Chapter III

Methodology
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Now is the right time to begin work on reinventing the nation’s health care delivery system. Technological advances are making it possible to accomplish things today that were impossible only a few years back. Health professionals and organizations, policy makers, and patients are becoming all too painfully aware of the shortcomings of the nation’s current system and of the importance of finding radically new and better approaches to meeting the health care needs of all people.

Scope of the study

During the past decade there have been a substantial number of studies directed towards the development of interventions for family caregivers. These interventions include family and community support groups, respite care programs, and psycho educational programs such as skills training. However, despite the proliferation of these intervention programs, they have had only limited success for a variety of reasons. Services are not always available to caregivers, and many caregivers are unwilling to use available community services because of issues such as cost, logistical problems, or feelings of guilt about receiving help outside the family structure. For example, problems such as difficulty arranging alternative help, inaccessible meeting places, or scheduling conflicts often prevent family caregivers from attending support group meetings (Wright et al 1987). These findings suggest that current intervention strategies may need to be modified to be more responsive to the needs of caregivers. Current information technologies offer the potential of providing support to family caregivers of dementia patients. Nevertheless, local-area information systems developed in accordance with the principles and minimal functional requirements could be built and implemented immediately, without great difficulty or cost, and with considerable benefit. There needs first to be some mechanism for the identification of cases in the community.

A major challenge for future health care is the care for dementia patients and their informal caregivers. In usual care, the problems of caregivers often remain invisible until a crisis occurs. This inhibition is partly the result of informal caregivers
paying scant attention to their own problems. Another reason is that professional may not know how to support informal caregivers pro-actively.

In developing the intervention, consideration must be given to the resources available to deliver it. The content and level of the intervention must be tailored to this, as well as to the cultural context. The caregivers need the support in the current point of time. Keeping this in mind, a cross sectional study of the selected population was opted, which represents various stages and degrees of psychosocial status at current point of time. And all the informal caregivers of persons with dementia irrespective of the type are recruited into the study.

The following variables were taken up for the study

I. Patient related variables
   • Socio-demographic information
   • Illness-related
   • Behaviors commonly observed in patients with dementia

II. Primary care giver’s related variables
   • Socio-demographic information
   • Coping
   • Social support

III. Effects on caregiver
   • Depression
   • Distress
   • Strain
   • Burden
   • Burnout

Due to the dearth of formal institutions caring for the persons with dementia in the Indian context and also as a result of the predominance of nuclear family set ups and dual earners, the stress experienced by the primary caregivers are enormous. To plan and institute any interventions for the caregivers it is imperative to know the psychosocial characteristics of the caregivers
Need for the study

In the Indian Society, the cultural values and the traditional practices emphasize that the elderly members of the family to be treated with honor and respect. The families of the aged persons are expected to ensure the needed care and support for the aged. However, recent changes in the size and structure of families have caused the re-arrangement of the roles and functions of members in the families.

The size of the elderly population in India increased from 20 million in 1951 to 57 million in 1991, and expected 107 million in 2010, 198 million in 2030 and 326 million in 2050 (United Nations, 1995).

Dementia has been recognized as the cause of disability in 5% of 10% of the world population aged over 60 years. Dementia is a chronic, progressive neurological disorder. It is therefore expected that the cost of caring for these patients is enormous. Besides the monetary cost, many spouses, relatives and friends take care of people with dementia. Providing care for a person with dementia in the community commonly places stress on the caregiver. In course of care giving, families experience emotional, physical and financial stresses. It is impossible to quantify this suffering.

The impact associated with caring for a person with dementia has been undertaken by 10/66 Research Group, which is a multicentre study, involving 25 centres including India. In the recent years they had conducted pilot studies in Kerala and Goa with the objectives:

- To investigate the prevalence of dementia in an urban population and to conduct awareness programs in various places in Cochin Corporation.

- To explore the caregivers knowledge and understanding of dementia, the nature of care arrangements for the person with dementia, the caregivers attitude towards the caring role and sources of strain for the caregivers (Shaji et al 2002).
As a conclusion it was stated that there is a need to raise awareness about dementia in the community and amongst health professionals and to improve access to appropriate health care for the elderly with dementia.

To the best of current knowledge, studies relating to the correlates of dementia are from west and such studies are modest in India. Hence the current study aims to examine the psychosocial characteristics of the informal caregivers of persons diagnosed with dementia (ICD-10) and to develop sustainable Decision Support System to accurately assess the caregivers' psychosocial status to support the health care professional to take decisions for intervention, research studies and education.

Researcher is from the field of Health Information Management and one of the objectives of Health Information Professionals is to assist the health care professionals in quality care and effective and efficient health care services. There have been many tools developed for qualitative studies at present. HIV, Cancer and Alzheimer are being the progressive diseases in India; more research work is going on with HIV and Cancer related fields. And more and more information support systems are being developed for the said diseases. As per the current review there is still a need for information support system for the caregivers of persons with dementia and cross-linkage systems to assess the frequency of different types of illness related variables on their primary care givers.

