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To study disease activity and various counseling techniques in Rheumatoid Arthritis patients

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TO STUDY DISEASE ACTIVITY AND VARIOUS COUNSELLING TECHNIQUES IN RHEUMATOID ARTHRITIS PATIENTS

A Project Report Submitted to

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Declaration

We hereby declare that the project entitled, **"TO STUDY DISEASE ACTIVITY AND VARIOUS COUNSELLING TECHNIQUES IN RHEUMATOID ARTHRITIS PATIENTS"** was carried out under the guidance of **Dr. Kanav Khera,** Assistant professor-senior, Department of Pharmacy Practice, Manipal College of Pharmaceutical Sciences, Manipal Academy of Higher Education, Manipal and co-guide **Dr. RaviRaja V Acharya,** Professor and Head, Medicine, ,KMC, Manipal Academy of Higher Education.

The extent and source of information derived from the existing literature have been indicated throughout the project work at appropriate places. The work is original and has not been submitted in part or full for any diploma or degree purpose for this or any other university.

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Acknowledgement

"In the name of God, the Almighty, the most Generous and Merciful"

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We would also like to thank SMRC for the Stanford HAQ 20-Item Disability Scale used in the study.

LIST OF ABBREVIATIONS

RA	Rheumatoid arthritis
PIL	Patient Information Leaflet
RF	Rheumatoid factor
ESR	Erythrocyte Sedimentation Rate
Anti- CCP	Anticitrullinated protein antibody test
CRP	C Reactive protein
NSAIDs	Non Steroidal Anti-Inflammatory Drugs
EULAR	The European League Against Rheumatism
DMARDs	Disease Modifying Anti Rheumatic Drugs
PRO	Patient reported outcome
HAQ	Health assessment questionnaire
HAQ-DI	Health assessment questionnaire disability index
DAS	Disease activity scale
BALD	Baker Able Leaflet Design
F-GL	Flesch-Kincaid Grade
FRE	Flesch Reading Ease

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ABSTRACT

ABSTRACT

Title: To study Disease Activity and various Counseling techniques in Rheumatoid Arthritis patients.

Background: Education and counseling creates awareness amongst RA patients regarding the nature of their disease, drugs and lifestyle. Often, early diagnosis of RA prevents permanent disability. However, this does not happen in many cases. With the intention of coping with RA related complications and promoting healthy living, this study assessed the importance of counseling interventions with the aid of patient information leaflets and digital media as an adjunct for better patient care.

Objectives: To study three counseling interventions, drug utilization, disease activity and quality of life in Rheumatoid Arthritis patients.

Methods: A prospective study was conducted where 30 patients were enrolled based on the inclusion and exclusion criteria of the study. The patients were randomly grouped into three categories by simple randomization using Quickcals- Graphpad software. After seeking the informed consent and providing participant information sheets, each group was given a different counseling technique with the aid of expert validated leaflets. Pre and post assessment of patient's knowledge regarding their condition was determined by administering the same questionnaire before and after the counseling session. Each session was completed within 10-15 minutes depending upon the co-operation and comprehension exhibited. A health assessment questionnaire was also administered during and after 3 months of hospitalization to assess the functional capacity of the patients.

Results: Various demographic parameters like age, sex, occupation, education, co morbidities, duration of RA, disease activity and physical disability were evaluated. Among n=30 patients, most patients fell under the age group of 51-70 years (46.7%). 3 (10%) were male and 27 (90%) were female. Out of n=30 patients,20(66.7%) patients were housewives and 9 (30%), were illiterate. The duration of RA for most of the patients were between 3-5 years. (26.7%). 2 male patients and 14 female patients tested positive for rheumatoid factor. Mean DAS28 was found to be 5.64 ± 1.65 and 17 (56.7%) patients fell under high disease activity. Mean HAQ was found to be 1.18 ± 0.87 and mean VAS score was 55.67 ± 27.50. MTX was widely prescribed (n=16, 53.3%) as monotherapy or in combination with other DMARDs followed by HCQ(n=15 50%). Among combination therapy MTX+HCQ combination was preferred over other combinations and was given in 7(23.3%) patients followed by HCQ+MTX+SSZ combination in 6(20%) patients. Group C demonstrated a greater improvement in understanding and decrease in pain scores in comparison to other groups post counseling where as Group B showed greater difference in HAQ scores.

Conclusion: The study demonstrated that pharmaceutical care counseling with the aid of leaflets and SMS reminders were well received by the patients resulting in improved understanding regarding their condition as well as improvement in the pain and HAQ scores. Majority of patients fell under high disease activity and MTX was widely prescribed as monotherapy. Among combination therapy MTX+HCQ combination was preferred over other combinations.

INTRODUCTION

1. INTRODUCTION

Definition

Rheumatoid arthritis (RA) is an autoimmune disease persisting for a long time that affects bilateral small joints, progressing to bilateral larger joints, and eventually the skin, eyes, heart, kidneys, and lungs. This damages the bone and cartilage of joints, and weakens the tendons and ligaments causing joint deformities and bone erosion. [1]

Signs and Symptoms

Typical symptoms of RA include morning stiffness lasting more than 30 minutes, tender, swollen joints, fatigue, fever, weight loss, and rheumatoid nodules. [2]

Risk factors

- Age: Most people are diagnosed between the ages of 40 and 60.[3]
- Sex: Women are more prone to RA than men.[3]
- Genetics: The risk of RA is highest when people with human leukocyte antigen class II genotypes genes are exposed to environmental factors like smoking or when a person is overweight.[3]
- Obesity: Overweight individuals have a significantly greater chance of developing RA in comparison to a healthy weight individual.[3]
- Smoking: Cigarette smoking increases the risk of developing RA.[3]

Diagnosis

The progression of RA can be slowed down by diagnosing the disease and initiating the treatment early which aids in preventing joint erosions. History and physical examination of the patient enables to diagnose RA. Clinical findings are the mainstay in selecting the appropriate laboratory test for the confirmation or ruling out of the disease.Abnormal values of laboratory tests like Rheumatoid factor (RF), Erythrocyte sedimentation rate (ESR), C-reactive protein (CRP), Anti-citrullinated protein antibody test (anti-CCP) and Antinuclear antibody test are most typical features of RA. The anatomic changes in RA patients such as joint space narrowing and erosions can be investigated by means of plain radiography, sonography and MRI.[4]

1.4.1 Diagnostic criteria

The criteria recommended by American College of Rheumatology in 2010 for diagnosing RA is as follows:[5]

CRITERIA	SCORE
A. Joints	
1 large joint	0
2-10 large joints	1
1-3 small joints	2
4-10 small joints	3
>10 joints	5
B. Serology	
Negative RF and negative anti-CCP	0
Low positive RF or low positive ACPA	2
High positive RF or high positive ACPA	3
C. Acute phase reactants	
Normal CRP and ESR	0
Abnormal CRP or ESR	1
D. Symptom duration	
<6 weeks	0
>6 weeks	1

Table 1: RA Classification Criteria - ACR/EULAR 2010

Treatment

Both pharmaceutical and non-pharmaceutical therapies aid in symptomatic management of RA and disease modification.[6]

1.5.1 Pharmacologic Therapy

Non Steroidal anti-inflammatory drugs (NSAIDs) aim to alleviate pain and decrease inflammation. Common examples include acetylsalicylate, naproxen, and ibuprofen that are available over-the-counter from pharmacies. If NSAIDS are ineffective, Corticosteroids are generally recommended. They work by reducing pain and inflammation, as well as delaying joint damage. However, serious side effects such as cataracts, osteoporosis, glaucoma, obesity and diabetes mellitus may occur due to prolonged usage of corticosteroids. Tapering the doses gradually may reduce side effects and improve a patient's condition. [1]

Promoting remission is the major goal of RA treatment. This is achieved by Disease-modifying antirheumatic drugs (DMARDs) which work by blocking the body's immune system and therefore delaying the progression of joint damage.Examples include leflunomide, methotrexate, sulfasalazine, and hydroxychloroquine. These medications take several weeks to months to be effective. [1]

A treat-to-target strategy should be used:[7]

- Low disease activity: DMARD monotherapy over double or triple therapy; Methotrexate is the preferred DMARD.
- Moderate or high disease activity: DMARD monotherapy over double or triple therapy.
- Moderate or high disease activity despite DMARD monotherapy: Combination DMARDs or a tumor necrosis factor (TNF) inhibitor or a non-TNF biologic agent is preferred.

1.5.2 Non Pharmacologic therapy

Non pharmacologic treatment is often recommended in addition to the pharmacologic therapies in patients with RA. Education, Guidance and support is vital for majority of patients so as to tackle the outcomes of the disease. Non-drug care includes healthy eating, daily movement, warm and cold treatments, balancing activity with rest, stress reduction, positive attitude and support system. [8,9]

Tools to monitor Disease Progression

Disease Activity Score

Disease activity in RA patients is determined using the DAS-28. It is used as a guide in the suppression of RA disease activity with DMARDs. A blood sample is taken from the patient for the assessment of ESR levels. In addition, tender and swollen joint counts are determined. A general health assessment score is obtained using a visual analog scale. [9]

DAS-28 is then calculated using a programmed calculator or computer. The scores obtained allow the classification of patients into: [10]

- Remission (0 - <2.6),
- Low disease activity (2.6 - 3.2),
- Moderate disease activity (3.2-<5.1)
- High disease activity (>5.1).

Joint score: • Tender joints (0-28) • Swollen joints (0-28)
Measures: • ESR (mm/first hour) • General health (0-100)
Score:

Table 2: The DAS-28 Calculator – Rheumakit

1.6.2 The Stanford Health Assessment Questionnaire (HAQ)

Among the first Patient Reported Outcome (PRO) instrument was HAQ, published in 1980.It is a widely used generic instrument that collects data on five patient centered health criteria's: avoiding disability; relieving pain and discomfort; avoiding treatment adverse effects; keep healthcare costs low and prevent death.[11-12]

The HAQ-Disability index (HAQ-DI) is a 2 page HAQ comprised of 20 questions, divided in 8 categories to assess the functional capacity of the patient such as dressing/grooming, arising, reach, grip, walking, eating, hygiene, and daily activities. The response is divided into 4 levels for each question and is scored from 0 to 3, [11-12]

- 0 = without any difficulty
- 1 = with some difficulty
- 2 = with much difficulty
- 3 = unable to do.

An aids or devices variable for each question is used to record the type of assistance required by the patient which lead to an increase in the score. The aids used include: dressing devices, special chairs, special utensils, canes, walkers, crutches, raised toilet seats, bathtub seats, bathtub bars and long handled appliances in bathroom, long handled appliances for reaching and jar openers for previously opened jars. The mean score calculated ranges from:

- 0 to 1 = mild to moderate difficulty
- 1 to 2 = moderate to severe disability
- 2 to 3 = severe to very severe disability.[11-12]

NEED FOR STUDY

2. NEED FOR STUDY

Rheumatoid Arthritis (RA) affects nearly 1% of the adult population globally.[13]India is a subcontinent with the second largest population worldwide and a socio cultural diversity that includes 20 official languages. Understanding the impact on RA on the population is necessary to come up with techniques for disease management. A study focused on the disease activity and quality of life of the population will increase the knowledge of disease burden RA presents in India.[14]

RA has been shown to have a higher incidence on people with low income and less education. RA has a significant impact in quality of life of patients and when it is left uncontrolled it is shown to decrease the quality of life of the patient and increase complications. Disease activity and the damage it causes to the joints are not enough to judge the impact it has on individuals. Quality of life assessment in RA provides the needed information on drug therapy for a long-term outcome.[15]

2.1 Patient education in RA

Owing to the complex nature of RA not one particular course of treatment has shown to be consistently effective. Patient education is one major area, which can improve the patient's quality of life. The personal need and belief of the patient must be addressed while developing a patient education program. This depends on the history of disease and experience of the patient with the health care professional. Work in the field of adult education has shown that an interactive method of learning approach is more successful and acceptable than an instructive style. This has been observed in chronic kind of diseases and also arthritis.[16]

Patients that received information leaflets from their healthcare professionals have shown more adherences to their medication. PILs can reduce anxiety about their condition and can contribute to a better outcome of illness in better-informed patients.

A recent evaluation of leaflets distributed by Arthritis and Rheumatism Council shows that for people with rheumatoid arthritis who received a PIL, the report states that "there was an increase in knowledge patients had of their condition, there was an associated decrease in pain and there was an associated decrease in depression".[17] The report also reminds us that better educated patients are able to participate more actively in their own treatment.

2.2 SMS Reminders

The fact that mobile phone ownership is high across the world and that people carry their phones with them almost all the time makes the mobile phones feasible tools for frequent data assessments. A high percentage of patients up to age 65 were successfully using SMS despite older age or functional disability caused by rheumatic diseases. From the clinician and researcher's point of view, the SMS method is very feasible. The SMS method may lead to a reduction in data management burden, processing time and costs.[18]

2.3 Challenges

Patients who are affected with RA experience chronic pain and suffering, deformities, disabilities to their fingers and joints. It is important to identify the availability of effective therapies so that inflammation, joint destruction and disability can be prevented.[19]

RA has a major impact in health related quality of life. This increases the health related costs and mortality of the patients when compared to the healthy population. There is an increased economic burden in the country as the patients are unable to work and are dependent on the state for the health and social welfare services. This makes it important to have educational programs to facilitate early diagnosis and proper management of RA. Many studies have shown early treatment can reduce the long-term disability, prevent joint damage and this can help the patients to maintain their functional independence.[19]

AIMS & OBJECTIVES

3. AIMS AND OBJECTIVES:

1. Primary Objective: To study three counseling interventions

GROUP 1	GROUP 2	GROUP 3
CONTROL GROUP Standard care in the hospital as part of standard procedure	Pharmaceutical care counselling (Drugs, Disease, Lifestyle)	Pharmaceutical care counselling (Drugs, Disease, Lifestyle) Digital media Notifications
• Counselling by consultant doctor and the nurse • General drug leaflet	• One to One counselling by clinical pharmacist • Drugs, Disease, Lifestyle Leaflets	• One to One Counselling, SMS reminders by clinical pharmacist • Drugs, Disease, Lifestyle Leaflets • Text message Reminders

Table 3: Various counseling groups

2. Secondary Objective: To study drug utilization and disease activity and quality of life in rheumatoid arthritis patients.

LITERATURE REVIEW

4. REVIEW OF LITERATURE

Patient education plays a major role in completing clinical care. Importance of patient education in clinical care includes facilitating the patients to play a vital role in their disease management and to enhance their coping with the disease, including limited demands for the health care system. The importance of patient education increases with the prevalence of the chronic illness. The better informed the patient the easier it is to limit the predisposing factors and managing the illness. [20]

Patients who are diagnosed with chronic and complex diseases find information regarding their illness and medication very beneficial. Patient self-care is important when it comes to the long-term management of their diseases. Several studies have shown that due to lack of information about the disease, patients were unable to manage their disease. The efficient management of RA comprises of a huge component of self-care, and this demands a level of knowledge that some patients gain with extra information. Various studies have shown widespread lack of education in patients diagnosed with RA, and patients themselves do not think they gain all the information they require. [21]

In case of arthritis, which has to be managed throughout the life, patient education improves behavior and knowledge as well as physical and psychosocial health status. An important part of this education involves teaching the patient necessary skills to manage the disease on a daily scale. This allows the patient to adjust to their medications and have skills to self-adjust to lifestyle to manage the disease. [22]

The aim of patient education programs have shown a wide spectrum of variation due to the complex nature of RA and its management, and because of no course of treatment alone has proven to be effective in a consistent manner. Some of the major areas considered are drugs, physical activity and lifestyle, nutrition, disease process and medical management, communication with doctors and family and stress management. The content of information given to the patient should comply with the belief and needs of the patient whose is receiving the information. [16]

Increase in level of patient knowledge can be achieved through written educational material, which is frequently used in clinical settings to aid verbal information. This gives a sense of reassurance to the patient. [23]

Certain studies show an improvement in knowledge in osteoarthritis patients with the use of leaflets. Barlow J et al found in his study that receiving PILs that have disease related information caused no negative psychological distress to the patients. This gives evidence to how receiving information does more good than harm. The study also found that there are outcomes that are more positive when the PILs are given by hand through a physician or pharmacist than be sent through mail. If the information delivered to the patient is specific to the disease progression, the patient's interest to know about the disease condition will not decline over time.[23]

Research has shown that qualities required for preparing a patient information leaflet (PIL) are that language should be simple and easy to understand, the content of the information should not be too long, information should be genuine and unbiased, information given on the leaflet should be most favorable as per patient requirement. Emphasis must be made on avoiding self-medication, sharing of medicines and the reader should be advised to use medicines only with medical advice. [24]

Design, readability and layout of the leaflet are also important. This is assessed by means of Flesch reading ease score and BALD criteria. The content has to be validated by a team who is an expert in the topic. A good patient information leaflet will have good scores, which will allow the patient to understand the content in the leaflet, which in turn would help them with improving the knowledge and having a positive attitude towards disease management. [24]

Various researches have investigated on the impact of written communication on knowledge and other therapy programs. Clark and Bayley observed in their studies that a "programmed instruction" booklet led to more knowledge than a handout or no written-information control. [25] The importance of leaflets and single page sheets to increase education in patients about drug therapy have also been discussed in various other studies.[26-27]

A research conducted by Livingstone et al. in a community pharmacy found out that patients when counseled with PILs, 65 percent of patients were able to recollect information about their drugs compared to 30 percent of patients previously without education and PIL on their drugs.[28]

Gibbs et al. have shown in their studies that PIL complementing a verbal advice greatly improved the level of knowledge in 67 percent of the patients in recognizing pros and cons of medications after education compared to 40 percent of patients at time of admission.[29]

Another way to patient aid is through SMS reminders. Adherence to medical appointments and taking medication can be improved with the help of SMS and Email remainders. Huges L et al conducted a study that in which 92% of the patients had mobile phone access. A large number of the patients responded in a positive way to receive appointment reminders and a quarter of patients to receive medication reminders. Since majority of people had access of mobile phones it was an easier method to give a reminder about their follow up reminders.[30] With the establishment of mobile network services with cheaper cost and higher coverage more people are making use of information and communication technology (ICT) such as email and SMS text messaging. [31]

Most of the patients with RA does not meet the recommendations of moderate to vigorous physical activity (MVPA) and spend a higher proportion of their waking hours sitting than the general population (71 % and 62 % respectively of awake hours). Sedentary behavior increases the risk of cardiovascular disease, premature death, cardio-metabolic biomarkers and certain types of cancer. Means to decrease sedentary activity includes sending the patient SMS reminders about their disease, and lifestyle modifications. This encourages people to make behavioral changes to improve their health. [32]

There is a wide variety of digital media such as social networking, online videos, animations, interactive and personalized websites or recorded audios/videos. They provide a huge advantage as they can deliver health related information to the patient at their ease at a time and place chosen by the patient. With the fast upcoming of mobile phones and other technology, there are many studies to observe if the digital media can serve as an adjunct to patient care. [33]

METHODOLOGY

5. METHODOLOGY

Study Site: The study was conducted in general medicine wards and orthopedics wards of Kasturba hospital.

