



**A mixed methods study to investigate medication adherence
in patients with rheumatoid arthritis of White British and
South Asian origin**

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A mixed methods study to investigate medication adherence in patients with rheumatoid arthritis of White British and South Asian origin

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Abstract

Background

Low adherence to medicines is an important issue as up to 40% of patients with chronic diseases do not take their medications as prescribed. This leads to suboptimal clinical benefit. In the context of rheumatoid arthritis there is a dearth of data on adherence to disease modifying anti-rheumatic drugs amongst minority ethnic groups. This study aims to assess the relationship between adherence to medicines and biopsychosocial variables in patients with rheumatoid arthritis of South Asian and White British origin.

Method / analysis

A mixed methods approach will be used, encompassing a cross-sectional survey of 176 patients with demographic and clinical data, including information on adherence behaviour collected using a questionnaire. This will be followed by in-depth qualitative interviews.

Ethics and Dissemination

This study has been approved by the South Birmingham (10/H1207/89) and Coventry and Warwickshire (12/WM/0041) Research Ethics Committees. The authors will disseminate the findings in peer reviewed publications.

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Key words:

Ethnicity, rheumatoid arthritis, medication adherence, beliefs.

For peer review only

Introduction

Rheumatoid arthritis (RA) is a chronic systemic inflammatory disorder that mainly affects the joints¹ and is often associated with a poor quality of life. The disease has a huge financial burden on the National Health Service and on individuals as about a third of patients stop work within the first five years of diagnosis². Recent therapeutic advances now enable effective control of disease in a large proportion of patients^{3;4}. Taking disease modifying anti-rheumatic drugs (DMARDs) as prescribed may not only reduce articular disease activity and progression but may also reduce the risk of extra-articular features of RA such as cardiovascular disease⁵. Adherence to medicines is thus likely to be an important determinant of RA treatment success. However, it is estimated that in developed countries, 40% of patients who suffer from chronic diseases do not adhere to treatment recommendations^{6;7} with adherence rates dropping most dramatically after the first six months of therapy⁸.

Efforts to improve treatment outcomes require a better understanding of the particular barriers to and facilitators of adherence to therapy, and of patient experience of taking treatment. This is a complex process and factors associated with non-adherent behaviour can be organised into the following interacting domains: (1) socio-economic factors; (2) health professional and health services related factors; (3) characteristics of the treatment regimen; (4) characteristics of the disease; (5) patient related factors⁷. Furthermore, to better understand patients' medicine taking many researchers have examined cognitive factors such as patients' perception of their disease, and factors which can be changed to enable more effective behavioural interventions⁷. Among the different models proposed^{9;10} Horne et al,¹¹ have developed the Necessity – Concern framework. This framework has been shown to explain non-adherence across a range of illnesses¹². According to Horne,^{13;14} patients' motivation

to start and to continue with medication is often influenced by the way in which they evaluate their need for treatment. Adherent behaviour depends on which of the two beliefs prevails, i.e. the necessity of the medicine or concerns about the possible threat of the medicines⁶. This can be captured by the two subscales of the Beliefs about Medicines Questionnaire (BMQ): firstly, the *specific necessity* scale which largely focuses on assessing the respondents' beliefs about the necessity of their prescribed medication for controlling their illness and maintaining their health (e.g., "my health, at present, depends on my medication"); and secondly, concerns about the adverse consequences of taking prescribed medication which mostly focuses on assessing the *specific-concerns* scale (e.g., "I sometimes worry about the long-term effect of my medication"). Together, the Necessity – Concern Framework model¹¹ and the Illness Perception Questionnaire (IPQ)¹⁰ provide a useful framework to study adherence in patients with RA of South Asian and White British origin.

Several studies have reported that higher levels of self-efficacy and social support are associated with improved medication adherence¹⁵ although there are conflicting data¹⁶. Other factors associated with adherence include age, income, level of education, knowledge of disease and satisfaction with information about medicines^{17;18}. Patients' beliefs about medicines play an important role in medication adherence in chronic diseases^{6;19;20}. For example, Neame and Hammond¹⁹ found that concerns about medicines were higher in non-adherent than adherent RA patients and were associated with feelings of helplessness. Patients with higher levels of concerns were those who reported more adverse effects from DMARDs. Also, disease severity plays a key role in patients' decisions to either take or not take their treatments²¹. However, few studies have investigated the role of ethnicity as a factor affecting medication adherence in patients with RA, particularly, in South Asian patients with

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3 RA^{22,23}. Garcia-Gonzalez et al²³ found that Hispanic and African American patients
4 with RA had significantly reduced medication adherence when compared with
5 patients of White origin. They attributed this to greater feelings of depression and the
6 perception of medication as harmful in the minority ethnic groups. Patients with a low
7 level of education and less knowledge about their disease were less likely to take their
8 medication. A pilot study by Kumar et al,²⁴ did not measure adherence rates to
9 medicines but did highlight that RA patients from a South Asian background had
10 more negative beliefs about their medicines compared to White British patients. These
11 negative beliefs were influenced by a range of factors including views about fate²⁵.
12 These more negative orientations towards medicines may have an adverse impact on
13 patients' clinical outcomes. Furthermore, South Asian patients with RA have also
14 been shown to be different in their help seeking behaviours²⁶. Patients' beliefs about
15 the meaning of symptoms were important when deciding to seek medical help. This
16 was sometimes related to a perception that their symptoms represented God's
17 punishment and medical help seeking was thus often delayed, contributing towards
18 delays in initiating treatment²⁶.
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39 This study aims to assess the relationship between adherence to medicines and
40 biopsychosocial variables (e.g. age, gender, level of education, postcode, occupation,
41 employment status and disease duration) in patients with RA of South Asian (i.e.
42 originating from India and Pakistan) and White British origin. Further, the study will
43 explore the reasons underlying high and low adherence amongst these two ethnic
44 groups.
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Methods and analysis

A two phased mixed methods approach encompassing both quantitative and qualitative designs will be used.

Phase 1: Quantitative survey

The valid and reliable Medication Adherence Report Scale (MARS)⁶ will be used to capture data to address the relationship between adherence to medicines used in RA and potential explanatory variables (identified from factors that are known to influence adherence⁷) in patients with RA of White British and South Asian origin. The Health Assessment Questionnaire (HAQ)²⁷ and the IPQ¹⁰ have been validated and are already available in different languages^{28;29} for example Hindi. For the purposes of this study the HAQ²⁷, IPQ¹⁰, BMQ¹¹, Satisfaction with Information about Medications questionnaire (SIMS)³⁰ and Medication Adherence Report Scale (MARS)⁶ will for the first time be independently audio translated into Hindi, Punjabi and Urdu followed by back translation to ensure linguistic validity. This is because the study will take place in a largely multicultural city in which 18.5% of the population is of South Asian origin³¹. Importantly, we have reported that about a third of the South Asian population attending Rheumatology clinics in Birmingham required interpreters and about 33% of that population were not able to read the script of their preferred language³². Consequently, written translation of the questionnaire would exclude a sizeable proportion of potentially eligible subjects. It has also been suggested that language is an important barrier to the participation of South Asian patients in research³³. To test the logistics of filling in the questionnaire the translated audiotapes will be piloted amongst a group of patients.

