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VIEWPOINT

Bridging the gap: facilitating the use of rheumatology research results in clinical practice with hybrid implementation effectiveness studies

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ABSTRACT

The implementation of proven effective pharmacological and non-pharmacological interventions into routine rheumatology practice is a lengthy and complex process. Bridging this gap between research and practice is crucial. Hybrid implementation effectiveness studies, integrating effectiveness and implementation aspects, emerge as a proactive and innovative solution to shorten the process of translation of proven interventions into clinical practice. This viewpoint provides an overview of the various types of hybrid implementation effectiveness studies including examples from rheumatology research practice, explains their pivotal role in speeding up the implementation of rheumatology research results and concludes with practical recommendations for the conduct of hybrid implementation effectiveness studies.

BACKGROUND

Rheumatology, as a medical field, faces a unique set of challenges, including the complexity of chronic autoimmune diseases, evolving treatment landscapes and the need for individualised patient care.

This dynamic landscape has increased the number of clinical trials evaluating pharmacological and non-pharmacological interventions and healthcare services rapidly. Despite the importance and relevance of outcomes from these clinical trials, the translation of proven effective interventions into routine clinical practice remains a lengthy and complex process. Frequently, large-scale implementation of interventions only follows after the common sequence of clinical studies: from efficacy studies, evaluating interventions under ideal and controlled circumstances, to effectiveness research, concerning the performance of innovations under 'real-world' conditions. This protracted timeline, spanning an average of 17 years,[1] reflects the complexities of implementing interventions in the dynamic and diverse landscape of clinical practice, the healthcare system and society as a whole. However, bridging this gap between research and practice is crucial for ensuring that patients with rheumatic and musculoskeletal diseases benefit from the latest evidence-based interventions. Against this backdrop, hybrid implementation effectiveness studies emerge as a proactive and innovative solution in the medical field. These studies break away from the traditional, sequential research pipeline by incorporating elements of both effectiveness and implementation studies within the same study.[2]

The aim of the present viewpoint is to give an overview of the various types of hybrid implementation effectiveness studies including examples from rheumatology research practice and to explain their pivotal role in speeding up the implementation of rheumatology research results. The viewpoint ends with practical recommendations for the conduct of hybrid implementation effectiveness studies in clinical rheumatology research.

HYBRID IMPLEMENTATION EFFECTIVENESS STUDIES

Hybrid implementation effectiveness studies combine research questions concerning intervention effectiveness and implementation within the same study, offering a comprehensive understanding of how interventions perform in practice. While the main aim of effectiveness research is to assess whether an intervention (ie, THE THING) is effective or works to improve patient outcomes, implementation research looks at how clinical practice can be assisted to perform the intervention (ie, how to DO THE THING) and evaluates the extent to which the intervention (THE THING) is used in practice (ie,

adoption and fidelity of the intervention).[3 4] Implementation activities (eg, education, audit and feedback) to support clinical practice to do the thing are called implementation strategies.

Although hybrid implementation effectiveness studies exist on a continuum, Curran *et al* proposed three types.[2] The three types differ in their primary focus and the degree of emphasis on effectiveness ersus implementation outcomes (see table 1). The main goal of the hybrid framework of Curran *et al* is to guide the selection of study aims and not to guide the selection of the study design. Originally, the hybrid effectiveness implementation study

