From theory to practice: insights into intervention development of the NON-STOP app for children with Perthes' disease

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The development of interventions in healthcare often lacks a robust theoretical basis, which may contribute to suboptimal engagement and effectiveness. This paper provides insights into and practical guidance on the development of complex interventions in healthcare, using the example of a digital self-management tool for children with Perthes' disease, called the Non-Surgical Treatment of Perthes' (NON-STOP) app. We applied the Medical Research Council framework, used psychological theory, and integrated stakeholder engagement to develop the intervention. The lessons learned and considerations for the developments of other complex interventions provide practical actions for clinicians and researchers in orthopaedics.

Introduction

Interventions in healthcare are continually being developed, with a recent explosion in digital tools such as apps. Often, these interventions are developed without a robust methodological basis, which may inhibit engagement and the implementation of the tool. The use of methodological frameworks underpinning the development of complex interventions, such as the Medical Research Council (MRC) framework, aim to optimize engagement with the intervention and ensure that this is sustained over time. This approach requires collaborative development of the tool, which includes experts with intervention development and content expertise (i.e. clinicians and individuals with lived experience of the condition for whom the tool is intended).

We were presented with the challenge of developing a digital self-management tool for children with Perthes' disease of the hip. In short, the treatment of Perthes' disease is controversial, with some surgeons advising surgery, and others advising no surgery.2 There was a strong desire among the clinical community to perform a randomized controlled trial, though there was no uniformity concerning 'best practice' in the non-surgical group. A set of consensus recommendations were made to optimize and unify the non-surgical approach, with an agreement that a digital app should be the primary means of presenting the self-management information to the patient population. We present insights arising from developing the Non-Surgical Treatment of Perthes' (NON-STOP) app, and guidance on practical considerations for



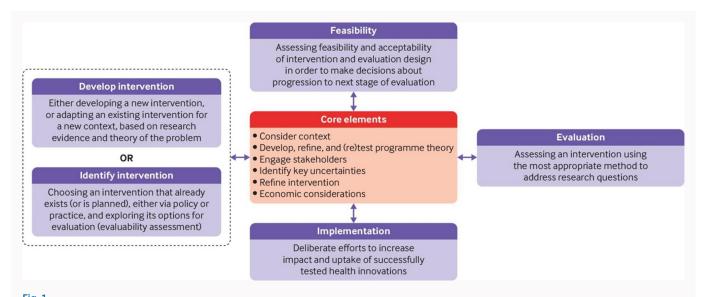


Fig. 1
The Medical Research Council framework for developing and evaluating complex intervention. *Reproduced from Skivington et al¹ (CC-BY, open access).

Element of intervention	Overview of element	Contribution to intervention development	
Learning section	Information is presented regarding Perthes' disease, how to manage the condition, and other topics such as nutrition and wellbeing guidance	Content derived from evidence base to be fun and accurate and meet the needs of the users 5.6	
Activities section	Demonstrations in a cartoon format of strengthening and stretching exercises for users to complete		
Progress section	Activity diary for users to log their daily/weekly use of the app and monitor their progress	Incorporates elements of SDT to increase motivation by giving individuals increased feelings of autonomy, competence, and relatedness which may lead to increased engagement with the intervention ⁴	
Customizable avatar	Bobby the bone, a customizable avatar that users personalized as they continued to engage with the app		

any future development of similar complex interventions in orthopaedics.

Intervention development overview

The MRC framework provides guidance on the development and evaluation of complex interventions. The MRC framework relies on the user considering core elements of the intervention at stages of development (i.e. intervention development and feasibility testing) using these 'core elements' as decision-making 'milestones', before progressing onwards with evaluation and implementation phases (Figure 1).

Psychological theories can also address certain aspects of self-management intervention development, particularly to help with optimizing sustained engagement with the tool and the health behaviours being targeting. Theories that relate to a change in an individual's behaviour use principles such as increasing motivation.³ In the development of the NON-STOP app, the 'social determination theory' (SDT) was used.⁴ SDT emphasizes the importance of the motivation of

an individual when encouraging a change in behaviour, i.e. sustained engagement with the intervention.

The MRC framework and SDT were used in combination in the design and development of the NON-STOP app, to ensure the app supports children to take an active role in managing their condition.

The NON-STOP app

The intervention development stage used a mix of methods to support creation. The evidence generated was combined with stakeholder input from Patient and Public Involvement Engagement (PPIE) members and participants with lived experience (children with Perthes' disease and their families), and clinicians who care for them. Involvement of these stakeholders led to the creation of clinical content based on clinical consensus recommendations,⁵ and suggestions based on findings of a qualitative study to explore children, families, and clinicians' experience of care.⁶ Regular PPIE and user engagement sessions took place in the development stage

