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The importance of embracing complexity in rehabilitation

Rachel C. Stockley PhD¹ | Ian S. Graham MA²

¹Faculty of Health and Care, University of Central Lancashire, Preston, UK

²Manchester, UK

Correspondence: Rachel C. Stockley, PhD, Faculty of Health and Care, University of Central Lancashire, Brook Building, Bldg, Preston PR1 2HE, UK.
Email: rstockley1@uclan.ac.uk

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1 | INTRODUCTION

In practice, clinicians recognize that the effectiveness of a rehabilitative intervention will be influenced by a range of uncontrollable, interrelated factors.¹ For at least 40 years, a holistic, 'whole person' approach has acknowledged, albeit implicitly, that many factors will affect the success of an intervention.² These influences are numerous and relate to social, personal, political and cultural variables: the very elements which together form the complex context in which rehabilitation occurs.^{3,4} The term 'complexity' is often used throughout rehabilitation; notions such as complexity in practice, complex patients and complex problems are all familiar enough.^{1,5,6} To understand what we mean by complexity, a contrast may be helpful: a system we think of as *complicated* has many intricate elements that, whilst they can interact with one another in several ways, do so in a linear and predictable fashion; within a *complex* system, however, these intricate elements interact in ways that cannot be easily understood or predicted.⁴ Consequently, it is simple enough to foretell the behaviour of a complicated system, but impossible to perform the same feat with a complex one.^{7,8}

2 | EXPLORING COMPLEXITY IN REHABILITATION PRACTICE

Healthcare and rehabilitation services typify many of the central features of a complex adaptive system (CAS).^{8–11} These key features are illustrated with practical examples in Figure 1.

A healthcare service comprises many different individuals or groups (actors), such as patients, carers, healthcare professionals and service leaders. They interact with each other and, crucially, with the *context* in which they operate, that is, the service itself.^{4,12} These interactions occur in limitlessly variable ways, none of which can be reliably predicted.¹³

Healthcare services are not static entities, unchanging across time. Rather, they evolve dynamically and rarely reach equilibrium. Any system or group is likely to be situated within other, larger systems, which are also evolving.⁹ With so many potential groups, each nested within another, it can be hard to tell where one system ends and another begins—CAS exhibit fuzzy boundaries in even the simplest of circumstances.⁹

Complex adaptive systems also operate as a smooth, harmonious whole without any discernible leader or organizing factor.¹² This is observable in rehabilitation teams—each individual acts largely autonomously whilst exhibiting synchronicity with their colleagues.¹⁴ Two further points are worth observing. First, CAS contain nonlinear interactions, which may yield counter-intuitive results.¹⁵ A seemingly trivial change in or by one actor can cause a significant, potentially unintended change in another or, conversely, a large change may result in surprisingly small changes elsewhere.^{16,17} Second, healthcare services, like all CASs, are emergent entities. Consequently, they cannot be reduced to their component parts, however convenient this might be.^{10,15,18} Rather, we must recognize—and be guided by—that their overall effect is greater than the sum of their parts.

