

**COLLABORATIVE STUDY
DHARMA FOUNDATION OF INDIA, PROCATOR KB
(SWEDEN) AND MÄNNISKANS RESURSER AB(SWEDEN)**



Study done under supervision of Dr. Alakananda Banerjee in collaboration with Swedish Scientist Dr. Boris Aranovich, the inventor and owner of the Smart Breathe and the concept of Effective Breathing.

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Title of study:

Effects of smart breathe in community dwelling elderly.

**1 Background:****1.1 Population Aging in India**

India is in a phase of demographic transition. As per the 1991 census, the population of the elderly in India was 57 million as compared with 20 million in 1951. There has been a sharp increase in the number of elderly persons between 1991 and 2001 and it has been projected that by the year 2050, the number of elderly people would rise to about 324 million⁽¹⁾ India has thus acquired the label of “an ageing nation” with 7.7% of its population being more than 60 years old. The demographic transition is attributed to the decreasing fertility and mortality rates due to the availability of better health care services. It has been observed that the reduction in mortality is higher as compared with fertility. There has been a sharp decline in the crude death rate from 28.5 during 1951–1961 to 8.4 in 1996; while the crude birth rate for the same time period fell from 47.3 to 22.8 in 1996⁽²⁾ Over the past decades, India's health program and policies have been focusing on issues like population stabilization, maternal and child health, and disease control. However, current statistics for the elderly in India gives a prelude to a new set of medical, social, and economic problems that could arise if a timely initiative in this direction is not taken by the program managers and policy makers. There is a need to highlight the medical and socio-economic problems that are being faced by the elderly people in India, and strategies for bringing about an improvement in their quality of life also need to be explored.

1.2 Health of elderly in India

In India, the elderly people suffer from dual medical problems, i.e., both communicable as well as non-communicable diseases. This is further compounded by impairment of special sensory functions like vision and hearing. A decline in immunity as well as age-related physiologic changes leads to an increased burden of communicable diseases in the elderly. The prevalence of tuberculosis is higher among the elderly than younger individuals. A study of 100 elderly people in Himachal Pradesh found that most of the patients came from a rural background. They were also smokers and alcoholics⁽³⁾ It is shown that among the population over 60 years of age, 10% suffer from impaired physical mobility and 10% are hospitalized at any given time, both proportions rising with increasing age. In the population over 70 years of age, more than 50% suffer from one or more chronic conditions⁽⁴⁾ The chronic illnesses usually include hypertension, coronary heart disease, and cancer. According to Government of India statistics, cardiovascular disorders account for one-third of elderly mortality. Respiratory disorders account for 10% mortality while infections including tuberculosis account for another 10%. Neoplasm accounts for 6% and accidents, poisoning, and violence constitute less than 4% of elderly mortality with more or less similar rates for nutritional, metabolic, gastrointestinal, and genito-urinary infections⁽⁵⁾ An Indian Council of Medical Research (ICMR) report on the chronic morbidity profile in the elderly states that hearing impairment is the most common morbidity followed by visual impairment⁽⁶⁾ However, different studies show varied results in the morbidity pattern. A study conducted in the rural area of Pondicherry reported decreased visual acuity due to cataract and refractive errors in 57% of the elderly followed by pain in the joints and joint stiffness in 43.4%, dental and chewing complaints in 42%, and hearing impairment in 15.4%. Other morbidities were hypertension (14%), diarrhea (12%), chronic cough (12%), skin diseases (12%), heart disease (9%), diabetes (8.1%), asthma (6%), and urinary complaints (5.6%).⁽⁷⁾ A similar study that had been conducted among 200 elderly people in rural and urban areas of Chandigarh in Haryana observed that as many as 87.5% had minimal to severe disabilities. The most prevalent morbidity was anemia, followed by dental problems, hypertension, chronic obstructive airway disease (COAD), cataract, and osteoarthritis⁽⁸⁾ A study on ocular morbidities among the elderly population in the district of Wardha found that refractive errors accounted for the highest number (40.8%) of ocular morbidities, closely followed by cataract (40.4%) while other morbidities included aphasia (11.1%), pterygium (5.2%), and glaucoma (3.1%).⁽¹⁰⁾ In a community based study conducted in Delhi among 10,000 elderly people, it was found that problems related to vision and hearing topped the list, closely followed by backache and arthritis⁽⁹⁾ Elderly people who belong to middle and higher income groups are prone to develop obesity and its related complications due to a sedentary lifestyle and decreased physical activity⁽¹¹⁾ In a study conducted among 206 elderly persons attending the Geriatric Clinic at a tertiary care hospital in Delhi, about 34% of the men and 40.3% of the women were obese respectively⁽¹²⁾ Elderly people are highly prone to mental morbidities due to ageing of the brain, problems associated with physical health, cerebral pathology, socio-economic factors such as breakdown of the family support systems, and decrease in economic independence. The mental disorders that are frequently encountered include dementia and mood disorders. Other disorders include neurotic and personality disorders, drug and alcohol abuse, delirium, and mental psychosis.⁽¹³⁾