Patient engagement

Using the BMQ to quantify adherence has the advantage that it will help embed the findings from this study within the Necessity-Concern Framework. However, before we made a final decision on which tool(s) to use to measure adherence, the views of patients were sought³⁴. A patient Steering Group was established with two White British and two South Asian patients. The most common methods of measuring adherence were discussed including patient questioning, patient logs, pill counts³⁵ and the widely used medication electronic monitoring system (MEMS)³⁶. This system involves a cap that measures opening and closing as dosages are taken, and is able to report on the time and dates that dosages were taken. The Steering Group strongly felt that the MEMS approach could have the potential to alert patient behaviour and was thus not felt to be appropriate. Patients felt that a self report tool such as the MARS which is phrased in a way that sanctions non-adherence was the preferred method⁶ and that data should be captured by self-report. They did however also acknowledge that by using this approach adherence might be over reported by some patients. A decision was thus made to use the MARS to investigate medication adherence.

In addition, data on demographic (variables such as age, gender, ethnicity, level of education) and disease related variables such as disease activity score (DAS28)³⁷, disease duration and functional disability measured using the Health Assessment Questionnaire (HAQ)²⁷ will be captured. A free text box will be included to allow patients to record information on other variables which they feel may influence their adherence.

Inclusion criteria

Patients with RA (according to the 1987 American College of Rheumatology criteria)³⁸ of either White British or South Asian origin will be invited to participate. Patients will have been diagnosed with RA for at least three months; be 18 years or over; be taking at least one DMARD / have been on a DMARD in the past³⁹. Patients will be classified as being of White British origin if they had three or more grandparents who had been born in the UK and regard themselves as being of White origin. Patients will be classified as being of South Asian origin if they had three or more grandparents who had been born in India or Pakistan and regarded themselves as being of South Asian origin.

Recruitment

Patients will be recruited from three hospitals centres in Birmingham, UK (Sandwell and West Birmingham Hospitals NHS Trust, University Hospitals Birmingham NHS Foundation Trust and Heart of England NHS Foundation Trust).

Data and Sample collection

Data will be collected by questionnaires, clinical assessments and case notes review. The sample size of 176 (88 patients from each ethnic group) will detect with at least 80% power a significant correlation at the 5% level if the true significant correlation of adherence and beliefs about medicines is less than or equal to -0.21 or greater than or equal to +0.21. This calculation has been based on a previous study that investigated the relationship between beliefs about medicine and adherence⁶. Data will be analysed by using the Statistical Package for Social Sciences (SPSS) and modelled to assess the relationship between adherence and the variables studied. The extent to which variation in adherence can be explained by the factors under

investigation will be assessed⁷. Furthermore, this study will assess to what extent these dimensions have an impact on adherence to DMARDs in RA and importantly will, for the first time, assess this issue in two distinct ethnic groups. Firstly, univariate analyses will be performed to test the association between the outcome (adherence to DMARDs) and potential explanatory variables in participants with RA. There will be two primary questions for the univariate analyses:

1. Is the BMQ necessity score correlated with adherence?
2. Is the BMQ concerns score correlated with adherence?

Secondly, general linear models with adherence to DMARDs as the dependent variable will be fitted, adjusting for age, sex, number of years of education, significant predictors on univariate analysis, and clinically relevant factors such as disease duration, DAS28, HAQ scores and DMARDs that are commonly used to treat RA. Interactions with ethnicity will be examined and if an interaction with ethnicity is identified, all subsequent analysis will be stratified by ethnicity (South Asian vs. White British).

Phase 2 In-depth qualitative interviews

To obtain a wide representation of views approximately 35 patients will be interviewed until theoretical saturation is reached to explore barriers to and facilitators of adherence. Patients will be identified from phase 1 with low adherence (defined as lowest tertile on MARS) and higher levels of medication adherence (defined as upper tertile on MARS) and invited for individual interviews. A semi-structured interview schedule will be developed from the literature and with input from the Patient Steering Group. A maximum variety approach will be used to capture a broad social and demographic subject range⁴⁰. Interviews will take place within the hospital in a non-clinical setting (e.g. in the postgraduate centre in dedicated rooms for

interviewing) to allow patients to talk freely about issues related to medication adherence.

Data analysis

Data collection and analysis will be iterative occurring as data collection proceeds, with new data informing subsequent interviews. The transcribed data will be analysed by using constant comparative analysis⁴⁰. This process involves looking at the different patterns and reflecting on them to seek similarities between emerging themes. Each transcript will be coded (labels) to capture the essence of the patients' narratives. By creating several labels, a structure of codes will be developed to understand the meaning of the data. The coding will be staged. During the coding the researcher will look for demographic, factual (disease symptoms) and /or conceptual meaning. For example, are some issues about medication adherence related to gender? Or what aspects of the patient's story help explain the meaning of medication adherence? The researcher will allow for spontaneous themes to emerge and, in addition, attention will be paid to more specific themes chosen from phase 1 of the study, that may help explain patient adherence. A separate list of themes for each ethnic group will be compiled. The analysis will be reviewed and validated by a second independent person.

Ethical approval and dissemination

This study has been approved by the South Birmingham (10/H1207/89) and Coventry and Warwickshire (12/WM/0041) Research Ethics Committees. Verbal and written consent will be obtained from all patients. For those in whom English is not their first language the researcher (KK) will conduct an oral discussion about taking part in the

study with patients in Hindi, Punjabi and Urdu. The authors will disseminate the findings in peer reviewed publications.

Summary

The aim of this study is to assess the relationship between adherence to medicines and biopsychosocial variables in RA patients of White British and South Asian backgrounds. Furthermore, it will explore the reasons underlying high and low adherence in these two ethnic groups.

Many studies to date have provided insight into approaches to improve the adherence in patients with chronic diseases⁴¹. A substantial literature has documented a number of factors related to adherence such as demographic, social, health care provider related, medical system related and disease and treatment related factors⁷. Furthermore, an emphasis has been placed on cognitive models that focus on patients' perceptions and beliefs as motivating factors for adhering to therapy^{6,12}. Appropriate health beliefs such as the perceived seriousness of disease, vulnerability to complications and the efficacy of treatment, can predict better adherence⁴². Patients are thought to adhere well when the treatment regimen makes sense to them, when it seems effective, and when from their perspective the benefits outweigh the concerns¹³. Such decision making is typically based on individuals' subjective perceptions of the pros and cons of the therapy⁴³. However, such issues have not been explored in patients with RA from the South Asian populations and this study will fill this gap in the literature. Importantly, this study will address two main issues. Firstly, the study will extract characteristics that are associated with high and low adherence among RA patients and assess the impact of ethnicity on this. Secondly, a strength of the study is that it will allow an opportunity to further explore issues that arise in phase 1 of the

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study using qualitative methodologies. The motivational factors that encourage patients to adhere well can be discussed in more detail. Furthermore, this will provide information for the development of an intervention to change beliefs and behaviours.

