutritional supplementation with Ensure on the general health of undernourished elderly patients in the community. Abbott UK Medical; 1990.


CHAPTER SEVEN
CHAPTER SEVEN:

Integrating chronic disease care at primary health care for frail older people:
Opportunities and Challenges

7.1 BACKGROUND:

In Low and Middle Income Countries (LAMICs), population ageing is expected to increase the occurrence of age-dependent chronic (non-communicable) diseases.\(^1\) While cancer and heart disease contribute mainly to mortality, much of the burden of other chronic diseases (stroke, dementia and mental disorders) arises from years lived with disability.\(^2\), \(^3\) Further, multi-morbidity is a particular characteristic of chronic disease among older people that complicates the coordination of chronic disease care.\(^4\)

Recently, there is a renewed interest in primary health care for managing chronic diseases in LAMICs, but existing models of care which are single diseases focused may be unsuitable for addressing the care needs of older people.\(^5\) On the other hand, older people in high need for care have limited access to health care services,\(^6\), \(^7\) mainly because, 1) they are mostly clinic-based with less or no outreach activities, and 2) their main focus is on the detection and treatment of acute health conditions, 3) mobility limitation and problems in getting the transport limits the access, 4) out of pocket expenditure (OOP) on health has strong link with poverty, and older people often do not have independent income and they rely on their families for social protection, 5) explicit ageism amongst older people, family member and health care provider leaves less opportunities to seek improvement in health.

Therefore, there is a pressing need to develop comprehensive and continuity of health and social care that is age appropriate, with complimentary strategies such as home based assessment and management.\(^8\) We conducted qualitative interviews with primary health care professionals to explore their knowledge, behaviours, attitudes and expectations regarding healthcare for older people, current health care practices, perceptions of the needs of older people, and the extent to which these are currently being met or unmet. Subsequently we also interviewed frail dependent older people and their caregivers to understand their care needs and to what extent these needs where
met. We believe, understanding these issues in the context would guide us for refinement of WHO-COPE (care for older people) programme to suite the health care facilities, health care professionals, care needs of dependent older people and their carers.

7.2 METHOD
Study design:
In the process of developing WHO–COPE package, we carried out a qualitative study involving primary health care professionals (doctors, community health workers, primary care managers) currently functioning in primary health care settings in Goa. In addition, dependent older people and family caregivers were also included in the in-depth interview. Focus group discuss with health care professional (mainly community health workers) was also conducted after first round of data analysis to confirm the emerging themes. We used COREQ (consolidated criteria for reporting qualitative studies) checklist to present the methodology and describe study results (Tong, Sainsbury & Craig, 2007). King’s College London Ethics committee and the Institutional review board of Sangath, Goa, India approved the study. All participants signed informed consent forms before participation.

Research Team:
An independent senior researcher with master’s level qualification in psychology conducted nine in-depth interviews with community health workers (CHWs). ATJ (PhD student) conducted in-depth interview with five primary health care doctors, and one interview with a primary health care facility manager. A trained research assistant, master’s level qualification, conducted the in-depth interviews with frail dependent older people and family caregivers. The research assistant underwent qualitative research training with ATJ, and three practice interviews were done before study participants were interviewed. Except ATJ, either interviewers or study participants had any prior contact before the study commenced.

Recruitment:
The study participants, mainly (doctors, CHWs, primary health care manager, dependent older people and family caregiver) were recruited from one primary health
centre (PHC) located in the Corlim area, a public service functioning under the Directorate of Health Services, Goa, India. Primary health care facility was purposively selected. Older people considered as dependent by CHWs were recruited for the study. Consecutively, older person’s family caregivers were also approached for the interview and recruited. ATJ visited the sub-centres, meet CHWs and primary care doctors individually and explained the study purpose. Similarly, research assistants made home visits and explained the study purpose and procedure to older persons and family caregivers for recruitment.

Interview settings:
Health professional’s interviews were conducted in the primary health centres or sub-centres, while interviews with older people and their family caregivers were conducted in their own homes. Focus group discussion (FDG) with CHWs was conducted in the primary health care centre.

Data collection:
Separate topic guides were prepared for primary health care professional, older people, and their family caregivers. For in-depth interview with health professionals, a case vignette method was used. Three case vignettes describing problems of older person with multi-morbidities (including arthritis, congestive heart failure, renal failure, delirium, depression and dementia) in combination of multiple impairments (including declining activities of daily living, mobility limitation, rapid weight loss, incontinence, pain, exhaustion, frequent tiredness, sleep disturbance, irritability, cognitive impairment, restlessness and agitation) were presented one after the other to health workers. After each vignette was presented, a series of open ended questions were asked to the health workers. Probes were also used where appropriate. At the end of the interview, the health professionals were encouraged to share their experience with similar older people they had come across during the field visits in the community. Further additional following questions were gather their opinion about home-based care for dependent older people: a) is there anything in particular that you, personally, feel that you could do differently to provide an improved service to older people such as these, and their families? b) Could the service that you work for provide better care? c) If so, how? d) Some people say that health care assessment and some interventions for
frail older people are better provided in the older person’s own home. What is your opinion? How easy or difficult would it be to provide such a service?

The topic for older people and caregivers were centered around four major topics, a) information on household composition, kin and significant others, b) the onset and progression of care dependence in the index older person, c) patterns of care-giving and care-receiving involving the index older person and others, d) experiences regarding use of health care services (see the appendix 8 for details). For the research assistant who conducted the interview with older people and caregivers, few pilot interviews were conducted with research team to develop qualitative interview skills and also communication skill that is appropriate for dependent older people. In the pilot interviews, ATJ was present as an observers and also played and older person and family caregiver, after the interview feedback were given for improvement the quality of the interview and also suggestion were given for probing questions to the research assistant.

All the interviews were conducted in one session. Interviews were recorded using digital audio recording device; however interviewers were also encouraged to take field notes where necessary (For example, presence of third person and interruptions during the interviews). Besides the participants and researchers, no other non-participants were present during the interviews conducted with CHWs. Older people were tried to interview as much as possible separately but family caregivers were present for most cases. Duration of individual interviews with health professionals ranged from 60 to 90 minutes, and the interviews conducted with dependent older people and their caregivers ranged from 45 to 60 minutes. All interviews were conducted in Konkani (local language) and transcripts were typed in English. We did not discuss or seek to clarify transcripts with individual participants. However, we conducted a focus group discussion only with the community health workers for reassurance and enlargement on the key issues emerging from the transcripts of their individual interviews. The FDG was conducted by ATJ, the key themes, from the preliminary analysis of individual interviews, mainly on current care provision available for frail and or dependent older people and their family caregivers within primary health care system and barriers in organizing care for such people in the community level was presented in Power Point Slides and then discussed with the CHWs. Duration of the FDG session was 60 mints. Entire session was recorded using audio recorder, then interview session was
transcribed and analyzed for participant’s endorsement and additional comments were added for refinement.

Data analysis approach:

A grounded theory method was used for content coding and identification of themes. Data analysis was performed at three stages. First, two researchers (ATJ AND KPA) independently marked the key text with a series of codes emerging from the transcripts. Secondly, codes were grouped together as representing similar concepts. Third, identified codes reflecting similar concepts were classified under broad themes for better understanding and description of findings. NVivo software version 8 was used for data analysis. The health professionals’ transcripts were reviewed and analyzed by three researchers independently (ATJ, KPA, MP authors) and older persons and family caregivers transcripts were analyzed by two researchers (ATJ and KPA). ATJ and KPA first analyzed the content of the transcript independently and listed the themes, sub-themes and supporting content from the text. Inter coder reliability was measured between the first coder (ATJ) and second coder (KPA), by counting the total number of agreements and dividing by the total number of agreements and disagreements. Third coder (MP) also independently coded the content and themes, which were then further compared for agreement. Similarly, two authors (ATJ and KPA) analyzed the transcripts of older people and family caregivers’ and results were compared for consistency. The content of the interviews were analyzed prior to focus group discussions, during the FDG the ATJ presented the themes emerged from the transcripts for cross validation.