The rapid urbanization and societal modernization has brought in its wake a breakdown in family values and the framework of family support, economic insecurity, social isolation, and elderly abuse leading to a host of psychological illnesses. In addition, widows are prone to face social stigma and ostracism⁽¹⁴⁾ The socio-economic problems of the elderly are aggravated by factors such as the lack of social security and inadequate facilities for health care, rehabilitation, and recreation.

1.3 Normal breathing function and respiratory diseases in elderly.

Breathing is a major function of the body which has an impact on our state of health and physical potential. The respiratory system includes the lungs as the organ responsible for gaseous exchange and ventilation as well as the blood circulation system which transports oxygen from the lungs to the cells and carbon dioxide from the cells to the lungs. There is external respiration and cellular respiration when the cells use oxygen for chemical reactions. It is known that hypoxia or deficiency of oxygen in the cells is the main cause of many diseases and aging of the body. Respiratory disease is a medical term that encompasses pathological conditions affecting the organs and tissues that makes gas exchange possible. As older people are more susceptible to chronic diseases, Age related associated diseases (comorbidity), decline/loss of social support, atypical clinical presentations and special diagnostic problems make the elderly patient with respiratory disease, a complex client for a physician. ⁽¹⁵⁾

1.4 Smart Breathe

Respiratory exercises boosting the oxygenation of cells is one of the most effective ways to normalize health parameters, enhance abilities, stabilize your psyche and fight off stress. Resistance breathing has long been known to medicine. This method is used in the Smart Breathe simulator. The principal benefits of Smart Breathe are its use of ease, convenience and efficiency Smart Breathe have passed all the necessary medical tests and therefor have achieved EU medical certificate class 1. Smart Breathe is designed and manufactured under the control of Quality Management System, which is certified to comply with harmonized standard EN ISO 13485:2012 + AC2009, Medical devices – Quality Management Systems – Requirements for regulatory purposes.

2 Need and relevance of the study:

Increasing longevity has resulted in rising medical costs and increasing demands for health services. Promoting awareness of the special features of respiratory diseases in the elderly and implementing interventions early have a favorable clinical and economic impact, Elders do not use energy from breathing as effective as when one is young. Elderly people have to breathe deeper to get enough energy but that also means they lose a lot of carbon dioxide, which regulates the oxygen uptake. Energy from our respiration system degenerate a lot with older age, women get less energy from this system than men.. Smart Breathe is used for treatment, rehabilitation and prevention of various diseases in adults and children. It can be used as a training simulator for the respiratory muscles to form the proper respiratory stereotype, enhance physical endurance, increase adaptation potential of the body and improve resistance to adverse environmental, weather and industrial factors as well as psycho-emotional distress. This study would focus on improving their breathing pattern and quality of life of elders by using Smart Breathe.

3. Objectives:

3.1 Primary objective: Effect of Smart Breathe

3.2 Secondary objective: Promote active ageing in community dwelling elderly.

4. Methods:

4.1 Study design: Randomized experimental design.

4.2 Sample size: 35 elderly male/females (members of Varishtha Nagrik Kendra Sansthan) above 60yrs of age

4.3 Area of Study: Office of Varishtha Nagrik Kendra Sansthan , Chattarpur Extension, New Delhi

4.4 Study duration: Three months (September 2013 – November 2013)

4.5 Outcome measures:

- Alfa
- Control pause
- Geriatric ICF Core Set
- Short Form-36
- Blood pressure
- Incentive spirometry

4.7 Selection and enrollment of participants

Inclusion criteria:

- a) >60 yrs of age
- b) Male or female
- c) Cognitive level; MMSE>23
- d) Resident of Chattarpur extension.

