UNIVERSITY OF BIRMINGHAM

Quality Control Document:
Protocol Template for non-CTIMPs & Studies
PROTOCOL

Full title of the project

Improving patient education for people of South Asian* origin living with rheumatoid arthritis in England

Short title/acronym

Patient education for people of South Asian origin living with RA

Protocol version number and date

Protocol version number:	Version 2
Protocol version date:	16/07/2025

Research reference numbers

IRAS number:	356140
Sponsor/RG number:	RG_25-035
REC reference number:	25/SC/0217
Public registry number:	NA
Funder number:	NIHR208620

Signature page

The undersigned confirm that the following protocol has been agreed and accepted and that the CI agrees to adhere to the signed University of Birmingham's sponsorship CI declaration. I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor. I also confirm that I will make the findings publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the project will be given; and that any discrepancies from the project as planned in this protocol will be explained.

Chief Investigator (CI)	
Name:	Dr Kanta Kumar
Date:	16/07/2025
Signature:	

Sponsor statement

Where the University of Birmingham takes on the sponsor role for protocol development oversight, the signing of the IRAS form by the sponsor will serve as confirmation of approval of this protocol.

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Key contacts

Role/function	Contact details
CI	Dr Kanta Kumar Health Sciences University of Birmingham k.kumar@bham.ac.uk
Co- Investigator	Professor Lisa Roberts School of Health Sciences, University of Southampton L.C.Roberts@soton.ac.uk
Other team members are listed in the IRAS for and are all external	

Project summary

Our study will see how well a new online programme, called "Apni Jung" ("Our Fight") against rheumatoid arthritis (RA), helps people from South Asian backgrounds in England living with RA. www.nras.org.uk/apnijung (National Rheumatoid Arthritis Society).

RA is a chronic long-term condition where the body's immune system attacks the joints, causing pain, swelling, and stiffness. If not managed well, it can cause joint damage. The Apni Jung programme was created for people who speak Hindi, Punjabi, or Urdu, and face language and cultural barriers managing their RA. It provides videos and advice that consider cultural preferences and help people better understand and manage their RA.

We will test whether we can:

- recruit people from South Asian backgrounds to take part in the study, use the Apni Jung programme and report any difference it makes vs with usual care.
- if usual care plus Apni Jung proves to be positive, plan a future study to test the programme widely and measure its impact for people with RA.

Why we need to do this? In our 20 years of research, we have found that people of South Asian background develop RA at a younger age and with more severe symptoms compared to other groups. Many struggle to access important information about managing their RA because of language or cultural differences and have worse outcomes. Apni Jung was created in partnership with the National Rheumatoid Arthritis Society (NRAS) to help with this. It was made just before the COVID-19 pandemic, and so, has not yet been formally tested.

How will the study happen? This study will take place in six early arthritis clinics. We will compare two groups of South Asian people with newly diagnosed RA: **one group will receive usual care**, and the other group will have **usual care plus Apni Jung programme (which lasts 2-3 hours).** We will collect information from both groups at the start and again after three months, using questionnaires in their preferred languages. The questions will focus on how people feel about their RA, their ability to

manage it, and how often they use healthcare services. We will also talk to people individually after they have used Apni Jung to learn more about what they thought of it.

Sharing findings: If people like in the Apni Jung programme and our methods work, we will seek funding for a larger study. Results of our study will be shared with researchers in top health journals and with people and communities through summary reports, a short film, and via an NRAS blog.

Funding and support in kind

Funder(s)	Financial and non-financial support given
NIHR	£263,304.00

Role of sponsor and funder

NIHR are funding the project

Roles & responsibilities of management committees/groups & individuals

The team has a diverse group of expertise. We also have patient organisations working closely with us National Rheumatoid Arthritis Society. Dr Kumar (CI) will have co-investigator – Professor Lisa Roberts from University of Southampton this is on request of NIHR. Professor Lisa Roberts will be mentoring Dr Kumar. All the research team will be working closely to ensure major milestones are met.

The team members are as follows and are listed in the IRAS allocation other than Professor Richard Osborne who is acting as an external advisor.