7.3 RESULTS:

Characteristics of the participants:

All participants who were approached consented to participate. Total n=27 participants participated in in-depth face to face interviews (n=9 community health workers, n=4 primary care doctors, n=1 primary care facility managers, and n=6 frail dependent older people and their family caregivers). Six of the 9 community health workers were female, and most of them were married. All of them had undergone some formal training in health care before joining the government service. Seven CHWs completed
12 years of school education, and four of them completed bachelor degree in Commerce and three completed bachelor degree in Science. Of the seven, four CHWs undergone Diploma in nursing training and three others completed multipurpose health workers training (9 months course). Two CHWs had completed 10 years of school education and one of them completed Auxiliary Nurse Midwife training and another completed multipurpose health worker training before join the service. Five CHWs had more than five years of experience in primary care service and four others had only two to three years of years. On average each health community health worker was responsible for providing primary care for a population of 3000 in their geographically defined sub-health centre area. All five primary care doctors including one PHC manager were male and all of them had completed four years of medical degree from Goa, three of them had more than 5 years of experience in primary health care and one doctor had only two years of experience.

Frail dependent older people four of six were recruited from one the main sub-health centre, mean age was 76.5, all them were females and all of them are housebound. Common self-reported and diagnosed health problems include hypertension, diabetes, arthritis, and ischemic heart disease. The caregiver were mainly daughter or daughter in law, all of them are currently residing with older persons.

**Perceptions of CHWs regarding their roles and responsibilities:**

At present, CHWs do not pay much attention to the care needs of older people. Older people’s problems were not assessed directly, and where they became aware of these this was generally through the report of other family members, in the course of their routine work.

A CHW described, “We detect malaria, filarial cases and such other cases, we also follow up antenatal and postnatal cases we try and find out if the child is vaccinated for polio, if pregnant ladies has done all their check-up. If the woman does not take tetanus injection or calcium then we register them. We also follow up vector bound diseases, provided leprosy care, TB care, outreach sessions like vaccination .If women cannot come to the clinic then we keep these sessions at nearest place in the Aganwadi. We give Vitamin A to children at Aganwadi. We also have health day, where talks are given on different topic .We have meeting for patients having TB, Leprosy and HIV.”
Figure: Barriers and challenges for integrating long term care for frail older people at primary health care settings

Knowledge and skill

The community health workers knowledge about chronic conditions such dementia and depression was adequate enough for offering support to dependent older people and family caregivers. However, many strongly acknowledged their lack of knowledge and skill as major barrier for providing any intervention.

CHWs said, “yes, we can assess and find out their problems but we cannot give them further help, we are not equipped to manage such old people”.

Some CHWs also expressed a fatalistic view towards problems of older people, but this may be due to lack of capacity and confidence.
A CHW said, “management is difficult because a problem faced in old age is not in our hands”.

Dependent older people are not in health care agenda. As many dependent older people suffer from long standing health condition, meeting the health care needs requires long term support for primary and secondary health care system. The present health care system is exclusively organised and trained health personels to offer curative care, and many CHWs blame the system as being not inclusive of all population in need for care. A CHW said, “Our system is like that, except vision, we don’t have anything for other problems of dependent older people. When we go in the field, people in the community talk to us about older people but we don’t directly collect information. I cannot remember properly, in Carmali there is an older lady who walks with hunch, she cannot hear or walk properly, she moves with her hand, I don’t have much details about her. I have seen her six months back and I have not asked any details about her to the family members”.

Another CHW said, “if there is rule that these are the things that needs to be done then service will be provided in a better way for older people”.

There is also a lack of awareness among the family members of elderly, a primary care doctor said, “Actually these things happen, they just think that elderly want some special attention or they want to make them feel irritated especially this daughter in laws and all this they used to think that they just want to irritate them, they are just acting but when we got those cases we tried to solve like talking to them and making them realize these things do exist like people do have this kind of problems and why it happens, what is the treatment to be given, it can be corrected, you can be safe meaning you can be support to the patient this type of cases, how you have to handle”.
Distance and transportation
Many CHWs, older people and family caregivers reported distance to health care and transportation as major barriers for providing and accessing health care services. The current health care system is clinic-based with no emphasis placed on out-reach programmes for housebound dependent older people.

A CHW said, “transportation is a main problem. In the field we identify older people having hearing problem and give referral - but who will take them for treatment? Family members are working, they cannot leave their work and stay at home”.

An older person said, “I would want to check my blood pressure, but I could not go, because I am scared to go alone. There is a bus from here to PHC, but while coming back there is no transportation on time, I may have to walk back to home. So, I felt its better to stay back at home instead of walking long distance”.

Having no one to accompany older person was also reported as barriers for accessing health service by family caregivers and CHWs.

A primary care doctor said ‘they need somebody to you know hold them, bring them, on their own they will not be able to come.’

Time and manpower
Some CHWs reported lack of time and insufficient manpower as barriers for providing care for dependent older people.

A CHW said, “I have interest in helping older people, but I am managing the work alone - my work load will increase. When I come back from field my time goes in preparing different reports, sometimes I remain in the field. I have to conduct immunisation programme in this centre, also take part in other programme conducted in other nearby centre, and prepare reports before four o’clock”. However, other CHWs were positive about availability of time for organising care for older people.

A CHW said, “As far as our work is concern it will not be affected, there won’t be any problem if we are properly trained”.

The timings of the clinic clash with the working hours of the family members, hence they cannot bring the elderly to the clinic, as quoted by one doctor “And our working timings are 9 to 5, which are the working times the children will not be there at home.”
So usually nobody is there to bring them. So they would prefer in the evening when we are closed”.

**Met and unmet needs of frail dependent older people and family caregivers**

In Indian settings, family members were the main caregivers, and most often it is either daughter in law or daughter who provides hands on care for older people. Basic care provided by family caregivers starts from helping the older person to maintain his/her personal hygiene, carrying out daily routine, and organising transportation for health service. Caregivers reported that functional dependency gradually increased over years and older people reported that they are completely dependent on their family caregivers for meeting their daily needs. Many caregivers acknowledged, organising care for dependent older people is round a clock business and most of them cannot be left alone.

A caregiver said: “She has to be given everything on time and I should be there in front for meeting her needs. And I don’t think she can be left alone for longer time”.

Another caregiver said, “if I tell her to have bath on her own and I go somewhere, there is a fear that she might fall in the bathroom, she cannot be left alone”. On the other hand, CHWs reported that health of older people is the last priority in poor families until the health condition becomes worse.

While one of the doctor said “Yah the family has very important role like they can help the elderly people to take their medications properly. They even know about the diet, like what the things to be taken are and what time it should be taken especially when a person has diabetes, where diet plays very important role and it should be taken.” Another doctor said, “Because they are so busy taking care of somebody else (elderly), they neglect and they forget to take rather they don’t have time to take care of themselves”.
Lack of support for family caregivers:

Although providing care for dependent older person is less rewarding job, many family caregivers reported greater sense of tolerance and consider caring for older people as a moral responsibility of their family.
A caregiver said, “We try not to hurt her in anyways, when she ask for things and if that is possible for us to provide - we do it”

Some caregivers reported that they received less support from other family members and most often it is either neighbours or other people in the community offered timely help.
A carer said, “I don’t have any support in the house, if anything happens to her, I remain responsible.”
Another caregiver said, “If he has to go for shaving the neighbour helps him .....and if anything happens to me neighbours come to help”.

And majority of the caregiver do not get sufficient information on problems faced by older person and how to cope with the increased dependency. Some elderly share their experiences at home with their health providers. One of the doctor said, “some elderly patients who come they say they don’t have family support they feel that they are burden to the family. I have also seen some old age ladies coming and crying nobody to take care of us”.

Financial security:

Furthermore, some caregivers reported that their caregiving role has restricted them from income generation activities for family and which might distort financial security in long run.
A caregiver said: “If not anything then I can at least make cotton Vaaties (Cotton used for lighting lamps for god), sell them and support my family. Something can be done by sitting at home”. Although minimal social security pensions were accessed by dependent older people, in most families these funds were used to meet family’s daily requirements or other household expenses.
A caregiver said, “My son even says, mummy at least save her money, tomorrow if anything happens to grandmother, we could use this money. But household needs increases day-by-day and there is no money left for saving’.