Study design: Randomized controlled study .

Study period: 6 months

Sample Size: 30 patients

Ethical Approval: Protocol for this study was approved by the Institutional Ethical Committee of Kasturba Hospital, Manipal.(IEC/ 584/2019) (APPENDIX I)

Study criteria: The study group comprised of patients admitted in the general medicine wards and orthopedics wards who met the following criteria during the study period:

Inclusion criteria:

Patients with confirmed diagnosis of Rheumatoid Arthritis according to 2010 ACR/EULAR Classification Criteria for Rheumatoid Arthritis admitted in General Medicine and Orthopedic wards of Kasturba Hospital, Manipal.

Patients above 18 years of age, irrespective of gender.

Patients willing to participate in the study.

Exclusion criteria:

Patients not willing to participate

Patients whose diagnosis is not confirmed

Hepatic and Renal impairment

Pregnant and lactating women

HIV or immunocompromised patients at an unacceptable risk

Patients who don't own phones for digital media group

Data source:

The study population broadly represents the South Indian population. All the necessary and relevant data were obtained from the medical records and interviews of patients diagnosed with Rheumatoid arthritis.

Study materials:

Participant Information Sheet (PIS) - Used to provide necessary details (purpose, benefits/risks, procedure) regarding the study. (APPENDIX IIa, IIb)

Informed Consent Form - An Informed consent form in Kannada or English was obtained from each participant before study initiation. (APPENDIX IIIa, IIIb)

Case Report Form (CRF) - A form containing various items were used to assess the information of the patients who had rheumatoid arthritis. (Physician information, demographic information, medical history, social history, occupational history, diagnostic parameters, treatment parameters, and outcomes). (APPENDIX IV)

Operation modality

The study was carried out in 6 main stages:

STAGE 1: **Designing prototype Patient information leaflets (PILs)**

Leaflets were prepared by referring to primary, secondary and tertiary sources such as Arthritis.org,[37] American College of Rheumatology,[38], Australian Rheumatology Association,[39] Arthritis Care, [40] Today's Dietitian, [41] and various articles related to patient education on rheumatoid arthritis respectively. Following which, standard prototype leaflets were designed keeping in consideration, the Flesch Reading Ease (FRE) and Flesch-Kincaid Grade Level (FK-GL) scores by using MS Office 2007. The leaflet content includes information about the disease; drugs used in the management of RA and lifestyle modifications.

Leaflet	FRE Score	FK-GL Score
Disease	70	5.4
General Drug	100	0
Methotrexate	69.5	5.6
Sulphasalazine	66.3	6.3
Leflunomide	73.8	5.5
Hydroxychloroquine	63.3	6.5
Corticosteroids	74.1	5.3
Lifestyle	71.6	5.6

Table 4: FRE and FK-GL scores

Scale for FRE: Very easy (90-100), Easy (80-89), Fairly easy (70-79), Standard (60-69), Fairly difficult (50-59), Difficult (30-49) and Very confusing (0-29).
FK-GL: Number of years of education required to understand the text.[42]

STAGE 2: Validation of the PILs

The designed leaflets were then validated to ensure their applicability, relevance, and accuracy. Validation procedure followed is as follows:

1. Experts in the field of rheumatoid arthritis including 2 physicians and academic pharmacists were consulted to validate the PILs and provide feedback.
2. All required modifications were made in order to improve the scores of the leaflet.
3. After the contents of English PILs were validated, the leaflets were then translated into Kannada with the help of experts familiar with the language and medical terminologies.
4. An expert physician familiar with Kannada language further validated the translated leaflets.

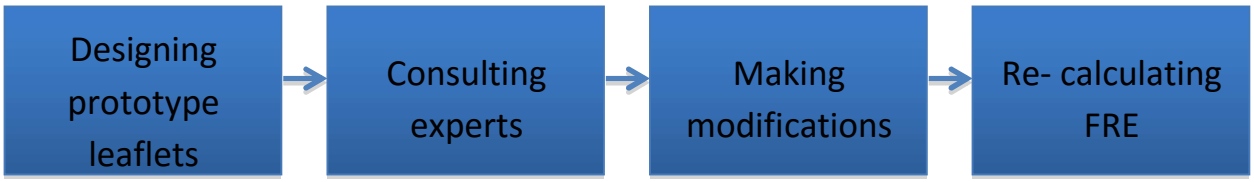


Figure 1: Flowchart depicting Validation of PILs

STAGE 3: Data collection

1. Data of 30 patients was collected based on inclusion and exclusion criteria.
2. After the informed consent was taken, the participant informant sheet was given.
3. The patient's pain score was recorded using a visual analogue scale.
4. The patient and/or patient party was asked 20 questions, divided in 8 categories to assess the functional capacity of the patient such as dressing/grooming, arising, reach, grip, walking, eating, hygiene, and daily activities.
5. The patient was further asked 10 questions in order to assess their knowledge regarding the disease, drugs and lifestyle modifications with respect to their condition.
6. After obtaining their baseline knowledge, leaflets were administered based on the group that the patient falls in, determined by simple randomization using Quickcals- Graphpad software:
   - GROUP 1: General drug leaflet
   - GROUP 2: Disease, Drugs and Lifestyle leaflet
   - GROUP 3: Disease, Drugs and Lifestyle leaflet and SMS reminders.
7. The patients were counseled according to their grouping and asked to read the leaflets.
8. The same 10 questions were asked again to determine any improvement in patient's ledge and understanding, post the counseling session and leaflet administration.

9. Data were simultaneously recorded on printed copies of CRFs, HAQ questionnaire (APPENDIX Va, Vb) sheets and pre and post knowledge assessment questionnaire (APPENDIX VI a, VI b) sheets.

STAGE 4: Data entry

1. The collected data was checked for aberrancies and collated thereafter.
2. It was then entered into MS Excel and re-checked for duplications.

STAGE 5: Evaluation & analysis

The data entered was analyzed based on demographic information, clinical characteristics of and markers of RA, physical disability assessment, prescription pattern and various counseling techniques.

RESULTS

6. RESULTS

6.1 Demographic Overview

A prospective pilot study was conducted in Medicine and Orthopedic wards of Kasturba hospital, Manipal, comprising of n=30 RA patients and their demographic characteristics were determined.

Basic demographic characteristics of RA patients	N=30
Patients demographic characteristics	
Mean age ±SD in years	59.14 ± 16.19
Male sex, n (%)	3 (10%)
Female sex, n (%)	27 (90%)
Non-Alcoholic, n (%)	30 (100%)
Non-Smoking, n (%)	30 (100%)
Patients clinical characteristics	
Duration of RA, Mean ± SD in years	10.50 ± 13.34 years
Morning stiffness, Mean ± SD in hours	1.14 ± 0.75 hours
Severity assessment	
ESR, Mean ± SD	57.18±34.24mm/hr
CRP, Mean ± SD	88.57 ± 87.45 mg/dl.
SJC (0-28), Mean ± SD	7.50 ± 9.95
TJC (0-28), Mean ± SD	11.57 ± 9.98
DAS28, Mean ± SD	5.64 ± 1.65
HAQ (0-4), Mean ± SD	1.80 ± 0.85
VAS Pain (VAS 100mm), Mean ± SD	55.67 ± 27.50

ESR: Erythrocyte sedimentation rate, CRP: C-reactive protein, SJC: Swollen joint counts, TJC: Tender joint counts, DAS28: 28 joint disease activity score, HAQ: Health Assessment Questionnaire, VAS: Visual analogue scale

Table 5: Demographic Overview

6.2 Sex

Among n=30 patients enrolled in the study, 3 (10%) were male and 27 (90%) were female. This shows majority of subjects in the study were female. There was 1 male in group A and 2 males in group C and no males in group C.

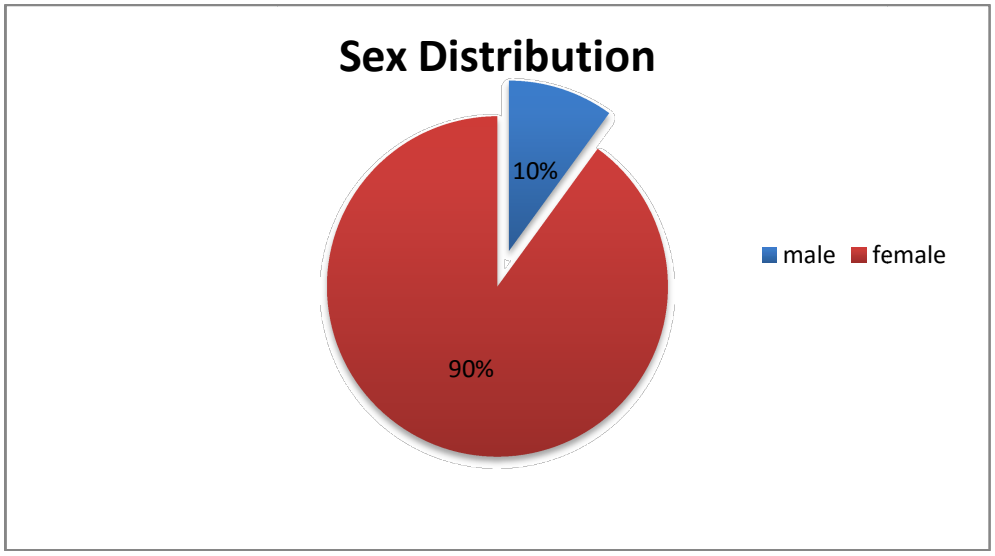


Figure 2: Sex Distribution

6.3 Age

Among n=30 patients, majority of the patients fell under the age group of 51-70 years (46.7%) followed by age groups >71 years (26.7%), 31-50 years (13.3%), 18-30 years (13.3%).

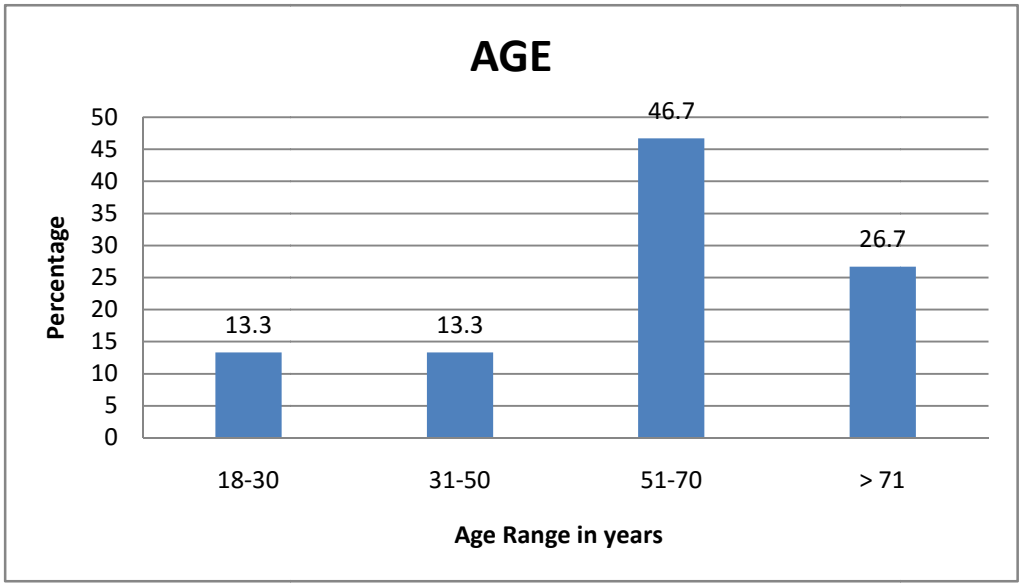


Figure 3: Eliciting ages of all patients

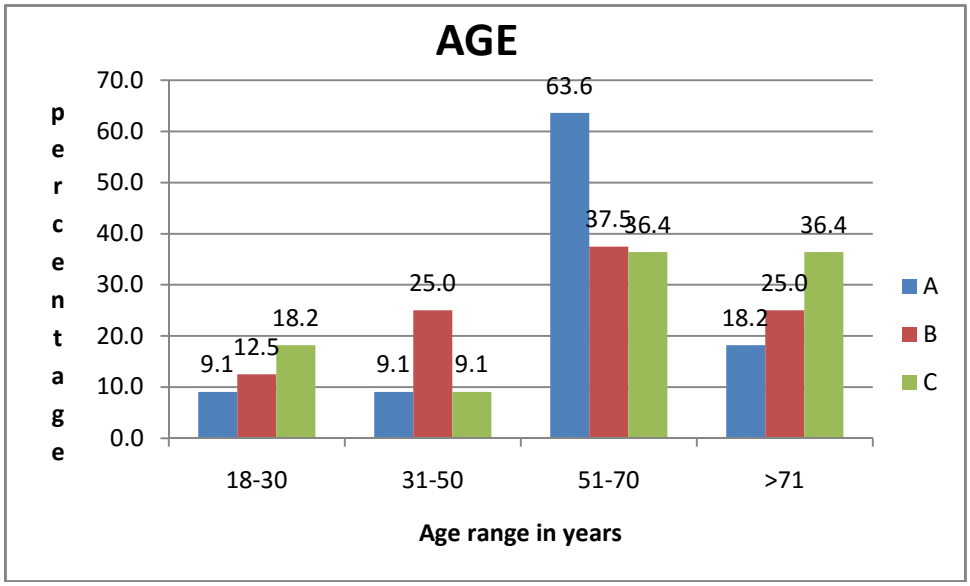


Figure 4 : eliciting age of patients in different groups

6.4 Occupation

Among n=30 patients, majority of them were housewives n=20 (66.7%) followed by others given in the figure below.

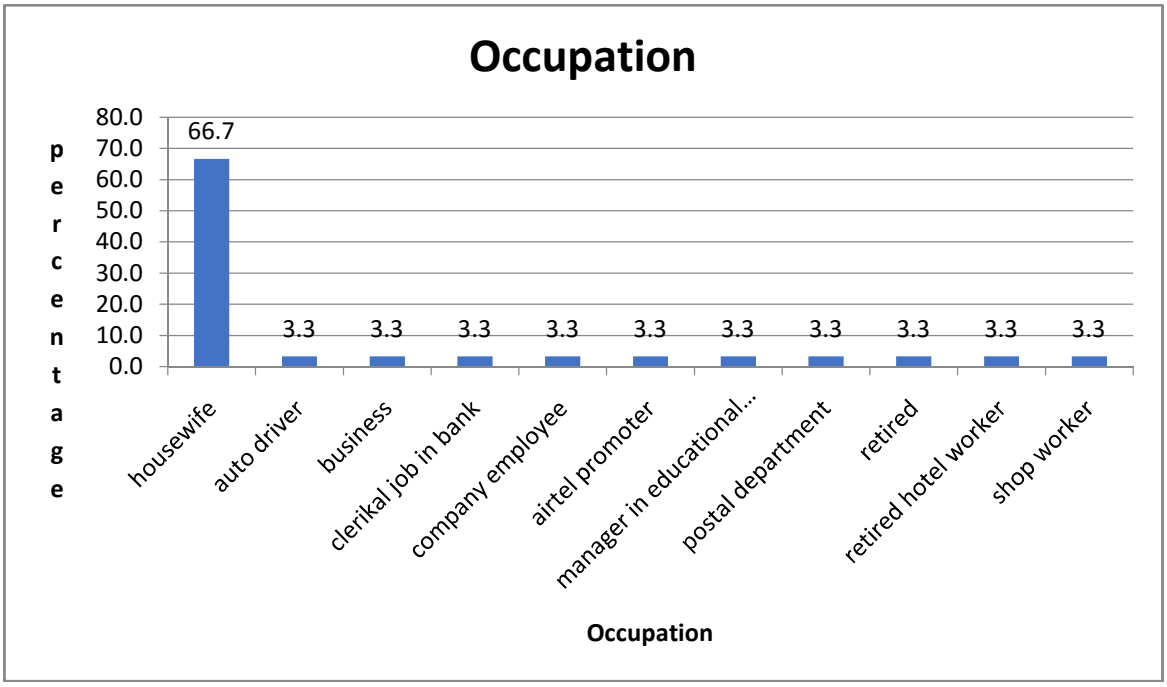


Figure 5: Occupation

Group	Occupation	N (%)
A	Housewife	9 (81.8%)
	Airtel Promoter	1 (9.1%)
	Retired hotel worker	1 (9.1%)
B	Housewife	4 (50%)
	Business	1 (12.5%)
	Auto driver	1 (12.5%)
	Manager in educational dept	1 (12.5%)
	Retired	1 (12.5%)
C	Housewife	6 (54.5%)
	Company employee	1 (9.1%)
	Clerical job in bank	1 (9.1%)
	Postal dept	1 (9.1%)
	Shop worker	1 (9.1%)

Table 6: Occupation of patients in different groups

6.5 Education

Among n=30 patients, majority were illiterate (45.5% in Group A, 12.5% in group B and 54.4% in group C), followed by others given in the figure below.