1.Mrs Felicity Evison, **(2.** Patient partners, Mrs Joti Reehal leading with others including Mrs Ailsa Bosworth MBE, Founder and National Patient Champion**), 3.** Professor Ade Adebajo, **4.** Professor Lisa Roberts, **5.** Dr. Shirish Dubey, **6.** Dr Atiya Kamal, **7.** Professor Sue Jowett. **8.** Professor Richard Osborne, the Director of the Centre for Global Health and Equity at Swinburne University of Technology in Australia, a global leader in intervention development, implementation, and evaluation across chronic diseases in both high income and low-income countries (Expertise in health literacy).

Patient & public involvement group

Recognising the crucial role of patient and public involvement (PPI) in shaping healthcare research, we have fully integrated their perspectives into every phase of this project, in line with NIHR guidelines. Key PPI group, including Mrs. Joti Reehal (from the Apni Jung team, living with RA), with rest of the PPI group, they have been instrumental in informing project planning, identifying outcome measures that matter, and ensuring the research remains relevant to South Asians needs.

Additionally, NRAS is represented by Mrs. Ailsa Bosworth MBE, former CEO of NRAS and current Patient Champion, who played a pivotal role in developing Apni Jung and continues to support its future evaluation. One key recommendation from the group has been to recruit a South Asian Research Associate to enhance engagement with minority ethnic communities.

This recommendation stems from the well-documented underrepresentation of ethnic minorities in research, often due to language and cultural barriers. In our previous studies, the employment of a culturally and linguistically aligned Research Associate significantly improved participant recruitment, and we plan to follow this approach again. Our PPI group have actively shaped the research process. They contributed to the creation of a plain language summary, participated in discussions about the design of the study questionnaires, and engaged in meetings regarding the NIHR Stage 1 feedback, where their input was crucial in further refining the plain language summary. They also provided valuable input into the potential ideas for the interview topic guide. The group also discussed at length with us whether people who undertake the Apni Jung should be contacted via telephone or attend

another visit in-person and ultimately advised the research team to use the telephone to avoid additional visits to the hospital.

Protocol contributors

The grant has been written with group mentioned above.

Key words: rheumatoid arthritis, ethnicity, self-management, patient education

Project flow chart: attached separately

1. Background and rational:

Background: Our research shows that people from South Asian backgrounds are diagnosed with immune-mediated diseases, including RA, significantly earlier than White individuals (by 2–30 years) [1]. Indeed, RA is diagnosed at a median age of 45–48 years in South Asian populations, compared to 56 years in White individuals [1]. The group also is known to be at a greater risk of most co-morbidities such as cardiovascular conditions [2]. The earlier onset highlights the need for accessible, proactive self-management, particularly when people are facing peak career and family responsibilities [1].

Outcomes have been shown to be poorest among non-English speakers from South Asian backgrounds. An analysis of national data (n=35,807) from the British Society for Rheumatology's National Early Arthritis Audit [3] shows that people from ethnic minority backgrounds had lower odds of RA remission at three months (adjusted odds ratio 0.79, 95% CI 0.65–0.96), compared to adjusted odds ratio 0.79 (95% CI: 0.65, 0.96) relative to White individuals [3]. Delays in achieving RA control, necessitate targeted interventions to mitigate for these disparities.

Empowering people with RA through supported self-management leads to improved health outcomes, lower healthcare use, and greater well-being. Yet, educational resources in rheumatology have predominantly been in English, limiting access for people with non-English-speaking skills. Addressing cultural and linguistic barriers is crucial, particularly as the NHS adopts remote appointments and Patient-Initiated Follow-up Pathways [4].

In summary, South Asian people develop RA earlier, with more severe symptoms, and face barriers to self-management resources. Without culturally tailored approaches, these challenges will continue, worsening health inequalities.

2. Theoretical framework

This is feasibility study

3. Research question/aims

Aims: **(1)** To test the recruitment methods, outcomes and retention rates appropriate for a future trial of Apni Jung; **(2)** to record the uptake and utility of Apni Jung for people with RA, in terms of how well it was received and the extent to which components of Apni Jung met the needs of the target population; and **(3)** to ensure the study design minimises the potential for contamination.