**Aim**

To design and develop accurate and sustainable “Decision Support System” to assist health care professionals based on the findings related to a study on psychosocial characteristics of informal caregivers of persons with dementia.

**Objectives**

1. To ascertain the following characteristics of persons diagnosed with dementia:
   - Socio-demographic
   - Illness related variables
• Commonly seen distressing/disturbing behaviors

2. To ascertain the Socio-demographic characteristics of informal caregivers of persons with dementia

3. To study the extent of social support as experienced by the informal caregivers

4. To ascertain the extent of perceived strain and burden experienced by the informal caregivers

5. To investigate the frequency of occurrence of depressive symptoms and depressive disorders in informal caregivers

6. To evaluate the frequency of burnout experienced by the informal caregivers

7. To ascertain the nature of coping strategies employed by the informal caregivers

8. To design and develop an accurate and sustainable Decision Support System that will comprehend/assist the health care professionals in taking decisions, prediction and interventional research

For convenience, methodology will be discussed in two sections. Section I for first seven objectives and section II for eighth objective

Section I

Sampling method

A purposive sampling method was chosen for the current study.

In purposive sampling, researcher sample with a purpose in mind. Researcher usually would have one or more specific predefined groups in his/ her mind. One of the first things they would likely to do is verify that the respondent does in fact meet the criteria for being in the sample. Purposive sampling can be very useful for situations where there is a need to reach a targeted sample quickly and where sampling for proportionality is not the primary concern. With a purposive sample, researchers are likely to get the opinions of the target population, but also likely to overweigh subgroups in the population that are more readily accessible.
Study type

Cross sectional - Descriptive study was selected for the current study.

A cross-sectional study is the simplest variety of descriptive or observational epidemiology that can be conducted on representative samples of a population. Simply put, it is a study that aims to describe the relationship between diseases (or other health-related states) and other factors of interest as they exist in a specified population at a particular time, without regard for what may have preceded or precipitated the health status found at the time of the study. Cross-sectional studies must be done on representative samples of the population if generalizations from the findings are to have any validity. These studies gather information about the prevalence of health-related status and conditions, but they cannot distinguish between newly occurring and long-established conditions. All they can do is measure the frequency (prevalence) of conditions and demonstrate associations. They cannot identify cause-and-effect relationships, though they do identify the existence of health problems. Cross-sectional studies, also known as surveys, are a useful way to gather information on important health-related aspects of people's knowledge, attitudes, and practices (such studies are known as "KAP" surveys). The distinction between a cohort study and a repeated cross-sectional study is that a cohort study is conducted with the same individuals who participate over a long period; repeated or serial cross-sectional studies, on the other hand, do not necessarily (or even usually) study the same individuals repeatedly.

Collection of data: Direct interviews & administration of Questionnaires in home environment of the informal caregivers of persons with dementia with their consent.

Sample size: Sample of 125 informal caregivers meeting the selection criteria; all the cases diagnosed as dementia (ICD-10) and their primary care givers visiting the OPDs of selected centers of Udupi Town were recruited into the current project.

Duration of data collecting period: 2 years 6 months.
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The Universe

1. Hospital A (Kasturba Medical College Hospital, Manipal University, Manipal)

   Excellence in Healthcare since 1961. Kasturba Hospital has emerged as a internationally recognized healthcare institution providing tertiary care to patients. 1612 bedded Kasturba Hospital is teaching hospital attached to Kasturba Medical College and an associate hospital of Manipal University and is managed by Manipal Health Systems. It has a dedicated team of 300 full-time consultant doctors of national and international repute, 200 duty doctors, 2200 paramedical, nursing and other support staff working round the clock for delivering compassionate and holistic care. The state-of-the-art facilities, sophisticated diagnostic and therapeutic care at an affordable cost are the hallmarks of patient treatment.

   Kasturba Hospital is the first Medical Hospital in Karnataka to get the prestigious National Board for Accreditation of Hospitals (NABH). It is ISO 9001:2000 & ISO 14001-2004 certified displaying the strong commitment to continuously improve the quality of patient care. The schemes offered by Manipal Group like Manipal Hrudaya Suraksha and subsidized treatment through Manipal Foundation take special care of the needy patients. The pharmacy has generic based formulary providing quality and affordable drugs. Trauma and Emergency Centre and Integrated Mother and Child Centre for comprehensive care of Women, children and neonatal with all contemporary and sophisticated facilities offer round the clock services.

Department of Psychiatry

   The clinical services offered by the department are, management of major psychiatric disorders using both pharmacological and psychosocial interventions. The department has specialty services for drug and alcohol abuse, geriatric psychiatric illnesses including dementia, child guidance clinics, consultation liaison services with other departments of the hospital and psycho oncology services for cancer patients. In addition, this department also provides psychiatric services at District hospital and
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Dr.T.M.A.Pai Hospital Udupi and Rotary Hospital, Karkala. School mental health programmes are also a part of the extension services.

The department also conducts clinical camps in remote areas of Udupi district like Karkala, Malpe, Udyavara and Kaup as part of community psychiatric services. These camps help to extend modern psychiatric treatment for mentally ill patients who are unable to attend hospitals because of cost and distance.