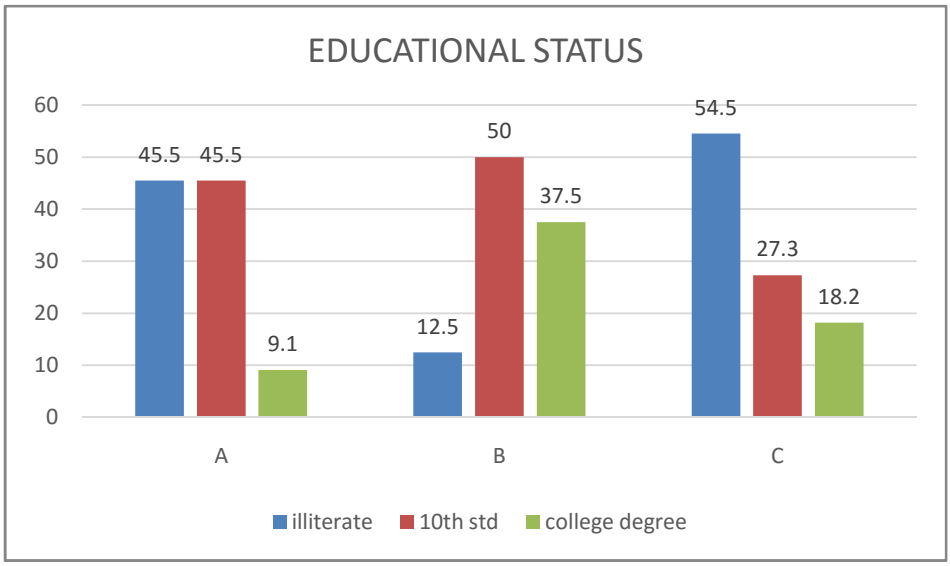


Figure 6: Educational Status

6.6 Clinical characteristics of RA

6.6.1 Duration of RA

Among n=30 patients, the duration of RA for most of the patients were between 3-5 years (26.7%), followed by >12 years (16.7%), 0-2 years (13.3%), 9-11 years (10%), 6-8 years (6.7%).

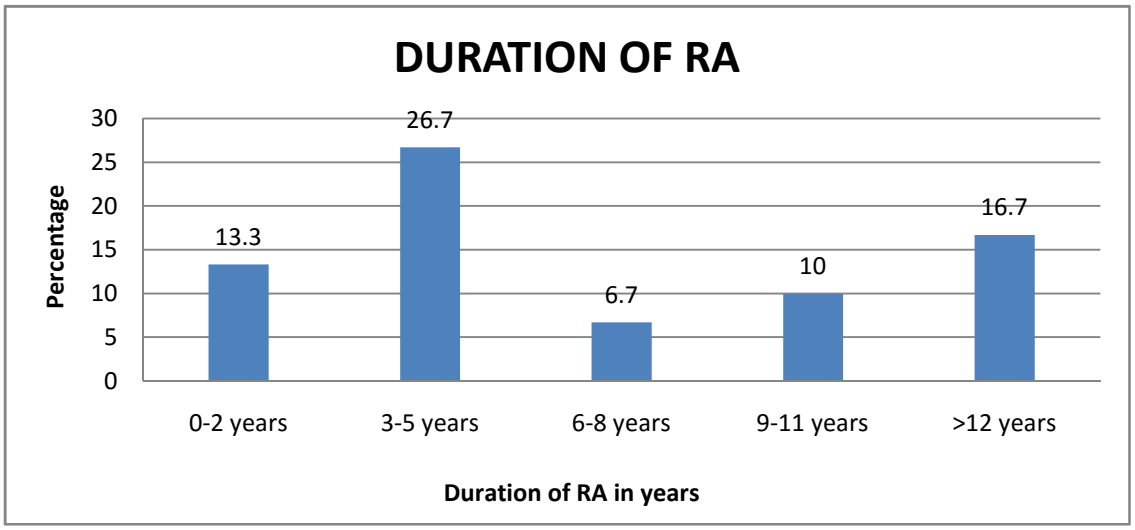


Figure 7: Duration of RA

6.6.2 Classification of RA

Gender wise distribution of rheumatoid factor (RF) among RA patients

Among n=30 patients, 2 male patients and 14 female patients tested positive for rheumatoid factor, where as 1 male and 7 female had negative rheumatoid factor. RF for 6 patients were not specified.

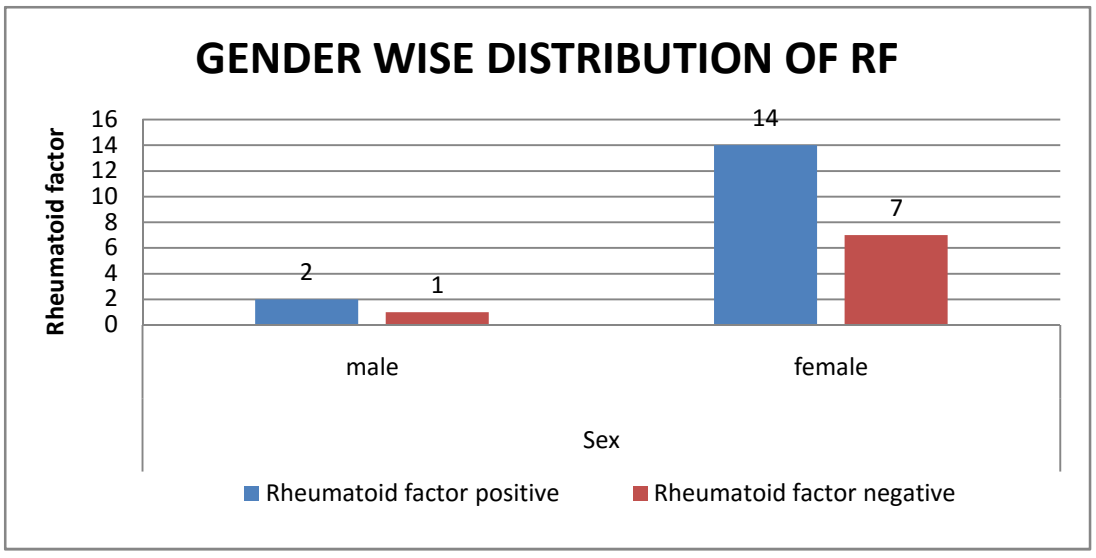


Figure 8: Gender wise distribution of RF

6.6.3 Co-morbidities

Among n=30 patients, 26 (87%) had presence of co-morbidities whereas 4 (13%) did not have co-morbidities.

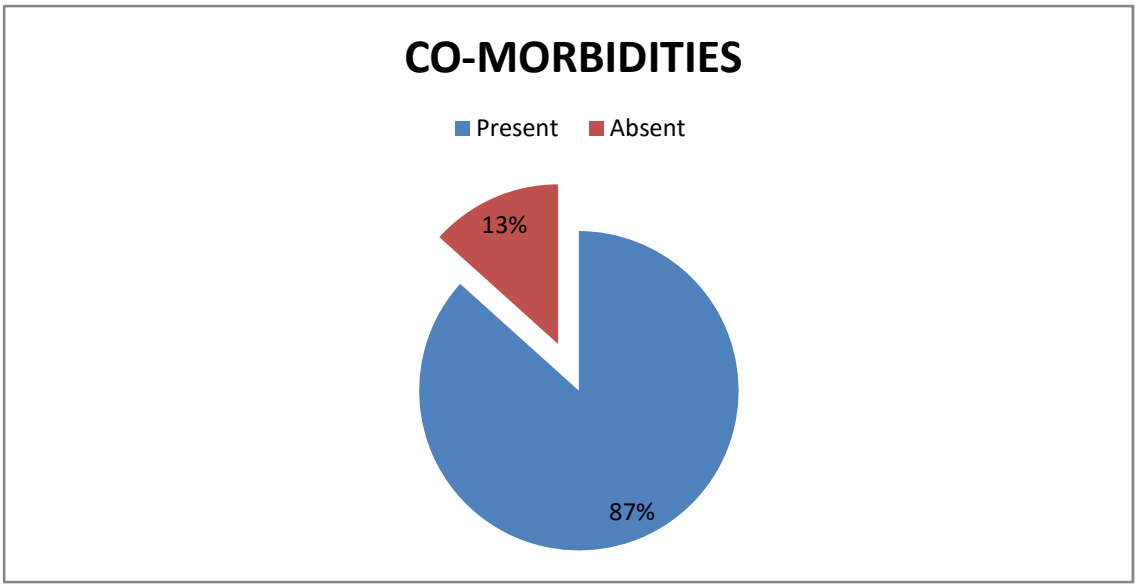


Figure 9: Co-morbidities

Sno:	Comorbidities	No: of patients (%)
1	Hypertension	10 (33.3%)
2	Anemia	5 (16.7%)
3	Hypothyrodism	5 (16.7%)
4	Diabetes mellitus	5 (16.7%)
5	Gastritis	3 (10%)
6	Lower Respiratory Tract Infection	3 (10%)
7	Cerebrovascular accident	2 (6.7%)
8	Interstitial lung disease	2 (6.7%)
9	Depression	2 (6.7%)
10	Vit D deficiency	2 (6.7%)
11	Osteoarthritis	2 (6.7%)
13	Henoch schontein syndrome	1 (3.3%)

14	Ischemic Heart Disease	1 (3.3%)
15	Peripheral neuropathy	1 (3.3%)
16	Splenic cysts	1 (3.3%)
17	Cellulitis	1 (3.3%)
18	leptospirosis	1 (3.3%)
19	parkinsonism	1 (3.3%)
20	Scrub typhus	1 (3.3%)
21	Addisons disease	1 (3.3%)
22	Acute adrenal insufficiency	1 (3.3%)
23	Metabolic encephalopathy	1 (3.3%)
24	Nonalcoholic fatty liver disease	1 (3.3%)
25	Acute respiratory distress syndrome	1 (3.3%)
26	Chronic diverculosis	1 (3.3%)
27	Urinary tract infection	1 (3.3%)

Table 7: Comorbidities

6.6.4 Morning stiffness

Among n=30 patients, 9 patients who tested positive for RF complained of morning stiffness, where as 6 patients who tested negative for RF did not complain of presence of morning stiffness. Data for the other patients are not known.

6.7 Markers of RA

6.7.1 Erythrocyte Sedimentation Rate (ESR)

The Mean ESR value was found to be 57.18 ±34.24 mm/hr. Among n=30 patients, Mean ESR value among male was 62.33 ±34.82 mm/hr and among female was 56.56 ± 34.85 mm/hr. 18 patients had high ESR values.

6.7.2 C-reactive protein (CRP)

The Mean CRP value was found to be 88.57 ± 87.45 mg/dl. In group A 7 patients had high CRP levels. Group B had 6 patients with high CRP levels. Group C had 6 patients with high CRP levels. Data for the other patients are not known.

6.8 Clinical severity assessment

DAS-28 is used for assessment of disease activity in RA patients by combining 28 TJC, 28 SJC, ESR and General health assessment using visual analogue scale (VAS).

6.8.1 Tender joint count (TJC) and swollen joint count (SJC)

Among n=30 patients, mean TJC was found to be 11.57 ± 9.98 and the mean SJC was 7.50 ± 9.95. For RF positive patients (n =16) the mean TJC and SJC was found to be lower than RF negative patients. (n= 8)

Mean TJC for RF positive patients was 11.73 ± 10.81 and mean TJC for RF negative patients was 14.50 ± 9.24.

Mean SJC for RF positive patients was 5.80 ± 10.41 and mean SJC for RF negative patients was 11.38 ± 10.30.

6.8.2 DAS28

Based on the Disease activity score, RA patients were categorized into four groups: High disease activity (>5.1), Moderate disease activity (3.2-<5.1), Low disease activity (2.6 - 3.2) and Remission (0 - <2.6). Among n=30 patients, 17(56.7%) fell under high activity, 10(33.3%) under moderate activity, 0 under low activity and 1(3.3%) under remission. Data for the other patients were not known. Mean DAS28 was found to be 5.64 ± 1.65.

DAS	N(%)	Mean ± SD
High disease activity (>5.1)	**17(56.7%)**	**6.69 ± 1.09**
Moderate disease activity (3.2-<5.1)	**10(33.3%)**	**4.24 ± 0.47**
Low disease activity (2.6 - 3.2)	**-**	**-**
Remission (0 - <2.6)	**1(3.3%**	**1.80**

Table 8: Categorizing Patients with respect to DAS28

6.9 Physical disability assessment

Among n=30 patients, mean HAQ was found to be 1.18 ± 0.87. After 3 months, the questionnaire was administered again and the mean HAQ was found to be 1.01 ± 0.89. The Mean VAS score was 55.67 ± 27.50. After 3 months, mean VAS score was found to be 44.3 ± 24.45.

7.0 Prescription pattern of RA patients

7.0.1 Prescription pattern of DMARD

Drug utilization was analyzed during this study. Among n=30 patients, 22 (73.3%) patients received DMARDs and 8 (26.7%) patients did not. Methotrexate (MTX) was widely prescribed in 16(53.3%) patients, followed by Hydroxychloroquine (HCQ) 15 (50%), Sulfasalazine (SSZ)10 (33.3%)and Leflunomide (LEF) 2 (6.7%). Among combination therapy MTX+HCQ combination was preferred over other combinations and was given in 7(23.3%) patients followed by HCQ+MTX+SSZ combination in 6(20% patients. Biologicals were not prescribed in the study population.

NSAIDS and other analgesics were prescribed in 14 (46.7%) patients for pain management.

Prednisolone was most frequently used for its anti inflammatory and immunosuppressive properties and was prescribed in 16 (53.3%) patients.

S.No	DMARDS combination	Non Biological DMARDs	No.Of patients (n=30) (%)
1	Single 7 (23.3%)	Methotrexate (MTX)	2 (28.5)
2		Hydroxychloroquine (HCQ)	2 (28.5)
3		Sulfasalazine (SSZ)	3 (42.8)
4		Leflunomide (LEF)	0
5	Dual 9 (30%)	Methotrexate + Sulfasalazine (MTX+SSZ)	1 (3.3)
6		Methotrexate + Hydoxychloroquine (MTX+HCQ)	7 (23.3)
7		Methotrexate + Leflunomide (MTX+LEF)	1 (3.3)
8	Triple 6 (20%)	Hydroxychloroquine+ Methotrexate+ Sulfasalazine (HCQ+MTX+SSZ)	6 (20)
9	Others	No DMARDs	8 (26.7)
		NSAIDs alone	14 (46.7)
		Corticosteroids+ NSAIDs	6 (20)

Table 9: Prescription pattern of DMARD combinations

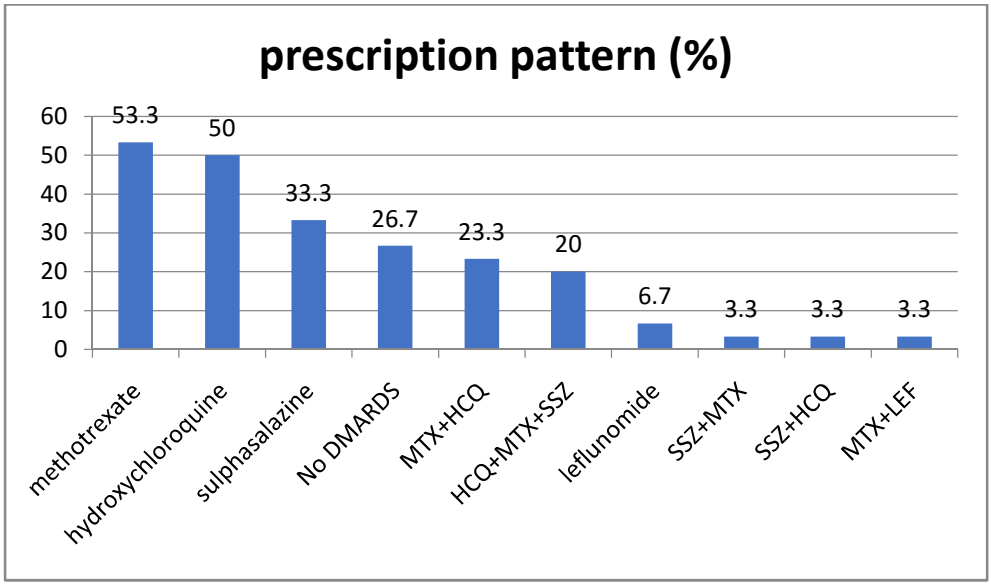


Figure 10: Prescription pattern of DMARD combinations

7.1 Counseling techniques

The study population was randomly grouped into three categories by simple randomization using Quickcals- Graphpad software. Among n=30 patients, 11 (36.7%) patients fell under category A, 8 (26.7%) in category B and 11 (36.7%) in category C. Each category received a separate type of counseling technique. Improvement in patient's knowledge, pain and physical disability were assessed with respect to the counseling technique.

Group A	Group B	Group C
• Counselling by consultant doctor and the nurse • General drug leaflet	• One to One counselling by clinical pharmacist • Drugs, Disease, Lifestyle Leaflets	• One to One Counselling by clinical pharmacist • Drugs, Disease, Lifestyle Leaflets • Text message Reminders

Table 10: Counseling techniques

7.1.1 Knowledge assessment with respect to counseling

During the study, improvement in patient's knowledge was assessed by administering a set of 10 questions to be answered by the patients before and after the counseling session. The responses were totaled and scored as follows: very poor understanding (1-1.9); poor understanding (2-2.9); moderate understanding (3-3.9); good understanding (4-4.9); very good understanding (>5).

For all the groups, the understanding after counseling improved from moderate to good understanding. Group C demonstrated a greater difference in understanding.

Patient Group		Pre assessment of knowledge	Post assessment of knowledge
A	**Mean ±SD**	3.15 ± 0.68	3.68± 0.48
B	**Mean ±SD**	3.65 ± 1.04	4.05±0.76
C	**Mean ±SD**	3.51 ± 1.21	4.12 ± 0.51

Table 11:Knowledge assessment with respect to counseling

7.1.2 Pain VAS with respect to counseling

During the study, patient's pain score was recorded. After 3 months, follow up pain score was recorded to determine any difference as a result of the counseling recommendations.

Group C demonstrated greater decrease in pain score in comparison to other groups.

Patient Group	Pre Pain VAS	Post Pain VAS
A. Mean ±SD	62.73 ± 24.94	49.09 ± 25.48
B. Mean ±SD	46.25 ± 21.34	46.25 ±25.60
C. Mean ±SD	55.45 ± 33.58	38.18 ± 23.59

Table 12: Pain VAS with respect to counseling

7.1.3 Physical disability with respect to counseling

During the study, patients HAQ score was recorded before the counseling session. After 3 months, follow up HAQ score was recorded to determine any difference as a result of the counseling recommendations.

Group B demonstrated greater difference in HAQ score in comparison to other groups.