Table 1 Types of hybrid implementation effectiveness studies

	Type 1	Type 2	Type 3
Primary focus	► To study the effectiveness of a clinical intervention	► To study the effectiveness of a clinical intervention And ► To study the adoption and feasibility of the implementation strategy used to deliver the intervention	► To study the effectiveness of an implementation strategy to deliver the intervention
Secondary focus	► To gather information on implementation aspects		► To assess patient outcomes as result of the intervention
Measures	► Effectiveness: patients symptoms and functioning, and possibly costs ► Implementation: barriers and facilitators for implementation, feasibility and acceptability of the intervention	► Effectiveness: patients symptoms and functioning, and possibly costs ► Implementation: adoption and fidelity of the intervention, and related barriers and facilitators	► Implementation: Implementation outcomes (acceptability, appropriateness, feasibility, adoption, fidelity, penetration and sustainability) and related barriers and facilitators ► Effectiveness: patient symptoms, functioning and service use
Evaluation methods	► Effectiveness: quantitative ► Implementation: mixed methods (eg, interview, survey and/ or observation of participants)	► Effectiveness: quantitative ► Implementation: mixed methods (eg, interview, survey and/ or observation of participants, administrative data)	► Implementation: mixed methods (eg, interview, survey and/ or observation of participants, administrative data) ► Effectiveness: quantitative (preferably administrative/ registry data)
When indicated?	► No or mixed data on intervention effectiveness.	► Evidence of intervention effectiveness in other settings or populations is available, but not in the context or population of the current study (so there is uncertainty whether the intervention leads to similar effects). Or ► Only preliminary effectiveness data available but there is a strong push to use the intervention because of system or policy requirements.	► When there are concerns about the extent to which the intervention can be delivered correctly in real-world settings. Or ► When there is a strong momentum for the implementation of an intervention despite a limited evidence base.
Requirement for using this hybrid type	► None	► Evidence of intervention effectiveness in other settings or populations available ► Enough data on barriers and facilitators for the implementation of the intervention to select implementation strategies	► Strong evidence of intervention effectiveness is available ► Enough data on barriers and facilitators for the implementation of the intervention to select implementation strategies

types were applied to experimental research designs.[2] However, the hybrid typology can and has been applied to observational designs and other interventional designs (non-randomised trial, pre–post measurements, stepped-wedge trials and so on). The choice of study design should be guided by the research questions and also takes into account feasibility of designs and preferences of researchers in research sites.[2]

In a hybrid type 1 study, the primary focus is on testing intervention effectiveness, with a secondary aim of gathering implementation-related information. This type typically combines an effectiveness study with a process evaluation to assess what facilitates or hinders the intervention's uptake and/or performance in clinical practice and to identify necessary adaptations for the setting.[4] Hybrid type 1 studies are warranted when there is insufficient evidence of intervention effectiveness, and it is premature to focus solely on its implementation.

An illustrative example of a hybrid type 1 study is the OCTOPUS trial, a randomised clinical trial comparing the effectiveness of stratified exercise therapy for knee osteoarthritis across three subgroups (high muscle strength, low muscle strength and obesity) with usual physical therapy.[5] The trial showed no differences in effectiveness between groups. The included process evaluation, a qualitative exploration of barriers and facilitators for implementing stratified exercise therapy, revealed that hesitancy among physical therapists to address obesity, a lack of collaboration between physiotherapists and dieticians, dieticians perceiving a need for more consultations and patients lacking motivation for at-home exercises hampered the correct execution of the stratified exercise therapy.[6] So, the process evaluation linked clinical effectiveness to the practical execution of the intervention, suggesting that the observed lack of effect might be attributed, in part, to insufficient intervention delivery.

In hybrid type 2 studies, there is a dual focus on assessing both intervention effectiveness and the implementation strategies employed to deliver the intervention. Unlike hybrid type 1 studies, hybrid type 2 studies necessitate a clear plan (implementation strategy) to integrate the intervention into practice. In hybrid type 2 studies, there are also explicit measurements of implementation outcomes such as how much the intervention is being adopted (adoption) or is executed correctly (fidelity). This type is suitable when studying interventions previously effective in other contexts but not in the current study population or setting. Additionally, hybrid type 2 studies are beneficial when there is a strong imperative to implement an intervention due to system or policy requirements, while there are only preliminary effectiveness data available. To be able to perform a hybrid type 2 study, data on barriers and facilitators for the implementation of the intervention should be available. A potential risk of a hybrid type 2 study is that the effectiveness study will be compromised when the used strategy to implement the intervention does not work well and leads to a poor adoption and/or fidelity of the intervention. To avoid this issue, it helps to use strategies that have been proven effective, to set specific goals for how well the intervention should be adopted and followed, to measure the results of these specific goals and to have plans ahead to fix any problems with the adoption or fidelity of the intervention.

