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Appraisal

Research Note: Designing implementation trials in physiotherapy

Introduction

Despite significant investment in health and medical research and the discovery of therapeutic interventions that can improve patient health, most effective interventions are never integrated into clinical care. Implementation science is the study of methods to promote the systematic uptake of evidence-based interventions or policies into routine practice to improve the quality and effectiveness of healthcare.[1] While it is increasingly being acknowledged that evidence-based medicine includes evidence-based methods of implementation,[2] conducting implementation research remains uncommon in the field of physiotherapy; for example, a search of the Physiotherapy Evidence Database (PEDro) for trials with the term 'implementation' in the title or abstract in November 2021 identified 658 records among the 40,814 total trials listed in the database. To support the conduct of implementation research, and in particular implementation trials in the field, this Research Note aimed to define implementation trials and provide guidance for designing these trials in physiotherapy.

What are implementation trials?

Implementation trials (often randomised) evaluate the success of strategies to help people or organisations put evidence-based interventions or policies into practice. Implementation strategies are defined as the methods or techniques used to enhance the adoption, implementation and sustainability of an evidence-based intervention.[3] Some common examples of implementation strategies include conducting educational meetings, creating a learning collaborative, identifying/preparing champions, and audit and feedback.[4]

It is important that implementation trials distinguish between

i) the evidence-based intervention that is the subject of implementation – interventions are typically directed at the patient, such as a therapy or drug – and
ii) the implementation strategy(s) that is being tested in the trial to facilitate effective adoption, implementation and/or sustainment of the intervention – these are typically directed at the clinician or the circumstances surrounding the clinician that will influence their practice, such as performance audit/feedback, training or incentives.

The primary outcome of an implementation trial should be to measure the extent and quality of the implementation of the intervention (eg, implementation fidelity such as provision of care to patients concordant with guideline recommendations). However, in instances where the effectiveness of the intervention on patient health outcomes has been insufficiently established, implementation trials may have a dual focus assessing both the effectiveness of the implementation strategy (on measures of implementation) and intervention effectiveness (on measures of patient outcomes); these trials are termed hybrid implementation-effectiveness trials[5] (see Figure 1).

When should you conduct an implementation trial?

An implementation trial is warranted when effective clinical interventions are not routinely implemented in practice; that is: there is an evidence-practice gap. Evidence to support effectiveness of an intervention to be implemented should ideally come from a systematic review of randomised controlled trials or from rigorously developed clinical practice guidelines, particularly if implementation is sought at a system-wide level. However, if evidence is less certain or indirect, a hybrid type 2 trial (Figure 1) can be used to test implementation strategies on a smaller scale together with intervention effectiveness, as a means to accelerate research translation.[5]

Designing an implementation trial

The following section provides guidance for designing an implementation trial. Table 1 provides definitions of key implementation terms used within this section.

Use of theories, models and frameworks

Changing the professional behaviour of clinicians to integrate evidence-based interventions within health systems is complex and influenced by a range of factors operating at different levels. To help navigate this complexity, the use of theories, models and/or frameworks is recommended within implementation research.[9] Although these three terms have different definitions (see Table 1), they are often used interchangeably in the literature. Frameworks can be used: to describe or guide the process of implementation (ie, process frameworks); to understand and or explain what influences implementation outcomes (ie, determinant frameworks); and to evaluate the success of implementation (ie, evaluation frameworks). Depending on the theory, model or framework selected, more than one may be needed in the planning and conduct of an implementation trial. An excellent web tool, developed and managed by researchers in the United States, provides a step-by-step guide to selecting the best framework(s) to suit the implementation trial (https://dissemination-implementation.org/index.aspx). Examples of some commonly used frameworks are provided in the sections below.