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Authors' contributions

KK is the Chief Investigator, PG and SG are the primary supervisors, KR is the clinical supervisor, PN has given statistical advice for the study. KS and RH are the external supervisors. KK led writing the manuscript, all authors contributed to the revision of the manuscript. KK is the guarantor of this paper.

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Competing interests

The authors declare that they have no competing interests.

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Abstract

Background

Low adherence to medicines is an important issue as up to 40% of patients with chronic diseases do not take their medications as prescribed. This leads to suboptimal clinical benefit. In the context of rheumatoid arthritis there is a dearth of data on adherence to disease modifying anti-rheumatic drugs amongst minority ethnic groups. This study aims to assess the relationship between adherence to medicines and biopsychosocial variables in patients with rheumatoid arthritis of South Asian and White British origin.

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Introduction

Rheumatoid arthritis (RA) is a chronic systemic inflammatory disorder that is characterized by joint inflammation¹ and is often associated with a poor quality of life². The disease has a huge financial burden on the National Health Service and on individuals as about a third of patients stop work within the first five years of diagnosis³. Recent therapeutic advances now enable effective control of disease in a large proportion of patients^{4,5}. Taking disease modifying anti-rheumatic drugs (DMARDs) as prescribed may not only reduce articular disease activity and progression but may also reduce the risk of extra-articular features of RA such as cardiovascular disease⁶. Adherence to medicines is thus likely to be an important determinant of RA treatment success. However, it is estimated that in developed countries, 40% of patients who suffer from chronic diseases do not adhere to treatment recommendations^{7,8} with adherence rates dropping most dramatically after the first six months of therapy⁹.

Efforts to improve treatment outcomes require a better understanding of the particular barriers to and facilitators of adherence to therapy, and of patient experiences of taking treatment. This is a complex process and factors associated with non-adherent behaviour can be organised into the following interacting domains: (1) socio-economic factors; (2) health professional and health services related factors; (3) characteristics of the treatment regimen; (4) characteristics of the disease; (5) patient related factors⁸. Furthermore, to better understand patients' medicine taking many researchers have examined cognitive factors such as patients' perception of their disease, and factors which can be changed to enable more effective behavioural interventions⁸. Among the different models proposed^{10,11} Clifford et al,¹² have developed the Necessity – Concern framework. This framework has been shown to

explain non-adherence across a range of illnesses¹³. According to Horne,^{14;15} patients' motivation to start and to continue with medication is often influenced by the way in which they evaluate their need for treatment. Adherent behaviour depends on which of the two beliefs prevails, i.e. the necessity of the medicine or concerns about the possible threat of the medicines⁷. This can be captured by the two subscales of the Beliefs about Medicines Questionnaire (BMQ)¹⁶: firstly, the *specific necessity* scale which largely focuses on assessing the respondents' beliefs about the necessity of their prescribed medication for controlling their illness and maintaining their health (e.g., "my health, at present, depends on my medication"); and secondly, concerns about the adverse consequences of taking prescribed medication which mostly focuses on assessing the *specific-concerns* scale (e.g., "I sometimes worry about the long-term effect of my medication"). Together, the Necessity – Concern Framework model¹² provide a useful framework to study adherence in patients with RA of South Asian and White British origin.

Several studies have reported that higher levels of self-efficacy and social support are associated with improved medication adherence¹⁷ although there are conflicting data¹⁸. Other factors may be associated with adherence including age, income, level of education, knowledge of disease and satisfaction with information about medicines^{19;20}. Several authors have suggested that patients' beliefs about medicines play an important role in medication adherence in chronic diseases^{7;21-24}. For example, in rheumatology, Neame and Hammond²¹ found that concerns about medicines were higher in non-adherent than adherent RA patients and were associated with feelings of helplessness. Patients with higher levels of concerns were those who reported more adverse effects from DMARDs. Also, disease severity plays a key role in patients' decisions to either take or not take their treatments²⁵. However, few studies^{26;27} have

investigated the role of ethnicity as a factor affecting medication adherence in patients with RA, particularly in South Asians. Garcia-Gonzalez et al²⁷ found that Hispanic and African American patients with RA had significantly reduced medication adherence when compared with patients of White origin. They attributed this to greater feelings of depression and the perception of medication as harmful in the minority ethnic groups. Patients with a low level of education and less knowledge about their disease were less likely to take their medication. A pilot study by Kumar et al,²⁸ did not measure adherence rates to medicines but did highlight that RA patients from a South Asian background had more negative beliefs about their medicines compared to White British patients. These negative beliefs were influenced by a range of factors including views about fate²⁹. Furthermore, South Asian patients with RA have also been shown to be different in their help seeking behaviours³⁰. Patients' beliefs about the meaning of symptoms were important when deciding to seek medical help. This was sometimes related to a perception that their symptoms represented God's punishment and medical help seeking was thus often delayed, contributing towards delays in initiating treatment³⁰. This study aims to assess the relationship between adherence to medicines and biopsychosocial variables (e.g. age, gender, level of education, socioeconomic status, occupation, employment status and disease duration) in patients with RA of South Asian (defined as originating from India or Pakistan) and White British origin. Further, the study will explore the reasons underlying high and low adherence amongst these two groups of patients.

Methods and analysis

A two phased mixed methods approach encompassing both quantitative and qualitative designs will be used.

Phase 1: Quantitative survey

The valid and reliable Medication Adherence Report Scale (MARS)⁷ will be used to capture data to address the relationship between adherence to medicines used in RA and potential explanatory variables (identified from factors that are known to influence adherence)⁸ in patients with RA of White British and South Asian origin. MARS is a five - item self-report scale for assessment of non-adherent behaviour (e.g. I forget to take them, and I alter the dose). The items are rated on a five point Likert scale⁷, ranging from 1= very often to 5= never.

The BMQ will be used to measure beliefs about medicines. The BMQ questionnaire consists of the BMQ specific which measures perceptions of specific medications and the BMQ General, which measures more general beliefs about medicines¹⁶. The Specific scales: assessing patients' beliefs about the necessity of medication for maintaining present and future health (Necessity, score range from 5-25, higher score indicating stronger need for medication), and the other assessing their concerns about the potential adverse consequences of using medication (Concern, score range from 6-30, higher score indicating more concerns about medication). The BMQ General scales: assessing patients' beliefs about the use of medicines and whether they are overprescribed by clinicians (Overuse, score range from 3-15). The Harm assessing patients' beliefs about the intrinsic nature of medicines and the degree to which they are perceived as harmful addictive (Harm, scores range from 5-25). For both, Overuse and Harm scales, higher scores indicate a more negative perception towards medication in general.

