EULAR points to consider on remote care
- Project plan -

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ORGANIZATIONAL LEADERSHIP AND SUPPORT

These Points to consider (PtC's) are being developed under the umbrella of the European League against Rheumatology (EULAR).

PROJECT DEVELOPMENT – RESPONSIBILITIES

The task force consists of the Steering Committee (convenors, methodologist, 2 co-methodologists, 2 fellows, 1 expert) and the remaining task force members (including rheumatologists, specialists in internal medicine, health professionals in rheumatology (HPRs), patient representatives and EMEUNET members).

The task force is responsible for the formulation of the key questions, for interprets the evidence of the literature and for the formulation of the PtCs. The literature review team is responsible, together with the convenors, methodologist and co-methodologists, for the design and conduct of the systematic literature review (SLR).

BACKGROUND

The prevalence of rheumatic and musculoskeletal diseases (RMDs) in developed countries has increased by 60% from 1990-2010, and it is expected to further increase in the future due to an aging population, increased awareness of RMDs among physicians and people with RMDs, earlier diagnosis of inflammatory RMDs, lower mortality among people with systemic diseases and other reasons.[1 2] At the same time, we witness a lack of rheumatologists and other HPRs[3] This has increased the pressure on the healthcare system and has called for alternative forms of remote care within for example conventional follow-up and self-management interventions. Further, many people try to avoid travelling from home to hospital due to climate and lifestyle changes. According to

the World Health Organization (WHO), remote care makes use of digital technologies[4] – the so-called telehealth interventions. It encompasses the use of telephone, apps, sensors, video, social media platforms and web-based programs, and it is used in all parts of the patient pathway, including communication with patients, but also in disease screening or monitoring of different aspects of the disease (disease activity, damage, quality of life, adherence etc.). It can be ”synchrone” (clinicians and patient present at the same time) or ”asynchrone”, supervised or unsupervised. While EULAR has defined points to consider for the development, evaluation and implementation of mobile health apps supporting self-management of people living with RMDs, the question how apps and other telehealth techniques should be integrated into remote care of patients with RMDs is elusive so far.[5] The WHO has defined telehealth as: ‘the use of telecommunications and virtual technology to deliver health care outside of traditional health-care facilities’.[6] According to the WHO, the basic principle of most telehealth interventions is that technology supports a dialogue between the patient and the healthcare provider, and relies on monitoring predefined data to enable a timely intervention.[7] Telehealth can improve healthcare access and outcomes, particularly in the treatment of chronic diseases, e.g. within asthma, diabetes and heart failure,[8] by reducing the demands on crowded facilities and by making the health sector more resilient.[6] This means that telehealth interventions have the potential to match up to the linked goals in the so-called Triple Aim model proposed in 2008 by the US Institute for Healthcare Improvement: ‘aiming at improving the individual experience of care; improving the health of populations; and reducing the per capita costs of care for populations’.[9] Hence, remote care may be a promising avenue and has become even more relevant with the COVID-19 pandemic, where it has been difficult to deliver face to face care and investigations.[10]

We expect that both, the COVID-19 and future pandemics, will force rheumatologists and HPRs to make use of remote care in order to offer care to RMD patients during an expected partial and/or complete closure of rheumatology services. Apart from the PtCs,

we aim to develop a research agenda which should highlight the gaps of evidence and drive future research in the field.

PROJECT OBJECTIVES

The broad objective of this project is to develop EULAR PtCs for the development, prioritisation and implementation of remote care for patients with RMDs.
Specific objectives comprise PtCs on:

- remote disease assessment (disease activity, function and quality of life) including tele-monitoring of treatment strategy
- remotely delivered consultations
- self-management interventions including self-management programs, videos for coping techniques, medication diaries and exercise logs, online discussion centers, one-to-one support and self-monitoring tools
- Implementation of remote care into daily clinical practice

Target users of the points to consider

Physicians and health professionals in rheumatology (HPR) involved in the care of RMD patients, patients and their careers, as well as regulators and policy makers

Definition of key terms

Remote care: the provision of care using telecommunication and virtual technology allowing patients to be evaluated, monitored, and possibly treated while the patient and health providers are physically remote from each other.