- Are the study design, recruitment methods, outcomes and retention rates sufficiently robust to support a future trial of Apni Jung? (Feasibility of a future trial will be informed by the data on recruitment and retention rates, effect sizes for sample size calculations, contamination (accessing Apni Jung in the control arm, recording healthcare utilisation, questionnaire completions and definitively identify the primary outcome, on which to base the sample size calculation).
- What is the uptake and reported utility of Apni Jung for people with RA? how well it was received and the extent to which components of Apni Jung met the needs of the target population.

3.1. Outcome

Potential impact: If the results demonstrate feasibility, we will advance to a larger 12-month trial to assess the clinical and cost-effectiveness of the Apni Jung programme in enhancing RA self-management among South Asians. We hypothesise that empowering self-management will reduce symptom severity, improve quality of life, and lower work loss, presenteeism, and healthcare use.

Outcome measures

The primary outcome measure

The primary outcome is the feasibility of the future trial design including recruitment and retention of people at 3-months, and any evidence of contamination (access to Apni Jung in the control group). Analyses will be conducted with the clinical outcomes, including Patient Enablement [5], at 3 months, to confirm the primary outcome for the future trial, in this population.

Secondary outcome measures

An improvement in these variables (quality of life, health literacy, illness perceptions and less use of health resources)

EuroQol (EQ-5D-5L) [6]

Health Education Impact Questionnaire [7] / Health Literacy Questionnaire [8]

Short Brief Illness Perception Questionnaire (IPA) [9]

RA-related healthcare resource utilisation

4. Design and methods of data collection and data analysis

Multicentred feasibility study with repeat measures design. Data collection through questionnaires and interviews.

5. Project setting

NHS sites in England

The study will be conducted in the following six sites centres: The University Hospitals Birmingham NHS Foundation Trust (1. QE and 2. Solihull sites), 3. The Royal Wolverhampton NHS Trust, 4. University Hospitals of Leicester NHS Trust and Sandwell and West Birmingham NHS Trust (5. city and 6. Sandwell sites). Approximately 30-40% (in rheumatology centres) of people report to be from South Asian background from the centres chosen for recruitment. On average clinicians see 2 or 3 people weekly from South Asian background in early arthritis clinics. Centres will be assigned as below to recruit data from usual care plus Apni Jung and usual care alone to minimise the possibility of contamination.

Usual care: Solihull site, QE site and City hospital.

Usual care plus Apni Jung: Royal Wolverhampton NHS Trust, Sandwell site, University Hospitals of Leicester NHS Trust.

6. Participant recruitment

6.1. Eligibility criteria

As below. People fulfilling the eligibility criteria and identifying as South Asian (visible through clinic lists) will be approached by the clinician during routine appointments.

6.1.1. Inclusion criteria

- People diagnosed with RA within a year, using the American College of Rheumatology/European League Against Rheumatism 2010 (ACR/EULAR 2010) criteria.
    - Adults ≥18 years old.
    - Ability to communicate in Hindi/ Punjabi/Urdu.
    - For usual care - People who have not previously received Apni Jung programme.
- People for usual care plus Apni Jung
    - Access to the internet / phone / you tube

6.1.2. Exclusion criteria

- People from non-South Asian backgrounds
- Members of the PPI team in this study.

6.2. Sampling

No formal sample size has been calculated in this feasibility study. 30 people in each arm is the number recommended by our statistician in order to estimate a standard deviation for the subsequent trial outcome measures. We will attempt to recruit up to 60 people overall to explore research processes, recruitment and retention. The study will be carried out in six sites; therefore, each centre will aim to recruit approximately 10 people (60 people in total). We have kept the sites for recruitment to usual care and usual care plus Apni Jung separate to avoid contamination. Randomisation will happen at the site level due to concerns about potential contamination (i.e. people not recruited to the Apni Jung website accessing the website) outweighing the bias introduced when randomising at this level.