The Health Assessment Questionnaire (HAQ)³¹ and the IPQ¹¹ have been validated and are already available in different languages^{32,33} for example Hindi. The HAQ will be used to assess function as we have shown that patients with negative beliefs have a

worse function scores²⁸. Thus, the association of HAQ with MARS may provide useful data. The Illness Perception tool¹¹ has five discrete attributes (identity, cause, timeline, consequences, cure and control), that patients tend to have about their condition (their illness perception). The scores range from a five – point scale, where 1 = strongly disagree and 5 = strongly agree). These help predict health behaviours such as medication adherence. Looking at the association of the IPQ and MARS will be useful to determine associations with medication adherence.

Patient satisfaction with information can be measured using the Satisfaction with Information about Medications questionnaire (SIMS)³⁴. This questionnaire has two subscales - action and usage of drugs (nine items), and potential problems (eight items). Those who report that the information is “about right” or indicate “none needed” will be classified as satisfied (scored 1). Those who report that the information is “too much”, “too little” or indicate “none received” will be classified as dissatisfied (scored 0). Responses will be recorded on a likert scale (i.e. too much – none needed). By capturing these data we will be able to assess the relationship between satisfaction with information about medication and adherence in our study population. For the purposes of this study the HAQ³¹, IPQ¹¹, BMQ¹⁶, Satisfaction with Information about Medications questionnaire (SIMS)³⁴ and Medication Adherence Report Scale (MARS)⁷ will for the first time be independently audio translated into Hindi, Punjabi and Urdu followed by back translation to ensure linguistic validity³⁵. This is because the study will take place in a largely multicultural city in which 18.5% of the population is of South Asian origin³⁶. Furthermore, we have reported that about a third of the South Asian population attending Rheumatology clinics in Birmingham required interpreters and about 33% of that population were not able to read the script of their preferred language³⁷.

Consequently, written translation of the questionnaires would exclude a sizable proportion of potentially eligible subjects. To test the logistics of filling in the questionnaire the translated audiotapes will be piloted amongst a group of patients.

Choice of questionnaires

The questionnaires were chosen based on their use in chronic diseases. MARS and BMQ has been used in patients with asthma, chronic obstructive pulmonary disease, diabetes, renal failure¹⁶. In RA, Neame et al³⁸ has shown that BMQ - concern scale distinguished between low and higher adherence (MARS). Whereas necessity scale was shown to be correlated with number of disease modifying anti-rheumatic drugs (DMARDs) and adherence.

Patients usually require a rationale for their medication before following advice about taking it³⁴. It is well known that 40% of patients on chronic medication do not take their medication as prescribed. It is likely that medication adherence is improved if patients are provided with information which addresses the issues they want to know about in a way that is comprehensible. Patient satisfaction with information can be measured using the Satisfaction with Information about Medications questionnaire (SIMS)³⁴. This questionnaire has two subscales - action and usage of drugs (nine items), and potential problems (eight items). Those who report that the information is “about right” or indicate “none needed” will be classified as satisfied (scored 1). Those who report that the information is “too much”, “too little” or indicate “none received” will be classified as dissatisfied (scored 0). Responses will be recorded on a likert scale (too much – none needed) by capturing these data we will be able to assess the relationship between satisfaction with information about medication and

adherence in our study population. Furthermore, the SIMS has been shown to be consistence in patients with asthma, cardiac rehabilitation, diabetes, and oncology)³⁴. It also distinguishes between low and high adherence in RA³⁹.

The IPQ again has been used in a variety of conditions such as diabetes, hypertension, and HIV¹¹. Amongst RA patients Hughes et al⁴⁰ found that some of the IPQ domains were associated with low and high adherence. There are very few studies that provide evidence regarding illness perception amongst RA patients of South Asian origin. The illness perception tool has five discrete attributes (identity, cause, timeline, consequences, cure and control), that patients tend to have about their condition (their illness perception) score ranging from a five – point scale, where 1 = strongly disagree and 5 = strongly agree). These help predict health behaviours such as medication adherence. For example, medication adherence in patients with hypercholesterolemia has been shown to be related to beliefs that the disease has severe coronary consequences^{41;42}. Hypertensive patients who believe that their condition is chronic are more likely to adhere to their antihypertensive medication than those who believe it to be an acute condition^{41;42}. The latter group of patients may view themselves to be cured. Looking at the association of the IPQ and MARS will be useful to determine associations with medication adherence.

Finally, the HAQ³¹ will be used to assess functional disability as our previous work has shown that patients with negative beliefs had a higher functional disability score. Thus, the association of HAQ with MARS may provide useful data.

Patient engagement

Using the BMQ to quantify adherence has the advantage that it will help embed the findings from this study within the Necessity-Concern Framework. However, before

we made a final decision on which tool(s) to use to measure adherence, the views of patients were sought⁴³. The study design was presented to the rheumatology departmental patient User Group. An invitation to join the project Steering Group was offered to all patients and four (two White British and two South Asian patients) joined this group. None of these patients' rheumatoid arthritis was being treated by the researchers from a clinical perspective. The most common methods of measuring adherence were discussed including patient questioning, patient logs, pill counts⁴⁴ and the widely used medication electronic monitoring system (MEMS)⁴⁵. This system involves a cap that measures opening and closing as dosages are taken, and is able to report on the time and dates that dosages were taken. The Steering Group strongly felt that the MEMS approach could have the potential to change the patients' behaviour and was thus not felt to be appropriate. Patients preferred a self reported tool such as the MARS⁷, which is phrased in a way that sanctions non-adherence. However, did acknowledge that by using this approach adherence might be over reported by some patients.

In addition, data on demographic (variables such as age, gender, ethnicity, level of education) and disease related variables such as disease activity score (DAS28)⁴⁶. A free text box will be included to allow patients to record information on other variables which they feel may influence their adherence.

Inclusion criteria

Patients with RA (according to the 1987 American College of Rheumatology criteria)⁴⁷ of either White British or South Asian origin will be invited to participate. Patients will have been diagnosed with RA for at least three months; be 18 years or over; be taking at least one DMARD / have been on a DMARD in the past. Patients will be

classified as being of White British origin if they had three or more grandparents who had been born in the UK and regard themselves as being of White origin. Patients will be classified as being of South Asian origin if they had three or more grandparents who had been born in India or Pakistan and regarded themselves as being of South Asian origin.

Recruitment

Patients will be recruited from three hospitals based Rheumatology clinics in Birmingham, UK (Sandwell and West Birmingham Hospitals NHS Trust, University Hospitals Birmingham NHS Foundation Trust and Heart of England NHS Foundation Trust).