Patient Group	Pre HAQ	Post HAQ
A. Mean ±SD	1.47 ± 0.87	1.31 ± 0.90
B. Mean ±SD	0.98 ± 0.89	0.73 ± 0.85
C. Mean ±SD	1.03 ± 0.84	0.92 ± 0.89

Table 13: Physical disability with respect to counseling

DISCUSSION

7. DISCUSSION

Education for individuals with RA is vital, since it enables them to adjust and adapt with the impacts of disease and treatments. [34] Inadequate knowledge of the matter directly influences patient's reaction to treatment and acquiring a satisfactory health-related quality of life.[35]

The study by Khoury V*et al* highlighted the importance of educating patients with RA using various techniques including leaflets and digital media for safe and effective use of the prescribed drugs. [43]

8.1 Comparing three counseling interventions

In this study, various counseling techniques provided to patients with RA were studied with respect to the level of knowledge gained, improvement in pain score, as well as HAQ score.

Patients understanding at baseline period showed low mean values of 3.15 ± 0.68 (A), 3.65 ± 1.04 (B), and 3.51 ± 1.21 (C); in comparison to the increased mean values post counseling 3.68 ± 0.48 (A), 4.05 ± 0.76 (B), 4.12 ± 0.51 (C) (table 9).These results demonstrated that pharmaceutical care counseling with the aid of leaflets provided to group B and C were increasingly useful in improving patients understanding regarding their condition as opposed to the control group A.

Pain score of the patients were recorded during the study and after 3 months to determine whether there was any improvement in the follow up pain score as a result of the counseling recommendations. Group C demonstrated greater decrease in pain score 55.45 ± 33.58 to 38.18 ± 23.59 (table 10).

These outcomes resemble those of authors such as Senara S*et al* who found a decrease in disability, pain, and other clinical parameters after the utilization of educational intervention in patients with RA. [34] In addition, a study by Lindroth Y*et al* proposed that the education programs should be incorporated in the RA treatment. [36]

8.2 Drug utilization, disease activity and quality of life

MTX was widely prescribed as monotherapy or in combination with other DMARDs in 16 (53.3%) patients, followed by HCQ in 15 (50%) patients (table 6). Among combination therapy MTX+HCQ combination was preferred over other combinations and was given in 7(23.3%) patients followed by HCQ+MTX+SSZ combination in 6 (20%) patients. Given that the standard DMARDs prescribed in all groups were the same, the improvement in patient's condition could be due to the educational program.

Mean DAS28 was found to be 5.64 ± 1.65 and 17 (56.7%) patients fell under high disease activity. During the study, patients HAQ score was also recorded before the counseling session. After 3 months, follow up HAQ score was recorded to determine any difference as a result of the counseling recommendations. Group B demonstrated greater difference in HAQ score in comparison to other groups.

LIMITATIONS

8. LIMITATIONS

1. Language barrier
2. Missing reports or lack of documentation if the patient gets transferred from another hospital
3. Follow up is time consuming
4. Interventions of forwards and messages may not be always acceptable to people and may disturb them.

CONCLUSION

9. CONCLUSION

The study demonstrated that pharmaceutical care counseling with the aid of leaflets as well as text message reminders were well received by the patients resulting in improved understanding regarding their condition as well as improvement in the pain and HAQ scores. This had a positive impact on the quality of life of RA patients

Majority of patients fell under high disease activity and MTX was widely prescribed as monotherapy or in combination with other DMARDs followed by HCQ. Among combination therapy MTX+HCQ combination was preferred over other combinations.

FUTURE DIRECTIONS

10. FUTURE DIRECTIONS

1. Further studies can be done in large multicenter hospitals with cultural variations
2. Patient information leaflets can be translated to other languages
3. This study was conducted only in Manipal and hence these results do not represent the whole India. In near future, more such studies should be carried.

BIBLIOGRAPHY

11. REFERENCES

1. Bullock J, Rizvi SA, Saleh AM, Ahmed SS, Do DP, Ansari RA, et al. Rheumatoid Arthritis: A Brief Overview of the Treatment. Medical Principles and Practice. 2018; 27(6):501–7.

2. Centers for Disease Control and Prevention. Available from: https://www.cdc.gov/ [2018].

3. Iqbal S, Rattu MA. Review of Rheumatoid Arthritis. US Pharm. 2019; 44(1):8-11.

4. Heidari B. Rheumatoid Arthritis: Early diagnosis and treatment outcomes. Caspian journal of internal medicine. 2011; 2(1):161.

5. Hodkinson B, Duuren EV, Pettipher C, Kalla A. South African recommendations for the management of rheumatoid arthritis: An algorithm for the standard of care in 2013. South African Medical Journal. 2013; 103(8):576.

6. Guo Q, Wang Y, Xu D, Nossent J, Pavlos NJ, Xu J. Rheumatoid arthritis: pathological mechanisms and modern pharmacologic therapies. Bone Research. 2018; 6(1).

7. Howard R Smith, MD. What are the ACR recommendations for the use of DMARDS in the treatment of rheumatoid arthritis (RA)? Available from: https://www.medscape.com/answers/331715-5450/what-are-the-acr-recommendations-for-the-use-of-dmards-in-the-treatment-of-rheumatoid-arthritis-ra [Accessed 30 Apr. 2020].

8. Vlieland TPMV. Non-drug care for RA is the era of evidence-based practice approaching? Rheumatology. 2007; 46(9):1397–404.

9. Arthritis Foundation. Available from: https://www.arthritis.org/arthritis-cure/scientific-facts [Accessed 30 Apr. 2020].

10. Fransen J, Stucki G, Piet L. C. M. Van Riel. Rheumatoid arthritis measures: Disease Activity Score (DAS), Disease Activity Score-28 (DAS28), Rapid Assessment of Disease Activity in Rheumatology (RADAR), and Rheumatoid Arthritis Disease Activity Index (RADAI). Arthritis & Rheumatism. 2003; 49(S5).

11. Bruce B, Fries JF. The Stanford health assessment questionnaire: dimensions and practical applications. Health and quality of life outcomes. 2003 Dec 1; 1(1):20.

12. Bruce B, Fries JF. The health assessment questionnaire (HAQ). Clinical and experimental rheumatology. 2005 Sep 1; 23(5):S14.

13. Malaviya AN, Kapoor SK, Singh RR, Kumar A, Pande I. Prevalence of rheumatoid arthritis in the adult Indian population. Rheumatology international. 1993 Nov 1; 13(4):131-4.

14. Handa R, Rao UR, Lewis JF, Rambhad G, Shiff S, Ghia CJ. Literature review of rheumatoid arthritis in India. International journal of rheumatic diseases. 2016 May; 19(5):440-51.

15. Bedi GS, Gupta N, Handa R, Pal H, Pandey RM. Quality of life in Indian patients with rheumatoid arthritis. Quality of life Research. 2005 Oct 1; 14(8):1953-8.

16. Tucker M, Kirwan JR. Does patient education in rheumatoid arthritis have therapeutic potential?. Annals of the rheumatic diseases. 1991 Jun; 50(Supplement 3):422.

17. Bishop P, Kirwan J, Windsor K. The ARC patient literature evaluation project. Chesterfield: Arthritis and Rheumatism Council. 1996

18. Christie A, Dagfinrud H, Dale Ø, Schulz T, Hagen KB. Collection of patient-reported outcomes;-text messages on mobile phones provide valid scores and high response rates. BMC medical research methodology. 2014 Dec 1; 14(1):52.

19. Mody GM, Cardiel MH. Challenges in the management of rheumatoid arthritis in developing countries. Best Practice & Research Clinical Rheumatology. 2008 Aug 1; 22(4):621-41.

20. Niedermann K, Fransen J, Knols R, Uebelhart D. Gap between short-and long-term effects of patient education in rheumatoid arthritis patients: A systematic review. Arthritis Care & Research. 2004 Jun 15; 51(3):388-98.

21. Hill J, Bird H. The development and evaluation of a drug information leaflet for patients with rheumatoid arthritis. Rheumatology. 2003 Jan 1; 42(1):66-70.

22. Riemsma RP, Taal E, Rasker JJ. Group education for patients with rheumatoid arthritis and their partners. Arthritis & Rheumatism. 2003; 49(4):556–66.

23. Barlow JH, Wright CC. Knowledge in patients with rheumatoid arthritis: a longer term follow-up of a randomized controlled study of patient education leaflets. British journal of rheumatology. 1998 Apr 1; 37(4):373-6.

24. Adepu R, Swamy MK. Development and evaluation of patient information leaflets (PIL) usefulness. Indian journal of pharmaceutical sciences. 2012 Mar; 74(2):174.

25. Clark CM, Bayley EW. Evaluation of the use of programmed instruction for patients maintained on Warfarin therapy. American journal of public health. 1972 Aug; 62(8):1135-9.

26. Clinite JC, Kabat HF. Pharmacist-patient intervention at time of dispensing results in highest level of patient compliance Improving Patient Compliance. Journal of the American Pharmaceutical Association (1961). 1976 Feb 1; 16(2):74-85.

27. Morris LA, Halperin JA. Effects of written drug information on patient knowledge and compliance: a literature review. American Journal of Public Health. 1979 Jan; 69(1):47-52.

28. Livingstone CR, Pugh AL, Winn S, Williamson VK. Developing community pharmacy services wanted by local people: information and advice about prescription medicines. International Journal of Pharmacy Practice. 1996 Jun; 4(2):94-102.

29. Gibbs S, Waters WE, George CF. Prescription Information Leaflets: A National Survey. Journal of the Royal Society of Medicine. 1990; 83(5):292–7.

30. Hughes LD, Done J, Young A. Not 2 old 2 TXT: there is potential to use email and SMS text message healthcare reminders for rheumatology patients up to 65 years old. Health informatics journal. 2011 Dec; 17(4):266-76.

31. Thakkar J, Kurup R, Laba TL, Santo K, Thiagalingam A, Rodgers A, Woodward M, Redfern J, Chow CK. Mobile telephone text messaging for medication adherence in chronic disease: a meta-analysis. JAMA internal medicine. 2016 Mar 1; 176(3):340-9.

32. Thomsen T, Aadahl M, Beyer N, Hetland ML, Løppenthin K, Midtgaard J, Christensen R, Esbensen BA. Motivational counselling and SMS-reminders for reduction of daily sitting time in patients with rheumatoid arthritis: a descriptive randomised controlled feasibility study. BMC musculoskeletal disorders. 2016 Dec; 17(1):434.

33. Badley EM, Davis AM. Meeting the challenge of the ageing of the population: issues in access to specialist care for arthritis. Best Practice & Research Clinical Rheumatology. 2012 Oct 1; 26(5):599-609.

34. Senara SH, Wahed WY, Mabrouk SE. Importance of patient education in management of patients with rheumatoid arthritis: an intervention study. Egyptian Rheumatology and Rehabilitation. 2019 Jan 1; 46(1):42.

35. Khoury V, Kourilovitch M, Massardo L. Education for patients with rheumatoid arthritis in Latin America and the Caribbean. Clinical rheumatology. 2015 Mar 1; 34(1):45-9.

36. Lindroth Y, Brattström M, Bellman I, Ekestaf G, Olofsson Y, Strömbeck B, Stenshed B, Wikström I, Nilsson JÅ, Wollheim FA. A problem-based education program for patients with rheumatoid arthritis: evaluation after three and twelve months. Arthritis & Rheumatism: Official Journal of the American College of Rheumatology. 1997 Oct; 10(5):325-32.

37. Diet for Rheumatoid Arthritis | Anti Inflammatory Diet | Arthritis Diet. . Available from: https://www.arthritis.org/living-with-arthritis/arthritis-diet/anti-inflammatory/rheumatoid-arthritis-diet.php. [Accessed 30 Apr 2020]

38. Rheumatoid Arthritis. Available from: https://www.rheumatology.org/Practice-Quality/Clinical-Support/Clinical-Practice-Guidelines/Rheumatoid-Arthritis. [Accessed 16 Sep 2019]

39. ARA- Condition Information. Available from: https://rheumatology.org.au/patients/condition-information.asp [Accessed 30 Apr. 2020].

40. Arthritis Care - an overview. Available from: https://www.sciencedirect.com/topics/immunology-and-microbiology/arthritis-care [Accessed 30 Apr. 2020].

41. Nancy Garrick, D.D. (2017). Arthritis and Rheumatic Diseases. National Institute of Arthritis and Musculoskeletal and Skin Diseases. Available from: http://www.niams.nih.gov/Health_Info/Rheumatic_Disease/. [Accessed 30 Apr. 2020].

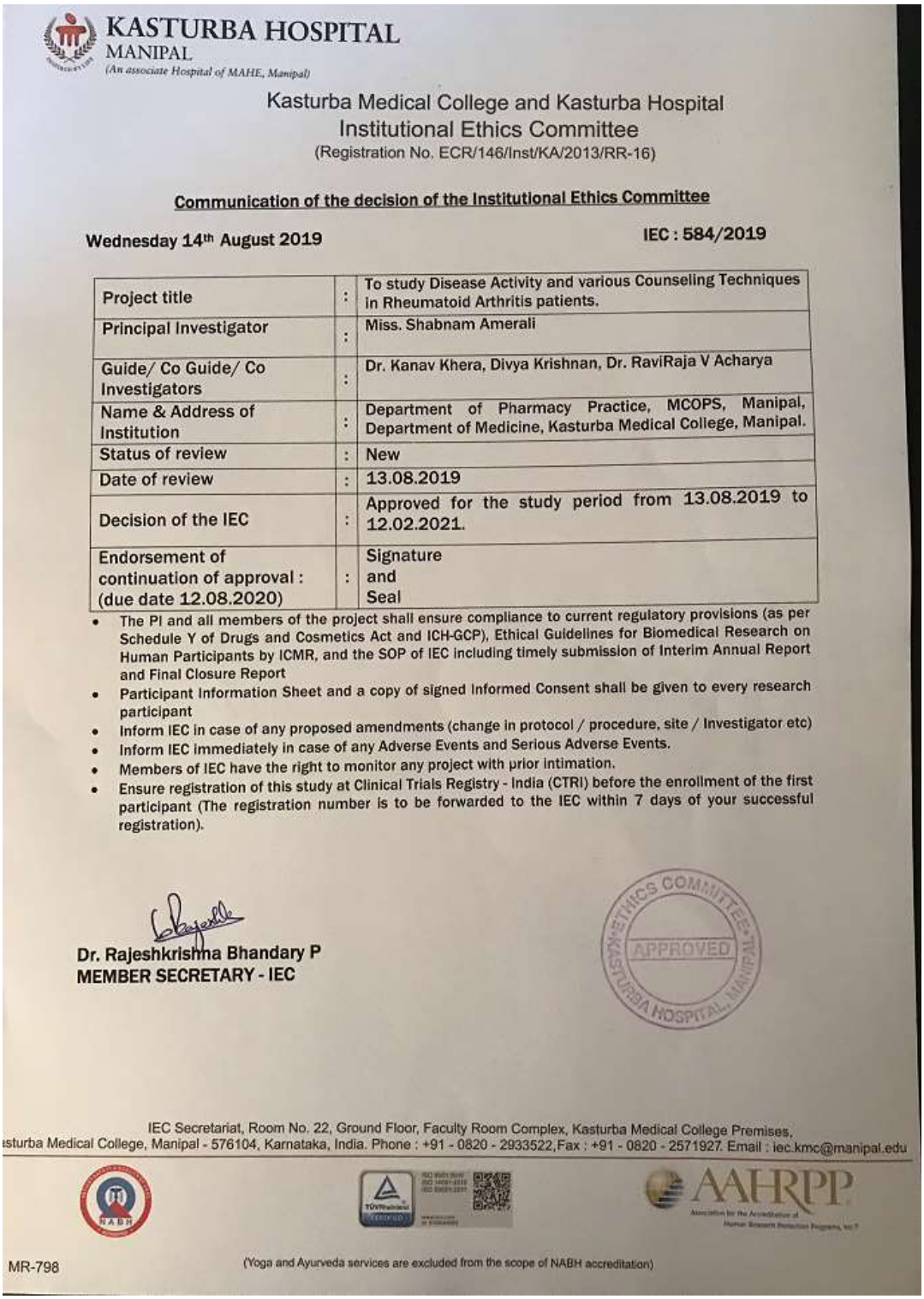
42. Renuka P, Pushpanjali K. Leaflet Preparation and Validation Procedures. Universal Journal of Public Health. 2013; 1(3):110-4.

43. Khoury V, Kourilovitch M, Massardo L. Education for patients with rheumatoid arthritis in Latin America and the Caribbean. Clinical Rheumatology. 2015;34(S1):45-49.

APPENDICES

APPENDIX I: CTRI REGISTRATION NO. & IEC CERTIFICATE

CTRI REGISTRATION NUMBER: CTRI/2018/10/016139



KASTURBA HOSPITAL
MANIPAL
(An associate Hospital of MAHE, Manipal)

Kasturba Medical College and Kasturba Hospital
Institutional Ethics Committee
(Registration No. ECR/146/Inst/KA/2013/RR-16)

Communication of the decision of the Institutional Ethics Committee

Wednesday 14th August 2019 **IEC : 584/2019**

Project title	:	To study Disease Activity and various Counseling Techniques in Rheumatoid Arthritis patients.
Principal Investigator	:	Miss. Shabnam Amerali
Guide/ Co Guide/ Co Investigators	:	Dr. Kanav Khera, Divya Krishnan, Dr. RaviRaja V Acharya
Name & Address of Institution	:	Department of Pharmacy Practice, MCOPS, Manipal, Department of Medicine, Kasturba Medical College, Manipal.
Status of review	:	New
Date of review	:	13.08.2019
Decision of the IEC	:	Approved for the study period from 13.08.2019 to 12.02.2021.
Endorsement of continuation of approval : (due date 12.08.2020)	:	Signature and Seal

- The PI and all members of the project shall ensure compliance to current regulatory provisions (as per Schedule Y of Drugs and Cosmetics Act and ICH-GCP), Ethical Guidelines for Biomedical Research on Human Participants by ICMR, and the SOP of IEC including timely submission of Interim Annual Report and Final Closure Report
- Participant Information Sheet and a copy of signed Informed Consent shall be given to every research participant
- Inform IEC in case of any proposed amendments (change in protocol / procedure, site / Investigator etc)
- Inform IEC immediately in case of any Adverse Events and Serious Adverse Events.
- Members of IEC have the right to monitor any project with prior intimation.
- Ensure registration of this study at Clinical Trials Registry - India (CTRI) before the enrollment of the first participant (The registration number is to be forwarded to the IEC within 7 days of your successful registration).