A doctor said, “As they grow old the finances becomes major and the families cannot afford because of the living cost has gone up. So the families may feel that this is adding to the burden of their expenditure. So they may not give them that much care”.

Health care needs:

Dependence in old age is largely attributed by impairments such as mobility problems, undernutrition, visual impairment, hearing impairment, cognitive impairment, urinary incontinence, and behavioural and psychological problem. Older people experiencing impairment might require long-term support for coping up with increasing disabilities. As many CHWs mentioned, existing primary health services do not meet the health care needs of dependent older people and their family caregivers.

A CHW said, “at PHC level we do not provide any services for older people who cannot come to clinic, If we come across any housebound older person who complain of aches and pain in the field, we provide pain killer however, before that assessment has to be done by the medical doctor, we are not allowed to provide medication before doctor assessment”. A physician said, “There is nothing called special in elderly care at the centre, except that a separate queue is kept for senior citizens”. In the absence of adequate formal health services, many family caregivers of dependent older people with chronic diseases such as dementia are likely to experience caregiving burden, which may lead to psychological symptoms or depression. Such caregivers require additional support from primary health care workers for organising care and coping with caregivers’ burden. On the need of caregiver counselling, a doctor responded, “it should be added. It should be done and family members should also be given due importance”.

Efficient primary health care services

Existing public health care settings focuses mainly on curative care and less emphasis has been paid on addressing the long-term care needs of older people. Five of six older people expressed greater sense of dissatisfaction with current health services, as their
problem never got better. However, older people who had access to services for blood pressure and diabetes expressed greater sense of satisfaction. Some also expressed their concern regarding waiting time in the health care facility.

An older person said, “If I go there, they make me wait - I cannot walk and cannot use the toilet on my own, another person is required to help me in accessing the toilet. And we have to wait longer time to meet the doctor, therefore I informed my family members that I not coming to meet the doctor any more”.

And other reported that basic equipment such as BP machines was not available at time in health centre. For these reasons, families who can afford many prefer accessing private health care.

Existing care provision for older people and family caregivers at PHC

Existing public health care settings focus mainly on curative care and less emphasis has been paid on addressing the long-term care needs of older people. Vision care to large extent normalised with PHC system, assessment for vision impairment is performed by ophthalmic assistant at PHC and glasses are provided for older people with refractive error at the centre. However, this is limited only to older people who were able to visit primary health centre, and such care provision is unavailable for housebound dependent older people in the community. Mobility impairment and weight loss were well recognised as serious problems among dependent older people by all CHWs, but inappropriately managed by distribution of iron, B complex, vitamin, and calcium supplement without detail assessment or medical review.

A CHW said, “When we go to field and if older people complain of walking difficulties or pain, according to our knowledge we recommend exercise such advice for walk or for a stroll. And we also distribute iron, calcium, B complex tables for older people with arthritis”.

Others expressed their concern regarding waiting time and transportation.

An older person said, “If I go there, they make me wait - I cannot walk and cannot use the toilet on my own, another person is required to help me in accessing the toilet. And
we have to wait longer time to meet the doctor, therefore I informed my family that I am not coming to meet the doctor any more”.

And others reported that basic equipment such as BP machines was not available at time in health centre. For these reasons, families who can afford prefer accessing private health care and older people in economically disadvantaged families remain non-seeker of medical attention.

Opportunities for integrating long term for older people at primary health care level

Willingness to provide care for frail dependent older people:
Most CHWs acknowledged the importance of the provision of basic care for frail and dependent older people at primary health care level.
A CHW said, “Population of all age group get medical facilities, even older people. They are also human being and part of the society, who require health care services”.

Although lack of training was reported as potential barriers, many CHWs expressed their willingness to get trained and offer health care for dependent older people.
A CHW said, “Many older people have mobility problem and mental stress - we need training on how to manage walking difficulties or memory problems... and whatever problems they facing”.

The CHWs also recognised the difficulties experienced by family caregivers and many expressed their willingness to offer support for family caregivers.
A CHW said, “I feel family caregiver require help. They should to be given counselling on how they can organise care for older person and how not to take stress”.

Another problem faced by elderly is that at each visit to the health centre, they come in contact with a different doctor. This reduces their chance of coming back to the centre.

A doctor said, “But some resident doctors may not be there. Also if somebody is on leave then can’t help it or somebody is committed to some other assignment and we
can’t help it, then the same doctor is not available. Otherwise they will be looking for that same person”.

**Home-based long term care and support for frail dependent older people**

The proximity of health care facility, transportation, and having no one accompany older person was reported as potential barrier for accessing adequate health care services. Alternatively, home-based care could be organised to support the dependent older people, such effort may bridge treatment gap and equity of health care. However, home-based services should be acceptable to older people and family members, and also feasible for CHWs worker to deliver and follow-up. Interestingly, there was strongly endorsement for home-based care by both services users and providers.

A caregiver said,“ He cannot walk on his own - so it will be good if care is provided at home. He has urinary incontinence. In case, if we take him to hospital, we may have to wait for long hours, and suddenly he might urinate on his dress -which is quite embarrassing for him and also for us”.

Another caregiver said, “It is good in a way - my father will get good services and also doctor will get sufficient time to know about his medical history”.

CHWs also felt care for dependent older people should be provided at their home and many agreed that such care provision will be beneficial to dependent older population and their families.

A CHW said,

“I feel that older people should be provided facilities, there are free services for older people with vision problem, but such facilities were not accessed by older people”.

Another CHW said, “Many older people require support from another person to visit the clinic, if intervention and treatment is provided in their home it will be benefit the older population”.

On the other hand, government doctors cannot provide home-based care for the elderly as it is not allowed by the system. All the doctors interviewed expressed this issue. A doctor said, “No usually we at primary health center level, there is nothing called we visit the house. That is done by private doctor.’ Another doctor said ‘Suppose even if I
feel that I should go and give care to the lady at home for even to check BP or even to write a death certificate we at not supposed to go the persons house”.

6.4 DISCUSSION:
In general, primary care health professionals and family members think that more should be done for older people, and they should not be excluded from equitable access to healthcare, simply because of their age and infirmity. Access to care mainly dependent upon proximity of primary care centre and transport difficulties were often highlighted by older people and health professionals as significant barriers to receiving or providing care.

Moreover, existing primary care services are mainly clinic based and home visits by doctors are rare. The only instances reported are visits by private doctors and nurses attached to their services (e.g. to perform blood tests for glucose monitoring in diabetes) and a favoured 95-year ‘celebrity’ patient who is visited by the PHC doctor. Furthermore, provision of care at primary health centres are limited more or less to medications and invasive PHC level is limited more or less to medications and no supports were available for managing mobility, undernutrition, cognitive, depression, urinary incontinence, preventing risk of falls or supporting family caregivers.

However, sensory impairments (vision and hearing) appropriate assessment and invasive and non-invasive services are available either in primary health care centre or secondary care hospital for free of cost, but these services are not within the reach of dependent older people who are housebound or bed bound and cannot travel to health facilities. Therefore, older people and their families use private medical services in preference to government services because of greater trust, potential to be visited at home by the doctor, and the provision of continuity of care – always seeing the same doctor, who is the family physician providing care for all household members.

However, there will be greater out of pocket health care expenditure involved in access to private health facilities from consultation fees and laboratory investigation (e.g. blood test for diabetes).

There was a strong endorsement of the view that assessment and care should be provided for frail and or dependent older people at their home through regular outreach.
Many health professionals agreed that home base care might overcome the difficulties that many older people have in visiting PHC or taking up referrals to secondary care. However, there were few shortcomings: a) many feel limited in what they can do for dependent older people, mainly because of time pressures given their many responsibilities for administering various programmes and enumerating the district b) intervention such as counselling’ is often thought to be required by older person and family caregiver under stress but this is either considered to be a specialist function, or it may be time consuming and they do not have enough time for proper delivery. c) legal right to prescribe medicine is in the hands of the medical doctors and for many cases doctors needs to initiate prescriptions, even for analgesics. Therefore, many community health workers feel that their role in managing complex problems of dependent older people is very limited .d) there was a consensus among CHWs that doctors involved in management is necessary for medical review and prescription, but many expressed their willingness to provide follow-up.