Data and Sample collection

Data will be collected by a researcher (KK) by questionnaires, clinical assessments and case notes review. The sample size of 176 (88 patients from each ethnic group) will detect with at least 80% power a significant Pearson correlation coefficient at the 5% level if the true significant correlation of adherence and beliefs about medicines is less than or equal to -0.21 or greater than or equal to +0.21. This calculation has been based on a previous study that investigated the relationship between beliefs about medicine and adherence⁷. In this paper the authors found a Pearson correlation coefficient of 0.21 between necessity score and adherence and a Pearson correlation coefficient of -0.33 between concern score and adherence. Thus, the sample size will enable us to detect correlations of these magnitudes with at least 80% power. Data will be analysed by using the Statistical Package for Social Sciences (SPSS) and modelled to assess the relationship between adherence and the variables studied. The extent to which variation in adherence can be explained by the factors under

investigation will be assessed⁸. Firstly, univariate analyses will be performed to test the association between the outcome (adherence to DMARDs) and potential explanatory variables in participants with RA. There will be two primary questions for the univariate analyses:

1. Is the BMQ necessity score correlated with adherence?
2. Is the BMQ concerns score correlated with adherence?

Secondly, general linear models with adherence to DMARDs as the dependent variable will be fitted, adjusting for age, sex, number of years of education, significant predictors on univariate analysis, and clinically relevant factors such as disease duration, DAS28, HAQ scores and DMARDs that are commonly used to treat RA. Interactions with ethnicity will be examined and if an interaction with ethnicity is identified, all subsequent analysis will be stratified by ethnicity (South Asian vs. White British).

Phase 2 In-depth qualitative interviews

There will be two primary questions for the qualitative phase

1. What factors motivate those with good adherence to adhere well?and
2. What strategies aid medication adherence in RA patients?

To obtain a wide representation of views about barriers to and facilitators of adherence, patients will be interviewed until theoretical saturation is reached. Patients will be identified from phase 1 with low adherence (defined as lowest tertile on MARS) and higher levels of medication adherence (defined as upper tertile on MARS) and invited for individual interviews. In each group (patients with good and poor adherence) there will be a mixture of White and South Asian patients. A semi-structured interview schedule will be developed from the literature and with input from the Patient Steering Group. A maximum variety approach will be used to capture

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2
3 a broad social and demographic subject range⁴⁸. Interviews will take place within the
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5 hospital in a non-clinical setting (e.g. in the postgraduate centre in dedicated rooms
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7 for interviewing) to allow patients to talk freely about issues related to medication
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9 adherence.
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11 12 *Data analysis*

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15 Data collection and analysis will be iterative occurring as data collection proceeds,
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17 with new data informing subsequent interviews. The transcribed data will be analysed
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19 by using constant comparative analysis⁴⁸. This process involves looking at the
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21 different patterns and reflecting on them to seek similarities between emerging
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23 themes. Each transcript will be coded (labels) to capture the essence of the patients'
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25 narratives. By creating several labels, a structure of codes will be developed to
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27 understand the meaning of the data. The coding will be staged. During the coding the
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29 researcher will look for demographic, factual (i.e.disease symptoms) and /or
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31 conceptual meaning. For example, are some issues about medication adherence
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33 related to gender? Or what aspects of the patient's story help explain the meaning of
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35 medication adherence? The researcher will allow for spontaneous themes to emerge
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37 and, in addition, attention will be paid to more specific themes chosen from phase 1
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39 of the study, that may help explain patient adherence. A separate list of themes for
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41 each ethnic group will be compiled. The transcripts will be read and independently
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43 coded by two other members of the research team a clinician (PG) and a medical
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45 sociologist (SG) to ensure an inter-disciplinary perspective. Discussion will be held
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47 between the team to finalise themes for the coding.
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Ethical approval and dissemination

This study has been approved by the South Birmingham (10/H1207/89) and Coventry and Warwickshire (12/WM/0041) Research Ethics Committees. Verbal and written consent will be obtained from all patients. For those in whom English is not their first language the researcher (KK) will conduct an oral discussion about taking part in the study with patients in Hindi, Punjabi and Urdu. The authors will disseminate the findings in peer reviewed publications.

Summary

The aim of this study is to assess the relationship between adherence to medicines and biopsychosocial variables in RA patients of White British and South Asian backgrounds. Furthermore, it will explore the reasons underlying high and low adherence in these two ethnic groups.

Many studies to date have provided insight into approaches to improve the adherence in patients with chronic diseases⁴⁹. A substantial literature has documented a number of factors related to adherence such as demographic, social, health care provider related medical system related and disease and treatment related factors⁸. Furthermore, an emphasis has been placed on cognitive models that focus on patients' perceptions and beliefs as motivating factors for adhering to therapy^{7;13}. Appropriate health beliefs such as the perceived seriousness of disease, vulnerability to complications and the efficacy of treatment, can predict better adherence⁵⁰. Patients are thought to adhere well when the treatment regimen makes sense to them, when it seems effective, and when from their perspective the benefits outweigh the concerns¹⁴. Such decision making is typically based on individuals' subjective perceptions of the pros and cons of the therapy⁵¹. However, such issues have not been explored in

patients with RA from the South Asian populations and this study will fill this gap in the literature. Importantly, this study will address two main issues. Firstly, the study will extract characteristics that are associated with high and low adherence among RA patients and assess the impact of ethnicity on this. Secondly, the study will allow an opportunity to further explore issues that arise in phase 1 of the study using qualitative methodologies within phase 2. The motivational factors that encourage patients to adhere well will be discussed in more detail. Furthermore, this will provide information for the development of an intervention to change beliefs and behaviours.

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Authors' contributions

KK is the Chief Investigator, PG and SG are the primary supervisors, KR is the clinical supervisor, PN has given statistical advice for the study. KS and RH are the external supervisors. KK led writing the manuscript, all authors contributed to the revision of the manuscript. KK is the guarantor of this paper.

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Competing interests

The authors declare that they have no competing interests.

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A mixed methods study to investigate medication adherence in patients with rheumatoid arthritis of White British and South Asian origin

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Abstract

Background

Low adherence to medicines is an important issue as up to 40% of patients with chronic diseases do not take their medications as prescribed. This leads to suboptimal clinical benefit. In the context of rheumatoid arthritis there is a dearth of data on adherence to disease modifying anti-rheumatic drugs amongst minority ethnic groups. This study aims to assess the relationship between adherence to medicines and biopsychosocial variables in patients with rheumatoid arthritis of South Asian and White British origin.

Method / analysis

A mixed methods approach will be used, encompassing a cross-sectional survey of 176 patients collecting demographic and clinical data, including information on adherence behaviour collected using a series of questionnaires. This will be followed by in-depth qualitative interviews.

Ethics and Dissemination

This study has been approved by the South Birmingham (10/H1207/89) and Coventry and Warwickshire (12/WM/0041) Research Ethics Committees. The authors will disseminate the findings in peer reviewed publications.

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Key words:

Ethnicity, rheumatoid arthritis, medication adherence, beliefs.

