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FROM EVIDENCE TO IMPLEMENTATION: HOW SYSTEMS DESIGN CAN FORESEE COMPLEX HEALTHCARE INTERVENTIONS

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Abstract

How can we design and engineer research that leads to the development and effective implementation of complex healthcare interventions? We advocate for a systems design-based approach when initiating clinical research to anticipate the proposition of complex interventions. Using cognitive care as an example, we investigate how hybrid design-inspired methodologies can promote organisational effectiveness and how strong clinical evidence can support successful conceptualisation and uptake of novel interventions into routine clinical practice.

Keywords: healthcare design, complex systems, engineering design, hearing care, cognitive decline

1. Introduction

An ageing population, a changing support ratio and the ubiquitous availability of new technology are all changing the global face of healthcare. For many chronic diseases, novel approaches are continuously developed and tested to improve diagnosis, increase quality of life and help futureproof our healthcare systems (Campbell et al., 2007). Yet many questions remain, particularly for pathologies with no straightforward treatment option. This makes non-pharmacological, multi-modal interventions essential in attempting to prevent, slow or mitigate the progression of disease. These generally run in parallel with the fast-paced development of advanced technologies. However, these interventions are slowed down by the stringent requirements of well-established clinical standards, the need for strong evidence of efficacy and the challenge of implementation and uptake in routine care practice (Craig et al., 2008; Michie et al., 2009; Richards and Hallberg, 2015). This leads us to consider the process by which complex healthcare interventions are imagined, engineered, refined and implemented into clinical practice (Craig et al., 2008).

The increasing use of advanced technologies within healthcare is one core reason why design and engineering become increasingly relevant disciplines to consider early in the formulation of clinical research hypotheses. Indeed, not all clinical research studies foster actionable knowledge. To date, there is no methodology that systematically offers to evaluate whether a clinical study generates evidence that may serve the later formulation of a new complex healthcare intervention, or whether the alteration of an existing intervention could tackle a disease or prevent its onset. For those clinical studies that do generate actionable evidence, one could therefore argue that the process of developing complex healthcare interventions begins with the formulation of fundamental clinical questions and explorative clinical research (see Figure 1).

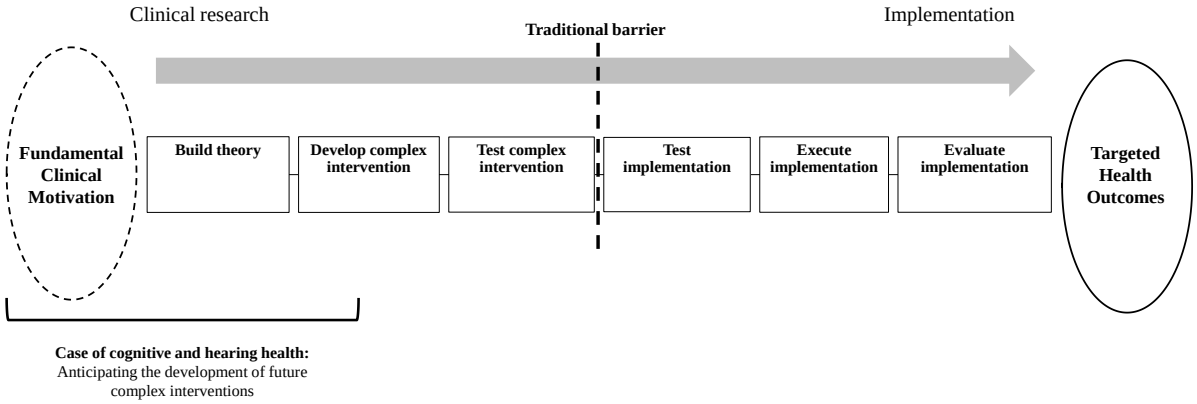

Figure 1. Design for effective adoption of complex healthcare interventions; Adapted from Craig et al. (2008); Curran et al. (2012)

This failure to acknowledge that early clinical research constitutes, on many occasions, the informal entry point to the design of a complex healthcare intervention brings about a number of important considerations: How can we design research to support clinical researchers in early phases of their scientific endeavours? As we continue to promote best practice in clinical research, how can we streamline the translation of clinical research findings into complex healthcare interventions that are effective in routine practice? Furthermore, which trade-offs are we prepared to accept?

This paper first discusses an engineering design approach to clinical research formulation that envisages, at the earliest stages, complex healthcare interventions and implementation strategies as a possible next step. An example of a study design that connects domains of hearing and cognitive care is then used to operationalise the argument put forward in this paper and to demonstrate the considerations that this framework (Figure 1) puts forth when used in practice.