Most of the CHWs accurately common impairments such as undernutrition, mobility impairments, cognitive impairment and condition chronic condition dementia and depression. This reflects a remarkable increase in awareness of this condition (furthermore not seen as a normal part of ageing) from a previous similar study conducted in Goa (Prince and Patel). However, a minority did not, and in their attributions demonstrated a poor understanding of the aetiology and causes of dementia, likely to result in stigma, and to be otherwise unhelpful to the person with dementia and their family. Furthermore diagnosis and management was seen as being the province of psychiatrists at mental health institutions and none of the CHWs could conceive of useful interventions that could be delivered at the community or PHC level.

Although there was excellent recognition of the likely extent of carer burden, and the mechanisms involved, there were again few perceived options for addressing this problem at the level of community or PHC.

Undernutrition is recognised as a significant problem, but with no sense of appropriate assessment and monitoring strategies. Micronutrients are considered to be the main therapeutic strategy, but these do not seem to be well targeted. They are provided to those who are ‘weak’ or ‘tired’ and calcium and vitamin B are thought to be appropriate treatments for those with joint pain. Full blood counts are only performed in health facility, which frail dependent older people are unlikely to attend. Therefore iron
prescriptions are, presumably, syndromal and presumptive. These therapeutic approaches were often considered in response to the depression vignette, with an older woman with variable aches and pains all over the body. A minority of CHWs understood the need for macronutrient renutrition (protein and calories) advising milk and grain supplementation.

Doctors and CHWs considered home assessment and treatment will address equity of services for older people and many find this approach desirable and achievable. However, this would need to be mainstreamed and otherwise there would be time pressures due to other roles and responsibilities. And many also felt there should be good support and clear referral pathways from community to PHC to secondary care in place for effective management. Further, many reported that their skills and knowledge is not adequate and need to be developed in assessment and treatment of complex health care needs of frail and dependent older people.

Other key barriers of successful integration of home based care at community level for frail dependent older people is apparently widespread fatalist view regarding frail older people with multiple chronic health conditions. Ill health in old age means that you are ‘near to the end’. Families may be unwilling to invest in costly interventions. Even when interventions are provided at low cost or no cost, the need to accompany the older person e.g. for a hospital admission may be prohibitive. Sometimes older people themselves are seen as the obstacle, either because of a shared fatalistic view, or because of their ‘obstinate’ mind-sets, and the amount of time that may need to be expended to persuade them to consider taking up a referral or intervention. On a darker side, there were several reports of younger relatives wanting the older person to die, neglecting or abusing them.
7.5 BIBLIOGRAPHY


CHAPTER EIGHT
CHAPTER EIGHT:

WHO-COPE: Feasibility Study Protocol

8.1 OBJECTIVE: To test the efficacy, acceptability, and fidelity of nutritional and physical activity interventions administered by community health workers functioning in sub-centres of primary health care centres.

8.2 METHOD:
A formal exploratory phase 2 trial will be conducted with respect two components of the intervention, nutrition and exercise. This will comprise structured training of the community health workers, followed by a full scale controlled administration of the recommended interventions for each of the two components on separate groups of up to 60 frail dependent older people and their carers/families. As is customary in such exploratory trials there will be no comparison group. To generate detailed descriptive information on the intervention, relevant details (target, mode of delivery, dose/duration, and degree of adaption) will be recorded by the CHW on structured delivery assessment forms. A random 20% of intervention sessions will be digitally audio-recorded (with the consent of all concerned) and a random 10% will be directly observed. All audio recordings and direct observations sessions will be independently co-rated for fidelity using a structured coding sheet. The likely effect size in the intervention group will be assessed through simple before and after assessment of appropriate outcomes, administered by independent research workers.

Sample size:
A sample size of 60 in each of the Phase 2 intervention component exploratory trials will allow me to estimate a proportion of 80% with a standard error of 5% and a proportion of 50% with an SE of 6%. A standardised change score (representing the likely effect size in the intervention group) could be measured with an SE of +/- 0.13 – since this has been computed on units of standard deviation, it does not vary according to the outcome or the observed effect size. We believe that this degree of precision is adequate to be used to inform the design and methodology for a subsequent definitive randomised controlled trial, and Dr Michael Dewey (a senior trials statistician in our Department) has confirmed this to be the case.
8.3 NUTRITION INTERVENTION:

According to the evidence-based recommendations of the WHO-COPE guideline development group, the nutrition intervention will be offered to those previously identified by CHW assessment as significantly undernourished (a mini nutritional assessment score of 7 or less). The nutritional intervention consists of three components, a) generic dietary advice, b) mealtime enhancement strategies and c) an oral nutritional supplement. Those with evidence of potentially serious underlying physical illness (gross cachexia, rapid weight loss, obstruction or difficulty swallowing, vomiting, chronic diarrhoea, abdominal pain or swelling) will be excluded from the trial and referred to a physician for assessment. Attention will also be given to the presence of depression, and poor dentition/ oral health; such persons will also be referred as appropriate, but not excluded from the trial.

Generic dietary advice will comprise information on a healthy balanced diet (and cheap and locally accessible sources of protein and carbohydrate), and optimal feeding strategies (at least three meals a day, with snacks, and advice on assisted feeding where appropriate). Mealtime enhancement strategies comprise attending to the pleasurable aspects of eating, most particularly eating as a social activity, ensuring that older people are, as far as possible included in family mealtime routines, and not left to eat on their own.

The nutritional supplement is a culturally acceptable powder product sourced from Voluntary Health Services, Chennai, where it has been widely used in community supplementation programmes for women and children. The powder can be mixed with water to make a soup-like drink, or mixed with or sprinkled on cooked food. The supplement product has been analysed as providing 1854 kcal, 86.8 g protein (174% RDA), 34.6 g fat (53% RDA), 12.9g fibre, 754.4 mg calcium (63% RDA), 27.4mg iron (343% RDA). Guidance for preparing and consuming oral nutritional supplement will be given to older people and other family members, as appropriate. Families will be advised

1) to increase gradually the amount of supplement provided daily over a period of 7-10 days up to the recommended quantity, watching out for possible side effects (diarrhoea, bloating).

2) to divide the daily amount into smaller quantities provided ‘little and often’. 
3) for those with disturbed eating behaviours (e.g. as seen sometimes in dementia), to identify times of day when appetite is greatest, often mid-morning between breakfast and lunch (ref).

4) most importantly not to reduce the usual dietary intake; stressing that this is a supplement, and not a replacement for usual diet.

Adherence to the protocol and potential adverse effects will be monitored at regular follow-up visits (weekly for 4 weeks, and monthly thereafter). Consumption of the product will be ascertained by self-report, and by checking for remaining nutritional supplement when re-stocking. At each follow-up visit the older person, and/ or their carers as appropriate will be asked systematically to report the occurrence of sense of fullness/ bloating, gastritis, nausea or vomiting, colic, diarrhoea, and any changes in normal diet. If these necessitate withdrawal of the supplement, this, together with the reason, will be recorded.

### 8.3.1 OUTCOME MEASURES OF NUTRITION INTERVENTION:

**Nutritional status:** The outcome most commonly studied, and for which there is strongest evidence of benefit from previous trials in high income countries, is weight gain. We will assess weight using digital scales at baseline and monthly intervals thereafter. Height will also be measured to calculate body mass index. Other nutritional assessments to be completed at baseline and three months only will be mid-upper arm circumference, and the full 18 item version of the Mini Nutritional Assessment.