For peer review only

Introduction

Rheumatoid arthritis (RA) is a chronic systemic inflammatory disorder that is characterized by joint inflammation¹ and is often associated with a poor quality of life². The disease has a huge financial burden on the National Health Service and on individuals as about a third of patients stop work within the first five years of diagnosis³. Recent therapeutic advances now enable effective control of disease in a large proportion of patients^{4,5}. Taking disease modifying anti-rheumatic drugs (DMARDs) as prescribed may not only reduce articular disease activity and progression but may also reduce the risk of extra-articular features of RA such as cardiovascular disease⁶. Adherence to medicines is thus likely to be an important determinant of RA treatment success. However, it is estimated that in developed countries, 40% of patients who suffer from chronic diseases do not adhere to treatment recommendations^{7,8} with adherence rates dropping most dramatically after the first six months of therapy⁹.

Efforts to improve treatment outcomes require a better understanding of the particular barriers to and facilitators of adherence to therapy, and of patient experiences of taking treatment. This is a complex process and factors associated with non-adherent behaviour can be organised into the following interacting domains: (1) socio-economic factors; (2) health professional and health services related factors; (3) characteristics of the treatment regimen; (4) characteristics of the disease; (5) patient related factors⁸. Furthermore, to better understand patients' medicine taking many researchers have examined cognitive factors such as patients' perception of their disease, and factors which can be changed to enable more effective behavioural interventions⁸. Among the different models proposed^{10,11} Clifford et al,¹² have developed the Necessity – Concern framework. This framework has been shown to

explain non-adherence across a range of illnesses¹³. According to Horne,^{14;15} patients' motivation to start and to continue with medication is often influenced by the way in which they evaluate their need for treatment. Adherent behaviour depends on which of the two beliefs prevails, i.e. the necessity of the medicine or concerns about the possible threat of the medicines⁷. This can be captured by the two subscales of the Beliefs about Medicines Questionnaire (BMQ)¹⁶: firstly, the *specific necessity* scale which largely focuses on assessing the respondents' beliefs about the necessity of their prescribed medication for controlling their illness and maintaining their health (e.g., "my health, at present, depends on my medication"); and secondly, concerns about the adverse consequences of taking prescribed medication which mostly focuses on assessing the *specific-concerns* scale (e.g., "I sometimes worry about the long-term effect of my medication"). Together, the Necessity – Concern Framework model¹² provide a useful framework to study adherence in patients with RA of South Asian and White British origin.

Several studies have reported that higher levels of self-efficacy and social support are associated with improved medication adherence¹⁷ although there are conflicting data¹⁸. Other factors may be associated with adherence including age, income, level of education, knowledge of disease and satisfaction with information about medicines^{19;20}. Several authors have suggested that patients' beliefs about medicines play an important role in medication adherence in chronic diseases^{7;21-24}. For example, in rheumatology, Neame and Hammond²¹ found that concerns about medicines were higher in non-adherent than adherent RA patients and were associated with feelings of helplessness. Patients with higher levels of concerns were those who reported more adverse effects from DMARDs. Also, disease severity plays a key role in patients' decisions to either take or not take their treatments²⁵. However, few studies^{26;27} have

investigated the role of ethnicity as a factor affecting medication adherence in patients with RA, particularly in South Asians. Garcia-Gonzalez et al²⁷ found that Hispanic and African American patients with RA had significantly reduced medication adherence when compared with patients of White origin. They attributed this to greater feelings of depression and the perception of medication as harmful in the minority ethnic groups. Patients with a low level of education and less knowledge about their disease were less likely to take their medication. A pilot study by Kumar et al,²⁸ did not measure adherence rates to medicines but did highlight that RA patients from a South Asian background had more negative beliefs about their medicines compared to White British patients. These negative beliefs were influenced by a range of factors including views about fate²⁹. Furthermore, South Asian patients with RA have also been shown to be different in their help seeking behaviours³⁰. Patients' beliefs about the meaning of symptoms were important when deciding to seek medical help. This was sometimes related to a perception that their symptoms represented God's punishment and medical help seeking was thus often delayed, contributing towards delays in initiating treatment³⁰. This study aims to assess the relationship between adherence to medicines and biopsychosocial variables (e.g. age, gender, level of education, socioeconomic status, occupation, employment status and disease duration) in patients with RA of South Asian (defined as originating from India or Pakistan) and White British origin. Further, the study will explore the reasons underlying high and low adherence amongst these two groups of patients.

Methods and analysis

A two phased mixed methods approach encompassing both quantitative and qualitative designs will be used.

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Phase 1: Quantitative survey

The valid and reliable Medication Adherence Report Scale (MARS)⁷ will be used to capture data to address the relationship between adherence to medicines used in RA and potential explanatory variables (identified from factors that are known to influence adherence)⁸ in patients with RA of White British and South Asian origin. MARS is a five - item self-report scale for assessment of non-adherent behaviour (e.g. I forget to take them, and I alter the dose). The items are rated on a five point Likert scale⁷, ranging from 1= very often to 5= never.

The BMQ will be used to measure beliefs about medicines. The BMQ questionnaire consists of the BMQ specific which measures perceptions of specific medications and the BMQ General, which measures more general beliefs about medicines¹⁶. The Specific scales: assessing patients' beliefs about the necessity of medication for maintaining present and future health (Necessity, score range from 5-25, higher score indicating stronger need for medication), and the other assessing their concerns about the potential adverse consequences of using medication (Concern, score range from 6-30, higher score indicating more concerns about medication). The BMQ General scales: assessing patients' beliefs about the use of medicines and whether they are overprescribed by clinicians (Overuse, score range from 3-15). The Harm assessing patients' beliefs about the intrinsic nature of medicines and the degree to which they are perceived as harmful addictive (Harm, scores range from 5-25). For both, Overuse and Harm scales, higher scores indicate a more negative perception towards medication in general.

The Health Assessment Questionnaire (HAQ)³¹ and the IPQ¹¹ have been validated and are already available in different languages^{32;33} for example Hindi. The HAQ will be used to assess function as we have shown that patients with negative beliefs have a

worse function scores²⁸. Thus, the association of HAQ with MARS may provide useful data. The Illness Perception tool¹¹ has five discrete attributes (identity, cause, timeline, consequences, cure and control), that patients tend to have about their condition (their illness perception). The scores range from a five – point scale, where 1 = strongly disagree and 5 = strongly agree). These help predict health behaviours such as medication adherence. Looking at the association of the IPQ and MARS will be useful to determine associations with medication adherence.

Patient satisfaction with information can be measured using the Satisfaction with Information about Medications questionnaire (SIMS)³⁴. This questionnaire has two subscales - action and usage of drugs (nine items), and potential problems (eight items). Those who report that the information is “about right” or indicate “none needed” will be classified as satisfied (scored 1). Those who report that the information is “too much”, “too little” or indicate “none received” will be classified as dissatisfied (scored 0). Responses will be recorded on a likert scale (i.e. too much – none needed). By capturing these data we will be able to assess the relationship between satisfaction with information about medication and adherence in our study population. For the purposes of this study the HAQ³¹, IPQ¹¹, BMQ¹⁶, Satisfaction with Information about Medications questionnaire (SIMS)³⁴ and Medication Adherence Report Scale (MARS)⁷ will for the first time be independently audio translated into Hindi, Punjabi and Urdu followed by back translation to ensure linguistic validity³⁵. This is because the study will take place in a largely multicultural city in which 18.5% of the population is of South Asian origin³⁶. Furthermore, we have reported that about a third of the South Asian population attending Rheumatology clinics in Birmingham required interpreters and about 33% of that population were not able to read the script of their preferred language³⁷.