The remainder of the paper is structured as follows: Section 2 discusses the need and the use of healthcare systems design in the early definition of clinical research hypotheses. Section 3 delves into targeted outcomes in the testing, execution and evaluation of the translational process from clinical evidence to practice implementation, resulting in a graphical overview (Figure 1). Section 4 illustrates these considerations in the context of a hybrid research design that simultaneously addresses effectiveness and implementation to support both the improved use of clinical research and the improved uptake of resultant health interventions. Section 5 includes a summary and conclusions for taking complex healthcare interventions successfully into clinical practice.

2. Systems design in the early formulation of clinical research

From clinical research and theory building to development and implementation, the translational process requires a number of considerations before best available evidence can be used to improve clinical outcomes. Moving in a bidirectional manner from basic research to patient-oriented and population-based research, this involves collaboration among scientists, practitioners and stakeholders from multiple disciplines. This helps to ensure that new treatments are implemented effectively and reach the intended population (Woolf, 2008; Rubio et al., 2010). Doing so requires, among other considerations, identifying shared goals and outcomes, determining external generalisability and identifying interacting components and potential barriers to effective translation. Figure 1 summarises these considerations and their use is illustrated with the use case example of the intersection between hearing care and cognitive care, an area with emerging knowledge that is to-date researched separately (Uhlmann et al., 1989; Lin et al., 2011; Lin and Albert, 2014). The items in Figure 1 will be elaborated upon in the following sections of this paper.

2.1. The role of systems design in healthcare

Systems thinking is characterised by its emphasis on linkages, view of interrelationships and patterns in contrast to individual components (Rouse and Serban, 2014; Clarkson, 2018). Just as

products need to be designed, tested and adapted by designers and engineers to meet user needs, clinical research and complex healthcare interventions may well benefit from the adoption of similar engineering design practices. Specifically, a holistic, healthcare system design approach is needed to identify solutions that address not only health outcomes but also behavioural awareness and process outcomes. As a field of research, healthcare systems design aims to apply systems thinking to novel frameworks and methodologies within engineering design to support the development of innovative healthcare interventions with value-effective outcomes (Patou and Maier, 2017; Clarkson, 2018; Ciccone et al., 2019).

One rationale for the role of design in healthcare is the multiplicity of outcomes that a system of care or a particular health-based intervention aim to address. These generally include multiple measures of clinical efficacy, such as improvement in quality of life and reduction in morbidity along with overall process cost-efficiency, stakeholder acceptance, patient satisfaction and uptake of the complex healthcare intervention. These various target outcomes will, in turn, often weigh against one another, bringing out the many challenges which engineers strive to address (Clarkson, 2018; Rouse and Serban, 2011, 2014). By taking a design perspective, we aim to address targeted health outcomes using iterative design and evaluation strategies that meet stakeholder needs early in the development process (Clarkson, 2018).

2.2. Developing and evaluating complex healthcare interventions

The role of systems design is relevant from the earliest phases of clinical research formulation, as soon as one can foresee or predict with some level of confidence, the formulation of a complex healthcare intervention as a next step. As mentioned earlier, the conceptualisation of a new or the update of an existing complex healthcare intervention to better tackle ill health often follows the validation of new medical evidence. However, as Topol (2013) notes, the concept of medical evidence itself is changing due to the advent of more digitally based and personalised medicine, unsettling our very notion of what Sackett and Rosenberg (1995) defined as evidence-based medicine or the "explicit and judicious use of current best evidence in making decisions about patient care".

The Medical Research Council (MRC) has proposed a number of strategies to address the complexity of these interventions and their evaluation. These interrelated components, such as practitioner behaviours, healthcare setting, stage of disease and treatment options all make the evaluation of effectiveness in routine care more difficult. To assist in this process, the MRC has proposed a five-phase strategy to develop, evaluate and implement complex healthcare interventions (Craig et al., 2008). They acknowledge that ideas for these interventions may emerge from sources such as existing practices, theory, policy makers or practitioners, new technology and commercial interests, which all influence the ability to modify, influence, design and evaluate a subsequent intervention. While this strategy is considered a stepwise process, Campbell et al. (2007) advocate for a more flexible use of this framework, arguing that defining and understanding the problem, developing the intervention and optimising the evaluation can be conducted simultaneously. This can be done by conceptually modelling the way in which a particular approach moves towards a targeted health outcome. Acknowledging the influence of these components at the initial research and design stages, and including them in the process along iterations may mediate these potential barriers. The framework illustrated in this paper (see Figure 1) outlines how we can use and expand on this strategy to assist in the development, implementation and evaluation of a complex healthcare intervention, while also approaching the clinical research evidence that precedes the intervention's conceptualisation.