In addition, the department is also participating in international and national multicentre Clinical trials in major psychiatric disorders and pharmacokinetic studies in the area of drug research. The department is also involved in the community psychiatry project for evaluating health care delivery systems in the community.

2. Hospital B (Dr. A V Baliga Memorial Hospital, Udupi)

Dr.A.V.Baliga Memorial Hospital at Doddanagudde, Udupi started serving the society in 2003 has an in-patient and out-patient general hospital run by Dr.A.V.Baliga Charities, Mumbai. This charitable hospital serves all sections of the society with quality medical care at an affordable cost. The hospital specializes mainly in Psychiatry in addition to General Medicine, General Surgery, Gynecology, Pediatrics, and Dental Surgery. Orthopedics, ENT and so on.

The hospital's full range of medical services enables cross-specialty consultation which assures comprehensive treatment for each patient at an affordable cost. Dr. A. V. Baliga Memorial Hospital has started social welfare schemes with a motto to provide good facilities for economically backward classes, no matter what caste creed or religion they belong to, and aspire to serve the society in the best way possible. Dr. A. V. Baliga Memorial hospital has an obligation to fight the evil effects of alcohol addiction, tobacco intake, smoking, drug abuse for the betterment of society. It is also dedicated to increasing awareness about mental health, psychological problems like depression, suicidal tendencies and so on.
3. Hospital C (District Hospital, Ajjarkad, Udupi)

It is 125 bedded hospital situated in the heart of Udupi town. Apart from the specialists who are employed by the government, specialists from other hospitals like Kasturba Hospital Manipal and Dr. A V Baliga Memorial Hospital Udupi provide their valuable services to the welfare of the community in the area of mental health. It is also dedicated to increasing awareness about mental health, women and child health, AIDS awareness and so on.
### Table 6: Sample selection process

<table>
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<th>Hospital</th>
<th>Total cases referred</th>
<th>Excluded cases</th>
<th>Total cases after exclusions</th>
<th>Excluded cases</th>
<th>Total cases after exclusions</th>
</tr>
</thead>
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<td>83 cases</td>
<td></td>
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</tr>
<tr>
<td>Hospital B</td>
<td>58 cases</td>
<td></td>
<td></td>
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<tr>
<td>Hospital C</td>
<td>03 cases</td>
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<td>Contact not possible - 4</td>
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<td>Contact not possible - 3</td>
<td>50 caregivers</td>
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<td>03 caregivers</td>
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<tr>
<td>Out of district – 07</td>
<td></td>
<td>Out of district – 02</td>
<td></td>
<td>Did not consent - 02</td>
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</tr>
<tr>
<td></td>
<td>72</td>
<td>50</td>
<td>03</td>
<td>03</td>
<td></td>
</tr>
</tbody>
</table>

**Total sample size = 125 caregivers**

The care givers who visited the above mentioned hospitals residing in Udupi district of Karnataka State, India were selected for the current study.
Fig 7: Map of India, showing the state of Karnataka
SELECTION CRITERIA

Inclusion criteria:

- Cases of dementia diagnosed by the medical professionals (ICD-10).
- Primary caregivers of either sex who is related to the patient and who is caring the aged persons with dementia at home and who is 18 years and above
- All cases of dementia irrespective of the subtype and degree of impairment
- Should be able to communicate in Kannada, Tulu or English
- Those willing to participate in the study
- Caregivers of patients with dementia residing in Udupi District
Exclusion criteria:

- Those not willing to participate
- Caregivers aged below 18 years
- Caregivers residing outside of the district
- Those with poor fluency in the mentioned three languages.
- Caregivers who had very poor health

Method of Sample Collection and Tools

All the informal caregivers of all the cases diagnosed with dementia (ICD-10) attending the OPDs of selected centers, during the study period in Udupi Taluk were recruited into the study.

Face to face interview with the structured questionnaires and schedules were conducted to collect information about the socio-demographic characteristics and illness related variables of the persons with dementia and other standardized rating scales were administered to the informal caregivers either in the center or at their respective homes.

The socio demographic questionnaire was devised by the investigator based on other research work conducted in this area to obtain the socio-demographic details of the patients and socio demographic details of the caregivers and personal details like knowledge about the disease, their health conditions and their attitude towards caregiving. It also contained items related to the information of the other family members involved in caregiving.

The psychiatrists, neurologists, psychiatric social workers in the selected hospitals who had examined the patients and interacted with the caregivers were requested for the contact numbers of the caregivers of patients with dementia. Screening was done as per the required criteria. All the caregivers were called up and were explained about the project and requested to participate. On getting their consent, home visits were scheduled. Home visits were conducted with prior appointments always. To rule out the bias in the data, before the actual interview a...
formal conversation with the family members including the primary caregiver was conducted. This helped the investigator to build up the trust and rapport with the caregiver. If the investigator felt the need for more time to come closer to the family members the interview was conducted in two sessions. Detailed interview were conducted with the primary caregivers usually which lasted for 2 to 3 hours per session. Usually the initial part of the session was devoted to listening when the caregiver ventilated about his woes and difficulties, their disappointments he/she is going through in the process of caregiving; listening helped, all of them had to be comforted and reassured to get through the other phase of the interview i.e., data collection. All of them at this point usually became amenable for further questioning and data collection was smooth and spontaneous. The attitudes, emotional responses and any other behaviour or observations, noted of the caregiver was also made note of, for further analysis.

