

Trial Description

Title

How much information and participation is just right? An exploratory study of the need for autonomy in outpatient care of patients with inflammatory rheumatic diseases

Trial Acronym

Autonomy in rheumatic diseases

URL of the trial

<https://forschung-sachsen-anhalt.de/project/viel-oder-wenig-explorative-studie-zum-19735>

Brief Summary in Lay Language

The participation of patients in decisions concerning their treatment is a basic principle of medical care. Former studies showed, indeed, that this participation not often led to positive results. One reason may be the fact that the need for autonomy, i.e. the need for information and participation, differs significantly between patients. Therefore, it could be important to address these different needs in the doctor-patient-communication. Positive effects on patient satisfaction, treatment adherence and health outcomes are expected when doctors consider these needs of their patients.

In this study, adult men and women with inflammatory rheumatic diseases (rheumatoid arthritis, spondylarthritis, or connective tissue diseases) are asked to participate.

In the first study phase, 400 members of a self-help group in Saxony-Anhalt will be asked to fill in a written questionnaire at one point in time. They answer questions about their need for participation concerning their treatment and various health-related topics. At the same time, adult patients across Germany with or without a self-help-group membership are asked to answer the same questions via an online survey.

In the second study phase, rheumatic outpatients are asked to participate in the study when visiting their doctor. If they agree, they fill in a questionnaire directly after their doctors' visit. The attending physicians, too, fill in a short questionnaire concerning the doctor-patient consultation. Three months later, the study participants receive another written questionnaire by mail.

The patients are free to participate or not to participate in this study. Their data will be used for scientific purposes only. The recognized principles of data security are accommodated.

The statements of the participants in the questionnaires help us to answer important, but to date unanswered questions about the medical treatment of patients with inflammatory rheumatic diseases.



Brief Summary in Scientific Language

The participation of patients in therapeutic decision-making in the sense of the “Shared Decision Making (SDM)” is a basic principle of medical care. However, systematic reviews recently proved only partially positive effects of SDM regarding health-related outcomes. One reason for these results may be the often neglected, individually differing need for autonomy of the patients, i.e. their need for information and participation. On the other hand, positive effects on patient satisfaction, treatment adherence and its results could be proved in studies with interventions that considered these needs. As a promising intervention approach, SDM has rarely been made a subject to discussion in the context of treating inflammatory rheumatic diseases so far. Until now, only different options for medication have been analysed for SDM purposes in this target group.

The exploration of situational and personal factors influencing the need for autonomy as well as the most significant decision situations during the course of the disease shall provide information on how rheumatologists can most effectively cope with the high demand for SDM in the therapeutic context. Furthermore, they can shed light on specific situations and/or specific persons that may favour a communication style with a higher or lower participation.

Organizational Data

- DRKS-ID: **DRKS00011517**
- Date of Registration in DRKS: **2017/02/17**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **2016-139 , Ethikkommission der Medizinischen Fakultät der Martin-Luther-Universität Halle Wittenberg**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1191-1673**

Health condition or Problem studied

- ICD10: **L40.5 - Arthropathic psoriasis**
- ICD10: **L93 - Lupus erythematosus**
- ICD10: **M07 - Psoriatic and enteropathic arthropathies**
- ICD10: **M08 - Juvenile arthritis**
- ICD10: **M32 - Systemic lupus erythematosus**
- ICD10: **M33 - Dermatopolymyositis**
- ICD10: **M34 - Systemic sclerosis**
- ICD10: **M35.0 - Sicca syndrome [Sjögren]**



ICD10: **M35.0 - Sicca syndrome [Sjögren]**

- ICD10: **M35.1 - Other overlap syndromes**
- ICD10: **M05 - Seropositive rheumatoid arthritis**
- ICD10: **M06.0 - Seronegative rheumatoid arthritis**
- ICD10: **M45 - Ankylosing spondylitis**
- Free text: **inflammatory rheumatic diseases**

Interventions/Observational Groups

- Arm 1: **First study phase:**
400 members of a self-help group in Saxony-Anhalt will be asked to fill in a written questionnaire at one point in time. They answer questions about their need for participation concerning their treatment and various health-related topics. At the same time, adult patients across Germany with or without a self-help-group membership are asked to answer the same questions via an online survey.
- Arm 2: **Second study phase:**
Rheumatic outpatients are asked to participate in the study when visiting their doctor. If they agree, they fill in a questionnaire directly after their doctors' visit (t1). The attending physicians, too, fill in a short questionnaire concerning the doctor-patient consultation. Three months later, the study participants receive another written questionnaire by mail (t2).

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Other**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Other**
- Purpose: **Prognosis**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

First study phase:

- **need for autonomy (Autonomy Preference Index; API)**

Second study phase (t1 and t2):

- **need for autonomy (Autonomy Preference Index; API)**



Secondary Outcome

First study phase:

Secondary outcomes of the first study phase are:

- pain (Numeric Rating Scale; NRS-10)
- general health status (NRS-10)
- fatigue (NRS-10)
- functional status and quality of life (Arthritis Impact Measurement Scales; AIMS2)
- depression (PHQ-8)
- health literacy (HELP-questionnaire)
- illness perception (Brief Illness Perception Questionnaire; BIPQ)

Important treatment decisions and other disease-relevant topics are asked by self-administered questionnaires (incl. personal relevance, perceived information status, need for information, exchange and/or participation).