2.3. The case of hearing care and cognitive health

How can we best help people stay cognitively healthy as they age? Currently, around 50 million people live with dementia worldwide, and there are 10 million new cases of dementia every year (World Health Organization, 2019). This places significant burden on both the healthcare system and the families and society that surround these individuals. Dementia represents a financial burden on society that is similar to that of heart disease and cancer, with an estimated annual cost between USD 157 and 215 billion (Hurd et al., 2013). According to a recent report from the Lancet Commission, there is evidence that an important fraction of dementia is preventable (Livingston et al., 2017). The report states that hearing loss holds nine percent of the predictive power amongst all risk factors

associated with the development of dementia. An increasing amount of evidence suggests an association between hearing loss and cognitive decline, and that hearing loss, even at mild levels, is associated with the long-term risk of cognitive decline and dementia (Uhlmann et al., 1989; Lin et al., 2013). Although no causal links have been established between these variables, there is research to support that hearing-based interventions are considered feasible among patients and that they have a positive impact on cognitive function and the reduction of cognitive decline (Dawes et al., 2015; Maharani et al., 2018; Hooper et al., 2019).

Despite an increasing amount of research on the topic, little is known on the nature of the link between hearing impairment, increased cognitive load, cognitive decline and the onset of dementia. Identifying avenues for new complex healthcare interventions within cognitive health would help prevent cognitive decline and address the rising rates of dementia amongst the ageing population.

In this context, the targeted health outcome is not only a reduction in cognitive decline, but would include an overall increase in quality of life for people as they age. Furthermore, with the indication of hearing loss as a potentially modifiable risk factor for cognitive decline, we possess elements pointing towards the formulation of a complex healthcare intervention that is rooted in audiology and hearing care.

3. Conceptualisation of a complex healthcare intervention

The generation of new medical knowledge should help in the creation of complex healthcare interventions for improved clinical outcomes, including cost-efficiency and user satisfaction. Yet there is a risk that new evidence from conventional clinical research gets 'lost in translation' and is not harnessed and explored as part of a complex healthcare intervention. Indeed, the barriers or disconnect between the domains of clinical research and clinical practice can be considered the 'knowing-doing gap', a concept widely used in organisational management (Pfeffer and Sutton, 2000; Pannunzio et al., 2019). In our efforts to provide the best possible care, we aim to fill or limit the gap between best available evidence and what is being done in daily practice. As new knowledge is created at increasing speed, how can we streamline the integration of complex healthcare interventions based on this evidence into practice? How can this process, in turn, be leveraged by the engineering design research community to gain insight on new design methodologies? This is where we can use the this process to generate new knowledge through design research as well as through clinical research (e.g. Pannunzio et al., 2019).

Complex healthcare interventions are generally made of several interacting components, they target several outcomes, are delivered in different ways and address various organisational levels across the healthcare system (Craig et al., 2008). Anticipating the future formulation of a complex healthcare intervention merely pushes our range of sight one step further. Below are three examples of how clinical research design can be utilised to anticipate a future complex healthcare intervention:

- Optimising early clinical endpoints that can help us better understand the coupling between interrelated variables of a complex healthcare intervention.
- Validating of a measurement tool or technical solution as part of the clinical study, gaining experience and feedback before the formulation and validation of the later complex healthcare intervention.
- Anticipating useful collaborations between various clinical domains, such as hearing and cognitive care. This same approach also foresees a strategy to implement the intervention.

Executing implementation (see block 5 in Figure 1) requires collaboration between policy makers, healthcare professionals, patients and caregivers. According to Pannunzio et al. (2019), this also includes the inputs from the healthcare recipients. Communication barriers and facilitators to complex healthcare intervention adoption in routine use should be considered at early stages of the clinical research study design. Any complex healthcare intervention resulting from this would adopt an approach to care that is service- and people-oriented, evidence-based, holistic and interdisciplinary (Leach et al., 2019).