Once all the questionnaires were administered with socio demographic details was the first questionnaire to be administered followed by questionnaires for strain, burden, depression, burnout, social support and coping.

In between the interview some gap was given between 2-3 questionnaires to tide over the fatigue or monotony the caregiver would in all likelihood have developed.

After completing all the questionnaires the data was entered into SPSS program manually by the investigator and the analysis and interpretation was done with the help of statistician.

Depending on the findings a software (SNEHA) was developed keeping in mind the requirements of both the health care managers and the caregivers of persons with dementia.

All questionnaires were pretested questionnaires and questionnaires were translated into the local language Kannada and back translated by the language experts and later verified by the professionals in the field.
Tools for data collection

1. socio-demographic proforma of the patients
   Socio-demographic proforma of patients diagnosed for dementia A proforma was devised by the researcher for the purpose. Regarding demographic factors, information on patient's age, gender, education, relationship to caregiver, family type, income was collected.

2. socio-demographic proforma of the caregivers
   Socio-demographic proforma of primary caregivers of patients diagnosed for dementia was also devised. Regarding demographic factors, information on caregiver's age, gender, marital status, relationship to patient, education, occupation, residence working status, income, period of nursing, daily hours spent on nursing, hours required for close supervision of the patient was collected.
   Apart from the demographic details the questionnaire included the questions about the health status, knowledge about the disease and their attitudes towards caregiving.

3. Neuropsychiatry Inventory Questionnaire
   The Neuropsychiatric Inventory Questionnaire (NPI-Q) is a rapidly administered instrument that provides a reliable assessment of behaviors commonly observed in patients with dementia and distress experienced by the caregivers (Kaufer et al 2000)

   NPI lists out 12 distressing symptoms seen in persons with dementia Delusions, Hallucinations, Agitation, Depression, Anxiety, Elation, Apathy, Disinhibition, Irritability, Motor disturbance, Night time behaviors, Appetite and eating. The NPI is based on a structured interview with a caregiver who is familiar with the patient.

   These variables of problem behaviors and care giver reactions were studied by asking caregivers to respond to NPI-Q. For each domain a screening question is asked to determine if the behavioural change is present or absent. If the answer is
positive the domain is explored at greater depth with the sub-questions. If the sub-questions confirm the screening question, the severity and frequency of the behaviour are determined according to the criteria provided for each domain.

This tool provides a reliable assessment of behaviours commonly observed in patients with dementia (delusions, hallucinations, motor disturbances etc.) and the distress experience by the caregivers. The NPI is a useful instrument for characterizing the psychopathology of dementia syndromes.

Each question is marked with “yes” or “no” answers and 3 levels for rating severity in the patient and 5 levels for rating distress in caregivers. Neuropsychiatric symptoms may contribute significantly to the overall morbidity of AD on both patients and caregivers, underscoring the importance of identifying and quantifying patient symptoms and their impact on caregivers. The NPI has been shown to have adequate test-retest and inter-rater reliability, as well as good content and concurrent validity. NPI is easy and screening strategy to minimize administration time and available in many languages.

4. Zarit Burden Scale

The Zarit Caregiver Burden Scale (ZCBS) is one of the most widely used scales. The ZCBS was developed by Zarit and coworkers in 1985 and is a self administered 22-item questionnaire. The questions refer to the caregiver/patient relationship and evaluate the caregiver's health condition, psychological well-being, finances, and social life. The questionnaire with a five-item response set ranging from "never" to "nearly always". The caregiver burden is evaluated by the total score obtained from the sub total of 22 questions and the caregiver distress is higher with higher scores, 0-20 points mean little or no burden, 21-40 points mean mild to moderate burden, 41-60 points mean moderate to severe burden, 61-88 points mean severe burden. The total score ranges from 0 to 88. A high score correlates with higher level of burden. Test-retest coefficient = .89 and α = .85. Cronbach’s alpha index varying from 0.79 to 0.91. Gallagher et al(1985) assessed the test-retest of the scale's original version and obtained a good result (alpha=0.71). Caregivers are
asked to indicate how often they had various thoughts or feelings on a scale from 0 (never) to 4 (nearly always) (e.g., how often do you feel that: he/she is dependent on you, your health has suffered because of your involvement with him/her, your relationships with others have been affected in a negative way). There is no reference time frame for this measure. The average score for this measure was 21.9 ($SD = 14.5$; range = 0 to 72) which is consistent with previous studies on family caregivers to depressed outpatients.

5. **Caregiver Strain Index**

This tested scale (M. Terry Sullivan, 2002) is a tool that can be used to quickly identify families with potential caregiving concerns. It is a 13-question tool with “yes =1” or “no =0” options that measures strain related to care provision. There is at least one item for each of the following major domains

a) Employment  
b) Financial  
c) Physical  
d) Social  
e) Time

Total score is the number of “yes” responses. Any positive answer may indicate a need for intervention in that area. A score of 7 or higher indicates a high level of stress.