Exclusion criteria:

- a) Cardiac arrhythmias
- b) Metal implants on the arm
- c) Cardiac pacemakers
- d) Unable to participate in group exercises.

4.8 Outcome Measures

- i. SF36: The SF-36 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale on the assumption that each question carries equal weight. The lower the score the more disability. The higher the score the less disability i.e. a score of zero is equivalent to maximum disability and a score of 100 is equivalent to no disability. (Fig 1)

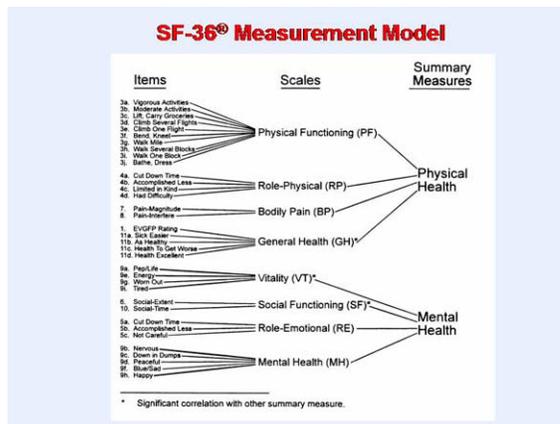


Fig 1

- ii. ALFA: It is a device which is used with great success in fitness, health, sports. It allows the therapist/ trainer to check the data for the client’s functional state anticipate changes and evaluate the body’s resources to evaluate their treatment and effectiveness of their training. (Fig 2)



Fig 2

- iii. THE INTERNATIONAL CLASSIFICATION OF FUNCTIONING, DISABILITY AND HEALTH (ICF):

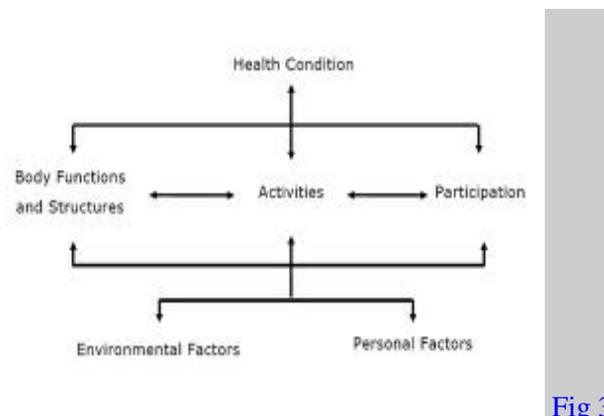


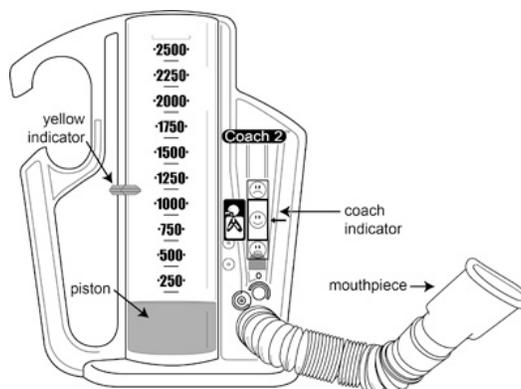
Fig 3

The International Classification of Functioning, Disability and Health (ICF) is a multipurpose classification which belongs to the WHO family of international classifications. The ICF provides a comprehensive framework for quantifying and depicting functioning, health and health-related domains, and was designed to facilitate communication between different users, including researchers, healthcare workers, policymakers and the public. The classification is organized in a hierarchical structure comprising of two main parts, each with separate components. The first part consists functioning and disability with 3 components: Body Functions (coded b) and Body Structures (s), and Activities and Participation (d). The second part of ICF encompasses contextual factors, and has two components: Environmental Factors (e) and Personal Factors (not coded).⁽¹⁶⁾ (Fig 3)