Consequently, written translation of the questionnaires would exclude a sizable proportion of potentially eligible subjects. To test the logistics of filling in the questionnaire the translated audiotapes will be piloted amongst a group of patients.

Choice of questionnaires

The questionnaires were chosen based on their use in chronic diseases. MARS and BMQ has been used in patients with asthma, chronic obstructive pulmonary disease, diabetes, renal failure¹⁶. In RA, Neame et al³⁸ has shown that BMQ - concern scale distinguished between low and higher adherence (MARS). Whereas necessity scale was shown to be correlated with number of disease modifying anti-rheumatic drugs (DMARDs) and adherence.

Patients usually require a rationale for their medication before following advice about taking it³⁴. It is well known that 40% of patients on chronic medication do not take their medication as prescribed. It is likely that medication adherence is improved if patients are provided with information which addresses the issues they want to know about in a way that is comprehensible. Patient satisfaction with information can be measured using the Satisfaction with Information about Medications questionnaire (SIMS)³⁴. This questionnaire has two subscales - action and usage of drugs (nine items), and potential problems (eight items). Those who report that the information is “about right” or indicate “none needed” will be classified as satisfied (scored 1). Those who report that the information is “too much”, “too little” or indicate “none received” will be classified as dissatisfied (scored 0). Responses will be recorded on a likert scale (too much – none needed) by capturing these data we will be able to assess the relationship between satisfaction with information about medication and

adherence in our study population. Furthermore, the SIMS has been shown to be consistence in patients with asthma, cardiac rehabilitation, diabetes, and oncology)³⁴. It also distinguishes between low and high adherence in RA³⁹.

The IPQ again has been used in a variety of conditions such as diabetes, hypertension, and HIV¹¹. Amongst RA patients Hughes et al⁴⁰ found that some of the IPQ domains were associated with low and high adherence. There are very few studies that provide evidence regarding illness perception amongst RA patients of South Asian origin. The illness perception tool has five discrete attributes (identity, cause, timeline, consequences, cure and control), that patients tend to have about their condition (their illness perception) score ranging from a five – point scale, where 1 = strongly disagree and 5 = strongly agree). These help predict health behaviours such as medication adherence. For example, medication adherence in patients with hypercholesterolemia has been shown to be related to beliefs that the disease has severe coronary consequences^{41;42}. Hypertensive patients who believe that their condition is chronic are more likely to adhere to their antihypertensive medication than those who believe it to be an acute condition^{41;42}. The latter group of patients may view themselves to be cured. Looking at the association of the IPQ and MARS will be useful to determine associations with medication adherence.

Finally, the HAQ³¹ will be used to assess functional disability as our previous work has shown that patients with negative beliefs had a higher functional disability score. Thus, the association of HAQ with MARS may provide useful data.

Patient engagement

Using the BMQ to quantify adherence has the advantage that it will help embed the findings from this study within the Necessity-Concern Framework. However, before

we made a final decision on which tool(s) to use to measure adherence, the views of patients were sought⁴³. The study design was presented to the rheumatology departmental patient User Group. An invitation to join the project Steering Group was offered to all patients and four (two White British and two South Asian patients) joined this group. None of these patients' rheumatoid arthritis was being treated by the researchers from a clinical perspective. The most common methods of measuring adherence were discussed including patient questioning, patient logs, pill counts⁴⁴ and the widely used medication electronic monitoring system (MEMS)⁴⁵. This system involves a cap that measures opening and closing as dosages are taken, and is able to report on the time and dates that dosages were taken. The Steering Group strongly felt that the MEMS approach could have the potential to change the patients' behaviour and was thus not felt to be appropriate. Patients preferred a self reported tool such as the MARS⁷, which is phrased in a way that sanctions non-adherence. However, did acknowledge that by using this approach adherence might be over reported by some patients.

In addition, data on demographic (variables such as age, gender, ethnicity, level of education) and disease related variables such as disease activity score (DAS28)⁴⁶. A free text box will be included to allow patients to record information on other variables which they feel may influence their adherence.

Inclusion criteria

Patients with RA (according to the 1987 American College of Rheumatology criteria)⁴⁷ of either White British or South Asian origin will be invited to participate. Patients will have been diagnosed with RA for at least three months; be 18 years or over; be taking at least one DMARD / have been on a DMARD in the past. Patients will be

classified as being of White British origin if they had three or more grandparents who had been born in the UK and regard themselves as being of White origin. Patients will be classified as being of South Asian origin if they had three or more grandparents who had been born in India or Pakistan and regarded themselves as being of South Asian origin.

Recruitment

Patients will be recruited from three hospitals based Rheumatology clinics in Birmingham, UK (Sandwell and West Birmingham Hospitals NHS Trust, University Hospitals Birmingham NHS Foundation Trust and Heart of England NHS Foundation Trust).

Data and Sample collection

Data will be collected by a researcher (KK) by questionnaires, clinical assessments and case notes review. The sample size of 176 (88 patients from each ethnic group) will detect with at least 80% power a significant Pearson correlation coefficient at the 5% level if the true significant correlation of adherence and beliefs about medicines is less than or equal to -0.21 or greater than or equal to +0.21. This calculation has been based on a previous study that investigated the relationship between beliefs about medicine and adherence⁷. In this paper the authors found a Pearson correlation coefficient of 0.21 between necessity score and adherence and a Pearson correlation coefficient of -0.33 between concern score and adherence. Thus, the sample size will enable us to detect correlations of these magnitudes with at least 80% power. Data will be analysed by using the Statistical Package for Social Sciences (SPSS) and modelled to assess the relationship between adherence and the variables studied. The extent to which variation in adherence can be explained by the factors under

investigation will be assessed⁸. Firstly, univariate analyses will be performed to test the association between the outcome (adherence to DMARDs) and potential explanatory variables in participants with RA. There will be two primary questions for the univariate analyses:

1. Is the BMQ necessity score correlated with adherence?
2. Is the BMQ concerns score correlated with adherence?

Secondly, general linear models with adherence to DMARDs as the dependent variable will be fitted, adjusting for age, sex, number of years of education, significant predictors on univariate analysis, and clinically relevant factors such as disease duration, DAS28, HAQ scores and DMARDs that are commonly used to treat RA. Interactions with ethnicity will be examined and if an interaction with ethnicity is identified, all subsequent analysis will be stratified by ethnicity (South Asian vs. White British).

Phase 2 In-depth qualitative interviews

There will be two primary questions for the qualitative phase

1. What factors motivate those with good adherence to adhere well?and
2. What strategies aid medication adherence in RA patients?