6.2.1. Size of sample

A formal calculation was not done. Given the lack of studies among the South Asian patients in rheumatology where feasibility of usual care and intervention has been conducted. We believe that this work will allow us to assess the recruitment rate from the chosen sites.

To evaluate the feasibility of recruitment (% of the target number of people recruited), retention (% of recruited people with follow-up data), percentage of people accessing Apni Jung, and engagement rates will be reported. We will look to understand the recruitment rates per centre and identify if there are issues at a centre level impacting recruitment and the ability to follow protocol. As well as the final recruited number, we will look to understand how many people were screened and found eligible at each site. We will also capture the number of people excluded because they have previously received the Apni Jung programme.

We will also investigate the time taken to recruit people per centre and identify potential barriers to recruitment. Baseline characteristics will be summarised via counts and percentages for categorical data, with mean and standard deviations or medians and interquartile ranges, as appropriate, for continuous data. To understand the risk of contamination we will also ask people in the usual care if they had heard of Apni Jung before.

6.2.2. Sampling technique

Recruiting sites will be kept separate as outlined in the earlier section.

6.3. Recruitment

Usual Care Sites

Three NHS sites will focus on recruiting patients who are receiving usual care. Our Principal Investigators at these sites have already started initial discussions with eligible South Asian patients during their routine rheumatology appointments about our upcoming study to gain interest.

Patients diagnosed within a year are closely monitored in early inflammatory arthritis clinics, as the goal is to control RA symptoms as early as possible. Doctors and nurses at each site will identify

suitable patients from clinic lists and once we have ethical approval, people who have shown an interest will be invited to take part.

Each site aims to recruit 10 patients, but more will be approached to allow for those who may choose not to participate.

Usual Care + Apni Jung Sites

Three sites here will recruit patients in the same way, but these patients will also have access to the Apni Jung intervention.

The sites have been kept separate to reduce contamination.

We have selected one additional site (Walsall Manor NHS Trust as a backup plan in case we need to use this for meeting our recruitment target (either for usual care or usual care plus Apni Jung).

6.3.1. Sample identification

The doctors and nurses at these sites looking after the patients will screen suitable people for the study. Then patient information will be sent out by the research nurse at each site. In the information sheet we will mention that a team member will contact you to ensure you have read the sheet.

Later, the Research Associate, who will be able to speak in Hindi, Punjabi and Urdu, will follow up with a phone call to ensure the sheet is read and set a meeting time at the hospital with the individual. The Research Associate will get phone numbers from the doctors and nurses to contact the patients who have might have already showed an interest in taking part in the study. The team would have alerted the patients that a team member will be in contact. The Research Associate will speak in Hindi / Punjabi and Urdu.

6.3.2. Consent

The first conversation about the study will be with the patient's doctor or nurse. We have discussed this approach with all Principal Investigators, and it is appropriate for the Research Associate to take consent when a meeting is arranged at the clinic.

Since the Research Associate will speak in Hindi, Punjabi, and Urdu, patients may feel more comfortable discussing the study with someone who speaks their language and shares a similar background. Our team has extensive experience working with the South Asian community and understands the importance of using culturally appropriate language. For example, instead of the word 'consent,' which some people may not fully understand, we use terms like 'permission' that feel more familiar and reassuring.

Our patient partner group has provided valuable guidance on ensuring people feel at ease during the process. Because this study focuses on recruiting individuals who are often underrepresented in research, we hope that our inclusive approach—proven effective in previous work—will also support success in this study.

Data collection

After the consent, patients will be asked to fill in questionnaires mentioned above together with a demographic sheet. Data will be collected at baseline and at three months later using the same questionnaires (except HLQ at three months).

Baseline data will be collected at the clinic and on follow (via phone) we will repeat questionnaires (please see flow chart). We have audio translated the questionnaires in Hindi (universal language understood across the Asian people), for those in whom reading English might be a problem. The Research Associate will assist the patients through the audio recorded questionnaires. The audio

recording has taken place between three people (Dr Shirish Dubey, a Rheumatologist), (Dr Kanta Kumar, Associate Professor and CI), and an independent person (Dr Anu Desi, a rheumatologist) to validate the back translation and patient partners.