GERIATRIC ICF CORE SET: Since we were interested in the modifiable physical condition as potential determinant of self-efficacy, categories of the ICF components Body Functions, Activity and participation and environment of the Geriatric ICF Core Set were used for assessment. The Geriatric ICF Core Set is a selection of categories out of the entire classification that can serve as the minimal standard of the assessment and reporting of functioning and health. All in all we applied 9 categories of the component Body Functions. We used the first qualifiers, which describe the extent of a problem in functioning – more precisely, it denotes the range from full functioning “0” (no problem) to complete disability “4” (complete problem). If a category was not specified it was coded with “8” and if a category was inapplicable then it was coded with “9”. Because the properties of all qualifiers are not sufficiently evaluated, we used, similar to Grill et al, a simplified qualifier: each category of the components Body Functions and was graded with the qualifiers “0” for “no impairment/restriction” and “1” for impairment/restriction”. The response option “9” was set to “0”, because an inapplicable ICF category cannot be a problem and the qualifier “8” was set to missing. We used 3 categories from the component activity and participation and 3 categories from the component environment. (table given below of item code and description)

Item code	Description
b1300	Energy level
b1301	motivation
b1302	appetite
b440	respiration functions
b445	respiratory muscle functions
b450	additional respiratory functions
b455	exercise tolerance functions
b460	sensations associated with cardiovascular and respiratory functions
b530	weight maintenance function
d455	Moving around
d460	Moving around in different locations
d910	Community life
e115	Products and technology for personal use in daily living
e225	Climate
e260	Air quality

- iv. **CONTROL PAUSE (CP):** The Control Pause CP is “the time that one can hold breath until one feels the first impulse to breathe in again”. On resumption of breathing one must be able to assume the pattern of breathing one had just before starting to hold breath. A stopwatch is needed to count the seconds.
- v. **INCENTIVE SPIROMETER:** An incentive spirometer is a medical device used to help patients improve the functioning of their lungs (Fig 4)



4.9 Study Procedure:

- i. **Training:**

Six physical therapist was trained (12 hours) by personals from Procator on usage of Smart Breathe and ALFA. Therapist underwent training for 24 hours on all outcome measures. (Mentioned above)



- ii. **Recruitment of subjects:**

Thirty seven elders were recruited according to the inclusion criteria. They were members of the organisation VNKS living in the neighbourhood colony of Chattarpur Extension.



They provided written informed consent for the study. Institutional review board approval was obtained at Max Super Speciality Hospital. The patron of VNKS was asked to select three team leaders amongst elderly members who volunteered to lead small groups of elderly of 10 subjects. A four hour training program was conducted by personals Proctor KB for three team leaders TL 1, TL 2, TL 3. They were taught on basics of Smart Breathe and study protocol. A Smart breathe device was given to each subject. Demographic profile of subjects was documented on the ICF Checklist Version 1A. Outcome measures of each subject were documented using the following measurement tools. ALFA, sphygmomanometer to measure blood pressure, control pause was checked using a stopwatch, inspiratory and expiratory capacity was checked using incentive spirometer Information of subjects on selected Items from ICF Geriatric Core Set, Functional Independence Measure, Mini Mental State Examination and Short Form-36 questionnaires were filled. Pulse rate was monitored manually

iii. Adverse events and safety:

Subjects were asked to report if there was transient side effects of Smart Breathe which persisted for more than 3-4 days

- a. Head ache/ Heaviness
- b. Excess salivation while using the device
- c. Rashes/ Diarrhea/Pain in the mouth

Intervention would be discontinued in case of

- a. Coughing,
- b. Provoked shortness of breath,
- c. Onset of angina pectoris
- d. Decreased blood pressure,
- e. Nausea,
- f. Confusion,
- g. Light-headedness,

h. Unprovoked exaltation, tiredness.

iv. Drop outs:

Out of 37 subjects (Male 69 %), 5 dropped out of the study due to following problems.

- a) Smart breathe usage caused headache
- b) Out of station due to personal problem
- c) Chest pain after using smart breathe(subject had undergone CABG procedure)
- d) Spouse not keeping well and hospitalized
- e) Not keeping well.

v. Demographic profile and study protocol.