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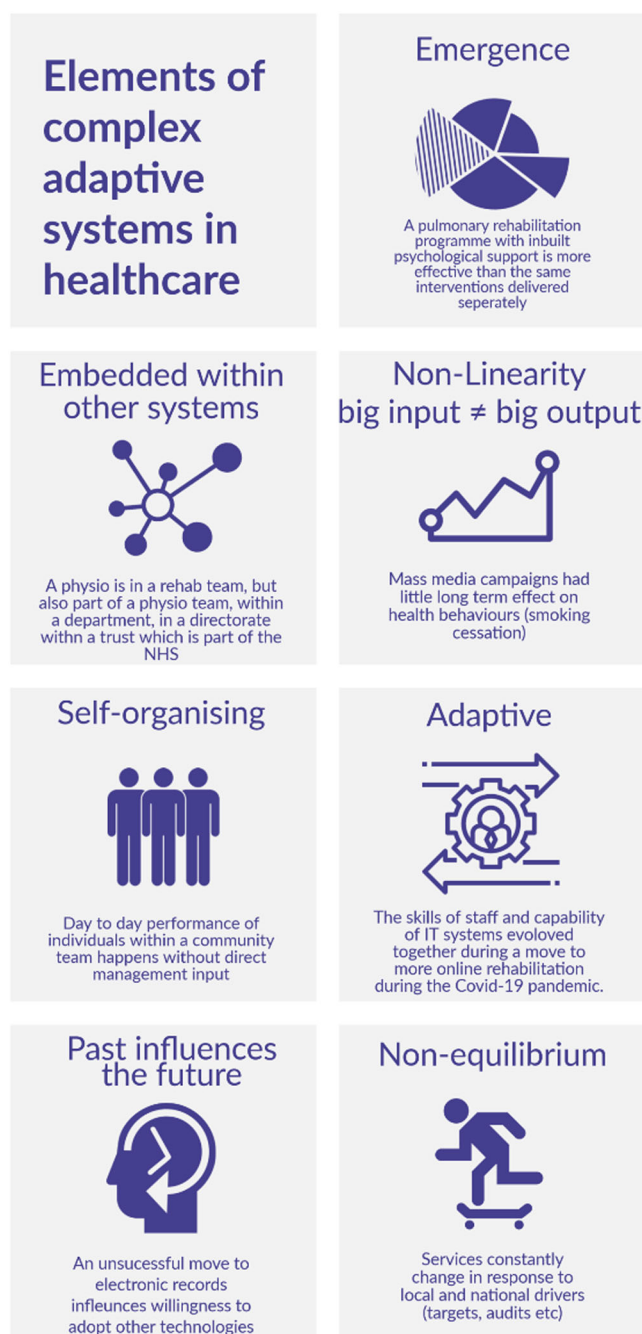


FIGURE 1 Elements of a complex adaptive system with fictional examples from rehabilitation and healthcare

3 | REHABILITATION RESEARCH AND COMPLEXITY—WHERE ARE WE NOW?

Rehabilitation research has embraced the language of complexity but largely ignores complexity's features, favouring instead reductionist methods when evaluating rehabilitative interventions. Ostensibly, this makes sense: a trial that minimizes biases by controlling variables, enforcing rigorous standardization of interactions across multiple sites, limiting interactions and testing a single, strictly defined intervention is appealing and, arguably, attractive to many funders.¹⁰ However, this

approach to rehabilitation research is fundamentally flawed. Researchers are helpless to eliminate the confounding effects of complexity upon outcome: even if they could do so, it would lead to a stifling—even elimination—of the very interactions between context and intervention which are vital to an intervention's wider implementation and success in practice.¹¹ Continuing to use a tightly controlled reductionist design also gives rise to several concerns. Whilst a noncomplex trial may accurately test a hypothesis, it may answer a question that, due to the constraints of the research design, is so far removed from clinical practice the findings have little relevance or impact as shown in Figure 2.^{3,9,11} The complexities of clinical rehabilitation also mean that the findings of reductionist designs often cannot be translated into practice so patients do not receive beneficial interventions. If the results of reductionist research are implemented into practice, but the complexities inherent to practice have not been considered in the research, there is the potential to actually *harm* the patient rather than benefit them.^{3,9,11,17} More broadly, and when evidence obtained from reductionist trials is embedded in practice guidelines, it will widen the chasm between the complex patient in front of the clinician (affected by multiple morbidities, social, cultural and environmental influences) and the 'paper' patient with a single isolated health condition included in research trials as shown in Table 1.¹⁵ It should be clear, then, that we ignore complexity at our—and our patients'—peril.

4 | WHERE NEXT?

