

**Assessment of Rheumatoid Arthritis Patients' Adherence to
Treatment at Ain shams University Rheumatology
Outpatients Clinics**

Protocol for Thesis Submitted for Partial Fulfillment of Master Degree in
Family Medicine

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Introduction

Rheumatoid arthritis(RA) is an autoimmune disorder of unknown etiology characterized by symmetric erosive synovitis, and in some cases extra articular involvement[1]. It is a chronic, progressive, debilitating disease demanding continuous therapy with multiple medications[2-4].

Efficient management of RA significantly reduces long-term functional disability [5].With respect to treatment for RA, drug efficacy and patient compliance with the treatment prescribed are equally important [6, 7].

Rheumatoid arthritis results in Reduction in the ability to work and concomitant loss of income and increased need for rest during the day, reduction in leisure activity difficulties with using transport, additional housing needs and increasing need for social support are some of the socio-economic consequences of RA [8]. with physical activities especially those requiring fine movements such as sewing [9-11]. Social isolation and loss of self esteem [12,13]. And loss of intimate relationships [14].

In USA the prevalence of rheumatoid arthritis range from 0.5-1.0% in the general population [15].In 2005,an estimated 1.5 million US adults aged = 18 (0.6%) had RA[16]. A decrease from the previous 1990 estimate of 2.1 million[17].Prevalence estimates derived from 2001-2005 US ambulatory health care system data estimated that 1.5 million US adults have RA[18].In 1995 in the Rochester Epidemiology Project (Minnesota), the age-adjusted prevalence of RA among women was 7.7 per 1000 compared with 4.4 per 1000among men). By 2005, the prevalence among women had increased (9.8 per 1000) but prevalence among men (4.1 per 1000) [19].

There are several definitions for adherence (or compliance) to a medication regimen. One definition states that it is" the extent to which patients take medications as prescribed by their health care Providers [20]. Yet, another definition states that it is "the extent to which a person's medication taking behavior coincides with medical advice [21]. Adherence is advocated by health care providers because compliance suggests that the patient is passively following the doctor's order. additionally, it suggests that the treatment plan is not based on a therapeutic alliance or contract established between the patient and the physician [20].

In noncompliant RA patients the risk of a disease flare has been found to increase significantly [6].]. Noncompliance increases the risk of unnecessary changes in treatment and causes preventable morbidity, mortality, and loss of health care resources and productivity [22]. Lack of compliance with treatment is a worldwide problem of a striking magnitude [23].

Compliance among, patients with different chronic diseases is low often below50% [24].Compared with chronic diseases such as asthma Chronic rheumatic conditions has not been well examined [25]. In A study done in Jordan compliance rate was 65% [26].

Several studies suggest that the ability of health workers to recognize non adherence is poor, and that interventions to improve adherence have had mixed results [20]. Key elements to determine an individual's adherence to treatment include: threat of illness, positive outcome expectancy (perceived severity and susceptibility), barriers for using the treatment (e.g. expected disadvantage from treatment), and intent (intention to adhere to the treatment regimen) [27].

Adherence to therapy is an individual patient behavior that is difficult to objectively measure, monitor, and improve. It is widely believed that non adherence is a serious problem, with particularly high estimates of non-adherence for older adults and for individuals with chronic disease as rheumatoid arthritis [28]. Non-adherence may result in unnecessary health costs, investigations, and changes in treatment, morbidity, and mortality [28].

The findings of the study could be used to improve the quality of patient care, decrease the health cost and decrease morbidity and mortality and A critical element in successful clinical treatment of a disorder is that patients take the medication that is prescribed to them [29].

Based on what is mentioned above. there is a need to assess rate of Adherence to treatment regimen among Rheumatoid arthritis patients attending Ain Shams Rheumatology Outpatients Clinics and factors affecting it.