Mean age of elders in the study was 66.84 ± 9 . Out of 32 Subjects 87% were married, 6 % were self employed , 31 % housewives 63 % subjects were retired .Data of prevalence of disease showed 41 % with hypertension, 21 % having asthma and 38 % having diabetes .16 % subjects were hospitalised in the past one year. The medication taken by subjects for different diseases were , 42 % for hypertension, 31 % diabetes ,12 % for pain and 15 % for asthma.9% subject were reported taking alcohol and smoking cigarettes.87 % were using spectacles and 6 % were using hearing aids.At the start of study breathing exercises was done using Smart Breathe device for duration of 15 minute from day two to end week two. Control pause and blood pressure was measured at the end week two. The duration of use of smart breathe was increased from 15 to 30 minutes each day from end of week two to end of week four. Exercises of two sessions of 15 minutes each was done under supervision of therapist. Pulse rate, blood pressure, control pause, spirometry and ALFA were measured at end of week four. The duration of use of device was progressed to 60 min each day with 3 sessions of 20 minutes each, under supervision of therapist, from end week four to end week six , After end week six, heart rate, blood pressure and control pause were again measured. The duration of breathing with Smart breathe progressed to 90 minutes. From end week six to end week eight , subjects used Smart breathe with 4 sessions of 20 min each, out of which 3 sessions were under supervision of therapist , and 1 session was done by the subject at home. At the end week eight, all the assessment that was done on day 1 was repeated. The subjects were briefly explained the changes and improvement in outcomes after week eight.

5 Results and discussion:

5.1Pre study outcomes of pulse rate (fig 5) and blood pressure (fig 6) showed no significant changes at the end of week eight.

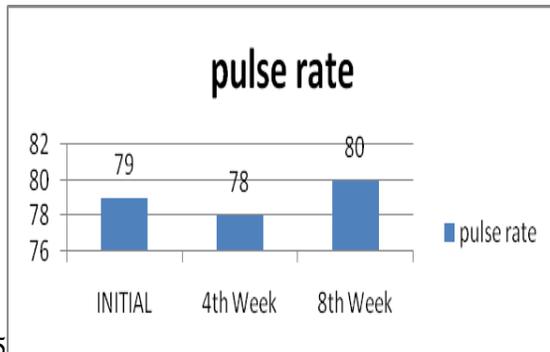


Fig5

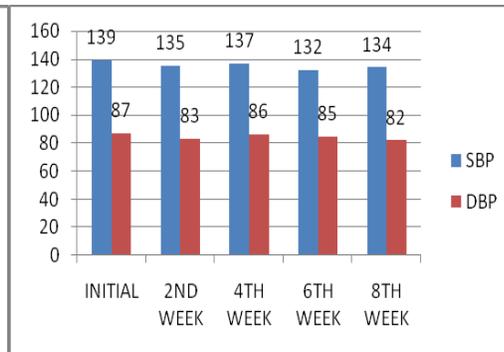


Fig 6

5.2 Control Pause:

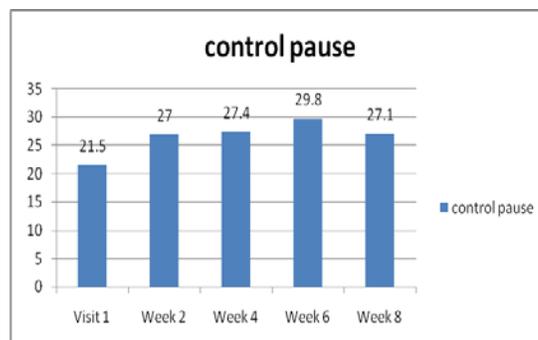


Fig 7

Parameters on control pause showed significant improvement in end week two and improvement was sustained till end week six. The dip in the improvement after week 6 till end week 8 (fig 7) may be due to irregularity in the subjects attending the group exercise sessions. The absence of most subjects was due to Diwali celebrations in week 7 and week 8 of the study.