7. Storage and analysis of data

All data will be securely stored on the University of Birmingham's server and can only be accessed using a password-protected, encrypted university computer. Any printed documents related to the research will be kept in a locked filing cabinet in the university office for ten years. Only the research team will have access to the computer passwords and the keys to the filing cabinet.

The phone numbers will be accessed through Dr. Kumar's NHS email account at the university. The Research Associate will retrieve them together with Dr. Kumar. Regarding the Each questionnaire will be assigned a number and stored electronically in a password-protected file on a university computer, separate from other research data. When the study results are published, no information that could identify participants will be included.

Regarding the interview recordings in the Apni Jung arm, these will also be stored at the University in the same manner as the questionnaires.

The Research Associate will analyse all questionnaires including the demographics with support from Mrs Felicity Evison, a statistician, and Professor Sue Jowett, a health economist. Both are co-authors of the grant. The interview data will be analysed again by the Research Associate together with Dr Kumar, Professor Atiya Kamal (listed as the co-author). Our patient partners will be invited to help interpret that data. The results will be presented in tables and themes to rest of the team and no raw data will be shared except Mrs Felicity, Professor Sue Jowett.

To evaluate the feasibility of recruitment (% of the target number of people recruited), retention (% of recruited people with follow-up data), percentage of people accessing Apni Jung, and engagement rates will be reported. We will look to understand the recruitment rates per centre and identify if there are issues at a centre level impacting recruitment and the ability to follow protocol. As well as the final recruited number, we will look to understand how many people were screened and found eligible at each site. We will also capture the number of people excluded because they have previously received the Apni Jung programme.

We will also investigate the time taken to recruit people per centre and identify potential barriers to recruitment. Baseline characteristics will be summarised via counts and percentages for categorical data, with mean and standard deviations or medians and interquartile ranges, as appropriate, for continuous data. To understand the risk of contamination we will also ask people in the usual care if they had heard of Apni Jung before.

The mean score for the PEI, Brief IPQ, health literacy, health education impact and EQ-5D-5L will be calculated at both baseline and follow-up. EQ-5D-5L responses will be converted to utility scores derived from NICE's recommended tariff values and QALYs will be calculated for each participant using the area under the curve approach [10].

Unit costs from standard sources will be attached to resource use. A descriptive cost-consequence analysis will be undertaken to report mean resource use, costs, EQ-5D-5L scores and QALYs over 3 months follow-up by study group.

Healthcare utilisation diaries will be assessed for completion rates. The nine scales of the HLQ will also be analysed. Analyses will be conducted using STATA statistical software (StataCorp. 2023 Stata Statistical Software: Release 18. College Station, TX: StataCorp LLC.). Missing data will be described

and described. The summaries of the questionnaires will be performed based on a complete case analysis.

The following criteria would suggest that a main trial is not feasible, i.e. dropout rates, recruitment rates that suggest the ultimate sample size would not be practical, no apparent change in the outcomes with wide confidence intervals, lack of engagement with Apni Jung, feedback from people that suggests the content or delivery were not acceptable or usable, or contamination in the control arm. We will use the usability data to understand how the intervention was experienced by people and any changes that they consider would improve the intervention.

Qualitative interviews; in the usual care plus Apni Jung group

The Research Associate will contact people to check whether they have managed to access the Apni Jung material after 1-2 weeks and ask structured questions. This will be to determine whether they have listened to all the material provided. The Research Associate will organise a time to interview the people and ask questions about their experiences of using the Apni Jung materials, using the bespoke topic guide (developed and piloted with the NRAS and PPI group prior to using it the main interviews). This phone-based approach eliminates the need for additional hospital visits, accommodating patients who may prefer not to attend further visits (informed by our PPI representatives).