3.1.1. Complexity of outcomes

Possible interventions become even more complex when emerging research and possible interventions fall outside of the current discipline's common practice. Those working closely with a specific area

may not be aware of the synergistic opportunities or links to another discipline. One such example is the case of cognitive healthcare (see section 2.3). Today, hearing and cognitive health remain as separated healthcare systems, and as Lin and Albert (2014) note, clinicians currently adopt a less proactive and more reactive approach toward hearing loss. In these cases, more attention is paid to what are often considered more pressing health issues in a mid-to-late aged population. However, the prevalence of both cognitive decline and hearing loss are rising (Lin and Albert, 2014; Livingston et al., 2017). The chronic and progressive nature of cognitive decline suggests that an approach based on emerging knowledge and new technology may be appropriate for promoting prevention and improving health outcomes (Thorpe et al., 2016). Recent research by Mahmoudi et al. (2019) found that hearing aid use was associated with delayed diagnosis of dementia, among older adults with hearing loss. It has also been suggested that this could lessen cognitive load, increase auditory stimulation and promote social engagement (Lin and Albert, 2014). These pieces of evidence seem to hint at complex healthcare interventions targeting the early diagnosis of hearing loss or prevention of hearing loss, for example, through audiogram tests for individuals at-risk for cognitive decline and hearing rehabilitative therapies such as hearing aid use. The initial step for identifying the credibility of a complex healthcare intervention is a fundamental clinical motivation. The next step is the formulation of both theoretical and practical aspects of how the intervention is likely to work, which we discuss throughout section 3.2 of the paper. We elaborate on these steps in the following section.

3.1.2. Identifying ideal outcomes

Targeting overall health benefits and wellbeing as key outcomes of a complex healthcare intervention requires acknowledging that patients are multi-faceted and exist in a broader social and environmental context. This perspective considers the importance of the linkages, relationships, feedback loops and interactions that characterise our complex healthcare system (Hawe et al., 2009). Therefore, the fundamental clinical motivation behind the formulation of a complex healthcare intervention should be the starting point of a broader evaluation of ideal targeted health outcomes (see Figure 1). In other words, the benefits of any one complex healthcare intervention on a particular outcome will surely depend on the effectiveness of other factors along the process. Hawe et al. (2009) assert that weak forms of health prevention programs may be a consequence of relying too heavily on individual-level theorising instead of a systems-based approach. Simple generalisation from individuals to populations can fail to consider the variability that often characterises an a priori homogeneous target population.

The outcomes of complex healthcare interventions are rarely achieved in a linear fashion. As Paterson et al. (2009) note, the notion of an outcome in complex healthcare interventions can differ from its original semantic term, which comes from the field of clinical trials for pharmaceutical products. In randomised controlled trial (RCT) research paradigms, outcomes are generally more straightforward, often with a single, linear cause and effect endpoint. On the contrary, in complex healthcare interventions it is generally combined multidisciplinary efforts across the patient journey that determine the intervention's efficacy. The notion of value becomes much more prominent: it is the best value for patients that is sought, and since value is defined as outcome relative to cost, efficiency is inherently connected in this analysis (Porter, 2010). This, in turn, means that outcomes of complex healthcare interventions will not be limited to improved health outcomes for patients, but would also include resource availability, cost-optimisation process efficiency and provider satisfaction. Problems arise when those making decisions hold interests that are not aligned with those providing and receiving care (Patou and Maier, 2017).

As stated previously, the mechanisms between hearing loss and cognitive decline are not fully clear, and research is just beginning to understand the nature of the link between hearing impairment, increased cognitive load, cognitive decline and the onset of dementia. It has been suggested that the weariness of decoding sounds with hearing loss might use more neural networks and result in a constant "cognitive overload", making the brain more vulnerable to cognitive decline (Cardin, 2016; Anzivino et al., 2019). If an association exists between effortful listening and cognitive decline, how could the current clinical study design best help to conceptualise a future complex healthcare interventions? If we find a significant correlation between listening effort and cognitive function, we

could consider a complex healthcare intervention that targets a reduction in listening effort, in an attempt to limit the progression of cognitive decline – even if causality is difficult to infer.
In this case, what would be the targeted outcomes of such complex healthcare interventions, and how should we determine the endpoints of this preliminary clinical study? Relevant outcomes to consider could be an increase in quality of life, the improvement in specific aspects of cognitive function, such as memory and attention. As we specify multiple outcomes for a complex healthcare intervention, we may look at the relevance of some of these outcomes as part of the early clinical study.