An example of a hybrid type 2 study is the study by Hilberdink *et al*, evaluating the effects of enhanced supervised group exercise (eSGE) for axial spondyloarthritis (axSpA) patients and piloting an implementation strategy.[7] The eSGE included high-intensity aerobic exercises, intensity monitoring and exercise personalisation through periodic assessments and patient education. The implementation strategy consisted of a training course, telephone support for exercise group supervisors (every 2 months) and the availability of a helpdesk. Clinical outcomes and implementation data including the fidelity of and satisfaction with the eSGE were assessed through patient records, questionnaires, interviews and questionnaires among patients and physiotherapists. Results showed increased aerobic capacity of AxSpA patients, but no change in health status and physical activity at home. The high-intensity aerobic exercises were implemented successfully while exercise personalisation using performing periodical assessments was only implemented partially and patient education was not implemented at all. The majority of the AxSpA patients considered the ESGE as an improvement in comparison to the SGE. Physiotherapists indicated that they needed more support in educating and motivating patients to exercise at home. The concurrently gathered effectiveness and implementation data made it possible to relate eSGE effectiveness outcomes and the actual delivery of the intervention and implementation strategy, offering insights into necessary improvements for the strategy used to implement the eSGE.

In a hybrid type 3 study, the primary focus is on evaluating the effectiveness of used implementation strategies to deliver the intervention. Secondarily, the study assesses patient outcomes resulting from the intervention. Effectiveness of the implementation strategies is measured by implementation outcomes, including intervention's reach, adoption and fidelity.[8] Hybrid type 3 studies are indicated when there are concerns about the extent to which the intervention can be delivered correctly in real-world settings. Since interventions should be adapted to the implementation setting, collecting patient outcomes is advisable in these studies. This type of study is also suitable when there is a strong momentum for implementing an intervention despite limited evidence. For feasibility, easily accessible clinical outcomes, such as medical outcomes routinely reported in medical records, are preferred.

An example of a hybrid type 3 study is the study of Ettlin *et al*, which is primarily studying the impact of a strategy to implement the GLA:D (Good Life with osteoarthritis Denmark) Switzerland programme for knee osteoarthritis (OA) patients on implementation outcomes

(acceptability, appropriateness, feasibility, adoption, fidelity, penetration and sustainability) and the influencing barriers and facilitators for the implementation of the GLA:D Switzerland programme.[9] Secondarily, the study assesses the effects of the implementation strategy on health services provision (equity, timeliness, patient-centredness, safety and efficiency) and patient outcomes (improvement of OA-related symptoms, function and quality of life based on registry data). While study results are not available yet, it is anticipated that findings on implementation outcomes and barriers/facilitators will elucidate the success or failure of specific implementation elements, guiding future implementation activities. Incorporating service and patient outcomes aids in understanding the contribution of the GLA:D Switzerland programme to the overarching goal of enhancing conservative non-pharmacological management for knee OA patients.

ROLE OF HYBRID STUDIES IN SPEEDING UP IMPLEMENTATION

The benefits of hybrid implementation effectiveness studies for speeding up the implementation of rheumatology research results are multifaceted. Hybrid studies are expected to contribute to a smoother transition of research findings into implementation by creating more commitment among relevant stakeholders and considering implementation factors from the outset. Besides hybrid studies allow for assessments in the complex and dynamic environments where rheumatology care is delivered. By incorporating real-world factors such as patient preferences, healthcare provider practices and organisational constraints, findings become more applicable to clinical settings and are more generalisable, which is expected to speed up the implementation.

However, the path to realising these benefits of hybrid studies for speeding up the implementation of rheumatology research results is not without challenges. Conducting hybrid studies demands a nuanced understanding of both clinical and implementation science. Researchers must navigate the complexities of study design, data collection and analysis, balancing the demands of effectiveness and implementation research. Mixed methods, incorporating both quantitative and qualitative methodologies, are frequently necessary to collect data on both effectiveness and implementation factors or outcomes. Additionally, hybrid studies may require additional resources compared with traditional research designs. Adequate funding, expertise and time are essential for the successful execution of these designs in rheumatology research. And finally, the success of hybrid designs in rheumatology hinges on effective engagement with stakeholders, including patients, healthcare providers and administrators. Ensuring their input throughout the research process enhances the relevance and feasibility of hybrid studies.