Dr. Rajeshkrishna Bhandary P
MEMBER SECRETARY - IEC

ETHICS COMMITTEE KASTURBA HOSPITAL, MANIPAL APPROVED

IEC Secretariat, Room No. 22, Ground Floor, Faculty Room Complex, Kasturba Medical College Premises,
Kasturba Medical College, Manipal - 576104, Karnataka, India. Phone : +91 - 0820 - 2933522,Fax : +91 - 0820 - 2571927. Email : iec.kmc@manipal.edu

MR-798

(Yoga and Ayurveda services are excluded from the scope of NABH accreditation)

APPENDIX ll a: PIS (ENGLISH)

PARTICIPANT INFORMATION SHEET

Project title: "**To Study Disease Activity and various Counseling Techniques in Rheumatoid Arthritis patients**"
IEC No.:
Sponsor Name: NA
Language: English

Principal Investigator: Shabnam Amerali
Designation: Student
Hospital: Kasturba Hospital, Manipal
Mobile number: 9741520873

Please read this form carefully. If you don't understand the language or any information in this document, please discuss with study doctor. Your participation in this study is voluntary, and you can enquire about all details before giving your written consent to participate in this study.

1. <u>Introduction to the research study:</u>

You are invited to participate in this study because you have Rheumatoid Arthritis. This study involves the use of a drug as prescribed by your treating physician. This is an Interventional study.

2. <u>Purpose of the study:</u>

1. The objective of this study is to assess three counseling interventions
2. To study Drug utilization and Disease Activity in Rheumatoid Arthritis patients

3. <u>Who can take part:</u>
Inclusion criteria:

- Patients with confirmed diagnosis of Rheumatoid Arthritis
- Patients who are above 18 years of age irrespective of gender
- Patients willing to participate in the study

Exclusion criteria**:**

- Patients whose diagnosis is not confirmed
- Hepatic and Renal impairment
- Pregnant and lactating women
- HIV or immunocompromised patients at an unacceptable risk

- Patients admitted in departments other than Medicine and Orthopedic
- Patients who don't own phones for digital media group

4. Information about the study (as a whole) :

- No. of patients expected to participate / sample size : TOTAL 294 (98 in each group)

5. What will happen to you (the individual participant) during the study :

Patients will be randomly grouped into 3 categories receiving three separate counseling techniques– Randomized Controlled trial.
Number of visits to the hospital: Only Once in 3 monthS during the study period
Upon visit, Patients will be asked regarding their current disease and medications, any past histories and counseled according to their grouping regarding their drugs, disease and lifestyle. They will also be asked to fill Health Assessment Questionnaire (HAQ).

Counseling will be done on patients visit to the hospital only. Patients will not be asked for any special visits to the hospital for the study.

- **Group 1** shall receive the standard care which involves routine counseling provided at the hospital (control group). They will also receive any additional general counseling regarding the drugs in form of leaflets.

- **Group 2** shall receive counseling regarding disease, drug and lifestyle. This will be achieved through one to one counseling and by means of patient information leaflets.

- **Group 3** shall receive counseling as stated in Group 2 along with text message for follow up reminders.

For all patients regardless of the grouping,
-HAQ will be used to evaluate patients overall global health assessment, Pain VAS (Visual Analogue Scale) and Physical Function assessment.
-The DAS will be used to measure disease activity in RA patients.

A feedback will be collected after three (3) months from the participants to assess whether the counseling technique improved their understanding of the disease.

- State the amount of time required by the individual participant for each phase of the study, with a clear statement of the total duration of the study: 15-20minutes will be required by each participant to fill the questionnaire and to attend the counseling session.

6. Your (the individual participant) role/responsibility in the study:

- Provide accurate information whenever asked.
- Inform the study doctor about any problem/side effects experienced during the study.
- Follow the investigators instruction.
- If you want to discontinue from the study, study doctor to be informed.

7. What are the risks?

- Extra time needing to be spent for the counselling sessions
- Some discomfort and anxiety may be experienced by a few patients while they receive text messages or undergo counselling

8. What are the potential benefits of participating in the study:

You may or may not get benefit from participating in this study. It is possible that you may get better, stay the same, or get worse. If you take part in this study you may help other patients with Rheumatoid Arthritis by contributing to the better understanding of the disease.

9. What are the alternative treatments available:

The alternative is to not participate and standard counselling will be done by the consultant doctor.

10. Cost of participating in the study:

There are no costs related to participation in this study.

11. Compensation for injury:

If a medical problem arises during this research study as a direct result of the study procedure, the study doctor will be responsible for making sure that proper medical care is provided to you. If you suffer any physical/mental injury or illness as a direct result of the properly performed study procedures, sponsorer will reimburse you for reasonable medical expenses that you incur to treat the injury or illness

12. Confidentiality of information:

Information from the study records including your name, address, medical records, results of tests, study results will be kept confidential and will be reviewed only by authorized personnel from the sponsor or their representative, Ethics Committee or regulatory bodies. The data will not be made available to another individual unless you specifically give permission in writing. Information and results from this study may be presented at meetings or published in journals without including your name and personal identifications. No reference will be made in oral or written reports which could link you to the study.

13. New information about the study:

Any new information available during the course of the study will be informed to you if it has relevance to your decision regarding continuing in the study. Results of your participation will be disclosed to you if you indicate your desire for it.

14. Voluntary participation:

Your participation in this study is voluntary; you may decline to participate at any time and you need not give any reason for the same, and such withdrawal shall be without penalty and without loss of benefits to which you are otherwise entitled. If you withdraw from the study prior to its completion, you will receive the usual standard of care for your disease, and your non participation will not have any adverse effects on your subsequent medical treatment or relationship with the treating physician.

If you withdraw from the study before data collection is completed, your data collected until you indicated withdrawal will be used in the study report. Sponsor or the investigator may stop the research or your participation in it at any time for some or other reason without your permission.

15. Whom to contact in case of any questions:

If you have any questions about the informed consent process or your rights as a participant, you may contact the Member Secretary of the Kasturba Medical College and Kasturba Hospital - Institutional Ethics Committee at Room 22, Ground floor, KMC Faculty Rooms, adjacent to KMC Administrative Block, Kasturba Medical College, Manipal - 576104. Phone: 0820 29 33522. Timings: 9 : 00 AM to 5 : 00 PM.

If you have any questions about this form or any study related issue, you may also contact the following person.

Name : Dr. GirishTunga
Address : Department of Pharmacy Practice
Manipal College of Pharmaceutical Sciences
Manipal, Karnataka, 576104

Telephone No: 9880151127

APPENDIX ll b: PIS (KANNADA)

ಭಾಗೀದಾರರ ಮಾಹಿತಿ ಪತ್ರ

ಅಧ್ಯಯನದ ಹೆಸರು: ಸಂಧಿವಾತವಿರುವ ರೋಗಿಗಳಲ್ಲಿ ರೋಗದ ಚಟುವಟಿಕೆ ಮತ್ತು ವಿವಿಧ ಸಮಾಲೋಚನಾ ತಂತ್ರಜ್ಞಾನಗಳ ಬಗ್ಗೆ ಒಂದು ಅಧ್ಯಯನ.

ಅಧ್ಯಯನದ ಸಂಖ್ಯೆ:

ಪ್ರಾಯೋಜಕರು: ಅನ್ವಯಿಸುವುದಿಲ್ಲ.

ಭಾಷೆ: ಕನ್ನಡ

ಮುಖ್ಯ ಸಂಶೋಧಕರು: ಶಬ್ನಮ್ ಅಮರಾಲಿ.

ಹುದ್ದೆ: ವಿದ್ಯಾರ್ಥಿನಿ.

ಆಸ್ಪತ್ರೆ: ಕಸ್ತೂರ್ಬಾ ಆಸ್ಪತ್ರೆ, ಮಣಿಪಾಲ.

ದೂರವಾಣಿ ಸಂಖ್ಯೆ: 9741520873

ದಯವಿಟ್ಟು ಈ ಮಾಹಿತಿ ಪತ್ರವನ್ನು ಜಾಗರೂಕತೆಯಿಂದ ಓದಿರಿ. ನಿಮಗೆ ಇದರಲ್ಲಿನ ಭಾಷೆ ಅಥವಾ ಯಾವುದೇ ಮಾಹಿತಿಗಳು ಅರ್ಥವಾಗದೇ ಇದ್ದಲ್ಲಿ, ದಯವಿಟ್ಟು ಅಧ್ಯಯನಕಾರ ವೈದ್ಯರುಗಳ ಜೊತೆಯಲ್ಲಿ ಚರ್ಚಿಸಿರಿ. ಈ ಅಧ್ಯಯನಲ್ಲಿ ನಿಮ್ಮ ಭಾಗವಹಿಸುವಿಕೆಯು ಐಚ್ಛಿಕವಾಗಿರುತ್ತದೆ. ನೀವು ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಒಪ್ಪಿಗೆ ನೀಡುವ ಮೊದಲು ಅಧ್ಯಯನದ ವಿವರಗಳ ಬಗ್ಗೆ ವಿಚಾರಣೆ ಮಾಡಬಹುದು.

1.ಅಧ್ಯಯನದ ಪ್ರಸ್ತಾವನೆ:

ನಿಮ್ಮನ್ನು ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಆಹ್ವಾಹಿಸುತ್ತಿದ್ದೇವೆ ಏಕೆಂದರೆ, ನಿಮಗೆ ಸಂಧಿವಾತವಿದೆ. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ನಿಮ್ಮ ಚಿಕಿತ್ಸಾ ವೈದ್ಯರು ಸೂಚಿಸಿರುವ ಔಷಧಿಗಳನ್ನು ನೀಡುವಿಕೆಯು ಒಳಗೊಂಡಿರುತ್ತದೆ. ಇದು ಕಾರ್ಯವಿಧಾನಗಳಿರುವ ಒಂದು ಅಧ್ಯಯನವಾಗಿರುತ್ತದೆ.

2. ಅಧ್ಯಯನದ ಉದ್ದೇಶ:

1. ಮೂರು ಸಮಾಲೋಚನಾ ಕಾರ್ಯವಿಧಾನಗಳ ಮೂಲಕ ಮೌಲ್ಯಮಾಪನ ಮಾಡುವುದು ಈ ಅಧ್ಯಯನದ ಉದ್ದೇಶವಾಗಿರುತ್ತದೆ.

2. ಸಂಧಿವಾತವಿರುವ ರೋಗಿಗಳಲ್ಲಿ ಔಷಧಿಯ ಉಪಯೋಗ ಮತ್ತು ರೋಗದ ಚಟುವಟಿಕೆಗಳ ಬಗ್ಗೆ ಅಧ್ಯಯನ ನಡೆಸಲಾಗುವುದು.

3. ಅಧ್ಯಯನದಲ್ಲಿ ಯಾರು ಭಾಗವಹಿಸುವರು:

ಒಳಗಿಡುವ ಮಾನದಂಡ:

- ಸಂಧಿವಾತದ ವರ್ಗೀಕರಣ ಮಾನದಂಡ ಎಸಿಆರ್/ಇಯುಎಲ್ ಎ ಆರ್ 2010ರ ಪ್ರಕಾರ ಸಂಧಿವಾತದ ರೋಗನಿರ್ಣಯವಾಗಿ ಕಸ್ತೂರ್ಬಾ ಆಸ್ಪತ್ರೆ ಮಣಿಪಾಲದ ಸಾಮಾನ್ಯ ಔಷಧಿ ವಿಭಾಗ ಮತ್ತು ಮೂಳೆಚಿಕಿತ್ಸಾ ವಿಭಾಗದಲ್ಲಿ ದಾಖಲಾಗಿರುವ 18 ವರ್ಷ ವಯಸ್ಸಿಗಿಂತ ಮೇಲ್ಪಟ್ಟಿರುವ ಎಲ್ಲಾ ಲಿಂಗದ ರೋಗಿಗಳು ಪಾಲ್ಗೊಳ್ಳುವರು.
- ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳಲು ಇಚ್ಛಿಸಿರುವ ರೋಗಿಗಳು.

ಹೊರಗಿಡುವ ಮಾನದಂಡ:

- ರೋಗ ಇರುವಿಕೆಯು ಖಚಿತವಾಗಿರದ ರೋಗಿಗಳು.
- ಹೆಪೆಟಿಕ್ ಮತ್ತು ಮೂತ್ರಪಿಂಡದ ದೌರ್ಬಲ್ಯವಿರುವವರು.

- ಗರ್ಭಿಣಿಯರು ಮತ್ತು ಹಾಲುಣಿಸುವ ತಾಯಂದಿರು.
- ಎಚ್‌ಐವಿ ಅಥವಾ ಇಮ್ಯುನೋಕಾಂಪ್ರಮೈಸ್ಡ್ ಸ್ವೀಕಾರಾರ್ಹವಲ್ಲದ ಅಪಾಯಗಳಿರುವ ರೋಗಿಗಳು.
- ಔಷಧಿ ವಿಭಾಗ ಮತ್ತು ಮೂಳೆಚಿಕಿತ್ಸಾ ವಿಭಾಗದಲ್ಲಿ ಹೊರತುಪಡಿಸಿ ಇತರೇ ವಿಭಾಗಗಳಲ್ಲಿ ದಾಖಲಾಗಿರುವ ರೋಗಿಗಳು.
- ಸ್ವತ: ಮೊಬೈಲ್ ಫೋನ್ ಅಥವಾ ಡಿಜಿಟಲ್ ಮೀಡಿಯಾ ಗ್ರೂಪ್ ಇಲ್ಲದೇ ಇರುವ ರೋಗಿಗಳು ಪಾಲ್ಗೊಳ್ಳುವಂತಿಲ್ಲ.

4.ಅಧ್ಯಯನದ ಬಗ್ಗೆ ಮಾಹಿತಿ (ಸಂಪೂರ್ಣ):

- ಭಾಗವಹಿಸುವ ರೋಗಿಗಳ ನಿರೀಕ್ಷಿತ ಸಂಖ್ಯೆ: ಮಾದರಿ ಅಳತೆ: ಒಟ್ಟು 294 (ಪ್ರತಿ ಗುಂಪಿನಲ್ಲಿ 98)
- ರೋಗಿಗಳ ಸ್ಕ್ರೀನಿಂಗ್, ಮಾದರಿಗಳನ್ನು ಪಡೆಯುವಿಕೆ, ಈಗ ರೋಗಿಯು ತೆಗೆದುಕೊಳ್ಳುತ್ತಿರುವ ಎಲ್ಲಾ ಔಷಧಿಗಳನ್ನು ನಿಲ್ಲಿಸುವಿಕೆ: ಆನ್ವಯಿಸುವುದಿಲ್ಲ.
- ಪರೀಕ್ಷೆಯ ಔಷಧಿಗಳು/ಪ್ರಮಾಣಿತ ಔಷಧಿಗಳ ರೋಗಿಗಳ ಗುಂಪುಗಳಾಗಿಸುವಿಕೆ: ಆನ್ವಯಿಸುವುದಿಲ್ಲ.
- ಔಷಧಿಗಳ ಪ್ರಮಾಣ, ಕಾಲಾವಧಿ: ಆನ್ವಯಿಸುವುದಿಲ್ಲ.
- ಮಾಹಿತಿಗಳಿಗೆ ಸಂಬಂಧಿಸಿರುವುದನ್ನು ಧ್ವನಿಮುದ್ರಿಸುವುದು ಅಥವಾ ಚಿತ್ರೀಕರಿಸುವುದು:(ಒಂದು ವೇಳೆ ಅನ್ವಯಿಸಿದ್ದಲ್ಲಿ) : ಆನ್ವಯಿಸುವುದಿಲ್ಲ.
- ಒಂದುವೇಳೆ ಅಂಗಾಂಶಗಳನ್ನು ಅಥವಾ ಜೈವಿಕ ಮಾದರಿಗಳನ್ನು ಉಳಿಸಿಕೊಂಡು ಸಂಶೋಧನೆಗೆ ನೀಡಿದ್ದಲ್ಲಿ, ಆ ಅಂಗಾಂಶಗಳನ್ನು ಏನು ಮಾಡಲಾಗಿದೆ ಎಂದು ವಿವರಿಸುವುದು: (ನಿಷ್ಕ್ರೀಯೆಗೊಳಿಸುವಿಕೆಯು ಒಳಗೊಂಡಿರುತ್ತದೆ): ಆನ್ವಯಿಸುವುದಿಲ್ಲ.

5. ಅಧ್ಯಯನದ ಸಂದರ್ಭದಲ್ಲಿ ನಿಮಗೆ ಏನಾಗಬಹುದು:

- ಆಸ್ಪತ್ರೆಗೆ ಎಷ್ಟು ಬಾರಿ ಭೇಟಿ ನೀಡಬೇಕು: ಈ ಅಧ್ಯಯನದ ಅವಧಿಯಲ್ಲಿ 3 ತಿಂಗಳಲ್ಲಿ ಒಮ್ಮೆ ಮಾತ್ರ.
- ಪ್ರತಿ ಬಾರಿಯ ಭೇಟಿಯ ಸಮಯದಲ್ಲಿ ಯಾವ ಮಾಹಿತಿಗಳನ್ನು ಕೇಳಲಾಗುವುದು ಮತ್ತು ನೀಡಲಾಗುವುದು: ರೋಗಿಗಳಿಂದ ಅವರ ಈಗಿನ ರೋಗದ ಬಗ್ಗೆ, ಔಷಧಿಗಳು, ಯಾವುದೇ ಹಿಂದಿನ ವೈದ್ಯಕೀಯ ಚಿಕಿತ್ಸೆಗಳು, ರೋಗದ ಬಗ್ಗೆ ತೆಗೆದುಕೊಂಡಿರುವ ಸಲಹೆಗಳು, ಔಷಧಿ ಮತ್ತು ಜೀವನ ಶೈಲಿಗಳ ಬಗ್ಗೆ ಕೇಳಲಾಗುವುದು. ಎಲ್ಲಾ ರೋಗಿಗಳಿಗೂ ರೋಗಿಗಳ ಮಾಹಿತಿ ಕರಪತ್ರವನ್ನು ನೀಡಲಾಗುವುದು. ಅಂತೆಯೇ ಅವರಿಂದ ಆರೋಗ್ಯದ ಮೌಲ್ಯಮಾಪನದ ಪ್ರಶ್ನಾವಳಿಗಳನ್ನು (ಎಚ್ ಎ ಕ್ಯು) ಭರ್ತಿ ಮಾಡುವಂತೆ ಕೇಳಲಾಗುವುದು.
- ಯಾವ ಶಾರೀರಿಕ ಪರೀಕ್ಷೆಗಳನ್ನು ನಡೆಸಲಾಗುವುದು? ತೆಗೆದುಕೊಳ್ಳುವ ರಕ್ತದ ಪ್ರಮಾಣವು ಒಳಗೊಂಡಂತೆ, ಯಾವ ಪ್ರಯೋಗಾಲಯದ ಪರೀಕ್ಷೆಗಳನ್ನು ನಡೆಸಲಾಗುವುದು– ಚಿಕಿತ್ಸಾ ವೈದ್ಯರ ನಿರ್ದೇಶನಕ್ಕೆ ಅನುಸಾರವಾಗಿ.
- ಔಷಧಿಗಳನ್ನು ನೀಡುವಿಕೆ– ಚಿಕಿತ್ಸಾ ವೈದ್ಯರ ನಿರ್ದೇಶನಕ್ಕೆ ಅನುಸಾರವಾಗಿ.
- ಯಾವುದೇ ಪ್ರಶ್ನಾವಳಿಗಳನ್ನು ನೀಡಲಾಗುವುದೇ–ಹೌದು (ಎಚ್ ಎ ಕ್ಯು)
- ಎರಡೂ ಭಾಗದವರಿಗೆ ಯಾದೃಚ್ಛಿತವಾಗಿ ಪ್ರಯೋಗದ ವಿವರಗಳನ್ನು ವಿವರಿಸಲಾಗುತ್ತದೆ.