Internal consistency reliability is high (alpha = 0.86) and construct validity is supported by correlations with the physical and emotional health of the caregiver and with subjective views of the caregiving situation. The CSI is a brief, easily administered instrument. The tool is limited by lack of a corresponding subjective rating of caregiving impact. The tool effectively identifies families who may benefit from more in-depth assessment and follow-up.
6. Brief COPE

The items of Brief COPE are an abbreviated version of the COPE Inventory. The shorter version was created partly because earlier patient samples became impatient at responding to the full instrument (both because of the length and redundancy of the full instrument and because of the overall time burden of the assessment protocol).

The Brief COPE scale (Carver, 1997) is a 28-item self-report measure of both adaptive and maladaptive/problematic coping skills. The Brief COPE was developed based on concepts of coping from Lazarus and Folkman (1984). The scale was designed to yield fourteen subscales, comprised of two items each of 14 scales. The 4 point Likert scale format was retained. The scales, which include both potentially dysfunctional as well as adaptive responses, are: active coping, planning, positive reframing, acceptance, humor, religion, using emotional support, using instrumental support, self-distraction, denial, venting, substance use, behavioral disengagement, and self-blame (Carver, 1997). The alpha reliabilities of the scales for the population of 294 participants involved in the validation study ranged from .50-.90, with only three falling below .60. A factor analysis yielded a structure generally consistent with the original version of the COPE. The factor structure is not entirely consistent with the 14 scale structure, but the scale structure is justified by a combination of theoretical constructs and factor structure (Carver, 1997; Carver, et al 1989).

This tested scale developed by Carver et al (1997) to assess the broad scope of coping responses. Response options range from score-1 (I haven’t been doing this at all) to score-4 (I’ve been doing this a lot). Scales are as follows (with no reversals of coding): Self-distraction, items 1 and 19 ($\alpha = .71$), Active coping, items 2 and 7 ($\alpha = .68$), Denial, items 3 and 8 ($\alpha = .54$), Substance use, items 4 and 11 ($\alpha = .90$), Use of emotional support, items 5 and 15 ($\alpha = .71$), Use of instrumental support, items 10 and 23 ($\alpha = .64$), Behavioral disengagement, items 6 and 16 ($\alpha = .65$), Venting, items 9 and 21 ($\alpha = .50$), Positive reframing, items 12 and 17 ($\alpha = .64$), Planning, items 14 and 25 ($\alpha = .73$), Humor, items 18 and 28 ($\alpha = .73$), Acceptance, items 20 and 24 ($\alpha = .57$), Religion, items 22 and 27 ($\alpha = .82$), Self-blame, items 13 and 26 ($\alpha = .69$)
The Brief COPE provides researchers a way to assess potentially important coping responses. The Brief COPE has also been translated into French and Spanish.

There is no such thing as an "overall" score on this measure, and the author recommends no particular way of generating a dominant coping style for a given person. The author generally recommends looking at each scale separately to see what its relation is to other variables. An alternative is to create second-order factors from among the scales and using the factors as predictors. The scale’s developer does not advise a particular method for second-order factoring and suggests that researchers develop their own models for second-order factors based on data from individual research samples.

**Scales are computed as follows (with no reversals of coding):**

1. Self-distraction, items 1 and 19
2. Active coping, items 2 and 7
3. Denial, items 3 and 8
4. Substance use, items 4 and 11
5. Use of emotional support, items 5 and 15
6. Use of instrumental support, items 10 and 23
7. Behavioral disengagement, items 6 and 16
8. Venting, items 9 and 21
9. Positive reframing, items 12 and 17
10. Planning, items 14 and 25
11. Humor, items 18 and 28
12. Acceptance, items 20 and 24
13. Religion, items 22 and 27
14. Self-blame, items 13 and 26

**7. Social Support Network Inventory**

Developed by Flaherty et al. (1983), is a 11-item scale and considers 5 network members or 4 network members and a group, in addition to queries in support
satisfaction, direction related to specific life events. Besides other components of social support like availability, reciprocity, practical support, emotional support and event related support are taken into account. No cut offs considered. Social support network inventory is categorized into frequency of contacts with person and group. Scoring: 1 = availability once in a year or less, 2=2 to 4 times in a year, 3 = once in a month, 4= once in a week, 5= usually daily; instrumental support related questions with maximum 10 scores; emotional support related questions with maximum 10 scores; positive appraisal related questions with maximum 10 scores; crisis related questions with maximum 10 scores. The total score =50.

8. **BDI-II (Beck Depression Inventory)**

The BDI-II was a 1996 revision of the BDI by Beck et al (1996), developed in response to the American Psychiatric Association publication of the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, which changed many of the diagnostic criteria for Major Depressive Disorder.