5.3 Incentive Spirometer:

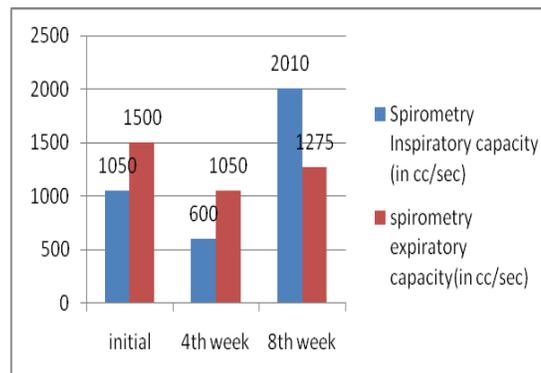


Fig 8

Subjects showed improvement in inspiratory capacity by end week eight. No improvement was noticed in expiratory capacity (Fig 8)

Smart Breathe improves respiratory functions which in turn affects physical, emotional and mental health in subjects. The study showed that group breathing exercises with Smart Breathe motivated elders to participate in community. Involvement of three team leaders to take responsibility of small groups of elders improved communication and comradeship. Sharing of changes in respiratory functions was reported to subjects who participated regularly in group exercises.

5.4 Short Form-36

Improvement in community participation improved quality of life, as the study showed the following changes in 4 domains of Short Form -36.

5 % improved in domain role limitation due to physical health, 14% improved in domain energy/fatigue, 23 % improvement in the domain of emotional well being and 15 % improved in domain of general health. (Fig 9)

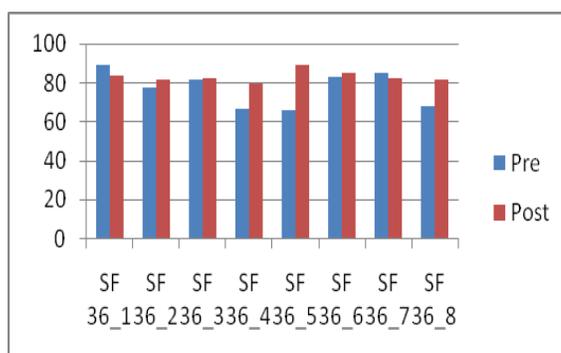


Fig 9

5.5 International Classification of Functioning:

Use of technology as environmental interventions affects participation. The *International Classification of Function and Disability* (ICF) has proposed a paradigm that considers the environment and technology in the determination of functional impairment.. A person's functioning and impairment is conceived as a dynamic interaction between impairments and environment. This new paradigm conceived by ICF has great potential for demonstrating the role of Smart Breathe in affecting impairment and, ultimately, an elder's participation.

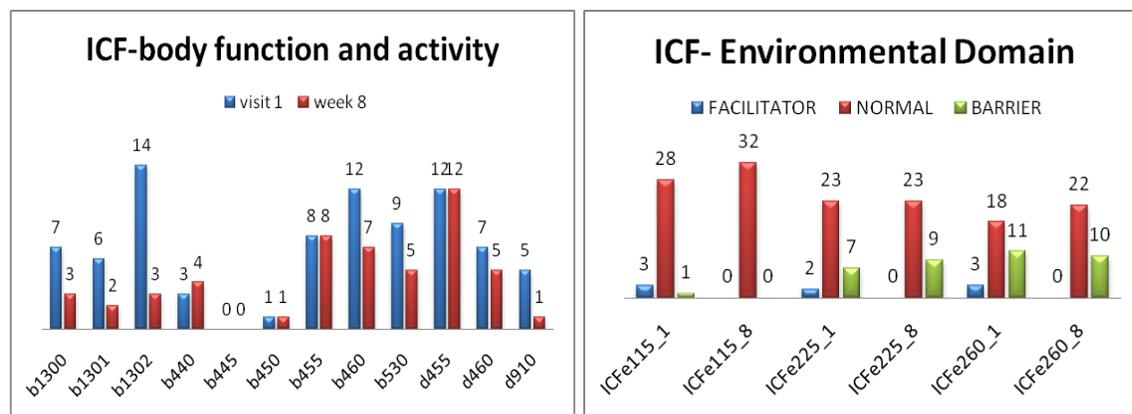


Fig 10

Improvement in functional capacity was observed in the following, 13 % showed improvement b1300 (energy level), 12 % improved in b1301 (motivation), 34% had improvement in b1302 appetite.13 % showed improvement in weight maintenance function b530 and improvement in b460 (sensation associated with cardiovascular and respiratory system) was 16%.