  ರೋಗಿಗಳನ್ನು ಯಾದೃಚ್ಛಿತವಾಗಿ 3 ಗುಂಪುಗಳಲ್ಲಿ ವರ್ಗೀಕರಿಸಲಾಗುವುದು.ಹಾಗೂ ಬೇರೆ ಬೇರೆ ಮೂರು ಸಮಾಲೋಚನಾ ತಂತ್ರಜ್ಞಾನಗಳನ್ನು ಪಡೆಯಲಾಗುವುದು.–ಯಾದೃಚ್ಛಿತ ನಿಯಂತ್ರಣಾ ಪ್ರಯೋಗ.

ಅಧ್ಯಯನದ ಸಮಯದಲ್ಲಿ ರೋಗಿಗಳಿಗೆ ನಂತರದ ಸುಧಾರಣೆಗಾಗಿ ಕರಪತ್ರಗಳನ್ನು ನೀಡಲಾಗುವುದು ಮತ್ತು ಅದನ್ನು ಸ್ಥಳೀಯ ಭಾಷೆಯಲ್ಲಿ ಭಾಷಾಂತರಿಸಿರಲಾಗುವುದು.

ರೋಗಿಗಳ ಆದ್ಯತೆಗೆ ಅನುಸಾರವಾಗಿ ವಿವಿಧ ಸಮಾಲೋಚನಾ ತಂತ್ರಜ್ಞಾನಗಳಿಂದ ಮೌಲ್ಯಮಾಪನ ಮಾಡಲಾಗುವುದು.

- **ಗುಂಪು 1** ರೋಗಿಯು ಅವರ ಔಷಧಿಯ ಬಗ್ಗೆ ಇರುವ ಸಾಮಾನ್ಯ ಸಲಹೆಗಳನ್ನು ಸ್ವೀಕರಿಸಬೇಕು.

- **ಗುಂಪು 2**– ಔಷಧಿ ಮತ್ತು ಜೀವನ ಶೈಲಿಗಳ ಬಗ್ಗೆ ಸಲಹೆಗಳನ್ನು ಸ್ವೀಕರಿಸಬೇಕು.
- **ಗುಂಪು 3**– ಗುಂಪು 2ರೊಂದಿಗೆ ಸಲಹೆಗಳನ್ನು ನೀಡುವುದರ ಜೊತೆಗೆ ಮತ್ತು ಆಕ್ಷರಸಂದೇಶಗಳು ಅಥವಾ ವಾಟ್ಸಪ್ ಸಂದೇಶಗಳ ಮೂಲಕ ನೀಡಲಾಗುವುದು.

ರೋಗಿಗಳ ಗುಂಪು ಲೆಕ್ಕಿಸದೆ:

ಎಚ್ ಎ ಕ್ಯು ಪ್ರಶ್ನಾವಳಿಗಳನ್ನು ಉಪಯೋಗಿಸಿ ಒಟ್ಟಾರೆ ಜಾಗತಿಕ ಆರೋಗ್ಯ ಮೌಲ್ಯಮಾಪನಗಳನ್ನು, ವಿ ಎ ಎಸ್ ನೋವು (ದೃಷ್ಟಿ ಮೂಲಕ ಮಾಪನ), ಮತ್ತು ಶಾರೀರಿಕ ಕಾರ್ಯನಿರ್ವಹಣೆಯ ಮೌಲ್ಯಮಾಪನಗಳನ್ನು ನಿರ್ಣಯಿಸಲಾಗುವುದು.
–ಸಂಧಿವಾತದ ರೋಗಿಗಳ ರೋಗದ ಚಟುವಟಿಕೆಗಳನ್ನು ಡಿಎಎಸ್ ಉಪಯೋಗಿಸಿ ಮಾಪನ ಮಾಡಲಾಗುವುದು.
ಭಾಗೀದಾರರು ಸಮಾಲೋಚನೆಯ ತಂತ್ರಜ್ಞಾನದ ಮೂಲಕ ಸುಧಾರಣೆಯಾಗಿ ಅವರ ರೋಗವನ್ನು ಅರ್ಥೈಸಿಕೊಂಡಿರುವ ಬಗ್ಗೆ ಮೂರು (3) ತಿಂಗಳ ನಂತರ ಪ್ರತಿಕ್ರಿಯೆಯನ್ನು ಸಂಗ್ರಹಿಸಲಾಗುವುದು.

ಅಧ್ಯಯನದ ಪ್ರತಿಯೊಂದು ಹಂತದಲ್ಲೂ ಭಾಗೀದಾರರಿಗೆ ವೈಯಕ್ತಿಕವಾಗಿ ಎಷ್ಟು ಸಮಯ ಬೇಕಾಗುವುದು ಎಂಬ ಬಗ್ಗೆ ಹಾಗೂ

- ಒಟ್ಟು ಅಧ್ಯಯನದ ಕಾಲವಧಿಯ ಬಗ್ಗೆ ಸರಳವಾಗಿ ತಿಳಿಸುವುದು: ಸಮಾಲೋಚನೆಯಲ್ಲಿ ಭಾಗವಹಿಸುವ ಪ್ರತಿಯೊಬ್ಬ ಭಾಗೀದಾರರು ಪ್ರಶ್ನಾವಳಿಯನ್ನು ಭರ್ತಿ ಮಾಡಲು 15 ರಿಂದ 20 ನಿಮಿಷಗಳನ್ನು ನೀಡುವ ಅವಶ್ಯಕತೆ ಇರುತ್ತದೆ.

6. ನಿಮ್ಮ ಜವಾಬ್ಧಾರಿ/ಪಾತ್ರ:

- ಕೇಳಲಾದ ವಿಷಯಕ್ಕೆ ಸರಿಯಾದ ಉತ್ತರವನ್ನು ಕೊಡಬೇಕಾಗುವುದು.
- ನಿಮಗೇನಾದರೂ ತೊಂದರೆ/ವ್ಯತಿರಿಕ್ತ ಪರಿಣಾಮದ ಅನುಭವವಾದಲ್ಲಿ ಅಧ್ಯಯನಕಾರ ವೈದ್ಯರಲ್ಲಿ ತಿಳಿಸಬೇಕಾಗುವುದು.
- ಸಂಶೋಧನಾಕಾರ ಸಲಹೆ ಸೂಚನೆಯನ್ನು ಪಾಲಿಸಬೇಕಾಗುವುದು.
- ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವಿಕೆಯನ್ನು ನಿಲ್ಲಿಸುವುದಿದ್ದಲ್ಲಿ ಸಂಶೋಧನಾಕಾರರಲ್ಲಿ ತಿಳಿಸಬೇಕಾಗುವುದು.

7. ಅಪಾಯಗಳಾವುವು?.

ಅನ್ವಯಿಸುವುದಿಲ್ಲ.

8. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಪಾಲ್ಗೊಳ್ಳುವುದರಿಂದ ಆಗಬಹುದಾದ ಸಂಭಾವ್ಯ ಪ್ರಯೋಜನಗಳು:

ನೀವು ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವುದರಿಂದ ಪ್ರಯೋಜನವನ್ನು ಪಡೆಯಬಹುದು ಅಥವಾ ಪಡೆಯದಿರಲೂಬಹುದು. ನೀವು ಗುಣಮುಖರಾಗಬಹುದು, ಹಾಗೇ ಇರಬಹುದು ಅಥವಾ ಇನ್ನೂ ಹೆಚ್ಚಾಗುವ ಸಾಧ್ಯತೆಗಳಿರುತ್ತದೆ. ಒಂದುವೇಳೆ ನೀವು ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಿದರೆ, ನೀವು ಇತರೇ ಸಂಧಿವಾತ ಇರುವ ರೋಗಿಗಳಿಗೆ ರೋಗದ ಬಗ್ಗೆ ಉತ್ತಮ ರೀತಿಯಲ್ಲಿ ತಿಳುವಳಿಕೆ ಪಡೆಯಲು ಸಹಾಯ ಮಾಡಿದಂತಾಗುತ್ತದೆ.

9.ಯಾವ ಯಾವ ಪರ್ಯಾಯ ಚಿಕಿತ್ಸೆಗಳು ಲಭ್ಯ ಇವೆ?.

ಪರ್ಯಾಯ ಚಿಕಿತ್ಸೆಗಳ ಬಗ್ಗೆ ನಿಮ್ಮ ಚಿಕಿತ್ಸಾ ವೈದ್ಯರು ನಿರ್ದರಿಸುತ್ತಾರೆ.

10. ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗಿಯಾಗುವುದರಿಂದ ತಗಲುವ ವೆಚ್ಚ:

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವಿಕೆಗೆ ಹಣ ಪಾವತಿಸಬೇಕಾಗಿಲ್ಲ.

11. ಗಾಯ/ತೊಂದರೆಗೆ ಪರಿಹಾರ.

ಅನ್ವಯಿಸುವುದಿಲ್ಲ.

12. ಮಾಹಿತಿಯ ಗೌಪ್ಯತೆ:

ಈ ಅಧ್ಯಯನದ ಮಾಹಿತಿ ಪ್ರತಿಯಲ್ಲಿ ನಿಮ್ಮ ಹೆಸರು, ವಿಳಾಸ, ವೈದ್ಯಕೀಯ ಸಂಗತಿ, ತಪಾಸಣೆಯ ಫಲಿತಾಂಶಗಳಿರುತ್ತವೆ. ಇವುಗಳನ್ನು ಗೌಪ್ಯವಾಗಿ ಇರಿಸಲಾಗುವುದು. ಈ ಅಧ್ಯಯನಕ್ಕೆ ಸಂಬಂಧಪಟ್ಟ ಸಂಶೋಧಕರು, ಸಂಘದ ನೈತಿಕ ಸಮಿತಿ ಪ್ರಮುಖರು ಅಥವಾ ನಿಯಂತ್ರಕ ಸಂಸ್ಥೆಯವರು ಪರಿಶೀಲಿಸುವರು ಇದರಲ್ಲಿನ ವೈಯಕ್ತಿಕ ಡಾಟಾಗಳನ್ನು ನಿಮ್ಮ ಲಿಖಿತ ಅನುಮತಿ ಇಲ್ಲದೇ ಅನ್ಯ ವ್ಯಕ್ತಿಗಳಿಗೆ ನೀಡಲಾಗುವುದಿಲ್ಲ. ಅದರ ಫಲಿತಾಂಶ ಹಾಗು ಮಾಹಿತಿಗಳನ್ನು ನಿಮ್ಮ ವೈಯಕ್ತಿಕ ಗುರುತು, ಹೆಸರು, ವಿಳಾಸಗಳಾವುದನ್ನೂ ತಿಳಿಯಪಡಿಸದೆ ಪ್ರಕಟಿಸಲೂಬಹುದು. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಯಾವುದೇ ರೀತಿಯ ಮೌಖಿಕ ಮತ್ತು ಲಿಖಿತ ಬರವಣಿಗೆಯ ವಿವರಣೆಗಳು ಅವಲಂಬನೆಯಾಗಿರುವುದಿಲ್ಲ.

13.ಅಧ್ಯಯನದ ಬಗ್ಗೆ ಹೊಸ ಮಾಹಿತಿ.

ಈ ಅಧ್ಯಯನದ ಅಭ್ಯಾಸದ ಸಮಯದಲ್ಲಿ ಯಾವುದೇ ಹೊಸ ಮಾಹಿತಿಗಳು ಕಂಡುಬಂದಲ್ಲಿ ಅಭ್ಯಾಸ ಮುಂದುವರಿಸುವ ಬಗ್ಗೆ ನಿಮಗೆ ನಿರ್ಣಯಗಳನ್ನು ತಿಳಿಸಲಾಗುವುದು. ಈ ಅಧ್ಯಯನದ ಫಲಿತಾಂಶಗಳನ್ನು ಪಡೆಯಲು ನೀವು ಇಚ್ಛಿಸಿದಲ್ಲಿ, ಅದನ್ನು ನಿಮಗೆ ನೀಡಲಾಗುತ್ತದೆ.

14. ಐಚ್ಛಿಕವಾಗಿ ಭಾಗವಹಿಸುವಿಕೆ:

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ನಿಮ್ಮ ಭಾಗವಹಿಸುವಿಕೆಯು ಐಚ್ಛಿಕವಾಗಿದ್ದು, ನೀವು ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಸಮ್ಮತಿಸಿದರೂ ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ನಿಮ್ಮ ಸಮ್ಮತಿಯನ್ನು ಹಿಂತೆಗೆದುಕೊಳ್ಳಬಹುದು. ಹಾಗು ಇದಕ್ಕೆ ಯಾವುದೇ ಕಾರಣ ನೀಡಬೇಕಾಗಿಲ್ಲ. ಇದಕ್ಕಾಗಿ ನಿಮಗೆ ಯಾವುದೇ ದಂಡವಿಲ್ಲ ಮತ್ತು ಸಿಗಬಹುದಾದ ಪ್ರಯೋಜನ/ನಷ್ಟವಿಲ್ಲ. ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸುವ ಮೊದಲು ಹೊರಬಂದರೆ ನಿಮಗೆ ಯಾವುದೇ ಚಿಕಿತ್ಸೆಗೆ ತೊಂದರೆಯಾಗುವುದಿಲ್ಲ. ನಿಮ್ಮ ಮುಂದಿನ ಚಿಕಿತ್ಸೆಯ ಮೇಲೆ ಯಾವ ಅಡ್ಡ ಪರಿಣಾಮ ಬೀರುವುದಿಲ್ಲ ಅಥವಾ ನಿಮ್ಮ ವೈದ್ಯರೊಂದಿಗಿನ ಸಂಬಂಧಕ್ಕೆ ಯಾವುದೇ ತೊಂದರೆ ಇರುವುದಿಲ್ಲ.

ಅಧ್ಯಯನ ಪೂರ್ಣಗೊಳಿಸುವ ಮೊದಲು ನೀವು ಹಿಂದೆ ಸರಿದರೆ ನೀವು ಅಧ್ಯಯನದಿಂದ ಹಿಂದೆ ಸರಿಯುವ ಮೊದಲು ಸಂಗ್ರಹಿಸಿದ ಮಾಹಿತಿಯನ್ನು ಅಧ್ಯಯನದ ವರದಿಯಲ್ಲಿ ಉಪಯೋಗಿಸಲಾಗುವುದು. ಪ್ರಾಯೋಜಕರು ಅಥವಾ ಅಧ್ಯಯನಕಾರರು ಯಾವುದೇ ಸಮಯದಲ್ಲಿ ಅವರ ಅಧ್ಯಯನವನ್ನು ಅಥವಾ ನಿಮ್ಮ ಭಾಗವಹಿಸುವಿಕೆಯನ್ನು ಒಂದಲ್ಲ ಒಂದು ಕಾರಣಕ್ಕಾಗಿ ನಿಮ್ಮ ಅನುಮತಿ ಇಲ್ಲದೆಯೇ ನಿಲ್ಲಿಸಬಹುದು.

15.ಒಂದು ವೇಳೆ ಪ್ರಶ್ನೆಗಳೇನಾದರೂ ಇದ್ದಲ್ಲಿ, ಯಾರನ್ನು ಸಂಪರ್ಕಿಸಬಹುದು.

ನಿಮಗೆ ಏನಾದರೂ ಪ್ರತಿಕೂಲ ತೊಂದರೆಗಳು ಅಧ್ಯಯನದ ಸಮಯದಲ್ಲಿ ಕಂಡುಬಂದಲ್ಲಿ ಕೂಡಲೇ ಮುಖ್ಯ ಸಂಶೋಧನಾಕಾರ ಶಬ್ನಮ್ ಅಮರಾಲಿ.ಯವರನ್ನು ಸಂಪರ್ಕಿಸಬಹುದು.

ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಿಹಿಸುವಿಕೆಯ ಒಪ್ಪಿಗೆ ಸಮಯದಲ್ಲಿ ಅಧ್ಯಯನಕಾರರಲ್ಲಿ ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳುವ ಹಕ್ಕಿರುತ್ತದೆ. ಹಾಗಿದ್ದಲ್ಲಿ,ನಿಮಗೆ ಸದಸ್ಯ ಕಾರ್ಯದರ್ಶಿಗಳು, ಕಸ್ತೂರ್ಬಾ ಮೆಡಿಕಲ್ ಕಾಲೇಜು, ಮಣಿಪಾಲದ ನೈತಿಕ ಸಮಿತಿ ಸಂಸ್ಥೆಯ ಕೊಠಡಿ ಸಂಖ್ಯೆ 22, ನೆಲಮಹಡಿ, ಕೆ.ಎಮ್.ಸಿ. ಸಿಬ್ಬಂದಿಗಳ ಕೊಠಡಿ, ಕೆ.ಎಮ್.ಸಿ ಆಡಳಿತ ವಿಭಾಗ ಕಛೇರಿಯ ಪಕ್ಕ, ಕಸ್ತೂರ್ಬಾ ಮೆಡಿಕಲ್ ಕಾಲೇಜು, ಮಣಿಪಾಲ–576 104 ಇವರು ವಿವರಗಳನ್ನು ನೀಡುತ್ತಾರೆ.