To obtain a wide representation of views about barriers to and facilitators of adherence, patients will be interviewed until theoretical saturation is reached. Patients will be identified from phase 1 with low adherence (defined as lowest tertile on MARS) and higher levels of medication adherence (defined as upper tertile on MARS) and invited for individual interviews. In each group (patients with good and poor adherence) there will be a mixture of White and South Asian patients. A semi-structured interview schedule will be developed from the literature and with input from the Patient Steering Group. A maximum variety approach will be used to capture

a broad social and demographic subject range⁴⁸. Interviews will take place within the hospital in a non-clinical setting (e.g. in the postgraduate centre in dedicated rooms for interviewing) to allow patients to talk freely about issues related to medication adherence.

Data analysis

Data collection and analysis will be iterative occurring as data collection proceeds, with new data informing subsequent interviews. The transcribed data will be analysed by using constant comparative analysis⁴⁸. This process involves looking at the different patterns and reflecting on them to seek similarities between emerging themes. Each transcript will be coded (labels) to capture the essence of the patients' narratives. By creating several labels, a structure of codes will be developed to understand the meaning of the data. The coding will be staged. During the coding the researcher will look for demographic, factual (i.e. disease symptoms) and /or conceptual meaning. For example, are some issues about medication adherence related to gender? Or what aspects of the patient's story help explain the meaning of medication adherence? The researcher will allow for spontaneous themes to emerge and, in addition, attention will be paid to more specific themes chosen from phase 1 of the study, that may help explain patient adherence. A separate list of themes for each ethnic group will be compiled. The transcripts will be read and independently coded by two other members of the research team a clinician (PG) and a medical sociologist (SG) to ensure an inter-disciplinary perspective. Discussion will be held between the team to finalise themes for the coding.

Ethical approval and dissemination

This study has been approved by the South Birmingham (10/H1207/89) and Coventry and Warwickshire (12/WM/0041) Research Ethics Committees. Verbal and written consent will be obtained from all patients. For those in whom English is not their first language the researcher (KK) will conduct an oral discussion about taking part in the study with patients in Hindi, Punjabi and Urdu. The authors will disseminate the findings in peer reviewed publications.

Summary

The aim of this study is to assess the relationship between adherence to medicines and biopsychosocial variables in RA patients of White British and South Asian backgrounds. Furthermore, it will explore the reasons underlying high and low adherence in these two ethnic groups.

Many studies to date have provided insight into approaches to improve the adherence in patients with chronic diseases⁴⁹. A substantial literature has documented a number of factors related to adherence such as demographic, social, health care provider related medical system related and disease and treatment related factors⁸. Furthermore, an emphasis has been placed on cognitive models that focus on patients' perceptions and beliefs as motivating factors for adhering to therapy^{7;13}. Appropriate health beliefs such as the perceived seriousness of disease, vulnerability to complications and the efficacy of treatment, can predict better adherence⁵⁰. Patients are thought to adhere well when the treatment regimen makes sense to them, when it seems effective, and when from their perspective the benefits outweigh the concerns¹⁴. Such decision making is typically based on individuals' subjective perceptions of the pros and cons of the therapy⁵¹. However, such issues have not been explored in

patients with RA from the South Asian populations and this study will fill this gap in the literature. Importantly, this study will address two main issues. Firstly, the study will extract characteristics that are associated with high and low adherence among RA patients and assess the impact of ethnicity on this. Secondly, the study will allow an opportunity to further explore issues that arise in phase 1 of the study using qualitative methodologies within phase 2. The motivational factors that encourage patients to adhere well will be discussed in more detail. Furthermore, this will provide information for the development of an intervention to change beliefs and behaviours.

Acknowledgements

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Authors' contributions

KK is the Chief Investigator, PG and SG are the primary supervisors, KR is the clinical supervisor, PN has given statistical advice for the study. KS and RH are the external supervisors. KK led writing the manuscript, all authors contributed to the revision of the manuscript. KK is the guarantor of this paper.

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Competing interests

The authors declare that they have no competing interests.

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Correction

Kumar K, Raza K, Nightingale P, *et al.* A mixed methods protocol to investigate medication adherence in patients with rheumatoid arthritis of White British and South Asian origin. *BMJ Open* 2013;**3**:e001836. In the Introduction, second paragraph, 'Necessity–Concern framework' should have read 'Necessity–Concern Framework'.

In the section 'Phase 1: quantitative survey' the second paragraph should have read as follows:

"The BMQ will be used to measure beliefs about medicines. The BMQ questionnaire assesses perceptions of medication necessity and perceived concerns about medicines.^{16 31} The Specific scale: assesses patients' beliefs about the necessity of medication for maintaining present and future health (Necessity, score range from 5–25), and the Concern assesses the potential adverse consequences of using medication (Concern, score range from 6–30). The BMQ General scales: assesses patients' beliefs about the use of medicines and whether they are overprescribed by clinicians (Overuse, score range from 3–15). The Harm assesses patients' beliefs about the perceived risk of medicines being harmful addictive (Harm, scores range from 5–25). For both, Overuse and Harm scales, higher scores indicate a more negative perception towards medication in general."

The third paragraph should have defined IPQ as 'Illness Perception Questionnaire (IPQ)'.

In the section 'Choice of questionnaires', first paragraph, 'BMQ–concern scale' should have read 'BMQ–Concern scale'.

In the section 'Choice of questionnaires', the second paragraph should have read as follows:

"Patients usually require a rationale for their medication before following advice about taking it.³⁵ It is well known that 40% of patients on chronic medication do not take their medication as prescribed. It is likely that medication adherence is improved if patients are provided with information which addresses the issues they want to know about in a way that is comprehensible. Patient satisfaction with information can be measured using the SIMS³⁵. Furthermore, the SIMS has been shown to be consistent in patients with asthma, cardiac rehabilitation, diabetes, and oncology).³⁵ It also distinguishes between low and high adherence in RA.⁴⁰

In the section 'Choice of questionnaires', the third paragraph should have read as follows:

"The IPQ again has been used in a variety of conditions such as diabetes, hypertension, and HIV.¹¹ Amongst RA patients Hughes *et al*⁴¹ found that some of the IPQ domains were associated with low and high adherence. There are very few studies that provide evidence regarding illness perception amongst RA patients of South Asian origin. These help predict health behaviours such as medication adherence. For example, medication adherence in patients with hypercholesterolemia has been shown to be related to beliefs that the disease has severe coronary consequences.^{42 43} Hypertensive patients who believe that their condition is chronic are more likely to adhere to their antihypertensive medication than those who believe it to be an acute condition.^{42 43} The latter group of patients may view themselves to be cured. Looking at the association of the IPQ and MARS will be useful to determine associations with medication adherence."

In the section 'Choice of questionnaires', fourth paragraph, the first two sentences should not have been included. The third sentence should have read: 'In addition, data on demographic variables (such as age, gender, ethnicity, level of education) and disease-related variables such as disease activity score (DAS28) will be collected.'⁴⁷

In the section 'Patient engagement', first paragraph, 'patient User Group' should have read 'Patient User Group'.

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