Addressing intervention fidelity within physical therapy clinical research

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Intervention fidelity is a key component of the design and conduct of physical therapy research; however, it currently does not receive the attention it deserves. Intervention fidelity is defined as the 'the methodological strategies used to enhance and monitor the reliability and validity of behavioural interventions'.[1] In other words, intervention fidelity includes enhancing and assessing the extent to which an intervention is implemented as intended by its developers, including how they envisage the participants or patients to interact with the intervention. While this concept of intervention fidelity encompasses the fidelity of training given to the providers of physical therapy interventions, and aspects such as participants' receipt and enactment of intervention skills, the focus of this 'Viewpoint' is predominantly on the fidelity of intervention *delivery,* i.e. ensuring that providers deliver the intervention as intended through enhancing (e.g. use of intervention manuals) and assessing fidelity (e.g. using direct observations, self-report checklists). This paper aims to highlight the importance of intervention fidelity for the physical therapy profession and its relevance for both physical therapy researchers and practitioners. Potential barriers to enhancing and assessing the fidelity of intervention delivery in physical therapy research will be discussed, and possible solutions with examples from the literature suggested. Although intervention fidelity can, in some circumstances, be challenging to achieve in physical therapy research owing to pragmatic concerns and the need for individualised treatment, we provide some recommendations on how to improve the enhancement and assessment of fidelity within physical therapy research and achieve a balance between idealism and pragmatism. Our goal is not to provide complete solutions to each of these barriers, but to introduce important issues for the physical therapy profession to be cognisant of with respect to current and future clinical practice and research.

Importance of intervention fidelity

A recently published editorial in several physical therapy journals by Yamato et al.[27] endorsed the use of the TIDieR guidelines[11] in physical therapy research to improve the quality of intervention reporting in this field.[27] While the quality of reporting of physical therapy research is crucial, intervention fidelity is a key issue to be addressed at the earlier stage of trial design and conduct. Fidelity of delivery concerns the procedures put in place to enhance and assess faithful implementation of the intervention, and is thus distinct from reporting. With adequate fidelity, one can attribute findings

confidently to the intervention itself and not to unknown elements omitted or added to it,[4] enabling a more accurate interpretation of research findings. Furthermore, assessing fidelity of intervention delivery provides more understanding of what has *actually* been delivered during an intervention, enabling effective and successful interventions to be more accurately replicated and implemented into clinical settings by practitioners.[1] Intervention fidelity partly overlaps with intervention reporting but is a distinct concept: a physical therapy intervention cannot be reported adequately if fidelity hasn't been previously considered. In other words, procedures for enhancing and assessing intervention fidelity must be adequately reported to facilitate replication and the uptake of published research into clinical practice.

Intervention fidelity within the physical therapy literature

Within physical therapy research interventions are often 'complex',[6] involving numerous stakeholders (i.e. physical therapists (providers) and patients (participants)) and often involve several 'active ingredients' or elements that must be delivered as intended by therapists in different settings. As multiple components could influence intervention outcomes separately, it is important to incorporate adequate intervention fidelity enhancement and assessment into physical therapy research. For example, an intervention to promote physical activity for people with multiple sclerosis could consist of five weekly sessions involving education and exercise to be delivered by primary care physical therapists. If the fidelity of delivery is not assessed, then we must rely on *assumptions* that the intended intervention elements (e.g. provision of education content, practice of exercises, five sessions) were actually delivered. In the *ProActive* trial which evaluated a physical activity intervention delivered by trained health facilitators, an in-depth fidelity assessment of 108 audio-recorded sessions showed that only 44% of the intervention techniques were actually delivered. This may provide one explanation why the intervention was no more effective than a brief advice leaflet.[7]

Despite its importance and its inclusion within the TIDieR checklist,[11] intervention fidelity in the field of physical therapy remains largely overlooked, with a paucity of detailed examples of fidelity assessment specific to physical therapy research,[9, 12, 22] and limited pragmatic guidance on how to develop feasible procedures to enhance and assess fidelity in this field.[15, 18, 24] Indeed, one of the few systematic reviews of intervention fidelity specific to physical therapy literature[23] found that the average fidelity score among 25 studies of physical therapist-led interventions to promote self-management for people with chronic musculoskeletal pain was just 37%. This was conducted using a validated checklist developed by the National Institute of Health Behaviour Change Consortium (NIHBCC) to assess reported fidelity, where a maximum score of 100% indicates that all elements of

the fidelity checklist have been addressed.[2, 3, 23] Similarly, in a recent review of manual therapy interventions for knee osteoarthritis, only one third of included studies were found to have 'high' fidelity.[21]

Potential barriers and solutions to enhancing and assessing fidelity of intervention delivery within physical therapy research