ದೂರವಾಣಿ ಸಂಖ್ಯೆ: 0820 2933522 ಸಮಯ: 9:00ಬೆಳಿಗ್ಗೆ. 5:00ಸಂಜೆ.

ಈ ಅಧ್ಯಯನದ ಬಗ್ಗೆ ಯಾವುದಾದರೂ ಪ್ರಶ್ನೆ ಅಥವಾ ಸಂಬಂದಿಸಿದ ವಿಷಯಗಳಿದ್ದಲ್ಲಿ ಈ ಕೆಳಗೆ ತಿಳಿಸಿದ ವ್ಯಕ್ತಿಗಳನ್ನು ಸಂಪರ್ಕಿಸಬಹುದು.

ಹೆಸರು: ಡಾ: ಗಿರೀಶ್ ತುಂಗಾ.
ವಿಳಾಸ: ಫಾರ್ಮಸಿ ಪ್ರಾಕ್ಟೀಸ್ ವಿಭಾಗ,
ಎಂ ಸಿ ಓ ಪಿ ಎಸ್, ಮಣಿಪಾಲ. ಕರ್ನಾಟಕ–576 104.
ದೂರವಾಣಿ ಸಂಖ್ಯೆ: 9880151127

APPENDIX III a: ICF (ENGLISH)

INFORMED CONSENT FORM

Project title: To study Disease Activity and various Counselling techniques in Rheumatoid Arthritis patients

I confirm I have read the Participant Information Sheet for the above study and its contents were explained and I have had the opportunity to ask questions and received satisfactory answers.

I understand that my participation in the study is voluntary and that I have the right to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

I agree to take part in the above study. I confirm that I have received a copy of the Participant Information Sheet along with this signed and dated informed consent form.

Name of the Research Participant :

Age of the Research Participant :

Address of the Research Participant :

Occupation :

Annual Income of the Participant :

Name & address of the nominee(s) and his relation to the Participant :

_____

_____ _____
Signature of the research subject Date

_____ _____
Name & Signature of the witness Date

_____ _____
Name & Signature of the person explaining the consent Date

APPENDIX lll b: ICF (KANNADA)

ಮಾಹಿತಿ ಒಪ್ಪಿಗೆ ಪತ್ರ

ಅಧ್ಯಯನದ ಹೆಸರು: ಶ್ವಾಸನಾಳದ ಆಸ್ತಮಾಕ್ಕೆ ಆಯುರ್ವೇದ ಮತ್ತು ಸಾಂಪ್ರದಾಯಿಕ ಚಿಕಿತ್ಸೆಗಳಲ್ಲಿ ಔಷಧ ಬಳಕೆಯ ಪರಿಣಾಮಗಳ ಪರಸ್ಪರ ತುಲನಾ ಅಧ್ಯಯನ.

ನಾನು ಈ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗೀದಾರರ ಮಾಹಿತಿ ಪತ್ರವನ್ನು ಓದಿ ತಿಳಿದುಕೊಂಡಿರುತ್ತೇನೆ. ಮತ್ತು ಅದರಲ್ಲಿನ ಮಾಹಿತಿಗಳನ್ನು ನನಗೆ ವಿವರಿಸಲಾಗಿದೆ. ನನಗೆ ಪ್ರಶ್ನೆಗಳನ್ನು ಕೇಳಲು ಅವಕಾಶ ನೀಡಲಾಗಿದ್ದು, ಅವುಗಳಿಗೆ ಸಮಾಧಾನಕರವಾದ ಉತ್ತರಗಳು ಲಭಿಸಿವೆ ಎಂದು ದೃಢೀಕರಿಸುತ್ತೇನೆ.

ಈ ಅಧ್ಯಯನದಲ್ಲಿನನ್ನ ಭಾಗವಹಿಸುವಿಕೆಯು ಐಚ್ಛಿಕವಾಗಿದ್ದು, ನನಗೆ ಯಾವುದೇ ಸಮಯದಲ್ಲಿ, ಯಾವುದೇ ಕಾರಣವಿಲ್ಲದೆ ವೈಯಕ್ತಿಕವಾಗಿ ಭಾಗಹಿಸುವಿಕೆಯಿಂದ ಹಿಂದೆ ಸರಿಯುವ ಹಕ್ಕಿದೆ. ಈ ನಿರ್ಣಯವು ಮುಂದಿನ ವೈದ್ಯಕೀಯ ತಪಾಸಣೆಗೆ, ಕಾನೂನು ಹಕ್ಕಿಗೆ ಯಾವುದೇ ತೊಂದರೆಯಾಗುವುದಿಲ್ಲವೆಂದು ತಿಳಿದಿರುತ್ತೇನೆ.

ನಾನು ಮೇಲೆ ತಿಳಿಸಿದ ಅಧ್ಯಯನದಲ್ಲಿ ಭಾಗವಹಿಸಲು ಒಪ್ಪಿಕೊಂಡಿದ್ದು ಹಾಗೂ ನಾನು ಸಹಿ ಮಾಡಿದ ಮಾಹಿತಿ ಒಪ್ಪಿಗೆ ಪ್ರತಿಯನ್ನು ಈ ಕೆಳಗಿನ ದಿನಾಂಕದಂದು ಸ್ವೀಕರಿಸಿರುವೆನೆಂದು ದೃಢೀಕರಿಸುತ್ತೇನೆ.

ಭಾಗವಹಿಸುವವರ ಹೆಸರು:

ಭಾಗವಹಿಸುವವರ ವಯಸ್ಸು:

ಭಾಗವಹಿಸುವವರ ವಿಳಾಸ:

ಉದ್ಯೋಗ:

ಭಾಗವಹಿಸುವವರ ವಾರ್ಷಿಕ ಆದಾಯ:

ನೊಮಿನಿಯ(ರ) ಹೆಸರು ಮತ್ತು ವಿಳಾಸ ಮತ್ತು ಭಾಗವಹಿಸುವವರ ಜೊತೆಗೆ ಇರುವ ಸಂಬಂಧ :

_____	_____
ಭಾಗವಹಿಸುವವರ ಸಹಿ	ದಿನಾಂಕ
_____	_____
ಸಾಕ್ಷಿಯ ಹೆಸರು ಮತ್ತು ಸಹಿ	ದಿನಾಂಕ
_____	_____
ಒಪ್ಪಿಗೆ ವಿವರಿಸುವ ವ್ಯಕ್ತಿಯ ಹೆಸರು ಮತ್ತು ಸಹಿ	ದಿನಾಂಕ

APPENDIX IV : CRF

CASE RECORD FORM (CRF)

STUDY: To study disease activity and various counseling techniques in Rheumatoid Arthritis patients

DEPARTMENT OF PHARMACY PRACTICE, MCOPS
KASTURBA HOSPITAL, MANIPAL

HOSP. NO: **SEX: M/F:** **AGE:** **WEIGHT:** **HEIGHT:** **BMI:**	**DOA:** **DOD:**

COMPLAINTS ON ADMISSION:

MEDICAL HISTORY:
DURATION OF RA:
MEDICATION HISTORY:

MORNING STIFFNESS (hrs):
SOCIAL HISTORY: ALCOHOLIC: **SMOKER:**
EDUCATION: **OCCUPATION:**
FAMILY HISTORY:
CO-MORBITIES:
SURGERY:

PHYSICAL EXAMINATION:	**DAS28 CALCULATOR:**
GENERAL:	Tender Joint Count (0-28):
VITAL SIGN: BP: PR: RR: TEMP:	Swollen Joint Count (0-28):
JOINT INVOLVEMENT/ DEFORMITIES:	ESR (mm/hr):
	VAS general health patient (mm):
	DAS28:
FATIGUE:	
RHEUMATOID NODULES:	

ROUTINE BIOCHEMICAL INVESTIGATIONS

UREA:	TP:	Alb:	
S.Cr:	T.Bili:	Glob:	
Na:	D.Bili:	AST:	
K:	ANA:	ALT:	
Ca:	Rheumatoid Factor:	ALP:	
Uric acid:	IL-6:	HDL:	
FBS:	T3:	LDL:	
RBS:	T4:	TG:	
PPBS:	TSH:	Tch:	

HAEMATOLOGY:

RBC:	Hb:
WBC:	HCT:
N:	MCH:
L:	MCHC:
M:	MCV:
E:	ESR:
B:	Platelets:
PT:	INR:
APTT:	RDW:

FINAL DIAGNOSIS:

SPECIAL INESTIGATIONS:

CORTISOL LEVELS:	PHOSPHORUS:
X-RAY:	PHOSPHATE:
BONE DENSITOMETRY:	TC/HDL:
VIT D:	Gly Hb:
	Anti CCP:

DRUG WITH DOSE, ROUTE & FREQUENCY												INVESTIGATIONS
GENERIC NAME	BRAND NAME	1	2	3	4	5	6	7	8	9	10	

DISCHARGE MEDICATION & FOLLOW UP:	RADIOLOGICAL CHANGES:
1. **2.** **3.** **4.** **5.** **6.** **7.** **8.** **9.** **10.**	1. Destructive changes 2. Erosions 3.Periarticular osteoporosis **COMMENTS:**

APPENDIX Va: Health Assessment Questionnaire

SMRC
Self-Management
Resource Center

Stanford HAQ 20-Item Disability Scale

Please check (✓) the **one** best answer for your abilities over the **past week.**

At this moment, are you able to:	**Without ANY difficulty**	**With SOME difficulty**	**With MUCH difficulty**	**UNABLE to do**
DRESSING & GROOMING				
1. Dress yourself, including shoelaces and buttons?	❑	❑	❑	❑
2. Shampoo your hair?	❑	❑	❑	❑
ARISING				
3. Stand up from an armless straight chair?	❑	❑	❑	❑
4. Get in and out of bed?	❑	❑	❑	❑
EATING				
5. Cut your meat?	❑	❑	❑	❑
6. Lift a full cup or glass to your mouth?	❑	❑	❑	❑
7. Open a new milk carton?	❑	❑	❑	❑
WALKING				
8. Walk outdoors on flat ground?	❑	❑	❑	❑
9. Climb up five steps?	❑	❑	❑	❑

Please check any AIDS OR DEVICES that you usually use for any of the above activities:

- ❑ Devices used for dressing (button hook, zipper pull, etc.)
- ❑ Special or built up chair
- ❑ Built up or special utensils
- ❑ Cane
- ❑ Walker
- ❑ Crutches
- ❑ Wheelchair

Please check any categories for which you usually need HELP FROM ANOTHER PERSON:

- ❑ Dressing and grooming
- ❑ Eating
- ❑ Arising
- ❑ Walking

Please check (✓) the **one** best answer for your abilities over the **past week.**

At this moment, are you able to:	**Without ANY difficulty**	**With SOME difficulty**	**With MUCH difficulty**	**UNABLE to do**
HYGIENE				
10. Wash and dry your body?	❑	❑	❑	❑
11. Take a tub bath	❑	❑	❑	❑
12. Get on and off the toilet?	❑	❑	❑	❑
REACH				
13. Reach and get down a 5-pound object (such as a bag of sugar) from just above your head?	❑	❑	❑	❑
14. Bend down to pick up clothing from the floor?	❑	❑	❑	❑
GRIP				
15. Open car doors?	❑	❑	❑	❑
16. Open previously opened jars?	❑	❑	❑	❑
17. Turn faucets on and off?	❑	❑	❑	❑
ACTIVITIES				
18. Run errands and shop?	❑	❑	❑	❑
19. Get in and out of a car?	❑	❑	❑	❑
20. Do chores such as vacuuming or yard work?	❑	❑	❑	❑

Please check any AIDS OR DEVICES that you usually use for any of the above activities:

- ❑ Raised toilet seat
- ❑ Bathtub seat
- ❑ Bathtub bar
- ❑ Long-handled appliances in the bathroom
- ❑ Long-handled appliances for reach
- ❑ Jar opener (for jars previously opened)

Please check any categories for which you usually need HELP FROM ANOTHER PERSON:

- ❑ Hygiene
- ❑ Reach
- ❑ Gripping and opening things
- ❑ Errands and chores

APPENDIX V b: Health Assessment Questionnaire

Kannada

SMRC
Self-Management
Resource Center

ಸ್ಟಾಂಡ್ ಫಾರ್ಡ್ ಎಚ್ಎಕ್ಯು 20- ಅಸಾಮರ್ಥ್ಯದ ವಿಧಗಳ ಮಾಪನ

ದಯವಿಟ್ಟು ಕಳೆದ ವಾರದಲ್ಲಿನ ನಿಮ್ಮ ಸಾಮರ್ಥ್ಯದ ಮೇಲೆ ಉತ್ತಮವಾದ ಒಂದು ಉತ್ತರವನ್ನು (✓)ಮೂಲಕ ಗುರುತು ಮಾಡಿರಿ.

ಈ ಸಮಯದಲ್ಲಿ, ನಿಮಗೆ ಸಾಧ್ಯವಿದೆಯೇ?	**ಯಾವುದೇ ಕಷ್ಟವಿಲ್ಲ**	**ಸ್ವಲ್ಪ ಕಷ್ಟವಿದೆ**	**ತುಂಬಾ ಕಷ್ಟವಿದೆ**	**ಮಾಡಲು ಸಾಧ್ಯವಿಲ್ಲ**
ಬಟ್ಟೆ ಧರಿಸುವಿಕೆ ಮತ್ತು ಸಿಂಗರಿಸಿಕೊಳ್ಳುವಿಕೆ.				
1.ನೀವು ಸ್ವತ: ಬಟ್ಟೆ ಧರಿಸಿಕೊಳ್ಳುವುದು, ಶೂ ಲೇಸ್ ಕಟ್ಟುವಿಕೆ – ಮತ್ತು ಗುಂಡಿ ಹಾಕುವಿಕೆಯು ಒಳಗೊಂಡಿರುವುದು.?.	☐	☐	☐	☐
2. ನಿಮ್ಮ ತಲೆಕೂದಲಿಗೆ ಶಾಂಪೂ ಹಾಕುವುದು.?.....	☐	☐	☐	☐
ಮೇಲೇಳುವಿಕೆ.				
3. ಕೈಗಳಿಲ್ಲದ ಕುರ್ಚಿಯಿಂದ ಮೇಲೆ ಎದ್ದು ನಿಲ್ಲುವುದು?.....	☐	☐	☐	☐
4. ಹಾಸಿಗೆಯಲ್ಲಿ ಮಲಗುವುದು ಮತ್ತು ಮೇಲೇಳುವುದು?.....	☐	☐	☐	☐
ತಿನ್ನುವಿಕೆ.				
5. ನಿಮ್ಮ ಊಟದಲ್ಲಿನ ಮಾಂಸವನ್ನು ತುಂಡು ಮಾಡುವುದು.?.....	☐	☐	☐	☐
6. ತುಂಬಿರುವ ನೀರಿನ ಲೋಟವನ್ನು ಎತ್ತುವುದು ಅಥವಾ ಲೋಟವನ್ನು ನಿಮ್ಮ ಬಾಯಲ್ಲಿರಿಸುವುದು?.....	☐	☐	☐	☐
7. ಹೊಸದಾಗಿ ಹಾಲಿನ ಪೊಟ್ಟಣವನ್ನು ತೆರೆಯಿರುವುದು?.....	☐	☐	☐	☐
ನಡೆಯುವಿಕೆ.				
8. ಮನೆಯಿಂದ ಹೊರಗಡೆ ಸಮತಟ್ಟಾದ ಪ್ರದೇಶದಲ್ಲಿ ನಡೆಯುವುದು?..	☐	☐	☐	☐
9. ಐದು ಮೆಟ್ಟಿಲು ಹತ್ತಿ ಮೇಲಕ್ಕೇರುವುದು?.....	☐	☐	☐	☐

ದಯವಿಟ್ಟು ಈ ಮೇಲಿನ ಎಲ್ಲಾ ಚಟುವಟಿಕೆಗಳಿಗೆ ನೀವು ಸಾಮಾನ್ಯವಾಗಿ ಉಪಯೋಗಿಸುವ ಯಾವುದೇ ಸಹಾಯಕ ಅಥವಾ ಸಾಧನಗಳನ್ನು ಗುರುತು ಮಾಡಿರಿ.

- ☐ ಬಟ್ಟೆ ಧರಿಸಲು ಸಾಧನಗಳನ್ನು ಉಪಯೋಗಿಸುವುದು. (ಗುಂಡಿ, ಕೊಂಡಿ ಹಾಕಲು, ಜಿಪ್ ಎಳೆಯಲು, ಇತ್ಯಾದಿ.)
- ☐ ವಿಶೇಷವಾಗಿ ಅಥವಾ ತಯಾರಿಸಿರುವ ಕುರ್ಚಿ
- ☐ ತಯಾರಿಸಿರುವ ಅಥವಾ ವಿಶೇಷವಾದ ಪಾತ್ರೆಗಳು
- ☐ ಕೈದೊಣ್ಣೆ
- ☐ ನಡೆಯುವ ಸಾಧನ
- ☐ ಊರುಗೋಲುಗಳು
- ☐ ಗಾಲಿ ಕುರ್ಚಿ

ದಯವಿಟ್ಟು ನಿಮಗೆ ಯಾವುದೇ ವಿಭಾಗದಲ್ಲಿ ಸಾಮಾನ್ಯವಾಗಿ ಇತರೇ ವ್ಯಕ್ತಿಗಳಿಂದ ಸಹಾಯ ಪಡೆಯುವಿಕೆಯ ಅವಶ್ಯಕತೆ ಇರುತ್ತದೆ ಅದನ್ನು ಗುರುತು ಮಾಡಿರಿ.:

- ☐ ಬಟ್ಟೆ ಧರಿಸಿಕೊಳ್ಳಲು ಮತ್ತು ಸಿಂಗರಿಸಿಕೊಳ್ಳಲು.
- ☐ ತಿನ್ನುವುದಕ್ಕೆ.
- ☐ ಎದ್ದೇಳಲು.
- ☐ ನಡೆಯುವಿಕೆಗೆ.