Randomized controlled trials are a powerful tool, enabling us to determine the efficacy and effectiveness of rehabilitation interventions. However, they are not the *only* design for rehabilitation research and often fall short of answering some of our most pressing research questions.³ Rather than trying to control or eradicate complexity in our research—both doomed endeavours—we could heed the advice of complexity scholars: we could study the *context* to explain and understand changes in outcomes.^{9,19} This approach is inherent in the recently updated Medical Research Council (MRC)/ National Institute for Health Research (NIHR) framework.^{18,20} There is likely to be a criticism that true exploration of complexity cannot produce the causal inferences many of us in health and rehabilitation research seek.^{21,22} Nonetheless, the new edition of this framework highlights a shift in focus, a move away from minimizing bias in research studies of complex interventions towards identifying research designs that generate clinically valuable data.²⁰ Crucially, this framework provides rehabilitation researchers with clear guidance and a compelling mandate to use different, nonreductionist designs to answer many of the pressing questions inherent to rehabilitation some of which are presented in Table 1. Exploratory designs can be used to observe and describe the context, identify the influential actors within an intervention, capture stakeholder views and ultimately generate clear theories of how complex interventions may work in practice.²³ New adaptive randomized controlled designs such as multi arm, multistage trials enable multiple

Comparison of reductionist and complex designs

Example question: Is physiotherapy (a complex intervention) for ankle osteoarthritis more effective than advice provided by GPs?

REDUCTIONIST DESIGN

Design: RCT - Participants with ankle osteoarthritis were randomly allocated to receive either GP led care or physiotherapy and their pain and function compared at 18 weeks. The GP led care comprised simple pain relief and activity advice. Physiotherapy comprised individually prescribed strengthening exercises and advice.

The findings indicated that: there was a small but significant change in pain and function in both groups. There was no significant difference between GP led care and Physiotherapy.

Implication: This finding suggests that physiotherapy was no more effective upon pain and function than GP led care for ankle osteoarthritis.

Potential Impact: people with ankle osteoarthritis who present to the GP would not be referred to receive physiotherapy despite it being beneficial for over a third.

COMPLEXITY FOCUSED DESIGN

Design: Master protocol, adapted multi-arm multi-stage trial. Participants with ankle osteoarthritis were randomly allocated to receive either GP led care or physiotherapy. The GP led care comprised pain relief and activity advice. Stage 1 physiotherapy comprised individually prescribed strengthening exercises and advice. In the physiotherapy group. Patients who did not initially respond to stage 1 treatment (non-response was determined using pre-set criteria based on validated outcome tools) were moved to stage 2. Stage 2 comprised a class-based behaviour-change based exercise and education intervention.

The findings indicated that: 35% of patients did not respond to advice and exercise in the physiotherapy group. These participants went on to receive the second stage physiotherapy intervention. They demonstrated significant benefit over the GP led care group. A priori analysis highlighted that those with pain greater than 7/10 and longer duration of pain were less likely to respond to stage 1 physiotherapy but made significantly greater improvements in stage 2 than those receiving GP led care.

Implication: These findings suggest that patients with more severe and a longer duration of osteoarthritic ankle pain do not benefit from advice and exercise or GP led care but significantly improve after a class-based behaviour-change based exercise and education intervention. Those with less severe and short duration pain benefit equally from GP led care and physiotherapy.

explaining how these effects were created.^{9,22,25} These designs are built upon a theory of 'the mechanism of effect': this theory articulates stable, noncomplex factors of how an intervention may affect a condition (e.g., how intensive therapy after stroke may improve arm function) but also considers the complex issues of the influence of behaviours and context (e.g., if and how an individual and clinicians will engage in the intensive intervention).^{9,22} By virtue of these approaches and designs, we will be able to generate an understanding of what works for whom, and this understanding will support the crucial translation of theory into practice.

However, including complexity-based studies alongside randomized controlled trials, or using more exploratory research designs in rehabilitation research, is unlikely to be easy or cheap. With their greater element of unpredictability, these designs may be deemed too risky by some research funders yet the development work to produce a theory of effect will be vital to inform trials of efficacy and effectiveness. Concerns about the potentially higher costs of this type of research should be offset against the likelihood of producing more useful, applicable research findings that have a wider positive impact on practice to the ultimate benefit of the rehabilitation profession and our patients.