Taking all of this into account, the questions that come to mind are 'why is intervention fidelity not being adequately enhanced and assessed in physical therapy research?' and 'how can fidelity of intervention delivery be adequately enhanced and assessed within physical therapy research?' In response to the first question, previous work identified the following barriers to intervention fidelity procedures for researchers in a psychotherapy setting: lack of knowledge about fidelity, lack of specific guidelines and lack of editorial requirement to report fidelity,[19] barriers that may also be relevant to the physical therapy field. Moreover, in physical therapy research the need to individualise treatment and tailor it for individual participants may be considered an even stronger barrier.[24, 25] However, increasingly researchers have explored how to balance fidelity with adaptation.[10] Rather than viewing them as two opposing extremes, it is possible for an intervention to be designed and delivered to allow for flexibility *within* fidelity, particularly in relation to individualisation or tailoring of treatment based on patient needs.[17] For instance, intervention manuals may specify that individualisation of certain aspects of treatment (e.g. tailoring of exercises) must be completed by providers, and fidelity assessment methods (e.g. self-report checklists) can be subsequently designed to reflect this.[24] One can also consider fidelity as fidelity to the underlying theory defined in a logic model, rather than specified activities or behaviours.[8] For example, in an intervention underpinned by self-determination theory, intervention manuals would promote the importance of fostering autonomous self-regulation in participants (in keeping with the core aspects of self-determination theory[20]), and assessments would focus on intervention providers' fidelity to these principles.

Recent physical therapy research has also identified time and labour constraints as barriers to enhancing and assessing intervention fidelity, both for the researchers designing and co-ordinating intervention procedures and for practitioners involved in the intervention delivery.[24] It is therefore important to strike a balance between idealism (comprehensive assessment) and pragmatism (feasibility). Therefore, we recommend that researchers identify the key uncertainties regarding intervention fidelity, e.g. fidelity of delivery across sites or between providers, and use comprehensive methods to enhance and assess these specific aspects; rather than attempting to address all aspects of fidelity. Instead of assessing all intervention contacts, one may select a random sample of contacts

for fidelity assessment, or use purposive sampling to include data from different sites or providers. For instance, fidelity assessment in the *ProActive* Trial focused on adherence to intervention scripts, and was conducted among 27 (of a possible 244) intervention participants who were sampled purposively to ensure a balance of intervention mode of delivery.[7]

Choices about the type and amount of fidelity assessment procedures may depend on the resources available, the size or scale of the research project (e.g. total number of intervention sessions being conducted), the type of assessment method used (e.g. self-report, direct observations or qualitative interviews) and the complexity of the intervention itself (e.g. number of providers, sites and intervention components). The comprehensiveness of fidelity assessment may also vary across different stages of a complex intervention described by the Medical Research Council (MRC) guidance (e.g. feasibility, effectiveness, implementation).[6] For example, recent research in a physical therapy setting used a mixed methods approach combining quantitative methods (direct and audio-recorded observations and provider self-report checklists) and qualitative methods (semi-structured interviews with intervention providers) to comprehensively assess fidelity of intervention delivery within a randomised feasibility trial.[13, 14, 24, 25] Direct observations were more comprehensive than self-report, but also more time-consuming and less feasible. The study found that use of robust methods such as direct observations during feasibility and pilot testing of the intervention can help develop the validity and reliability of more feasible methods, such as self-report, that focus on the delivery of core processes or components. Furthermore, specific fidelity probes had been included within routine qualitative data collection, as recommended by the MRC for intervention development.[6] The study also concluded that mixed methods were invaluable for understanding the factors influencing fidelity, and that qualitative data on intervention fidelity could be feasibly collected without much additional burden.

Conclusions

As a field we cannot rely on assumptions that physical therapy interventions are delivered as intended, in research *and* practice. Instead we recommend that researchers attempt to assess what has actually been delivered to enable accurate evaluation and to promote truly evidence-based practice. Clinicians and practitioners also have an imperative to ensure that evidence-based treatment is delivered with good fidelity, otherwise the effectiveness of this treatment may be diluted or even eliminated. It has been estimated that as much as 85% of healthcare research may be wasted across the stages of intervention design to reporting,[5] and a recent survey found that only 30% of physical therapists adhered to evidence-based guidelines for low back pain.[16] Health service

resources are directed towards evidence-based practices; however, if the evidence base is questionable due to poor intervention fidelity in evaluation studies, or poorly reported to inhibit replication in clinical settings, or if clinicians and practitioners deliver evidence-based treatments with poor fidelity, then precious resources in both research and clinical settings are wasted and patients are given false promise.[26] Therefore, there is an urgent need for researchers to improve the design and conduct of physical therapy research by incorporating intervention fidelity enhancement and assessment from the outset, and for clinicians and practitioners to use this research to faithfully deliver effective evidence-based treatments in practice. For researchers, insight into intervention fidelity will ensure greater certainty in, and better interpretation of, research findings. For clinicians and practitioners, this will help ensure that high-quality evidence informs clinical decisions, and enhance the successful reproduction of effective interventions in clinical settings, ultimately improving outcomes for patients. By improving intervention fidelity practices in physical therapy research, we can be confident that what we report using TIDieR guidelines is as accurate and valid as possible, overall maximising the yield of our research for the benefit of patients and health care systems.

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