RECOMMENDATIONS FOR HYBRID DESIGNS IN RHEUMATOLOGY

While hybrid studies might seem like a new concept in rheumatology research and any other area of medicine, it is important to recognise that they may be more common than initially thought. In fact, all effectiveness studies in rheumatology research already use what we can essentially call 'implementation strategies' to assist in delivering the intervention.[2] These strategies are typically resource-intensive and include actions like educating physician to deliver the intervention, covering care expenses and regularly checking and intervening to ensure fidelity. Even though many of these strategies may not be practical for widespread adoption, studying how the intervention is delivered during an effectiveness study can provide insights into potential implementation challenges. Furthermore, as described above there are already a number of examples of hybrid studies researching non-pharmacological interventions in rheumatology. However, it is important to note that not every study that assesses the effectiveness of a non-pharmacological intervention is a hybrid study. It is only a hybrid study when it combines research questions concerning intervention effectiveness (on patient outcomes) and implementation of the interventions (barriers and facilitators for implementation and/or adoption and fidelity of the delivery of the intervention). Besides, sometimes the effectiveness and implementation part of a hybrid study is published in separate manuscripts, and therefore, remains unnoticed as hybrid study. This may also be the reason why a hybrid study that assesses the effectiveness and implementation of pharmacological interventions were hard to find. As shown in other medical fields, hybrid studies also apply to the evaluation and implementation of pharmacological interventions. Van der Schoot *et al* performed, for example, a hybrid type 3 study for the evaluation of the implementation of protocolised biological dose reduction in psoriasis patients and the assessment of patient outcomes resulting from the dose reduction.[10]

So, to move forward and actually speed up the implementation of study results in rheumatology and any other area of medicine we have some important recommendations. First, we should—at a minimum—routinely study how an intervention is delivered in rheumatology effectiveness studies and assess what facilitates or hinders the intervention's performance in clinical practice (hybrid type 1). It is a relatively small effort to also look at how an intervention is put it into clinical practice and which barriers and facilitators influence this when studying the effectiveness of the intervention. Potential questions that can be addressed in a process evaluation are: How did the intervention work in your hospital/clinic? Were adaptions of the intervention needed? How did the intervention affect the organisation of care (workload, capacities and sequence of care)? How was the intervention received by you and your hospital/clinic? What barriers and facilitators for the implementation of the intervention did you experience? (eg, barriers and facilitators related to the characteristics of the intervention, the inner setting or

the outer setting of your hospital/clinic, the individuals involved and the implementation process). What worked and what did not work in implementing the intervention (so which activities helped or did not help to do the intervention?). Second, stakeholders (patients, healthcare providers and administrators) and implementation science experts should be involved from the onset of the study. Stakeholder involvement throughout the research process enhances the relevance and feasibility of hybrid studies. Implementation expertise is necessary to collect implementation-related aspects with appropriate data collection methods, supported by implementation theories, models, frameworks.[11] Further, researchers but also funding agencies should be willing to allocate additional resources for the successful execution of hybrid studies.

CONCLUSION

In conclusion, hybrid effectiveness-implementation designs offer a novel and robust approach to advancing rheumatology research. By seamlessly integrating clinical effectiveness and implementation considerations, these designs have the potential to enhance the relevance, efficiency and impact of interventions in real-world settings. As rheumatology continues to evolve, embracing hybrid designs can contribute significantly to the translation of research findings into improved patient care. Researchers, clinicians and stakeholders alike must collaborate to leverage the full potential of hybrid effectiveness-implementation designs. Not collecting implementation data such as barriers and facilitators in effectiveness studies is a lost opportunity to speed up the implementation of rheumatology research results.

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