3.2. Implementation of a complex healthcare intervention

Here we move from the clinical research, conceptualisation and testing stages of the design framework to the implementation stages (see Figure 1). Clinical and implementation research rarely share the same outcome measures. Classic implementation research centres upon the adoption or uptake of interventions by healthcare providers and uses outcome measures such as behavioural change, adoption rates and intervention fidelity (Curran et al., 2012; Grol et al., 2013). In contrast, controlled clinical research tends to rely on internal validity and more direct, symptom-focused outcome measures. Moving separately from one stage to another can hinder the success or prolong the delay of adoption of a complex healthcare intervention, and does not help us understand how the intervention may interact with its environment during implementation. Any change within an organisation requires strategic planning. Resistance to change, rigid hierarchies and established workflows are just some of the many reasons that new complex healthcare interventions may not be effectively adopted into routine care practice. As Curran et al. (2012) note, few studies are designed to address both clinical intervention and implementation aims, nor do they describe the trade-offs and considerations required in their approach. Here, we outline the effectiveness-implementation hybrid design by Curran et al. (2012) and discuss its implications for our design framework (Figure 1) and the cognitive care use case.

3.2.1. Implementation-effectiveness hybrid research designs for successful interventions

How can the design of successful complex healthcare interventions leverage new knowledge and improve healthcare outcomes while meeting diverse stakeholder objectives? Even if a complex healthcare interventions is tested within a standard clinical research framework, more work is needed to ensure it can function efficiently in a real-world environment. In the implementation-effectiveness hybrid design, an intervention is tested simultaneously with an implementation strategy (Curran et al., 2012).
This configuration adopts a dual focus towards assessing clinical effectiveness and implementation and is preferred in situations when interventions hold at least indirect effectiveness evidence, exhibit strong face validity, target a specific population and pose minimal risk to patients and clinicians. In the three types of intervention-implementation research configurations (hybrid types 1, 2 and 3), the clinical intervention is tested simultaneously with the implementation strategy. This is done through information gathering only (type 1), alongside strategy testing (type 2) or with full implementation testing while the clinical intervention is still in the information-gathering stage (type 3), with the latter placed furthest to the implementation end of the research spectrum. This helps identify interactions between the intervention and its environment, providing information that researchers can take forward to make more strategic decisions earlier in the process. These, in turn, can inform and influence future implementations. In a type 2 hybrid study, complex healthcare interventions are tested separately but simultaneous to the implementation strategy. As illustrated in Figure 1 and discussed in the following paragraph, such configuration can begin with 'indirect evidence' being used to conceptualise a complex healthcare intervention. The most useful clinical research may come at an exploratory, theory building level. In this configuration, an intervention "test" requires that at least one outcome measure is being used, and at least one hypothesis is being studied.
"Intervention testing", in this context, does not always necessitate randomised designs with a strong power. While randomised controlled trials (RCTs) are considered the gold standard for the evaluation of clinical efficacy, they may come at the expense of external generalisability in complex systems. Healthcare systems may be one of the most complex organisations, and RCTs as they exist today may not accurately reflect the extremely complex healthcare system (Klein and Young, 2015; Lamé, 2018).

Clinic-specific factors that are intentionally controlled, such as workflow habits, patient relations and patient demographics may indeed be an important consideration in a healthcare context before effective implementation is possible. This where engineering designers can contribute by systematising how we look at clinic outcomes, help identify relevant behavioural aspects, investigate workflows and explore relationships between interrelated components.
As noted in Curran et al. (2012), an effectiveness-implementation research design is advisable in situations where six key criteria are in place:

1. There is strong face validity for the clinical and implementation strategies.
2. There is some indirect evidence for the clinical and implementation strategies' generalisability.
3. There is minimal risk associated with the strategies.
4. There should be implementation momentum within the clinical system or literature toward routine adoption.
5. There are reasonable expectations that the strategy is supportable in the organisational context.
6. There is reason to gather more effectiveness data regarding the intervention.

The cognitive care use case would satisfy the previously mentioned criteria by testing the question "how can we keep people cognitively healthy as they age?" and using "reduction in cognitive decline" as an outcome measure. Using the momentum that comes from previous literature and large-scale reports (Lin and Albert, 2014; Thorpe et al., 2016; Livingston et al., 2017) and clinical evidence demonstrating a significant association between the intervention method and related health outcomes (1, 2), we could imagine using this strategy to test implementation alongside a given intervention. As hearing-based cognitive interventions have not been implemented on a large scale within this context, effectiveness data would be extremely useful for further exploring the value of the complex healthcare intervention (6). Any hearing rehabilitative strategy used would be considered non-invasive and already safely used within a hearing care context (3). Furthermore, support within the organisational context can be upheld by collaborating and consulting stakeholders across the patient journey, such as care coordinators, nurses and neuropsychologists (4, 5). With rapid translation as one of the central goals, this approach aims to target the methods and procedures needed to deliver interventions in practice settings and aims for increased intervention awareness, faster translation and increased adoption of complex healthcare interventions.