**Physical functioning:** There is limited evidence from a small number of previous trials of improvement in hand grip strength. The cost of the equipment required for this test are prohibitive, and we shall instead assess walking speed, the 30 second chair stand test, and the ability to raise a 1kg water bottle to shoulder height (for details of these assessments, see physical exercise training, below)

**Willingness to pay:** The nutritional supplement will be provided free of charge, but in ‘real life’ a small charge would probably have to be levied to make the financing of the intervention sustainable and scalable. We will therefore at the end of the intervention assess (from the family budget decision-maker) what amount they would be willing to pay to receive the intervention. This will also serve as a proxy measure of satisfaction.
8.4 PHYSICAL EXERCISE TRAINING:

According to the recommendations of the Guideline Development Group, the physical exercise training intervention will be offered to those with significantly impaired mobility (taking longer than 15 seconds to walk 10 metres and/or completing fewer than 7 stands from a chair in 30 seconds, or being incapable of completing these tasks). The intervention is multicomponent, comprising four interactive elements; strength training, balance training, flexibility and endurance (aerobic exercise).

Based on advice from the GDGs, those with significant undernutrition will, initially, be excluded from this intervention, although they may later be offered it when their nutritional status has improved; undernutrition may make it difficult for older people to participate in exercise training, they may not benefit, and aerobic exercise may exacerbate weight loss. Other exclusions will be those with severe heart failure, unstable angina or myocardial infarction over the last one month, and those with extensive and/or severe pain exacerbated by, or limiting exercise.

Strength training will focus on lower and upper limbs, particularly quadriceps, comprising progressive resistance training using theraband (lengths of elastic providing different grades of resistance). We will aim to build up to 30 minute sessions, two or more times per week for each major muscle group. Each session will comprise sets of 8-10 repetitions building up to 2-3 sets with 2 minutes rest periods in-between. Increased resistance will be applied when these goals are achieved.

Balance training involves a series of increasingly challenging exercises that progressively reduce the base of support, and/or sensory input. This can include, for example, standing on two legs then one leg (eyes open, then closed) and tandem gait (heel/toe) walking.

Flexibility exercises are designed to move joints through their range to improve or maintain flexibility. Two or three repetitions of each exercise are performed using slow, smooth movements, to the extent that they can be completed without causing pain. Current national guidelines for aerobic exercise (e.g. US Centres for Disease Control) recommend 150 minutes per week of moderate aerobic activity (e.g. walking briskly, sufficient to increase pulse and breathing rate). This is unlikely to be achieved, or achievable by many frail older persons, necessitating individual tailoring of intervention targets. We will assess current levels and modes of physical activity, exploring potential
for these to be increased in duration and intensity in a graded fashion. The aim will be to propose, encourage and facilitate activities that are perceived culturally, and by the older individual to be appropriate, interesting and pleasurable.

Individualised exercise programs will, of necessity, vary somewhat according to mode, intensity, duration, frequency and progression. However, standard recommended packages will be prepared for those who are at baseline a) largely chair bound, b) largely house bound, and c) able to move around outside of the home. Visual schematic cards will be provided illustrating the correct performance of each activity. Programmes will be subject to modification according to baseline abilities, limitations and barriers (e.g. painful joints), cultural and personal factors.

**Safeguards:** Participants will be advised to warm up (light aerobic exercise) and cool down (stretching exercises) before and after each exercise session. The importance of taking adequate fluids will be stressed. Exercise should be avoided when acutely unwell and/ or febrile. Participants will be advised to cease exercise and seek medical advice if they; have pain or pressure in their chest, neck, shoulder, or arm; feel dizzy or sick to their stomach; break out in a cold sweat; have muscle cramps; feel severe pain in joints, feet, ankles, or leg. All exercises will be taught and supervised by the CHW, with another family member present, until they are understood and performed accurately and safely. The need for safety at all times will be stressed, particularly the avoidance of falls through close supervision and use of supports (chairs/ walls) as indicated.

Adherence to the protocol and potential adverse effects will be monitored at regular follow-up visits (weekly for 4 weeks, and monthly thereafter). Engagement in structured activities and aerobic exercise will be recorded in daily ‘activity logs’ reviewed by the CHW at each follow-up assessment. At each follow-up visit the older person, and/ or their carers as appropriate will be asked systematically to report the occurrence of pain, episodes of faints or dizziness, falls and other accidents and injuries (distinguishing between those occurring during or outside of the exercise activities), and the onset of any serious health condition.
8.4.1 OUTCOME MEASURES OF PHYSICAL EXERCISE TRAINING:
At baseline and after three months, we shall perform the following assessments
1. Walking speed (timed to walk 5 metres, turn and return)
2. the ‘get up and go’ test – time to stand from sitting, walk three metres, return and resume sitting position
3. 30 second chair stand test (numbers of stands from sitting position completed in 30 seconds)
4. The ‘one leg standing test’ – time, up to 60 seconds that the person can stand on one leg with eyes open (two attempts with the longest time recorded
5. Fear of falling – the Falls Efficacy Scale a 10-question scale that assesses the impact of fear of falling on a person’s confidence to perform everyday tasks.
6. The modified Chicago pain scale
7. Cognitive function (the Community Screening Interview for Dementia COGSCORE cognitive test battery)

8.5 OUTCOME EVALUATION:
We would use both qualitative and quantitative method for evaluating the efficacy, feasibility, acceptability, and fidelity of the intervention. Outcomes can be divided into those proximal outcomes that are mostly (but not uniquely) relevant to particular intervention components, and those more distal outcomes that may be both more relevant to policy and practice, and, being more global in orientation, might be capable of summarising the combined and synergistic effects of all components of the complex intervention. For the Phase 2 exploratory trial I shall prioritise the proximal outcomes, but will also assess global distal outcomes to gather evidence on the possible impact of these component interventions on wider quality of life and functioning.
8.6 GENERIC OUTCOMES (relevant to both interventions):

**Mortality:** Any deaths during the trial period will be recorded, and a verbal autopsy completed with appraisal of any relevant clinical records, to attribute cause of death.

**Disability:** The 12-item WHODAS 2.0, a short version of the WHODAS 2.0 covers all six domains of the full 36-item version; five activity-limitation domains: understanding or communication, getting around (mobility), self-care, getting along with people (interpersonal interaction), and life activities. A sixth domain, participation in society, assesses broad social aspects of disability. Each domain is covered by two questions, with scores ranging from 0 (no difficulty) to 4 (extreme difficulty or cannot do). The standardised global score ranges from 0 (non-disabled) to 100 (maximum disability). WHODAS 2.0 has high internal consistency, moderate to good test–retest reliability, and good concurrent validity in many clinical populations with chronic disease. Sensitivity to change over time is also established for a wide range of interventions of known clinical effectiveness.

**Quality of life:** The 17 item WHOQOL-BREF comprises 26 items assessing QoL in four domains; physical, psychological, social relations and environmental. Each item has a five point response option. Scores are transformed to generate scores for each domain ranging from 0 (worst possible QoL) to 100 (best QoL). An international field trial demonstrated that the WHOQOL-BREF is a cross-culturally valid assessment of generic quality of life with good discriminant and content validity, internal consistency and test-retest reliability.
Global outcomes for the carer are likely to include

**Care inputs:** the time in hours spent by the carer in the last 24 hours in specific caregiving activities; communicating, using transport, dressing, eating, looking after one's appearance, and general supervision, using a standard structured assessment;

**Carer perceived strain:** The Zarit Burden Interview (ZBI) assesses the carer's appraisal of the impact their involvement has had on their lives, and has been widely used in LMIC contexts, including the 10/66 Dementia Research Group’s pilot and population-based studies. It comprises 22 items assessed by a 5-point Likert scale to provide a total score of 0 to 88, with a higher score representing a greater care burden. When used in the 10/66 pilot studies in 24 centres in Latin America, India, China and Africa it was found to be practical, culturally relevant, and to have robust psychometric properties. It was also responsive to change in the context of carer interventions in Russia, India and Peru.

**Carer quality of life:** The WHOQOL Bref-quality of life assessment will be carried to measure the quality of life of the caregivers. The WHOQOL-BREF (World Health Organization is an abbreviated 26-item version of the WHOQOL-100. This instrument has been tested cross culturally. This instrument consist of four domains: Domain 1: Physical health, 2: Psychological, 3: Social relations and 4: Environment, domain. Each item has a five-point response option. Scores are transformed to generate scores for each domain ranging from 0 (worst possible QoL) to 100 (best QoL). An international field trial demonstrated that the WHOQOL-BREF is a cross-culturally valid assessment of generic quality of life with good discriminant and content validity, internal consistency, and test-retest reliability.