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Remote care can be used in all parts of a patient's pathway, including communication with patients, disease screening or monitoring of different aspects of the disease and decision making. It can be "synchrone" (clinicians and patients are using remote care/tele-health the same time) or "asynchrone" (when only either clinicians or patients are using remote care/tele-health) as well as supervised or unsupervised.

Self-management: the ability of the individual to manage symptoms, treatment/interventions, lifestyle changes, and psychosocial and cultural consequences of health conditions.[11 12]

METHODS

We will follow the EULAR standard operating procedures to develop these Points to consider.[13]

Key questions

The key questions guiding the SLRs will be the basis of these Points to consider and have been formulated by the task force members during their first TF meeting. Subsequently, they have been translated into the PICO (=Population, Intervention, Comparator, Outcome) format. The PICO questions identify the population of interest (=target population), the alternative strategies and patient-important outcomes.[14]

PICO 1: Effectiveness and safety of remote care:

What is the efficacy (O1) / safety (O2) / cost-effectiveness (O3) / user perception (O4) / adherence (O5) of remote care method A (I1) or blended care (I2) as compared to remote care method B (C1) / standard care (C2) in people with RMDs (P)?

Population: People with RMDs defined according to EULAR as "a diverse group of diseases that commonly affect the joints, but can also affect the muscles, other tissues and internal organs."[15]

Intervention/Comparator: Remote care (see definition above). Standard care comprises face-to-face interaction and care according to the respective community guidelines between physicians and people with RMDs. Blended care is a hybrid form of care including elements of remote and standard care.

Outcomes: We will follow suggestions from the literature review.

PICO 2: Integration of remote care into clinical practice

In people with RMDs (P), how is remote care (I) delivered/tailored to people (O1) / integrated into clinical practice (O2)?

Population: People with RMDs

Intervention: Remote care (see definition above).

Outcomes: These outcomes are of descriptive nature, giving information on how remote care is delivered/tailored and how it is integrated into clinical practice.

PICO 3: drivers and barriers of remote care

In people with RMDs (P), what are the drivers and barriers for implementation in clinical practice (O) of remote care (I)?

Population: People with RMDs (see target population definition above).

Intervention: Remote care (see definition above).

Outcomes: The outcomes are of descriptive nature, giving information what drivers and barriers exist for the implementation of remote care in clinical practice.

Comment: Here we will mainly search for surveys and qualitative studies on barriers and implementation of remote care and order them in evidence tables for before and after COVID-19. We will do a hierarchical search: If no studies can be found for RMDs, then systematic reviews of systematic reviews for other chronic diseases such as diabetes or heart failure will be assessed.

Systematic Literature Review

Role of the literature review team

Andréa Marques (fellow) will lead the SLR, Philipp Bosch serves as a second reviewer, Tanja Stamm (methodologist) and the co- methodologists (Yvette Meissner, Chetan Mukhtyar) will help with methodological questions. Both reviewers will independently perform screening, selection of articles, data extraction and quality/risk of bias appraisal. Results will be compared between the 2 reviewers and any discordance will be resolved by discussion. In case consensus cannot be reached between AM and PB, Tanja Stamm (methodologist) will be consulted for a final decision.

***Search strategy**: Databases for the identification of relevant articles*

We will search the Ovid MEDLINE (1946), EMBASE (1988) and Cochrane datasets from their inception dates, noted in parentheses, to present.

Search terms

A search strategy was developed by an experienced librarian (Louise Falzon, Columbia University Medical Center, New York, New York, USA), with expertise in searches in the area of rheumatology. We use several combinations of key words according to each component of the PICOs including the thesauri for each database, i.e., Medical Subject Headings for OVID Medline, and EMTREE terms for Embase. A monthly update will be performed to retrieve new articles published after the initial search.