ದಯವಿಟ್ಟು ಕಳೆದ ವಾರದಲ್ಲಿನ ನಿಮ್ಮ ಸಾಮರ್ಥ್ಯದ ಮೇಲೆ ಉತ್ತಮವಾದ ಒಂದು ಉತ್ತರವನ್ನು (✓) ಮೂಲಕ ಗುರುತು ಮಾಡಿರಿ.

ಈ ಸಮಯದಲ್ಲಿ ನಿಮಗೆ ಸಾಧ್ಯವಿದೆಯೇ?	ಯಾವುದೇ ಕಷ್ಟವಿಲ್ಲ	ಸ್ವಲ್ಪ ಕಷ್ಟವಿದೆ	ತುಂಬಾ ಕಷ್ಟವಿದೆ	ಮಾಡಲು ಸಾಧ್ಯವಿಲ್ಲ
ನೈರ್ಮಲ್ಯತೆ.				
10. ತೊಳೆಯಲು ಮತ್ತು ದೇಹವನ್ನು ಒಣಗಿಸಿಕೊಳ್ಳಲು.?....	☐	☐	☐	☐
11. ಸ್ನಾನದ ತೊಟ್ಟಿಯಲ್ಲಿ ಸ್ನಾನ ಮಾಡಲು.....	☐	☐	☐	☐
12. ಕಕ್ಕಸ್ಸು ತೆರೆಯಲು ಮತ್ತು ಮುಚ್ಚಲು?.....	☐	☐	☐	☐
ತಲುಪುವಿಕೆ.				
13. ನಿಮ್ಮ ತಲೆಯಿಂದ ಸ್ವಲ್ಪ ಮೇಲಿನ ಜಾಗದಲ್ಲಿ 5 ಪೌಂಡ್... ಭಾರದ ವಸ್ತುವನ್ನು (ಸಕ್ಕರೆಯ ಚೀಲದಂತಹ) ಮೇಲಿರಿಸಲು ಮತ್ತು ಕೆಳಗಿಳಿಸಲು?.	☐	☐	☐	☐
14. ನೆಲದ ಮೇಲೆ ಇರುವ ಬಟ್ಟೆಯನ್ನು ಬಗ್ಗಿ ಮೇಲೆತ್ತಿಕೊಳ್ಳಲು?...	☐	☐	☐	☐
ಹಿಡಿತ.				
15. ಕಾರಿನ ಬಾಗಿಲನ್ನು ತೆರೆಯಲು.?.....	☐	☐	☐	☐
16. ಈ ಹಿಂದೆ ತೆರೆದಿದ್ದ ಭರಣಿಯ ಮುಚ್ಚಳ ತೆರೆಯಲು?.....	☐	☐	☐	☐
17. ನಳ್ಳಿಯನ್ನು ತೆರೆಯಲು ಮತ್ತು ನಿಲ್ಲಿಸಲು?.....	☐	☐	☐	☐
ಚಟುವಟಿಕೆಗಳು.				
18. ಆಚೀಚೆ ತಿರುಗಾಡುವುದು ಮತ್ತು ನಿಲ್ಲುವುದು?.....	☐	☐	☐	☐
19. ಕಾರಿನ ಒಳಗೆ ಹೋಗುವುದು ಮತ್ತು ಹೊರಬರುವುದು.?.....	☐	☐	☐	☐
20. ಮನೆಯನ್ನು ಸ್ವಚ್ಛಮಾಡುವ ಅಥವಾ ತೋಟದ ಕೆಲಸ?.....	☐	☐	☐	☐

ದಯವಿಟ್ಟು ಈ ಮೇಲಿನ ಎಲ್ಲಾ ಚಟುವಟಿಕೆಗಳಿಗೆ ನೀವು ಸಾಮಾನ್ಯವಾಗಿ ಉಪಯೋಗಿಸುವ ಯಾವುದೇ ಸಹಾಯಕ ಅಥವಾ ಸಾಧನಗಳನ್ನು ಗುರುತು ಮಾಡಿರಿ.

☐ ಕಕ್ಕಸಿನಿಂದ ಮೇಲಕ್ಕೇಳಲು.
☐ ಸ್ನಾನದ ತೊಟ್ಟಿಯಲ್ಲಿನ ಹಿಡಿ.
☐ ನಡೆದು ತಲುಪಲು ಉದ್ದನೆಯ ಹಿಡಿಯಿರುವ ವಸ್ತುಗಳು.
☐ ಸ್ನಾನದ ತೊಟ್ಟಿಯಲ್ಲಿ ಕುಳಿತುಕೊಳ್ಳಲು.
☐ ಸ್ನಾನಗೃಹದಲ್ಲಿ ಉದ್ದನೆಯ ಹಿಡಿಯಿರುವ ವಸ್ತುಗಳು.
☐ ಭರಣಿ ಮುಚ್ಚಳ ತೆರೆಯಲು (ಈ ಹಿಂದೆಯೇ ಮುಚ್ಚಳ ತೆರೆದಿರುವ ಭರಣಿ)

ದಯವಿಟ್ಟು ನಿಮಗೆ ಯಾವುದೇ ವಿಭಾಗದಲ್ಲಿ ಸಾಮಾನ್ಯವಾಗಿ ಇತರೇ ವ್ಯಕ್ತಿಗಳಿಂದ ಸಹಾಯ ಪಡೆಯುವಿಕೆಯ ಅವಶ್ಯಕತೆ ಇರುತ್ತದೆ ಅದನ್ನು ಗುರುತು ಮಾಡಿರಿ.

☐ ನೈರ್ಮಲ್ಯಕ್ಕೆ.
☐ ವಸ್ತುಗಳನ್ನು ಹಿಡಿದುಕೊಳ್ಳಲು ಮತ್ತು ತೆರೆಯಲು.
☐ ತಲುಪಲು
☐ ಆಚೀಚೆ ತಿರುಗಾಡುವುದು ಮತ್ತು ಮನೆಗೆಲಸಕ್ಕೆ.

APPENDIX VI a: Pre and post assessment of knowledge questionnaire English

WE WOULD LIKE TO KNOW YOUR UNDERSTANDING OF THE DISEASE YOU ARE SUFFERING FROM, BEFORE AND AFTER THE COUNSELLING WE HAVE PROVIDED.

CHECK THE OPTION THAT MATCHES YOUR ANSWER

1. I know what is Rheumatoid Arthritis
- Strongly Disagree
- Somewhat Disagree
- Neither Agree or Disagree
- Somewhat Agree
- Strongly Agree

2. I am aware of the symptoms of this disease
- Strongly Disagree
- Somewhat Disagree
- Neither Agree or Disagree
- Somewhat Agree
- Strongly Agree

3. I am taking my medications everyday
- Strongly Disagree
- Somewhat Disagree
- Neither Agree or Disagree
- Somewhat Agree
- Strongly Agree

4. I have basic knowledge regarding the medications I am taking
- Strongly Disagree
- Somewhat Disagree
- Neither Agree or Disagree
- Somewhat Agree
- Strongly Agree

5. Exercise helps reduce my joint stiffness and ease my pain
- Strongly Disagree
- Somewhat Disagree
- Neither Agree or Disagree
- Somewhat Agree
- Strongly Agree

6. I exercise at least three times a week
- Strongly Disagree
- Somewhat Disagree
- Neither Agree or Disagree
- Somewhat Agree
- Strongly Agree

7. I am aware that excessive sugar intake will aggravate my condition
- Strongly Disagree
- Somewhat Disagree
- Neither Agree or Disagree
- Somewhat Agree
- Strongly Agree

8. I take extra care when it comes to my lifestyle and eating habits
- Strongly Disagree
- Somewhat Disagree
- Neither Agree or Disagree
- Somewhat Agree
- Strongly Agree

9. A healthy diet including fruits and vegetables will be beneficial for my condition
- Strongly Disagree
- Somewhat Disagree
- Neither Agree or Disagree
- Somewhat Agree
- Strongly Agree

10. Early treatment reduces chances of having permanent joint damage
- Strongly Disagree
- Somewhat Disagree
- Neither Agree or Disagree
- Somewhat Agree
- Strongly Agree

APPENDIX VI b: Pre and post assessment of knowledge questionnaire Kannada

ಜ್ಞಾನದ ಮೌಲ್ಯಮಾಪನೆ ಮಾಡಲು ಪ್ರಶ್ನಾವಳಿ

ನಾವು ಸಮಾಲೋಚನೆ ಒದಗಿಸಿದ್ದನಂತರ ನಿಮ್ಮ ಕಾಯಿಲೆಯ ಬಗ್ಗೆ ನಿಮ್ಮ ತಿಳುವಳಿಕೆಯನ್ನು ನಾವು ತಿಳಿಯಲು ಬಯಸುತ್ತೇವೆ

ನಿಮ್ಮ ಉತ್ತರವನ್ನು ಆಯ್ಕೆಮಾಡಿ

೧. ಸಂಧಿವಾತ ಏನು ಎಂದು ನನಗೆ ಗೊತ್ತು

- ಖಂಡಿತವಾಗಿಯೂ ಒಪ್ಪುವುದಿಲ್ಲ
- ಸ್ವಲ್ಪಮಟ್ಟಿಗೆ ಒಪ್ಪುವುದಿಲ್ಲ
- ಒಪ್ಪಿಕೊಳ್ಳಲು ಹಾಗೂ ಒಪ್ಪದೆ ಇರಲೂ ಆಗುವುದಿಲ್ಲ
- ಸ್ವಲ್ಪಮಟ್ಟಿಗೆ ಒಪ್ಪುತ್ತೇನೆ
- ಖಂಡಿತವಾಗಿಯೂ ಒಪ್ಪುತ್ತೇನೆ

೨. ಈ ರೋಗದ ಲಕ್ಷಣಗಳ ಬಗ್ಗೆ ನನಗೆ ತಿಳಿದಿದೆ

- ಖಂಡಿತವಾಗಿಯೂ ಒಪ್ಪುವುದಿಲ್ಲ
- ಸ್ವಲ್ಪಮಟ್ಟಿಗೆ ಒಪ್ಪುವುದಿಲ್ಲ
- ಒಪ್ಪಿಕೊಳ್ಳಲು ಹಾಗೂ ಒಪ್ಪದೆ ಇರಲೂ ಆಗುವುದಿಲ್ಲ
- ಸ್ವಲ್ಪಮಟ್ಟಿಗೆ ಒಪ್ಪುತ್ತೇನೆ
- ಖಂಡಿತವಾಗಿಯೂ ಒಪ್ಪುತ್ತೇನೆ

೩. ನಾನು ಪ್ರತಿದಿನ ನನ್ನ ಔಷಧಿಗಳನ್ನು ತೆಗೆದುಕೊಳ್ಳುತ್ತಿದ್ದೇನೆ

- ಖಂಡಿತವಾಗಿಯೂ ಒಪ್ಪುವುದಿಲ್ಲ
- ಸ್ವಲ್ಪಮಟ್ಟಿಗೆ ಒಪ್ಪುವುದಿಲ್ಲ
- ಒಪ್ಪಿಕೊಳ್ಳಲು ಹಾಗೂ ಒಪ್ಪದೆ ಇರಲೂ ಆಗುವುದಿಲ್ಲ
- ಸ್ವಲ್ಪಮಟ್ಟಿಗೆ ಒಪ್ಪುತ್ತೇನೆ
- ಖಂಡಿತವಾಗಿಯೂ ಒಪ್ಪುತ್ತೇನೆ

೪. ನಾನು ತೆಗೆದುಕೊಳ್ಳುತ್ತಿರುವ ಔಷಧಿಗಳ ಬಗ್ಗೆ ನನಗೆ ತಳಮಟ್ಟದ ತಿಳಿವು ಇದೆ

- ಖಂಡಿತವಾಗಿಯೂ ಒಪ್ಪುವುದಿಲ್ಲ
- ಸ್ವಲ್ಪಮಟ್ಟಿಗೆ ಒಪ್ಪುವುದಿಲ್ಲ
- ಒಪ್ಪಿಕೊಳ್ಳಲು ಹಾಗೂ ಒಪ್ಪದೆ ಇರಲೂ ಆಗುವುದಿಲ್ಲ
- ಸ್ವಲ್ಪಮಟ್ಟಿಗೆ ಒಪ್ಪುತ್ತೇನೆ

- ಖಂಡಿತವಾಗಿಯೂ ಒಪ್ಪುತ್ತೇನೆ

೫. ವ್ಯಾಯಾಮವು ನನ್ನ ಜಂಟಿ ಠೀವಿ ಮತ್ತು ನೋವನ್ನು ಕಡಿಮೆ ಮಾಡಲು ಸಹಾಯ ಮಾಡುತ್ತದೆ

- ಖಂಡಿತವಾಗಿಯೂ ಒಪ್ಪುವುದಿಲ್ಲ
- ಸ್ವಲ್ಪಮಟ್ಟಿಗೆ ಒಪ್ಪುವುದಿಲ್ಲ
- ಒಪ್ಪಿಕೊಳ್ಳಲು ಹಾಗೂ ಒಪ್ಪದೆ ಇರಲೂ ಆಗುವುದಿಲ್ಲ
- ಸ್ವಲ್ಪಮಟ್ಟಿಗೆ ಒಪ್ಪುತ್ತೇನೆ
- ಖಂಡಿತವಾಗಿಯೂ ಒಪ್ಪುತ್ತೇನೆ

೬. ನಾನು ವಾರದಲ್ಲಿ ಕನಿಷ್ಠ ಮೂರು ಸಲ ವ್ಯಾಯಾಮ ಮಾಡುತ್ತೇನೆ

- ಖಂಡಿತವಾಗಿಯೂ ಒಪ್ಪುವುದಿಲ್ಲ
- ಸ್ವಲ್ಪಮಟ್ಟಿಗೆ ಒಪ್ಪುವುದಿಲ್ಲ
- ಒಪ್ಪಿಕೊಳ್ಳಲು ಹಾಗೂ ಒಪ್ಪದೆ ಇರಲೂ ಆಗುವುದಿಲ್ಲ
- ಸ್ವಲ್ಪಮಟ್ಟಿಗೆ ಒಪ್ಪುತ್ತೇನೆ
- ಖಂಡಿತವಾಗಿಯೂ ಒಪ್ಪುತ್ತೇನೆ

೭. ಜಾಸ್ತಿ ಸಕ್ಕರೆ ಸೇವಿಸಿದ್ದಲ್ಲಿ ನನ್ನ ಸ್ಥಿತಿ ಉಲ್ಬಣಗೊಳ್ಳುತ್ತದೆ ಎಂದು ನನಗೆ ತಿಳಿದಿದೆ

- ಖಂಡಿತವಾಗಿಯೂ ಒಪ್ಪುವುದಿಲ್ಲ
- ಸ್ವಲ್ಪಮಟ್ಟಿಗೆ ಒಪ್ಪುವುದಿಲ್ಲ
- ಒಪ್ಪಿಕೊಳ್ಳಲು ಹಾಗೂ ಒಪ್ಪದೆ ಇರಲೂ ಆಗುವುದಿಲ್ಲ
- ಸ್ವಲ್ಪಮಟ್ಟಿಗೆ ಒಪ್ಪುತ್ತೇನೆ
- ಖಂಡಿತವಾಗಿಯೂ ಒಪ್ಪುತ್ತೇನೆ

೮. ನನ್ನ ಜೀವನಶೈಲಿ ಹಾಗೂ ನನ್ನ ಆಹಾರದ ಬಗ್ಗೆ ನಾನು ಹೆಚ್ಚಿನ ಕಾಳಜಿ ವಹಿಸುತ್ತೇನೆ

- ಖಂಡಿತವಾಗಿಯೂ ಒಪ್ಪುವುದಿಲ್ಲ
- ಸ್ವಲ್ಪಮಟ್ಟಿಗೆ ಒಪ್ಪುವುದಿಲ್ಲ
- ಒಪ್ಪಿಕೊಳ್ಳಲು ಹಾಗೂ ಒಪ್ಪದೆ ಇರಲೂ ಆಗುವುದಿಲ್ಲ
- ಸ್ವಲ್ಪಮಟ್ಟಿಗೆ ಒಪ್ಪುತ್ತೇನೆ
- ಖಂಡಿತವಾಗಿಯೂ ಒಪ್ಪುತ್ತೇನೆ

೯. ಹಣ್ಣುಗಳು ಮತ್ತು ತರಕಾರಿಗಳು ಸೇರಿದಂತೆ ಆರೋಗ್ಯಕರ ಆಹಾರವು ನನ್ನ ಸ್ಥಿತಿಗೆ ಪ್ರಯೋಜನಕಾರಿಯಾಗುತ್ತದೆ

- ಖಂಡಿತವಾಗಿಯೂ ಒಪ್ಪುವುದಿಲ್ಲ
- ಸ್ವಲ್ಪಮಟ್ಟಿಗೆ ಒಪ್ಪುವುದಿಲ್ಲ

- ಒಪ್ಪಿಕೊಳ್ಳಲು ಹಾಗೂ ಒಪ್ಪದೆ ಇರಲೂ ಆಗುವುದಿಲ್ಲ
- ಸ್ವಲ್ಪಮಟ್ಟಿಗೆ ಒಪ್ಪುತ್ತೇನೆ
- ಖಂಡಿತವಾಗಿಯೂ ಒಪ್ಪುತ್ತೇನೆ

೧೦. ಆರಂಭಿಕ ಚಿಕಿತ್ಸೆ ಮಾಡುವುದರಿಂದ ಜಂಟಿಗಳ ಶಾಶ್ವತ ಹಾನಿಯ ಸಾಧ್ಯತೆಗಳನ್ನು ಕಡಿಮೆ ಮಾಡಬಹುದು

- ಖಂಡಿತವಾಗಿಯೂ ಒಪ್ಪುವುದಿಲ್ಲ
- ಸ್ವಲ್ಪಮಟ್ಟಿಗೆ ಒಪ್ಪುವುದಿಲ್ಲ
- ಒಪ್ಪಿಕೊಳ್ಳಲು ಹಾಗೂ ಒಪ್ಪದೆ ಇರಲೂ ಆಗುವುದಿಲ್ಲ
- ಸ್ವಲ್ಪಮಟ್ಟಿಗೆ ಒಪ್ಪುತ್ತೇನೆ
- ಖಂಡಿತವಾಗಿಯೂ ಒಪ್ಪುತ್ತೇನೆ

APPENDIX VII: VISUAL ANALOGUE SCALE