**Evaluation of treatment acceptability:** Treatment acceptability will be measured by conducting in-depth interviews with the older person and family members involved in supporting and/ or implementing the intervention (see appendix 4 for the topic guide).
Figure 1: FLOWCHART OF RECRUITMENT:

8.7 INFORMED CONSENT PROCESS:

Each participant will be given a written information sheet explaining in simple, non-technical terms, the procedures, any potential risks and hoped-for benefits (see enclosed). Potential participants who can not read will be given an oral explanation. We will allow the participants to discuss the information provided in the information sheet with their family member and/or carer before giving their consent. Each participants will be given reasonable time to consider this information and to consult others as necessary. Participants will be allowed to withdraw from the study at any time up approximately 1-2 months after completion of the follow up. The right to withdraw information is clearly stated in the information sheet.
8.8 BENEFITS AND RISKS:
As part of the development of the WHO-COPE evidence-based guidelines, I systematically reviewed trials that reported adverse events among those receiving nutritional supplementation and exercise interventions, and compared these rates to those among controls. Meta-analysed estimates did not suggest any difference in adverse events between intervention and control groups. Experts in the field of nutrition and physical activity (members of the WHO-COPE Guideline Development Group) consider that these interventions are capable of being safely administered by non-specialist health workers with appropriate training. As described in the protocols above, we have clearly identified exclusion criteria for the intervention trials, and warning signs (red flags) that would trigger immediate medical referral and may constitute indications for withdrawal from the trial. Adverse events will be very closely monitored throughout the intervention period, by the PhD student, Dr Amit Dias the medical supervisor in Goa, and Prof Martin Prince in London. Any concerning patterns emerging will be discussed with the relevant WHO-COPE Guideline Development Group experts. Both interventions will be introduced gradually and emphasising safety throughout. In the event of any serious adverse event, the participant will be immediately referred to Goa Medical College for medical attention.
CHAPTER NINE
CHAPTER NINE

9. DISCUSSION:

The evidence gained and summarized in this thesis has important implications for developing packages of care for frail and/or dependent older people in low resourced primary health care settings in India and other Low and Middle Income Countries (LAMICs).

9.1 Is frailty a useful concept for low resourced health care settings in LAMICs?

The evidence presented (chapter two) underscores the public health relevance of frailty in LAMICs. Frailty indicators may assist in developing and targeting effective primary and secondary prevention strategies to delay or prevent the onset of dependence, and in providing holistic, coordinated care for older people with complex multimorbidities, particularly at the primary care level.¹ The data support the argument that frailty is likely to be a multidimensional construct, and that we need therefore to consider ‘frailties’ in different organ-based and physiological systems, and their individual and joint impacts on functional decline, loss of independence and survival. There are likely to be benefits in moving beyond the physical frailty phenotype to consider at least the effects of chronic undernutrition, sensory and cognitive impairment. A broader range of frailty indicators may cluster into meaningful sub-domains of frailty with common underlying patho-physiological mechanisms.²

In LAMICs, the resources available to address the population’s health care needs are very limited; particularly specialist health professionals are very scant in rural regions. Lack of consensus on appropriate target populations is one of the factors that have undermined the development and implementation of national programmes. Dependence is a key public health outcome, for which frailty indicators make larger contribution. Therefore, identifying frail older people and targeting intervention at impairment level is likely to yield better impact for public health programmes in LAMICs. In low resourced primary health care settings, community health workers (CHWs) are the main actors in implementing public health programme. Training CHWs in identifying frailty
older people and diagnosing impairments will be less challenging than diagnosis of underlying chronic diseases.

9.2 Is it efficacious to employ existing community health workers for identification of frail older people and diagnose the impairments at primary health care level? (Chapter three and four)

Presently, health care service for older people is not prioritized in the primary health agenda. There are also increasing concerns about the capacity of primary health care professionals to deliver health care services for older people in LAMICs. Building capacity for the public health care system and professionals is flagged as the main priority for LAMICs to address increasing epidemics, particularly chronic non-communicable diseases. Training existing staff members faces many challenges, such as the limited time available for training. Often, health systems challenges are quite similar across developing countries. However, this study suggests that it is feasible to train the community health workers, briefly (three hours and one visit on-job supervision) to enable them to identify of frail older people in routine primary health care practice.

Given the modest cost of the training procedure, and the high yield of valid cases delivered by the CHWs based simply on their knowledge of the local population, it is likely that this would be a cost-effective approach for identifying frail or dependent older people in the community. Prior to this study, there has been a paucity of evidence on possibilities of training and engaging existing non-specialist health professionals for identification and management of older people in need for care. In the last few years, the health of the ageing population in India has become a prioritized concern, and there is an increased commitment to improve health and social care for older people through existing health care systems. In 2012, India signed the Yogyakarta declaration on ‘Ageing and Health’, the Ministry of Health committed to strengthen the primary health care system to address the health needs of the older population including in-service training of health professionals. In 2011, India developed a national programme for health care of older people through community-based primary health care. However, the proposed strategies have not been successfully implemented and the objectives not achieved through the existing primary health care system. The clinic-based model of
care with little or no outreach activities is a significant obstacle to be overcome, together with the primary focus upon the identification and treatment of acute conditions. This study (chapter three) suggests that non-specialist CHWs can play a useful role in case identification. Given that referral up to primary health care remains problematic, the next step would be to demonstrate that the same CHWs could conduct comprehensive structured assessments in the community, in such a way as to identify and distinguish between common impairments, hence informing the delivery of simple evidence-based home interventions for, for example, undernutrition, mobility impairment, incontinence, cognitive impairment, depression. Family caregivers might also be advised and supported. Other interventions, for example refraction to provide glasses, or surgery for cataract would still require referral, but this could now be targeted on those most at need, and lack of help-seeking might not constitute a barrier to care. Beyond the ability of CHWs to conduct more detailed assessments, and evaluation of the feasibility and effectiveness of any home-based interventions that were subsequently delivered, it would be important to assess the readiness of the health system, the CHWs, and the potential users of such home-based services, to embrace the necessary system change, comprising task-shifting from non-specialist doctors in primary care to CHWs, and assessment and care provided in the community rather than the primary care facility.

In low resourced health care settings, it is rare for clinicians to visit patients in the community, and this is even considered undesirable. Physical mobility impairment and lack of transportation limits the scope for frail dependent older people to visit the primary health care facilities for assessment and treatment. Community health workers (who are currently the interface between the community and primary health care facility) could bridge this divide by performing home based assessments, consulting doctors or initiating referral where necessary, and implementing some indicated evidence-based interventions themselves, in the patient’s own home. This kind of collaborative working model is already in practice for improving maternal and child health, but its potential is rarely considered for managing dependent older people. The evidence presented here suggests that the COPE assessment is a useful tool for identifying specific impairments linked to needs for home care and support. The high positive predictive value of the CHW identification using the COPE assessment tool suggests that local physicians could have confidence in the accuracy of the CHW
assessments, whether in authorising them to initiate interventions based upon their findings, or in accepting referrals arising from these assessments.

**Strengths and limitations of the study:**

- First, some of the participants were chosen from the existing sub-health center case registry. For those older people both CHWs and primary care clinicians were already aware of their health conditions. Therefore CHWs might have chosen the participants who are more likely to be diagnosed by clinicians.

- It would have been helpful if a clinician assessment was performed for at least 5% of older people considered as non-frail by the community health workers. However, the ‘rule out’ was not made explicit in the detection process (CHWs were not asked to identify those who did not meet criteria for frail or dependence), hence this would not have been feasible without redesigning the procedure. Secondly recorded morbidity and impairments were based on self-reported information and the judgment of clinicians, and over reporting problems are very likely. Nevertheless, this was a pragmatic trial in which currently employed and functioning community health workers in government health system were trained for the identification of frail dependent older people at primary health care level. I wanted to assess how the structured assessment might work in real world primary care settings, and how the results of the assessment might converge with those of clinicians working in the same settings.

- The clinicians conducted an independent assessment and were completely masked from the CHW COPE assessment results.