Items involving changes in body image, hypochondria, and difficulty working were replaced. Also, sleep loss and appetite loss items were revised to assess both increases and decreases in sleep and appetite. All but three of the items were reworded; only the items dealing with feelings of being punished, thoughts about suicide, and interest in sex remained the same. Finally, participants were asked to rate how they have been feeling for the past two weeks, as opposed to the past week as in the original BDI.

Like the BDI, the BDI-II also contains 21 questions, each answer being scored on a scale value of 0 to 3. The cutoffs used differ from the original: 0–13: minimal depression; 14–19: mild depression; 20–28: moderate depression; and 29–63: severe depression. Higher total scores indicate more severe depressive symptoms.

The BDI-II has been validated with college students (Beck et al., 1996; Dozois, Dobson & Ahnberg, 1998; Osman et al 1997), adult psychiatric outpatients (Beck et al 1996; Steer, Ball, Ranieri, & Beck, 1999), and adolescent psychiatric outpatients
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(Steer, Geetha, Ranieri, & Beck, 1998). Although the BDI-II demonstrated excellent test-retest reliability, high internal consistency, and moderate to high convergent validity, the factor structure varied across studies.

9. **Family Maslach Burnout Inventory (M.B.I.)**

The MBI is a self-administered survey that was developed to measure burnout in occupations providing human services by Maslach (1986). The MBI General Survey version is a 16-item, seven-point Likert scale (0 to 6) instrument with three subscales: Emotional exhaustion, Depersonalization, feeling of poor attainment. Consists of total 16 items, in which 8 items for “Emotional exhaustion, 4 items of “Depersonalization”, 4 items of “feeling of poor attainment”. The MBI is the most widely used instrument to measure burnout. Emotional exhaustion is the most reported subscale measurement of burnout (Maslach et al 1997). The MBI is scored by computing an average rating of 0 to 6 for each subscale. Average scores greater than three on the emotional exhaustion subscale are indicative of burnout. Reliability for the EE subscale is .65, .60 for cynicism and .67 for professional efficacy (Maslach et al 1997). The MBI has been used extensively in studies in the nursing profession and has been used with nephrology nurses (Argentero et al 2008; Flynn et al 2009; Klersy et al 2007; Lewis et al 1994).

**Measures used in Decision Support System**

1. **CES – D (Center for Epidemiological Studies Depression Scale)**

The CES-D scale is a short self-report scale designed by the Center for Epidemiological Studies to measure depressive symptomatology in the general population. The items of the scale are symptoms associated with depression which have been used in previously validated longer scales. The new scale was tested in household interview surveys and in psychiatric settings. It was found to have very high internal consistency and adequate test-retest repeatability. Validity was established by patterns of correlations with other self-report measures, by correlations with clinical ratings of depression, and by relationships with other variables which support its construct validity. Reliability, validity, and factor structure were similar across a wide variety of demographic characteristics in the general
population samples tested. The scale should be a useful tool for epidemiologic studies of depression. It is a 20-item questionnaire.

**Scoring for All Except Questions 4, 8, 12, and 16:**

- 0 points Rarely or none of the time (< 1 day)
- 1 point Some or a little of the time (1-2 days)
- 2 points Occasionally or a moderate amount of the time (3-4 days)
- 3 points Most or all of the time (5-7 days)

For questions 4, 8, 12, and 16, the scoring is exactly the same except that it is reversed: "Most or all of the time" is scored 0 points, "Rarely or none of the time" is scored 3 points, etc.

- Once you have assigned a value for each item, compute a total, adding the values for each of the 20 items. The resulting score should range between 0 and 60. Do not compute a total if there is more than one answer missing.
- High scores on the CES-D indicate high levels of distress. A score ≥ 16 suggests a clinically significant level of psychological distress. It does not necessarily mean that the participant has a clinical diagnosis of depression. In a general population, about 20% would be expected to score in this range.

2. **Oslo Social Support Scale -3**

The three items in the OSS-3 (Oslo – Social Support Scale by Dalgard et al., 2006a) shown separately include: 'confidants' (no. of people close enough to count on when in problems, scale 1-4); 'concern' (concern shown by other people in what you are doing, scale 1-5); and 'neighbours' (how easy to get practical help from neighbours, scale 1-5). The total score is calculated by summarizing the scores for each item. Cases with lacking information on one or more items are excluded. The scoring is as follows - It is recommended to use the OSS-3 for each separate item as well as for the total score. The total score is calculated by adding up the raw scores for each item.
The sum of the raw scores has a range from 3-14.

- A score ranging between 3 and 8 is classified as poor support,
- A score between 9 and 11 as intermediate support
- A score between 12 and 14 as strong support

3. **The Satisfaction With Life Scale- (SWLS)-**

   SWLS is a measure of life satisfaction developed by Ed Diener and colleagues (Diener, Emmons, Larsen & Griffin, 1985). Life satisfaction is one factor in the more general construct of subjective well being. Theory and research from fields outside of rehabilitation have suggested that subjective well being has at least three components, positive affective appraisal, negative affective appraisal, and life satisfaction. Life satisfaction is distinguished from affective appraisal in that it is more cognitively than emotionally driven. Life satisfaction can be assessed specific to a particular domain of life (e.g., work, family) or globally. The SWLS is a global measure of life satisfaction.