Process of implementation

The process of implementation is often divided into several steps or phases: pre-implementation, implementation and sustainment.[11] The preparatory work for an implementation trial is conducted within the pre-implementation phase, deciding on an evidence-based intervention to implement, exploring the local context where the trial will be conducted, identifying implementation barriers and

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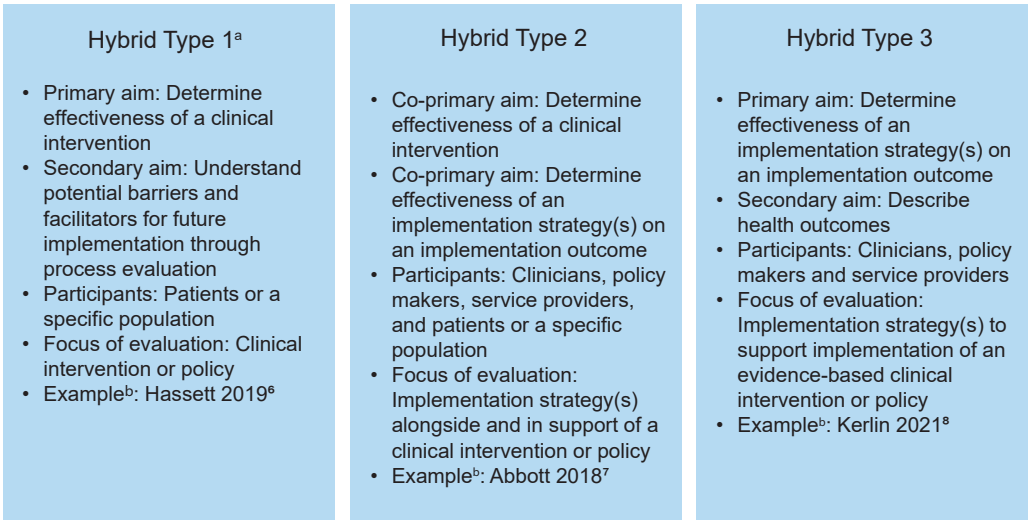

Figure 1. Key features of hybrid implementation-effectiveness trials. Figure is informed by Curran et al 2012.[5]
[a] Hybrid Type 1 is not considered an implementation trial.
[b] Protocol paper for each hybrid design describing the implementation of physiotherapy -relevant clinical interventions.[6–8]

Table 1
Common terminology used in implementation science.

Terminology	Definition
Implementation strategy	A discrete method or technique used to enhance the adoption, implementation and sustainability of an evidence-based intervention.[4]
Theory	An idea or set of ideas to help inform observations and understanding of a particular topic. They are typically predictive with specified relationships between concepts.[9]
Model	A simplified representation of a more complex phenomenon. A theory may be operationalised within a model.[9]
Framework	A structure, overview or outline consisting of various descriptive categories. Causal relationships are not specified.[9]
Organisational readiness	A construct encompassing both the willingness and perceived capacity of stakeholders within an organisation to engage in adopting a new intervention.[10]

facilitators, developing a logic model,[12] and preparing the local context for implementation. An implementation trial is usually undertaken in the implementation phase and may extend into the sustainment phase if the trial's aims include evaluating sustainment of the intervention. Alternatively, the sustainment phase may include additional research where further strategies to sustain implementation may be employed when there is evidence of implementation decay. A commonly used process framework is the Exploration Preparation Implementation Sustainment framework.[11] This framework considers the inner and outer contexts (ie, within and external to the implementation setting), bridging factors that span across the inner and outer context, as well as the suitability of the evidence-based intervention to be implemented throughout the different phases of implementation.

Understanding the implementation context and building implementation strategies

Formative research undertaken in the pre-implementation phase is critical for informing the development of an implementation trial. This work is important to help understand current usage of the evidence-based intervention in a specific setting, the barriers and facilitators that hinder or assist local clinicians being able to put the evidence-based intervention into practice, and to assess organisational readiness for implementation (eg, leadership, culture).[10] As stakeholders have a key role to play in the success of an implementation effort, this work should include engagement with a range of stakeholders (eg, clinicians, managers, patients, community providers, funders), and is likely to be undertaken both formally and informally using quantitative and/or qualitative research methods.

Determinant frameworks such as the Consolidated Framework for Implementation Research[13] can be useful for conducting formative pre-implementation research. The Consolidated Framework for Implementation Research includes five domains of potential influences on implementation: intervention characteristics (eg, complexity, adaptability), outer setting (eg, patient needs and resources), inner setting (eg, culture, learning environment), characteristics of the clinicians (eg, knowledge and beliefs about the intervention), and the planned process of implementation (eg, engaging opinion leaders). Identifying barriers and facilitators to implementation across the five domains can help to guide the selection of implementation strategies to address barriers (eg, education to address lack of knowledge about the intervention) and leverage facilitators (eg, use of opinion leaders as clinical champions). A single implementation strategy may be selected; however, it is more common that multiple implementation strategies are used together to address multiple barriers to implementation.