The following search terms will be used:

Medline

1 exp Musculoskeletal Diseases/
2 ((muscular or musculo$ or bone or cartilage or joint or rheumatic) adj2 (disease$ or condition$ or syndrome$ or pain or abnormalit$ or deformit$ or instabilit$)).tw.
3 (arthrit$ or arthralg$ or arthropath$ or osteoarthrit$ or spondyl$ or Ankyl$).tw.
4 (sPa or axSpa or PsA or jia).tw.
5 fibromyalg$.tw.
6 gout$.tw.
7 (systemic adj (sclerosis or lupus erythematosus)).tw.
8 (SSc or SLE).tw.
9 or/1-8
10 exp Telemedicine/
11 (telemonitor$ or telemedicine or telehealth).tw.
12 ((remote or mobile or virtual) adj2 (health or medicine or evaluat$ or assess$ or consult$ or care or appointment$)).tw.
13 (mhealth or telehealth or ehealth).tw.
14 or/10-13
15 9 and 14
16 (animals not (humans and animals)).sh.
17 15 not 16

The Cochrane Library

#1 MeSH descriptor: [Musculoskeletal Diseases] explode all trees

#2 ((muscular OR musculo* OR bone OR cartilage OR joint OR rheumatic) NEAR/2 (disease* OR condition* OR syndrome* OR pain OR abnormalit* OR deformit* OR instabilit*)):ti,ab
#3 (arthrit* or arthralg* or arthropath* or osteoarthrit* or spondyl* or Ankyl*):ti,ab
#4 (sPa or axSpa or PsA or jia):ti,ab
#5 fibromyalg*:ti,ab
#6 gout*:ti,ab
#7 (systemic NEXT (sclerosis or "lupus erythematosus")):ti,ab
#8 (SSc or SLE):ti,ab
#9 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8
#10 MeSH descriptor: [Telemedicine] explode all trees
#11 ((remote or mobile or virtual) NEAR/2 (health or medicine or evaluat* or assess* or consult* or care or appointment*)):ti,ab
#12 (mhealth or telehealth or ehealth):ti,ab
#13 #10 OR #11 OR #12
#14 #9 AND #13

Embase

#16. #10 AND #14 AND ([article]/lim OR [article in press]/lim OR [review]/lim) AND [humans]/lim
#15. #9 AND #14
#14. #10 OR #11 OR #12 OR #13
#13. mhealth:ab,ti OR telehealth:ab,ti OR ehealth:ab,ti
#12. ((remote OR mobile OR virtual) NEAR/2 (health OR medicine OR evaluat* OR assess* OR consult* OR care OR appointment*)):ab,ti
#11. telemonitor*:ab,ti OR telemedicine:ab,ti OR telehealth:ab,ti
#10. 'telemedicine'/exp
#9. #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8

#8. ssc:ab,ti OR sle:ab,ti
#7. 'systemic sclerosis':ab,ti OR 'systemic lupus erythematosus':ab,ti
#6. gout*:ab,ti
#5. fibromyalg*:ab,ti
#4. spa:ab,ti OR axspa:ab,ti OR psa:ab,ti OR jia:ab,ti
#3. arthrit*:ab,ti OR arthralg*:ab,ti OR arthropath*:ab,ti OR osteoarthrit*:ab,ti OR spondyl*:ab,ti OR ankyl*:ab,ti
#2. ((muscular OR musculo* OR bone OR cartilage OR joint OR rheumatic) NEAR/2 (disease* OR condition* OR syndrome* OR pain OR abnormalit* OR deformit* OR instabilit*)):ab,ti
#1. 'musculoskeletal disease'/exp

Additionally, the abstract archives of the EULAR and ACR congress 2020 will be searched with the follow free terms (app,digital, ehealth, mhealth, mobile, online, remote, tele, video, virtual) will be screened for relevant abstracts.
Furthermore, EULAR national societies and PARE organizations will be contacted for reports and position papers on Pico 3.

Data management

References and abstracts will be imported into the online bibliographic management software Covidence, and duplicates will be removed.