A sample of 10-15 qualitative semi-structured interviews will be undertaken using a bespoke topic guide, informed by NRAS, and PPI group. The number of interviews has been informed by current literature [11]. These interviews will explore peoples' experiences with the Apni Jung programme, and as recommended by our PPI group, will include discussion of both the content and delivery. Our PPI group suggested exploring what aspects of the Apni Jung webpage were most helpful and why, the layout of material, which specific content improved their understanding of RA, self-management, and medication adherence. Additional questions will explore the perceived value of patient stories featured on the site, such as whether these narratives fostered a sense of belonging and/or helped mitigate feelings of isolation in living with RA, and whether the cultural content helped them to relate to their journey of living with RA.

The group also advised on asking about their usage of the programme's resources and feedback on areas for improvement. We will ask whether people shared these resources with family members and if so, how this impacted on their engagement with the Apni Jung programme. It is likely this qualitative data will offer valuable insights into the acceptability and impact of Apni Jung from the peoples' perspective, guiding any change to be made prior to the future trial.

The telephone interviews will be digitally recorded using the RecordACall software. This programme is a simple application that can be used to record from a telephone recording device or microphone attached to a PC. This software easily allows for saving and archiving of the audio files, in line with the data management plan and ethical approval.

We recognise that there are likely to be some people who might react differently to the information. Consequently, their experience of receiving information might work in two potential ways. (1) They might either welcome the information or (2) they might feel overwhelmed. There might be people who have not experienced any change because they already have good knowledge and/or social support.

Qualitative analysis: usual care plus Apni Jung

We will collect and analyse data concurrently, as is usual in qualitative research, to aid the analysis and development of themes. To do this, we will manage the data using NVivo. Our research team and

PPI group will scrutinise the developing themes, to help ensure rigour, transparency, face and content validity [12].

Thematic analysis [13] was selected for this study to provide a nuanced, detailed account of peoples' views and experiences with Apni Jung materials, well-suited for exploring perceptions. Data will be analysed inductively, avoiding pre-set coding frames and minimising researcher bias. Reflexive thematic analysis will follow the methods described by Braun and Clarke [13,14] which includes familiarisation, coding, theme development and refinement.

To ensure rigor, we will apply the COREQ checklist [15] where relevant, alongside evaluative criteria to maintain quality and trustworthiness. The Research Associate will closely review the data, generating initial codes and themes, which will then be refined through team discussions to deepen insights and strengthen interpretations.

The code system developed will be then discussed in data workshops with NRAS and our PPI group to ensure that peoples' perspectives are fully integrated. Consensus on the final set of codes will be reached collaboratively. The research team, together with NRAS and the PPI group, will review the final coding framework, making any necessary recommendations for modifications.

After agreement on the final coding framework, we will summarise multiple statements from people who took part in the interviews within each category and subcategory, synthesising the data into key themes that reflect the peoples' experience. This structured approach will allow us to systematically analyse qualitative data while ensuring that the voices of NRAS and our PPI group shape the interpretation process.

8. Ethical and regulatory considerations

The Research Associate will be supported by Dr. Kumar/ Professor Roberts and the entire team, so they will never be working alone on the project. There is no alone working.

As for any risks to patients, they are minimal. We will only be asking general questions about how we provide patient education and how patients understand and use health information. If a patient feels uncomfortable or upset at any point, we will stop the questions immediately and provide any necessary support.

8.1. Assessment and management of risk

We do not anticipate risks from this study. Our Research Associate will be supported at the clinical setting and by the research team. Our Research Associate will meet with Dr Kumar and Professor Roberts regularly - weekly and any issues with the study will be discussed and resolutions will be implemented as required.

Timely reports will be made to the funder as they require and the University of Birmingham, as sponsor may require auditing the conduct of the study.

8.2. Research ethics committee (REC) and other regulatory review & reports

We are seeking these approvals now

8.2.1. Regulatory review & compliance

We are seeking sponsorship from the University of Birmingham. In order to minimise risks the following steps will be taken:

• Guidance: Best practice in ethical research will be followed.

• Informed consent/assent: Information sheets and consent/assent forms will be prepared in accordance with National Research Ethics Service guidelines

• Confidentiality: Confidentiality will be guaranteed and data protection policies adhered to.