   The SWLS consists of 5-items that are completed by the individual whose life satisfaction is being measured. Administration is brief--rarely more than a few minutes--and can be completed by interview (including phone) or paper and pencil response. The instrument should not be completed by proxy, though a proxy can ask questions to the individual and convey answers to an interviewer. The scoring is as follows:
   7 - Strongly agree; 6 – Agree; 5 - Slightly agree; 4 - Neither agree nor disagree; 3 - Slightly disagree; 2 – Disagree; 1 - Strongly disagree

**Statistical analysis**

   The analysis was conducted in a three-step process. First, data from the surveys were hand entered into the Statistical Packages for the Social Sciences (SPSS) and was computed for all questions, with the exception of those with open-ended responses. Finally, the open-ended responses were thematically coded.
Descriptive statistics
For various categorical variables in SPSS (version 11.5)

Cross-tabulations, chi-square tests and correlations in SPSS

Cross-tabulation is the procedure with which a Table of two (or more) categorical variables is produced, in order to compare the incidence of one characteristic against another. Using the above cross-tabulation, you have all the necessary information in order to perform a chi-square SPSS allows you to obtain directly the chi-square statistic, together with the associated significance level.

Tests of statistical significance were conducted in order to determine whether responses varied by various demographic categories. This type of analysis allows one to explore the unique needs of informal caregivers. Investigator used the analysis to determine if there were differences in caregiving with respect to whom the caregiving was provided.

A standard Chi-square test was used in the analysis. Tests of statistical significance indicate whether the distribution of responses is statistically different to the different categories and subcategories. Indicators that revealed a statistically significant difference in responses are noted in the section beginning on, entitled “Tests of Significance.”

The Spearman Rank Correlation Coefficient is a form of the Pearson coefficient with the data converted to rankings (i.e. when variables are ordinal). It can be used when there is non-parametric data and hence Pearson cannot be used.

The raw scores are converted to ranks and the differences between the ranks of each observation on the two variables are calculated. The Spearman coefficient is denoted with the Greek letter rho (ρ).

All the patient related variables and caregiver-related variables are correlated with distress, depression, burden, strain and burnout experienced by the caregivers.
Section II

Development of decision support system

Computer software, or just software, is the collection of computer programs and related data that provide the instructions telling a computer what to do. Decision support systems (DSS) are interactive computer programs, which are designed to assist physicians/health care managers and other health professionals with decision making tasks. There are two main types of DSS (dictionary.reference.com)

- Knowledge-Based
- Non Knowledge-Based

Features of a Knowledge-Based DSS

Most CDSS consist of three parts, the knowledge base, inference mechanism, and mechanism to communicate. The knowledge base contains the rules and associations of compiled data which most often take the form of IF-THEN rules. The inference engine combines the rules from the knowledge base with the patient’s data. The communication mechanism will allow the system to show the results to the user as well as have input into the system.

Fig 9: Basic components of a Knowledge-Based DSS
Features of a non-Knowledge-Based DSS

DSS that do not use a knowledge base use a form of artificial intelligence called machine learning, which allow computers to learn from past experiences and/or find patterns in clinical data. Two types of non-knowledge-based systems are artificial neural networks and genetic algorithms.

The software currently developed is knowledge based decision support system. This software is named as “SNEHA”, which consists of 2 main components:

Front – end created on Visual Basic 6.0 version
Back – end created on Microsoft Access

The front end of the software act as an user-interface through which user can do various activities like data entry, editing, viewing, searching, querying, reports, statistic generation etc..

Back end is linked with front end and acts as Database Management system and ensures safe storage of all information.

Study design

Fig 10: Flow chart showing the study design
Steps involved
Step 1: caregivers encounter with health care providers with the person with dementia.
Step 2: Caregiver’s consent, baseline assessment by interviewing caregiver for patient distressing behaviors, strain, depression experienced by them, coping skills and quality of life questions. Data is entered to the developed Software (SNEHA).
Step 3: Case summary with the actual value, mean and median values for strain, depression and coping skills is obtained.
Step 4: Case management/intervention by care professionals/managers.
Step 5: Follow up (after time gap), assessment of previous report to be compared (mean, median & SD) with the current status.
Step 6: depending on the current status, future management plans to be decided.

Various phases in development of software “SNEHA”

As the initial part socio demographic characteristic of the care recipient, informal caregivers was analyzed and was correlated with psychosocial variables of the caregivers

Creating a decision support system (SNEHA) with reference to the results obtained was created with the help of the health care managers and experts in the field & inference mechanism was developed with the help of software engineers.

The development of “SNEHA” has gone through various phases. All the components developed through these phases underwent regular systematic validation and efficiency check in giving the values. Adequate trial run and modifications based on expert opinion was carried out before finalization of each component in package.
Phase 1: Designing and selection of components
Phase 2: Designing and development of main user-interface structure
Phase 3: Designing and development of query module
Phase 4: Designing and development of follow-up module
Phase 5: Designing and development of various utilities
a) Display selected fields
b) Search options
c) Report generation
d) Statistics generation
e) Summary

Validation of SNEHA
Validation was done with a case report. The statistical analysis was done manually in SPSS and was compared with the values displayed in the software.