As control variables in the first study phase the following variables are considered:

- disease background (diagnosis, disease duration, comorbidity, body mass index, attending physicians)
- socio-demographics (age, sex, social status, employment status)

Second study phase:

The following variables are assessed at baseline only (t1):

- Shared Decision Making (MAPPIN'SDM; doctors' and patients' sheet)
- disease background (diagnosis, disease duration, comorbidity, body mass index, further attending physicians)
- socio-demographics (age, sex, social status, employment status)

The following secondary outcomes are assessed at baseline (t1) and follow-up (t2):

- patient satisfaction (ZUF-8)
- pain (NRS-10)
- general health status (NRS-10)
- fatigue (NRS-10)
- functional status and quality of life (Arthritis Impact Measurement Scales; AIMS2)
- depression (PHQ-8)
- health literacy (HELP-questionnaire)
- illness perception (Brief Illness Perception Questionnaire; BIPQ)

The following secondary outcome is assessed at follow-up (t2):

- treatment adherence (Compliance Questionnaire for Rheumatology; CQR5)

Countries of recruitment

- DE Germany

Locations of Recruitment

- other **Deutsche Rheuma-Liga Sachsen-Anhalt e.V. (German League Against Rheumatism Saxony-Anhalt), [---]***
- Doctor's Practice **Sachsen-Anhalt (Saxony-Anhalt)**
- University Medical Center **Rheumatologische Fachambulanz, Halle Saale**
- other **Onlinebefragung (online survey)**
- Doctor's Practice **Deutschland (Germany)**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/01/18**
- Target Sample Size: **1000**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

men and women at the age of 18 years and above with an inflammatory rheumatic disease (rheumatoid arthritis, spondylarthrititis, connective tissue disease)

Exclusion criteria

deficient German language skills, insufficient writing skills

Addresses

■ Primary Sponsor

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Sources of Monetary or Material Support

■ **Institutional budget, no external funding (budget of sponsor/PI)**

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Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): [---]*

Trial Publications, Results and other documents

- Abstract <style fontName='DejaVu Sans' isBold='true'>Mattukat, K., Müller, A., Keyßer, G., Schäfer, C. & Mau, W. (2016). Zu viel oder zu wenig? Eine explorative Studie zum Autonomiebedürfnis von mit entzündlich-rheumatischen Erkrankungen in der ambulanten Versorgung. (Poster beim 44. Kongress der Deutschen Gesellschaft für Rheumatologie vom 31.08. bis 03.09.2016 in Frankfurt/Main) DOI: 10.3205/16dgrh041</style>
- Abstract <style fontName='DejaVu Sans' isBold='true'>Mattukat, K., Raberger, K., Müller, A., Keyßer, G., Schäfer, C. & Mau, W. (2017). Wie groß ist das Bedürfnis von Patienten mit entzündlich-rheumatischen Erkrankungen nach Information und Partizipation bei therapeutischen Entscheidungen - und wovon wird es beeinflusst? (Poster EV.01 und Vortrag beim 45. Kongress der Deutschen Gesellschaft für Rheumatologie vom 06.-09.09.2017 in Stuttgart) DOI: 10.3205/17dgrh052</style>
- Abstract <style fontName='DejaVu Sans' isBold='true'>Mattukat, K., Raberger, K., Müller, A., Keyßer, G., Schäfer, C. & Mau, W. (2017). Entzündlich-rheumatische Erkrankungen in der ambulanten Versorgung: Welche Themen sind den Patienten im Krankheitsverlauf am wichtigsten? (Poster EV.04 beim 45. Kongress der Deutschen Gesellschaft für Rheumatologie vom 06.-09.09.2017 in Stuttgart) DOI: 10.3205/17dgrh055 </style>
- Abstract <style fontName='DejaVu Sans' isBold='true'>Mattukat, K., Raberger, K., Böhm, P., Müller, A., Keyßer, G., Schäfer, C. & Mau, W. (2018). Wie wichtig ist die medizinische Rehabilitation für Patienten mit entzündlich-rheumatischen Erkrankungen? Ergebnisse eines partizipativen Forschungsprojekts. DRV-Schriften, 113, 154-156. (Vortrag beim 27. Rehabilitationswissenschaftlichen Kolloquium vom 26.-28.02.2018 in München)</style>
- Abstract <style fontName='DejaVu Sans' isBold='true'>Mattukat, K., Raberger, K., Keyßer, G., Schäfer, C., Müller, A. & Mau, W. (2018). Zu viel oder zu wenig? Ergebnisse einer explorativen Studie zum Autonomiebedürfnis von Patienten mit entzündlich-rheumatischen Erkrankungen in der ambulanten Versorgung (Studienphase 1). (Poster bei der 19. Jahrestagung des Deutschen Netzwerks Evidenzbasierte Medizin vom 08.-10.03.2018 in Graz, Österreich) DOI: 10.3205/18ebm065</style>
- Abstract <style fontName='DejaVu Sans' isBold='true'>Mattukat, K., Raberger, K., Keyßer, G., Schäfer, C., Müller, A. & Mau, W. (2018). Wie sehr wollen Patienten mit entzündlich-rheumatischen Erkrankungen in therapeutische Entscheidungen einbezogen werden und welche krankheitsbezogenen Themen sind ihnen am wichtigsten? (Poster beim BMC-Kongress [Bundesverband Managed Care] vom 23.-24.01.2018 in Berlin)</style>

* This entry means the parameter is not applicable or has not been set.

*** This entry means that data is not displayed due to insufficient data privacy clearing.