• Anonymity: Will be maintained by the use of pseudonyms and no information will be shared or published where it may lead to the identification of a participant.

• Support for RA: It is unlikely that the researcher will be exposed to sensitive or distressing information, however, the researcher will be encouraged to debrief regularly within the study team.

Patient who participate in the study, while the risks anticipated are low, in the event that a participant becomes distressed or upset at any stage of the study or as a result of the interview process, they will be sign posted to additional support and where necessary the research team will pause or terminate the discussions when collecting either questionnaire data / interview data.

8.2.2. Amendments

If we need to add new sites in case recruitment is slow, we will submit amendments to the sponsor and ethics. The Chief investigator has responsibility for amendments. They will liaise with the sponsor to jointly determine if an amendment is substantial or non-substantial. Any amendment will be recorded in an updated protocol with an amendment history.

8.3. Peer review

Before being submitted to the NIHR, the project was carefully reviewed by an independent academic internally at the university. It was then reviewed again by the NIHR peer review panel and the scientific committee to ensure its quality and validity.

8.4. Patient & public involvement

We have stated this in the earlier section under **"Patient & public involvement group"**

8.5. Protocol compliance

To ensure compliance, following steps will be taken:

• Guidance: Best practice in ethical research will be followed.

• Informed consent/assent: Information sheets and consent/assent forms will be prepared in accordance with National Research Ethics Service guidelines

• Confidentiality: Confidentiality will be guaranteed, and data protection policies adhered to.

• Anonymity: Will be maintained using pseudonyms and no information will be shared or published where it may lead to the identification of a participant.

8.6. Data protection and confidentiality

The data protection is aligned with the UK General Data Protection Regulation (UK GDPR). The University of Birmingham requires hard copy study data to be stored for 10 years. Hard-copy study data will be stored in a clearly labelled locked filing cabinet at the University of Birmingham for ten years. Electronic files will be archived according to University Guidelines, using Bear Archive. The study PI will keep a record of the date when the data can be securely disposed of. At this time they will follow the University of Birmingham guidelines. Should the PI leave the University, a suitable member of staff at the University will take over responsibility for this.

8.7. Indemnity

The University of Birmingham has in force Public Liability policy which provides cover for claims for negligent harm and the activities here are included within that coverage.

8.8. End of study and archiving

End of study will be by May 2027. Anonymised data from the outcome measures and qualitative interviews will be shared through publications (academic and with the Asian community) and dissemination to study participants. The data from the outcome measures and interviews will be stored in line with University of Birmingham data management policies.

8.9. Access to the final dataset

The University will be responsible as Sponsor for the research data storage and ownership of the data. However, all project partners will have equal unrestricted rights to access the data for publication and dissemination purposes, for the use in further research purposes.

9. Dissemination policy

9.1. Dissemination policy

All project partners will help share the findings in different ways. The results will be published in academic journals and presented at conferences. The National Rheumatoid Arthritis Society will spread the findings across England through its networks. Patient partners will help share the results by giving community talks and creating short videos in Hindi.

9.2. Authorship eligibility guidelines and any intended use of professional writers

We expect to publish two major papers from this research.

One paper may be an editorial, where we work with South Asian patient partners to share their experiences as being part of a research team. Editorials like this are rare in rheumatology, especially from the South Asian community. Our goal is to share these lessons with other researchers and encourage them to involve minority ethnic groups in their studies.

The second, and main, paper will present the key research findings. The Research Associate will be the first author, while Dr. Kumar and Professor Lisa Roberts will be the stared senior (last) authors, as they are both leading the project. The rest of the research team, including patient partners, will be listed as co-authors. Everyone will contribute equally to writing the paper, and of course patient partners will be fully supported throughout the process.

The interim and final reports to NIHR will also have equal contribution from the research team. We do not anticipate in using professional writers.

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10. Appendices

10.1. Appendix 1 – required documentation

10.2. Appendix 3 – amendment history

The following amendments and/or administrative changes have been made to this protocol since the implementation of the first approved version

Amendment number	Date of amendment	Protocol version number	Type of amendment	Summary of amendment