- The clinician assessment may have been adversely affected by the doctors’ non-specialist background, the short time available for the assessment, and the lack of equipment (for, for example audiometry or visual acuity testing). For all these reasons, the clinician judgment certainly cannot be considered to represent a ‘gold standard’ and we have carried out a construct validation rather than a criterion validation of the COPE assessment.
• It would be possible to carry out a more detailed criterion validation of the COPE in the future. However, evidence, mainly from high-income countries, already supports criterion validity for most of the components. Arguably, the convergence with local clinician opinion may be most relevant to considering its utility and acceptability within the local health system.

• Pain is a common and burdensome impairment, which is not yet assessed as part of COPE, and may be a relevant co-factor in other impairments. Pain management may be challenging unless prescribing restrictions that pertain in many health systems, including that in Goa, are eased. More information would be required to plan interventions; for example a dietary assessment for nutritional intervention, and assessment of pain, recent fractures, and safety aspects prior to exercise interventions to improve mobility. However, such additional assessments could be conducted as part of the intervention, after screening using COPE.

9.3 Is there any evidence to support the effectiveness of strategies for the prevention and management of dependence among frail older people?

We found good evidence to support interventions targeting indicators of frailty among older people, mainly mobility impairment, undernutrition, urinary incontinence, vision, and risk of falls. Except for falls, for all other conditions we consulted experts in the field. For mobility impairments we considered progressive resistance training and multi component exercise programmes. There was a consensus agreement and recommendation for multi component exercise programmes that focused on strength, balance, aerobics, flexibility training. For frail and or dependent older people with undernutrition consensus agreement was in favor of dietary advice as first line of treatment for frail older people at risk of malnutrition and oral nutritional supplement that is enriched in macro and micro nutrient component was recommended. For frail dependent older people with urinary incontinence, experts’ consensus agreed that prompted voiding should be recommended for older persons with cognitive impairment or who cannot toilet independently. For frail older people who can reach the toilet
independently and have stable cognitive function, pelvic floor muscle and bladder training can be administered.

We have consulted the experts in vision impairments for understanding the benefits or harm of cataract surgery and usefulness of corrective eyeglasses. The expert group agreed that corrective eyeglasses should be recommended for frail dependent older people with low vision acuity. There was also agreement that community health workers can be trained to identify frail older people with vision impairment. In many LMICs cataract surgery and eye-glasses to correct refractive error are already provided free of cost. However, these services are effectively limited to older people who are able to visit primary health care or district hospital facilities for assessment. Eye camps are sometimes organized for community outreach, particularly in rural areas, but even then home-based assessment is not routinely available. Alternatively CHWs could be trained to identify frail older people with limited access to health services and perform assessment for vision and refer them for surgery. For near vision impairment, it was agreed that non-specialist health workers could effectively distribute magnifying (reading glasses) of appropriate strength to correct near vision problems in the older person’s home. Provision of cataract eye surgery was considered and harm was also discussed, but since the benefit outweighs the harm, the experts agreed that cataract eye surgery should be recommended for frail older people with cataract. However, following non-specialist community health worker detection of older people with vision problems, it was recommended that referral to PHC or eye clinic at district level hospital would be necessary to exclude retinal problems, for example diabetic retinopathy, as an alternative or comorbid explanation for visual impairment. Detection of diabetic retinopathy may be particularly important since the underlying diabetes may be undiagnosed. For cognitive and behavioral impairment, there is already a strong evidence-based package of care recommended in the WHO mhGAP (Mental Health GAP) guideline. However the generalizability to older people of the recommendation for management of depression and other common mental disorders needs to be discussed with the expert panel.
Strength and limitations of the WHO COPE recommendation:

- This was a first attempt to draft evidence-based recommendations for frail older people in low and middle-income countries.
- The strength of guideline recommendations rely heavily on the process, WHO COPE was developed systematically, incorporating systematic reviews and assessment of the quality of evidence and balance of benefits and harms. In addition, explicit consideration of other issues such as value judgments, resource use, and feasibility, which are major considerations, need to be incorporated.
- All consultations with expert panels were conducted over teleconference with individual sub groups working on different impairment. In frail older people multiple impairments and multi morbidity are very common, therefore it unclear how these interventions can be packaged and delivered. Therefore a further face to face meeting with all members working on different sub groups is required.

9.4 Is it viable to integrate home-based care for frail dependent older people in low resourced health care settings?

In LAMICs, existing primary health care model is mainly clinic based, home visits by doctors are rare. On the other hand, limitation in mobility and transportation limit the ability of many frail older people to access basic health services in the public health system. Therefore, there is a pressing need to develop a comprehensive home-based care system for frail older people that could address their health care needs at community level. However, integrating a care programme for frail older people into low resourced primary health care settings poses many challenges, these include: 1) inadequate provision of services to address the care needs of frail older people, 2) available service (e.g. for correcting refractive errors) are effectively limited to older people who could visit the PHC facility, which is often challenged by lack of transportation and the mobility of the older person, 3) primary health care staff are untrained to assess the health care needs of older people and their skills are very limited to address the problems, 4) existing human resources are insufficient and preoccupied in organising care for acute health conditions (infectious diseases) and implementing the nation’s priority programmes (maternal and child health). On the other hand, there was
a strong endorsement among key actors (CHWs, family doctors, service managers) for providing home-based care for frail older people and a willingness to consider extended or modified job roles, and a degree of service restructuring to achieve this objective.

Generalising these findings to other settings is limited by the fact that this study was conducted in one primary health care facility in Goa, which may not be representative of health facilities across the State, or of health systems in other LAMICs. However, many of the challenges highlighted in this study are similar across many low resourced health care settings. In a primary health care based study conducted by WHO (in Malaysia, the Philippines, Jamaica, Canada and Australia) lack of human resource, training and education, transportation, lack of continuity in care and fragmented services were flagged by primary health care professionals and older people as major impediments for developing age-friendly primary health care. In high-income countries, primary health care services have an important, but often under-realised role in coordinating specialist care for older patients with complex multimorbidities, in a holistic way, supporting the preferences and priorities of the patient. Identification of frailties can inform simple interventions that may have the potential to limit progression of disability and delay onset of needs for care. There is a strong evidence-base, from high income countries, to support the effectiveness of multidimensional geriatric assessment of the kind described in this thesis. The original element is the adaptation of these approaches as home-based assessments and interventions for use by non-specialist CHWs. As home-based outreach by formal health care services is rationed in many high income countries, there may be opportunities for applying knowledge from piloting of these approaches in LMIC to different cadres in HIC, for example lay volunteer or third sector support workers, and home care professionals.

In India, although existing national programmes address common impairments such as under nutrition, vision, and hearing impairment, beneficiaries of these national programme still remains young children and adult not older people. For example, a national nutrition programme was first introduced in India in 1962, under this programme, oral nutritional supplementation and nutrition-dense mid-day meals was provided to undernourished people. Thus far, this programme predominantly focused on children and mothers, although the original policy was not restricted to these specific
populations.\textsuperscript{15} In LAMICs, national health programmes are generally organised in co-ordination with primary health care and community health workers. Integrating care for frail older people in public health care settings will avoid inequality in coverage of national programmes that could improve the health and quality of life of older people.

**Strength and limitations of the study:**

- In low and middle income countries primary health care systems (PHC) are very diverse in terms both of human resources and also priority health care activities.\textsuperscript{16} Therefore generalising my findings to other health care settings will be difficult. However, in India there is more homogeneity in the levels, types and educational backgrounds of primary care professionals, and the priority activities of PHCs, and therefore the findings may be more generalizable within the country.\textsuperscript{3}
- The interview transcript, particularly community health workers were analysed independently by three researchers, increasing the quality of the analysis and the likely validity of the findings.
- The qualitative data was summarized from three perspectives (CHWs, primary care doctors, frail older people and their family caregivers) and themes were derived and confirmed using a process of triangulation, further Contributing to the validity of the findings.