Titles and abstracts will be screened by two independent reviewers (AM and PB) to assess eligibility according to the inclusion criteria for the review (see criteria below).

Inclusion/Exclusion criteria

We will include:

1) full research articles and research letters of **prospective studies**
2) studies without restriction on the number of patients/sample size or age

3) qualitative research studies and surveys (only for PICO 3 on drivers and barriers for implementation)

We will exclude

1) studies that cannot be assigned to any of the key questions
2) case reports

Full text articles that do not meet the inclusion criteria will be excluded and reasons for exclusion will be provided in an appendix.
Multiple publications from the same trial will be identified, and additional reports from the same trial will only be considered if separate, pre-specified outcomes are reported.

The results of the search will be reported in the final report and presented in a Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) flow diagram.

Quality assessment or risk of bias (ROB)

All identified studies will be quality-assessed using the appropriate tools.

For the evaluation of randomized controlled trials, the Cochrane risk-of-bias tool for randomized trials version 2 (ROB 2) will be used.[16]
For non-randomized studies, the risk-of-bias tool for non-randomized studies of interventions (ROB-INS-I) will be used.[17]
For cross-sectional studies, the appraisal tool for cross-sectional studies (AXIS) will be used.[18]
For qualitative studies, the Critical Appraisal Skills Program (CASP) will be used (https://casp-uk.net/wp-content/uploads/2018/01/CASP-Qualita-tive-Checklist-2018.pdf).
For the assessment of surveys, the following checklist for web-based surveys will be used (https://www.jmir.org/2004/3/e34/).

Data extraction

The data will be extracted from the selected studies by two independent reviewers (AM and PB) using a predefined data extraction form, according to the type of study (see appendix 1). The preliminary data extraction form will be piloted in 5 articles and evaluated for completeness and handling.

Any disagreements that arises between the reviewers at this point, will be resolved through discussion or with the additional help of a third reviewer (TS). Authors of papers will be contacted to request missing or additional data, where required.

The data extract from EULAR and ACR abstract databases will be performed at the same way.

References

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Appendix I – Data extraction for the different type of studies included

Details of included RCTs

	Study and data of publication (month/year)	*Study*
Participants characteristics (number, age, disease criteria, details)		
Intervention(s)		
Intervention(s) characteristics		
Professional that promoted the interventions		
Intervention(s) setting		
Control		
Outcomes of interest (types and measuring instruments)		
Methods of analysis		
Effect size		
95% Confidence intervals		
P value		
Follow-up		
Conclusions		

Details of included qualitative studies

	Study	*Study*
Methodology		
Method		
Phenomena of interest		
Geographical		
Setting		
Participants characteristics		
Findings (Illustration form)		
Evidence (Unequivocal, Credible, Unsupported)		
Conclusions		

Details of included Systematic Review

	Study	*Study*
Databases searched and language limits		
Range of included studies		
Number, type of studies included and countries of origin		
Instruments used for bias appraisal		
Bias appraisal rating		

Participants characteristics (number, age, RA criteria, details)		
Intervention(s)		
Intervention(s) characteristics		
Professional that performed the interventions		
Intervention(s) setting		
Control		
Outcomes of interest (types and measuring instruments)		
Methods of analysis		
Heterogeneity (I^2)		
Effect size		
95% Confidence intervals		
P value		
Follow-up		
Conclusions		

Details of included Observational/cohort studies

	Study	*Study*
Participants characteristics (number, age, disease criteria, details)		
Study design		

Setting		
Recruitment procedures		
Follow-up or study duration – any details on the duration of the study or follow-up of the participant		
Exposure(s) of interest (Independent variable) – type, frequency, intensity, duration		
Outcomes – the primary outcome measured and where relevant includes associated secondary outcomes.		
Outcome measurements – describe the scales or tools used to measure the outcomes		
Data analysis methods including statistical technique		
Risk ratio		
Relative risk ratio		
Odds ratio		
95% Confidence intervals		
P value		
Conclusions		