5 | CONCLUSIONS

Despite their vital role in the success or failure of an intervention, randomized controlled trials can overlook the context and behaviours of those involved in rehabilitation. If we are to make progress in developing effective, implementable rehabilitative treatments we must consider problems using questions and tools designed to deal with the complexities that are unavoidably part of healthcare. To fail to consider these complexities is to threaten the success, progression and perception of rehabilitation. Potentially beneficial treatments may be wrongly judged to be ineffective, and ineffective treatments falsely deemed useful. As a result, patients will be offered suboptimal care. We should be clear that a complexity-focussed approach to rehabilitation research would not herald the end of randomized control trials. But we must recognize that other research designs are also needed if our research is to answer a relevant question and generate clinically useful data. Complexity-focussed designs will complement standard trials, not detract from them, and will confer multiple benefits. We will be able to not only understand which interventions work well for our patients but also to learn from trials in which there was no significant benefit to an intervention. We will have heightened confidence in our interventions, knowing which factors are vital to ensure implementation in practice and understanding when and if an intervention will deliver similar results across a range of clinical settings.

Whether we like it or not, complexity is an integral aspect of healthcare that rehabilitation research cannot ignore. Embracing the messy realities of complexity¹⁰ is vital to better understand and address the challenges in rehabilitation research and practice. This will enable us to understand what interventions work for who and in

FIGURE 2 Comparison of reductionist and complexity focused designs in a fictional research question

treatments to be tested in a single arm and personalization of interventions, which could provide the flexibility that rehabilitation research requires to embrace complexity.²⁴ Similarly, pragmatic and critical realist randomized control trial designs and process evaluations within more traditional randomized controlled trials provide methods for both determining the effects of an intervention and

TABLE 1 Potential risks to practice from over reliance on reductionist trials and complexity-focussed alternatives

Characteristics of overly reductionist trials	Risks to rehabilitation practice, which could lead to harm	Complexity embracing alternatives to address risks
Tend to select a specific, tightly constrained group of patients, which may only represent a small proportion of the clinical population: for example, participants are rarely included if they have any other comorbidities or pre-existing diagnoses	Little or no research evidence that is applicable for rehabilitative interventions in those who have multimorbidity despite nearly all adults over the age of 65 having two or more health conditions— <i>patients given untested interventions</i>	Realist trial designs or embedded process evaluations within trials provides an ability to include specified comorbidities and determine what works for whom
Focus on a specific subgroup/presentation with uncertainty if findings could then be extrapolated to other presentations of the same condition	Insufficient research to inform practice in smaller groups (e.g., people living with severe stroke) leads to clinicians having to use variable and untested interventions— <i>patients are given untested interventions</i>	Umbrella trials enable the inclusion of different presentations of the same condition with different treatment arms. This means a range of severities can be included and their response to different treatments identified
Rarely allow tailoring of interventions for personal or environmental circumstances	Research intervention does not resemble clinical practice, presenting a significant barrier to the implementation of research findings into practice— <i>patients do not get to benefit from new effective interventions</i>	Adaptive interventions enable the personalization of interventions Multiarm, multistage designs mean that multiple treatments can be delivered and tested
Cannot adapt interventions to changing healthcare practices during a trial, for example, initiatives within the same community to promote physical activity	Research may mislead if based on 'old' and restricted practice— <i>suboptimal practice and research waste</i>	Stepped wedge or cluster randomized controlled trial designs enable centres to act as their own control Use of (high quality) real-world data
Not always representative of the wider population	Challenges of Each Approach	Requires large samples to account for patient variability May take longer to complete than simple trials
Little flexibility to individual, social and cultural needs		Requires significant trial infrastructure
Minimal adaptability to the wider context		Likely to cost more

what circumstances and support the implementation of beneficial treatments that can transform our patients' outcomes.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no datasets were generated or analysed during the current study.

ORCID

Rachel C. Stockley  <https://orcid.org/0000-0003-4441-6860>

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