The choice of implementation strategies can also be informed from the literature of known barriers and facilitators to implementation and/or known effective implementation strategies for similar settings, clinician groups or clinical interventions. The Cochrane Effective Practice and Organisation of Care group publishes systematic reviews on effectiveness of different implementation strategies (eg, conducting educational meetings).[14] It is recommended that implementation strategies are named and defined using a standardised taxonomy to enable comparison between studies and build the evidence-base for particular strategies;[3] for example, the Expert Recommendations for Implementing Change taxonomy provides a list and definitions of 73 discrete implementation strategies.[4] It is also recommended that sufficient detail about the implementation strategy is included to enable the strategy to be replicated in different settings (eg, who is delivering it; who, how and what is it targeting; what is the mode of delivery and dose; when is it delivered; and what is the justification for this strategy).[3]

Research design and measurement

Selecting the type of design to use in implementation trials depends on many factors, including: potential sample size and funds available, risk of contamination, and the outcomes of interest and how easily they can be collected.[15] While randomised designs are frequently used in implementation trial designs, random allocation may not be appropriate (or possible) in many circumstances, and so

non-randomised designs are often also employed.[16] For randomised designs, an individually randomised controlled trial where clinicians are individually randomised to one of two or more groups is uncommon for implementation trials because clinicians typically work in teams and therefore there is risk of contamination between groups. In addition, influences on clinicians' ability to implement an evidence-based intervention are likely to be multilevel (ie, at the individual, organisation, community and/or system level)[17] with implementation strategies often targeting organisation or system level determinants of implementation (eg, change record systems).[4] For these reasons, cluster randomised trials are more common for implementation trials where teams of clinicians (eg, clinics) are randomised to one of two or more groups. A stepped wedged design where groups (eg, whole departments) can be randomised to receive the implementation strategy(ies) in a sequential order can also reduce the risk of contamination, but require fewer clusters. For a more detailed description of different study design options see Wolfenden 2021.[15]

Implementation trials have an implementation outcome as their primary outcome. McKay et al 2019[18] provide a framework for recommended implementation outcomes and determinants for use in implementation trials. The framework describes five key implementation outcomes – reach, adoption, fidelity, dose and sustainment – and suggests that these measures should be collected both for the delivery of the evidence-based intervention and implementation strategy(ies); for example, fidelity of the evidence-based intervention delivered by the clinicians and fidelity of the implementation strategies used to facilitate implementation of the intervention should both be measured. It is worth noting that some of these measures may only be collected from the group(s) randomised to receive the implementation strategy(ies). Measures of acceptability, feasibility and cost have also been suggested as useful determinant measures for inclusion in implementation trials and can be assessed using both quantitative and qualitative methods.[18]

Reporting implementation trials

To report implementation trials, the Standards for Reporting Implementation Studies (STaRI) guideline[19] should be used in conjunction with the relevant Consolidated Standards for Reporting Trials (CONSORT) guideline for the type of randomised controlled trial chosen.

Future directions for implementation research in physiotherapy

Strengthening implementation research in physiotherapy can be facilitated in a few ways. When designing interventions, future implementation settings and key stakeholders should be borne in mind and effectiveness trials be conducted while collecting data to inform future implementation (hybrid type 1 study design).[5] For existing effective evidence-based interventions in physiotherapy, consider randomised implementation trials to assess how these interventions can be implemented in practice. This requires pre-implementation work, including good engagement with local stakeholders, a good understanding of the local context and the use of frameworks to guide implementation and evaluation. Health systems should be 'learning health systems' where research is embedded into practice and research is valued as a part of a physiotherapist's workload, with appropriate time carved out for them to participate in implementation research, including education and training.[20]

Conclusion

Adoption and implementation of effective physiotherapy interventions into clinical practice does not happen automatically, and there is now greater understanding of the complexity of changing clinician behaviour and organisation practice. Implementation science seeks to generate new knowledge to guide how best such practice change can be achieved. This article introduces key terminology in implementation science, includes a reference list of useful methodology papers in the field, and provides guidance for conducting implementation trials in physiotherapy. It is hoped that this will provide further interest of physiotherapists in conducting implementation trials to enable more evidence-based interventions to be embedded into healthcare systems.

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