Objectives:

1-Measure Adherence Rate in rheumatoid arthritis patients attending Ain shams university rheumatology outpatients' clinics

2-Assess Factors Affecting Adherence in Rheumatoid arthritis patients attending Ain shams university Rheumatology outpatients clinics

Subjects and Methods

Study design

This is a descriptive study followed by internal analysis for expected barriers of compliance and includes all patients attending clinic 2 days a week in Ain shams Rheumatology

Out patients clinics

Sample size:

- Using Epi info statistical package for cross sectional study
- Total number of rheumatoid arthritis patients attending outpatients Rheumatology clinics in Ain shams university hospital is 200
- Expected frequency of compliance rate among rheumatoid arthritis patients revealed from A Jordan study is 65%[24]
- Calculation of sample size at 95% confidence interval and power of test 80% ,127 will be at least required and after adjusting for 10% dropout a sample size of 140 Rheumatoid arthritis patients will be suggested.

Inclusion criteria

- Rheumatoid arthritis patients attending ain shams rheumatology out patient clinic
- Age above 18 year
- Duration of illness not less than one year
- Patient who accept participating on study

Exclusion criteria

- Patient with mental problems that could hinder their participation in study
- Patient under 18 years
- Duration of illness less than one year

Sampling Methods:

A study will include all patients attending Ain Shams University Rheumatology out patients' clinics two days a week until reach the sample size measured

Tool of the study

An interview questionnaire by one interviewer will be constructed to measure

- Adherence to treatment guided with (morisky scale) [30] and reasons of non Adherence.
- Factors affecting Adherence to treatments.

Data management and Statistical analysis:

Pilot study will be conducted on 10 patients (will not including in the sample) to test feasibility and applicability of the questionnaire and any modification will be done. Data will be collected by the researcher through structured interview using the above mentioned questionnaires. The obtained data will be entered and analyzed using Statistical Package of Social Science (SPSS 12). Chi-square test will be used for categorical variables and the level of significance will be consideration statistically significant if (p-value is <0.05) and will be high statistically signification if (p-value is 0, 01). T-test will be used for continuous variables. The result will be presented in the appropriate form of tables and graphs using Microsoft Excel. Data will be presented using Microsoft power point.

Ethical consideration:

- 1- Approval for study conduction will be obtained from Ethical Committee at Faculty of Medicine Ain Shams University
- 2- Approval from the director of out patient clinics of the hospital before the start of the study.
- 3- An oral informed consent will be taken from the patient
- 4- Questionnaire will be anonymous

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List of Abbreviations

ALK	Alkaline phosphatase
ACPA	Anti-citrullinated protein/peptide antibodies
BMQ	Beliefs medication questionnaire
BMI	Body Mass Index
CRP	C reactive protein
CVD	Cardiovascular disease
C4-5	Cervical spine four - five
COPCORD	Community-Oriented Programme for Control of Rheumatic Diseases
COX	Cyclo oxygenase enzyme
DAS	Disease activity score
DMARDS	Disease modifying anti rheumatic drugs
DIP	Distal interphalangeal joints
\$	Dollar
ESR	Erythrocyte sedimentation rate
EULAR	European liege against rheumatism
FBC	full blood count
GLA	Gamma linoleic acid
GPs	General parishioners
HLA	Human leukocytic antigen
LFTS	liver function test
MCP	Metacarpophalangeal joints
MXT	Methotrexate
MMAS	Morisky Medication Adherence Scale
MI	Myocardial infarction
NSAIDS	Non steroidal anti inflammatory drugs
OCS	Oral contraceptives
PSQ	Patient satisfaction questionnaire
PCOS	Polycystic ovarian syndrome
PIP	Proximal interphalangeal joints
X RAY	Radiological imaging
RA	Rheumatoid Arthritis
RF	Rheumatoid factor
TENS	Transcutaneous electrical nerve stimulation
TNF	Tumor necrosis factor
USA	United States of America

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Introduction





Abstract





Aim of the Work