Questionnaires used
Keeping in mind the end users of the software, and for making it simple and user friendly the following questionnaires available on the public domain were used for “SNEHA”
1. NPI – Q
2. Caregiver Strain Index
3. CES – D (Center for Epidemiological Studies Depression Scale)
4. Brief COPE
5. OSS -3
6. Satisfaction With Life Scale

Apart from these measurable scales, to assess the caregiver perception about burden experienced by them and probable solution 2 questions with options was developed. It is as follows:
1. What do think is the major cause of your burden?
   a. Sleep distress/ health problem
   b. Symptoms exhibited by the patient
   c. Social isolation/stigma
   d. Fear of losing your loved ones
   e. Transformation of your loved ones due to disease process
   f. Family problem
   g. Financial problem
Chapter - III

2. In your opinion what is the most probable solution to bring down your burden?
   a. Improvement in Social networks
   b. Personal Counseling
   c. Family counseling
   d. Respite care
   e. Friend for venting
   f. Education about the disease & its prognosis

**Operational definitions**

**Informal caregivers**

An informal caregiver provides needed care on a long term basis to a care recipient, who is most often a relative, friend, or neighbor and includes those individuals who provide extraordinary, uncompensated care, predominantly in the home setting, involving significant amounts of time and energy for months or years, requiring the performance of tasks that may be physically, emotionally, socially, or financially demanding. Care often involves assisting the care receiver with personal hygiene, getting dressed, using the bathroom, or household tasks such as preparing meals.

The most common type of informal caregiving relationship is an adult child caring for an elderly parent or spouses caring for elderly husbands or wives

**Dementia**

Dementia is a progressive degenerative neurological condition in which there is a gradual loss of brain function; it is decline in cognitive/intellectual functioning. The main symptoms are usually loss of memory, confusion, problems with speech and understanding, changes in personality and behavior and an increased reliance on others for the activities of daily living. It is not a disease in itself but rather a group of symptoms which may result from age, brain injury, disease, vitamin or hormone imbalance, or drugs or alcohol. A person with dementia may also exhibit changes in mood, personality or behavior. The loss of mental functions must be severe enough to interfere with daily living. Confusion and disorientation may be present.
Strain

The terms care givers strain, stress, distress or burdens are used interchangeably. Caregiver stress is the emotional and physical strain of caregiving. It can take many forms. Stress associated with expected roles or positions, experienced as frustration. Role ambiguity is a type of role strain that occurs when shared specifications set for an expected role are incomplete or insufficient to tell the involved individual what is desired and how to do it. Role incongruence is role stress that occurs when an individual undergoes role transitions requiring a significant modification in attitudes and values.

Burden

Caregiver burden refers to a high level of stress that may be experienced by people who are caring for another person (usually a family member) with some kind of illness. For example, a person caring for someone with a chronic illness may experience such stressors as financial strain, managing the person's symptoms, dealing with crises, the loss of friends, or the loss of intimacy. This is also known as Caregiver strain, caregiver stress. Caregiver Burden is defined here as “the state resulting from necessary caring tasks or restrictions that cause discomfort for the caregiver”. (Zarit, Reever, Bach-Peterson, 1980).

Burnout

Burnout is a psychological term, a state of emotional, mental, and physical exhaustion caused by excessive and prolonged stress. It occurs when you feel overwhelmed and unable to meet constant demands. As the stress continues, you begin to lose the interest or motivation that led you to take on a certain role in the first place.
Depression

Depression—a psychiatric disorder characterized by an inability to concentrate, insomnia, loss of appetite, anhedonia, feelings of extreme sadness, guilt, helplessness and hopelessness, and thoughts of death. Mental depression is characterized by persistent low mood or sadness. There is also loss of interest in all usually all pleasurable activities such as food, sex, work, friends, hobbies, or entertainment. Without treatment, symptoms can last for weeks, months, or years. Appropriate treatment, however, can help most people who suffer from depression.

Coping

Coping refers to the thoughts and actions we use to deal with stress. In short, coping has been described as attempts to meet environmental demands to prevent negative consequences.

Social support

Social support is a concept that is generally understood in an intuitive sense, as the help from other people in a difficult life situation. A network of family, friends, neighbors, and community members that is available in times of need to give psychological, physical, and financial help. These functions include instrumental aid, socio-emotional aid and informational aid.

Decision support system

A health information system (HIS) is a system for collecting, processing, analyzing, disseminating and using information about a health service and the health needs of the population it serves.

The HIS aims to enable managers and service providers to make more informed decisions for improving the quality of care.
Ethical considerations

*Informed Consent*: The caregivers were informed verbally about the purpose of the study and consent was taken (Appendix V). The ethical committee of the university has waived the ethical clearance as this study did not involve the interaction with the patient and proxy information was collected from the caregivers regarding the socio demographic details and symptoms shown by the persons with dementia. The data will be treated confidentially.