In the domain activity and participation 6% improvement were seen in moving around in different location (d 460), and 13% improved in community life (d 910)

In the domain of environment e 115(product and technology) none of the subjects had any problem with Smart Breathe. The study which started in September weather in Delhi hovered around 34 degrees centigrade. The end of study in November changed into early winter months making it difficult for few subjects to participate in group exercises. This was captured in e225 where 6 % elders reported changed weather to be a barrier on their functioning. (Fig10)

5.6 Alfa

The Alfa measurement showed how the body's regulating mechanisms reacted during research (training) period and foremost the reactions from the vegetative nervous system.

Smart Breathe exercises during this period showed that 60% of the subjects increased the parasympathetic level which indicates a more balanced nervous system which in its turn led to better sleep, better mood and less stress. Alongside positive physiological improvements the report shows that the usage of energy in the cells increased at 81% of the subjects. This shows that the changes in the body need extra energy. Continuing with the exercise will lead to normalization of the energy level.

5.7. Feedback from elders on use of Smart breathes:

- Improved appetite
- Improved sleep
- Feeling of well being and being energetic throughout the day
- Improvement in eyesight vision.

5.8. Participation in group exercise session

- Average no. of participants in first four weeks -25
- Average no. of participants in last 4 weeks -18

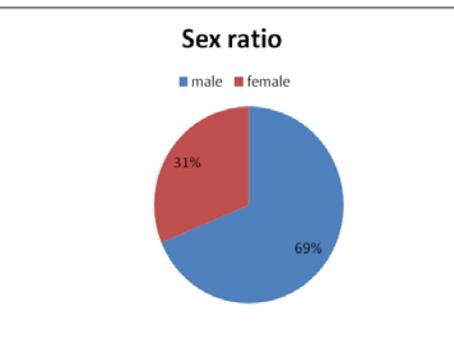
5.9. Reasons for not attending the group exercise session

- a) Health issue either self or spouse
- b) Out of town
- c) Festival season in last 4 weeks
- d) To take care of grand children at home

5.10 Participation of leaders

Out of 3 team leaders team TL 1 was very consistent in the complete study weeks of group exercise session. TL 3 underwent surgery for prostate tumor. TL 3 could not participate regularly as he had construction work at home and wedding of his daughter.

5.9 Participation of female subjects:



31% females participated in the study. The team leaders were instrumental in motivating their spouses to participate in study, who in turn talked to other females to take part. Females were more regular in attending group exercise sessions compared to males. This was in complete contrast, as traditional culture of India do not motivate female to participate socially with their male counterparts. This study revealed that meetings to improve health may motivate female to improve their presence in the community programs.

6 Conclusions:

Smart Breathe is a breathing simulator can help elders to have healthy life. Using the Smart Breathe helped elders to improve appetite, sleep, motivation and mental well being.

The Smart Breathe was easy to use and the exercises on the device could be done while watching TV or working on computers. Group exercise sessions with Smart Breathe helped elders to follow a strict schedule in the day so that they could reach the study venue to meet each other. The study showed improved mobility of subjects around their house and community life. This pilot study show that technology which help group participation play an important role in Active Ageing, There are senior citizen organizations in India who organize group activities like yoga classes/discussions on

literature/indoor plays. These activities bring about a sense of comradeship. Fostering team leaders within these organizations may motivate elders to have a purposeful life.



7 Future Studies:

We need to study the significance of active ageing from an individual as well as from a societal perspective. Taking an individual perspective, maintaining activity in later years is linked to successful ageing because of empirical relationships to positive self-perception, satisfaction with life, and development of competences, whereas from a societal perspective, active ageing may initiate usage of older people's life competences as a human capital of society⁽¹⁷⁾ Technology like Smart Breathe, virtual training programs, communication and education technology etc may help elders in India to develop physical and emotional wellbeing. Innovative technology which involve elder participation can be a future studies to promote Active Ageing in India.

7 Acknowledgements

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