**9.5 IMPLICATIONS REGARDING FUTURE RESEARCH:**

Research interest in frailty has grown considerably in recent years.\textsuperscript{17} This is partly due to the dynamic nature of frailty, which occurs in absence of chronic disease in some older people and as a result in others.\textsuperscript{18} The measurement models (Fried and Strawbridge phenotypes) tested in this study are theoretically strong, but psychometrically naïve, and further empirical work on the construct validity of these and other approaches to assessing frailty should be a priority for future research. It is likely that more objective measurement of frailty indicators (including underlying physiological biomarkers) may provide better risk stratification. However, the best assessment approach for frailty indicators is still a matter for debate. This study
measured sensory impairments using self-reported measures and found poor predictive validity for mortality outcome. Further research should consider objective evaluation of vision and hearing impairment to clarify the association of these two frailty indicators with mortality and dependence. Further, a better understanding of the frailty phenotypes and the pathways to adverse outcomes could inform simple multi-dimensional assessment and multi-component intervention strategies with considerable potential to add life to years as well as years to life.\textsuperscript{19}

A short duration training programme for case-identification is effective in low resourced health care settings (chapter three). Although this was a pragmatic trial, due to limitation in funds and time, we could only re-assess all the older people identified by CHWs as frail. Future, research should check the specificity of CHWs case-identification by cross verifying at least 10\% of older people who were known to CHWs but not considered to be frail or dependent.

I found that a simple multi-dimensional assessment can be effective in identifying common impairments (Chapter 4) that could inform multi-component intervention strategies (Chapter 5). Some needs for refinement were noted in the course of this pilot evaluation of the COPE assessment. A portable light source and a mirror could facilitate the administration of the Snellen chart vision test, where space is cramped and lighting inadequate. Vision testing should be extended to include near vision testing (reading), since unlike refraction errors (which would require optometry and a prescription for glasses or cataract surgery), hyperopia can be corrected by low cost magnifying lens glasses, which could be dispensed by the CHW. Pain is a common and burdensome impairment,\textsuperscript{11}, which is not yet assessed as part of COPE, and may be a relevant co-factor in other impairments. Pain management may be challenging unless prescribing restrictions that pertain in many health systems, including that in Goa, are eased. More information would be required to plan interventions; for example a dietary assessment for nutritional intervention, and assessment of pain, recent fractures, and safety aspects prior to exercise interventions to improve mobility. Further research should consider including such additional assessments as part of the intervention, after screening using COPE.
The effort undertaken to develop COPE programme for prevention and management of dependence among frail older people, opens new directions for primary care research. Future research should prioritise on developing a conceptual framework for COPE programme in LAMICs. More work is needed to understand the theoretical basis for the intervention, and to characterize the intervention according to the mechanisms linking specific components to specific targets, be those underlying risk factors, frailties or other outcomes. Attention will need to be given to the likely effective dose and duration for each intervention component. The mapping exercise will inform the integration of components and sub-components into a single streamlined package of care, which will be efficient (maximising synergistic potential) and simple to administer and receive. The final product will be a standardised assessment and intervention tool that has progressed from a set of evidence-based clinical guidelines to a manualised intervention guide, supported by recommended training procedures.

The next step would be to evaluate the implementation of the COPE programme for cost–effectiveness, in the context of a cluster randomised controlled trial, comprising case identification by CHWs, screening assessment and intervention with evidence-based packages of care. Clusters could be health care facilities; comparing facilities at which all attached CHWs were trained in these procedures with those in which they were not (treatment as usual). It is unlikely that overall healthcare costs would be reduced in the intervention group, given the usually low levels of health service utilisation among frail and dependent older people. It would therefore be important to relate costs to outcomes in both arms so that the incremental cost effectiveness ratio ($s invested per DALY or QALY averted) could be calculated. Regardless of the clinical effectiveness of individual components of the package of care, such evidence is nowadays crucial to make convincing arguments to policymakers to invest in scaling up.

While my planned work in Goa on individual components of the intervention is limited to non-randomised phase II pilot trials of feasibility, fidelity and efficacy, some would consider that each important element of the intervention should be tested experimentally prior to constructing the package of care from effective components. Such evidence does already exist to support most of the components recommended in the guidelines, but mainly from trials conducted in high-income countries and with the quality of
evidence generally rated low to moderate. Evidence with respect to some components is likely to be more generalizable than others. Additional calories ingested as nutritional supplements are likely to be generally effective in improving nutritional status. However, progressive resistance training may be associated with greater benefits when guided by a physiotherapist in a specialist facility in a high-income country as compared to a non-specialist CHW in rural India. The phase II intervention trials should highlight components with doubtful efficacy, where further refinement may be necessary, followed by rigorous testing in individual patient randomised controlled trials.

In my experience (as a trainer), non-specialist community health workers can be easily trained in assessment methods. But the hardest and most time-consuming task is to train these professionals in clinical decision-making, and in the timely and appropriate administration of interventions. This problem could be partly resolved by introducing decision making automated clinical algorithms in an m-health platform. Development of such applications in m-health platform will promote patient safety and limit medical errors in routine primary care practice. However, the utility of m-health application for assessment and clinical decision-making would need to be examined carefully in future pragmatic trials.

9.6 IMPLICATIONS FOR PRACTICE AND POLICY IN LAMICs:

In the 21st century, India, similar to other low and middle-income countries is encountering unprecedented challenges in population ageing. While global advocacy to improve the health of older people in LAMICs proceeds apace, implementation through regional and country level initiatives are rather slow. Although progress towards achievement of Alma Ata objectives has fallen short of expectations, the 30 years old declaration on “health for all” is still relevant for many LAMICs. In India, the health of the population is beginning to receive more attention from national policy makers, and was prominent in national election manifests. In the last two decades, population ageing received national importance in many LAMICs, and there has been an increasing commitment to improve the health and social care for older people. Without doubt, in coming years, a rapidly ageing and increasingly vocal population will demand greater social protection and more options for long-term care, and enhanced support from the public health care system.
In many LAMICs, national programmes are in place to improve health care for older people.\textsuperscript{10, 31} However, proposed strategies have not been successfully implemented or achieved through the existing public health care system.\textsuperscript{3, 14} For frail older people there are many barriers to accessing specialised health care. Most specialist health care facilities are located in urban settings, while most older people live in rural regions where basic health care is entrusted to untrained and non-specialised health professionals.\textsuperscript{22, 30} Disease specific programmes have achieved only marginal benefits, particularly in LAMICs.\textsuperscript{28} Vertical programmes are intrinsically inefficient, with each disease control programme requiring its own bureaucracy, leading to uncoordinated use of existing resources – perversely, these are likely to increase the treatment gap for older people with multi-morbidities.\textsuperscript{29} Among frail older people multi-morbidities are very common, and are thus best addressed in a horizontally structured programme. Dependence and mortality are key public health outcomes, to which frailty indicators (chapter two) made a large independent contribution. Therefore, frail older people should be a focus for future public health programmes attempting to improve the health of ageing population in LAMICs.

In many LAMICs, community health workers are the first point of contact in the health system for people in the community.\textsuperscript{32} The shortage of medical doctors favours task shifting. However, CHWs are currently untrained in comprehensive geriatric assessment and diagnosing prominent conditions, and lack knowledge of evidence-based interventions and how to administer them.\textsuperscript{7} I have demonstrated that it is feasible, in principle, to train CHWs in the identification of frail or dependent older people and to diagnose specific impairments using the structured COPE assessment (chapter three and four).

National programmes in LAMICs envisage home- and community-based primary health care for older people.\textsuperscript{10, 31} Poor coordination between health professionals (doctors and community health workers) has contributed to the lacuna in health care services for older people.\textsuperscript{13} Findings from this study suggest possibilities for more co-ordinated care services within existing primary health care systems (chapter seven). However, existing community health care workers are already over burdened with routine preventive and
curative care activities, therefore there may be a need to strengthen existing services or develop a separate geriatric community health worker cadre to better coordinate care for frail older people.
9.7 BIBLIOGRAPHY:


14. GoI. Indian Public Health Standards(IPHS) , Guidelines for Sub-Centres Revised In: Directorate General of Health Services MoHFW, editor. New Delhi, India: Government of India(GoI); 2012.


34. Jacob KS. Public health in low- and middle-income countries and the clash of cultures. *Journal of Epidemiology and Community Health* 2009; 63(7): 509.