3.2.2. Delivering interventions in practice settings: Going beyond scientific dissemination

Can the creation and distribution of guidelines, articles and educational materials lead to sufficient uptake in practice? A review of 11 studies found that disseminating educational materials, including guidelines, audio-visual materials and electronic publications resulted in no statistically significant improvement in practice (Giguère et al., 2012). Another review of 19 studies of consensus-based recommendations for practice found little evidence that passive dissemination on its own can result in behaviour change (Lomas, 1991). It has been estimated that just 14% of research disseminated passively becomes incorporated into everyday practice (Balas and Boren, 2000; Green et al., 2009; Douglas et al., 2015).
The general effectiveness of dissemination of complex healthcare interventions therefore appears limited, and strategies are needed to assess, evaluate and plan alternative implementation strategies over a longer period of time. Kryworuchko et al. (2009) found that guideline developers are engaging in fewer dissemination and implementation activities, but are spending increasing effort evaluating their dissemination strategies and the impact of their guidelines on health outcomes. These efforts would take place in the later stages of translational process (see test, execute and evaluate implementation, Figure 1). As Halladay and Bero (2000) note, more research is needed towards development of research techniques to evaluate complex healthcare interventions. At its earliest stages, and where this paper sets its focus, this means translating the evidence into a tangible, simple and understandable description of the intended practice. Beyond this dissemination practice, obstacles to and opportunities for change should be identified. The intervention should then be based on the identified needs, obstacles and opportunities within the given context.

For our use case, this would mean considering the current attitudes and beliefs across the cognitive and hearing care organisational environments. How often are patients who present with cognitive difficulties tested or questioned about their hearing? Alternatively, are hearing care practitioners aware or interested about their patients' cognitive health? By targeting factors for influencing change across the patient journey, a complex healthcare intervention harnessing elements of hearing care as a strategy for limiting cognitive decline should aim to address implementation barriers, beyond the passive dissemination of recommendations and scientific publications. Including stakeholders at the earliest stages, such as nurses, clinicians and neuropsychologists may ensure that those who can implement change are well-versed in the intervention. Finally, the intervention should have a clear plan for monitoring and evaluation. For instance, the Medical Research Council (MRC) has outlined a development-evaluation-implementation process for complex healthcare interventions (Craig et al., 2008). They acknowledge that ideas for these interventions may emerge from sources such as existing practices, theory, policy makers or practitioners, new technology and commercial interests, which all influence the ability to modify, influence, design and evaluate a subsequent intervention. Acknowledging the influence of these sources at the initial design stage, and including them in the process may mediate these potential barriers.

4. Summary and conclusions

This paper argues design has an important role to play when translating clinical research results and fostering their successful uptake in practice. More specifically, this paper argues that incorporation of design is fruitful from the earliest stages of conceptualising and planning clinical research studies – a novel point that has thus far not been explicitly emphasised in literature. In this paper, we take a systems design-based approach at early stages of exploratory evidence-based research – one that foresees the future implementation of complex healthcare interventions.

By outlining the considerations to be addressed in early phases of clinical research, we aim to provide a framework to guide the process when anticipating the future development, testing, implementation and evaluation a complex healthcare intervention. For instance, how systematising early clinical endpoints can help us better understand the coupling between interrelated variables of a complex healthcare intervention. Additionally, how identifying obstacles to and opportunities for change can assist in translating evidence into tangible descriptions of intended practice. From fundamental clinical motivation towards targeted health outcomes, we outline what these considerations imply for any complex healthcare intervention meant to broadly promote cognitive health using elements of hearing care. We discuss specifically how a hybrid effectiveness-implementation study design can test a possible intervention in early stages of clinical research and gather feedback for future implementation, thereby mediating traditional barriers for more effective adoption of complex healthcare interventions.

With the view towards bringing cognitive and hearing care closer together, we conclude by asserting that anticipation of the later development and implementation of complex healthcare interventions may reduce the amount of clinical research that lays dormant in guidelines, journals and educational materials. By taking a more active approach of bringing clinical research closer to the real-world healthcare environment and approaching research design in a way that identifies the various interacting components of the healthcare system, we can identify avenues for targeted care at different stages of the patient journey and bring our research at its earliest stages even closer to our goal – providing more valuable health outcomes.

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