

Trial Description

Title

A Personalised Integrated Care Approach for Service Organisations and Care Models for Patients with rheumatoid arthritis and cardiovascular comorbidity

Trial Acronym

PICASO - UDUS

URL of the trial

<http://www.picaso-project.eu/>

Brief Summary in Lay Language

Better coordination of care plans between healthcare sectors is high on the European health agenda. So is efficient management of the steadily rising number of patients with co-existing chronic conditions. The PICASO project aims to develop information and communication technologies which meet these demands, by supporting a continuum of care from hospitals and outpatient clinic to the home.

The PICASO platform will enable the sharing of a patient's complete care pathways with tools to establish health status, predict risks and adjust care. Based on monitoring of different physiological parameters at home, the patients can actively participate in their own care. The result is better management of co-existing diseases and coordination of care plans for the benefit of patients and carers across organisations.

To demonstrate the platform and its wide applicability, the technologies will be trialled in two different national settings with two different patient groups. In Italy, the University Hospital of Tor Vergata in Rome will enrol patients with Parkinson's disease and in Germany, the University Hospital of Düsseldorf will engage patients diagnosed with Rheumatoid Arthritis. Both patient groups have cardiovascular Diseases as co-morbidities and both settings share the complexity of treating co-occurring diseases, also known as multimorbidities.

The trials will establish how PICASO can improve the exchange of data between stakeholders in the workflow and validate the effect of PICASO on the care systems as well as the acceptance of the system by the wider group of stakeholders such as patients, relatives and physicians.

Brief Summary in Scientific Language

Better coordination of care plans between healthcare sectors is high on the European health agenda. So is efficient management of the steadily rising number of patients with co-existing chronic conditions. The PICASO project aims to develop information and communication technologies which meet these demands, by supporting a continuum of care from hospitals and outpatient clinic to the home.

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Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00013637**
- Date of Registration in DRKS: **2018/01/17**
- 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.: **6139R , Ethik-Kommission an der Medizinischen Fakultät der Heinrich-Heine-Universität Düsseldorf**

Secondary IDs

Health condition or Problem studied

- ICD10: **M05 - Seropositive rheumatoid arthritis**
- ICD10: **M06 - Other rheumatoid arthritis**

Interventions/Observational Groups

- **Arm 1: Patients with rheumatoid arthritis use the PICASO Platform for 6 months and report their experiences. In addition, they use home-monitoring devices (blood pressure, balance and activity tracker) and transfer the data to the PICASO Platform. Treating physicians interact with the platform and share their experiences.**

Characteristics

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

Primary Outcome

Proof-of concept

Primary end-points:

- **User acceptance, adaptability and usability factors (patients and physicians perspective) of the PICASO platform and the integrated features (physician and patient dashboard, home monitoring devices, patient reported outcome measurement, care plans)**
- **Active participation of patients and their informal carers in the care process and management reflected by the ongoing use of the PICASO platform**
- **Improved outcome (health and quality of life and improved activity by creating consciousness for self-management through the visualization of current values and activity as well as reminder functions)**
- **Evaluate the impact and workflows of the platform on the participating stakeholders and society**
- **Reduced number and length of admissions to hospital compared to the individual patients' history (preceding 6 months)**
- **Integrate PICASO into existing technical infrastructures**
- **Secure and accurate handling of data and data sharing in PICASO**

Secondary Outcome

evaluation questionnaires

Countries of recruitment

- **DE Germany**



Locations of Recruitment

- University Medical Center **Düsseldorf**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/01/31**
- Target Sample Size: **30**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

rheumatoid Arthritis, cardiovascular comorbidity and/or cardiovascular risk profil

Exclusion criteria

Participation in clinical trial

Addresses

■ Primary Sponsor

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■ Contact for Scientific Queries

Universitätsklinikum Düsseldorf

Contact for Scientific Queries

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

Directorate-General for Communications Networks, Content and Technology, European Commission, Horizon 2020

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2019/06/18**

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Trial Publications, Results and other documents

* *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.*