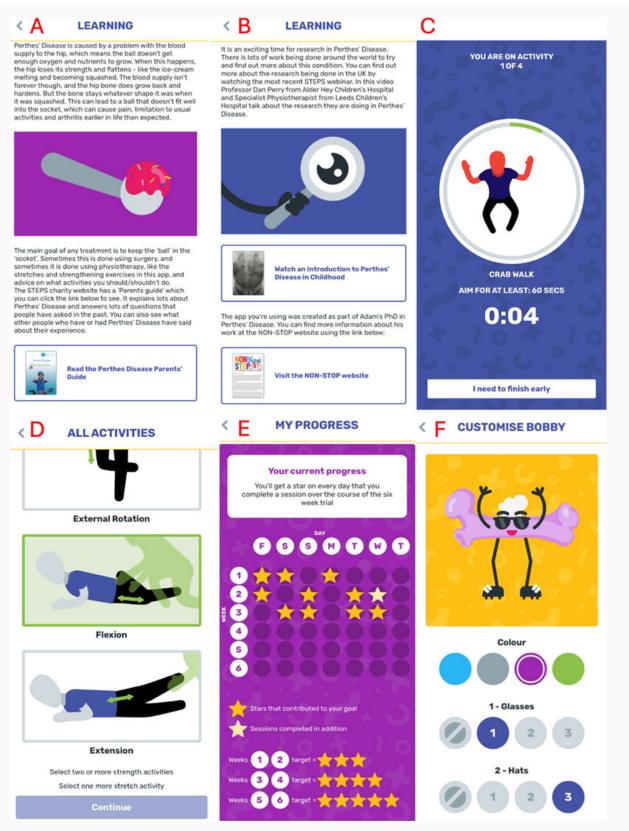


Fig. 2

Example views of the Non-Surgical Treatment of Perthes' app components. A and B display the 'Learning section' which provides text (written with input from Patient and Public Involvement Engagement (PPIE) members) and links to educational videos and resources from national guidance on physical activity levels. C and D show the 'Activities section', where users select and complete exercises. There are timers to countdown during the exercise as well as instructional videos to assist the user. E demonstrates the 'Progress section' where users can review their app use, allowing them to review how often they have completed their activities. This was needed to earn the rewards to customize the avatar. F displays an example of where users can use their rewards (stars) to customize their avatar using different styles/themes that were largely selected by children with Perthes' disease in PPIE and user-testing sessions.

824 Bone & Joint Open Volume 6, No. 7 July 2025

Key elements	Considerations and challenges	NON-STOP examples	Practical considerations
	Understanding the problem is the first part of the development process.	PPIE work identified an app as a reasonable intervention to explore further.	Include diverse stakeholders, e.g. clinicians and patients.
	Time and resource requirements exist when developing an intervention.	The procurement process alone takes 3 to 4 months. App development time is similar.	Seek advice/guidance from those with experience when planning resources.
Planning the process	Costings for PPIE and EDI are required and need specialist input.8	External (NIHR) funding secured to support.	Seek guidance from relevant parties e NIHR EDI toolkit ⁹ and PPIE advice.
	Content was created from a range of sources and evidence and was user-driven.	Findings informed by qualitative work, clinical consensus study, and user design sessions.	Maintain an awareness of the evidence base, but also have strong PPIE.
	Contextual factors are specific to the project, and need considering.	NON-STOP app was used at school, training for staff needed creating/adapting.	Ensure a clear understanding of the range of contexts in which the intervention may be used.
Developing the content	Theoretical underpinning maximizes the potential for engagement.	SDT outlines autonomy increases motivation. Factored in independent use for children.	Seek methodological support to select suitable psychological theory to drive engagement.
Bringing together a	One person cannot, and should not, do everything.	Wide team with methodology, app development, PPIE, and clinical expertise.	Create a strong team, with expertise from each domain represented.
	When working in larger teams, clearly defined roles increase the efficiency.	Clinical content created by clinicians and users, integrated with app developers.	Establish a team roles/responsibilities document or plan in early stages.
	Clear timelines and deadlines, and it is important that decisions made as a team.	App developers, clinicians, and academic staff all work in different ways.	Hold regular meetings for discussion and create a 'safe environment' for interaction.
Refining the content of the intervention	Practical changes to the intervention are more efficient when done together.	Physical meetings to work through versions of the intervention and make changes.	Create time/space to collaborate through regular meetings.
	Refinements to the intervention take time, factor in more user testing after changes.	Acceptability and usability study highlighted changes needed for the app.	Consciously plan for app refinement, and a work plan with the team.
	Refinements can include new content to be designed/developed.	App-testing study only six weeks, so needed more customization options.	Consider the refinement-related time implications and plan accordingly.
	Training needs of clinicians and users are time- and resource-consuming.	Individual sites needed training on how to deliver the app to families.	Potentially provide a standalone training mechanism such as recorded e-learning.
	Implementation is not only done at the end, includes evaluation.	App-testing study gave valuable insight into user experience.	Seek feedback regularly throughout tintervention development process.
Considering the implemen- tation	Real-world implementation should include evaluation that may be outside of scope.	No long-term implementation data from NON-STOP.	Have a plan for where implementation evaluation may come from.

to refine the app content, working with an app development team who had expertise in the creation of digital interventions for children. The feasibility test stage, exploring NON-STOP app engagement and acceptability, has recently been completed. Further evaluation is underway as part of a new nationwide clinical trial comparing surgical and non-surgical intervention for children with Perthes' disease (ISRCTN ref: ISRCTN83315571).⁷

The NON-STOP app is divided into four key elements, which align with the intervention development processes described (Table I) and includes a training package embedded within it. Training was incorporated into the app as 'My Journey' which opens on the first login on the app, and is

available to review at any point from the main menu. The training package guides users through each element of the app, with instructions to facilitate their ability to use the NON-STOP app independently. In Figure 2 examples of the content of the NON-STOP app are provided, with lettered keys for more information.

Intervention development elements to consider

The MRC framework provides guidance on the key elements for consideration in intervention development. Key areas of the intervention development process are outlined in Table II. Along with these are some considerations and challenges that arose from the NON-STOP app development process,

examples from the intervention development process, and finally, practical considerations for those developing interventions in the future.

Conclusion

Rigorously developing interventions has the potential to lead to increased engagement and effectiveness, although the process is resource-heavy in terms of the time and expertise of relevant stakeholders. A clear evidence base demonstrating the need for the intervention is recommended. This should include careful consideration of the patient population and consideration towards PPIE and Equality, Diversity, and Inclusion to ensure that content is suitable for people from diverse backgrounds, which will in turn maximize the potential impact.

The NON-STOP app development exemplifies a rigorous intervention development process, which integrated guidance from the MRC framework, psychological theory, and broad stakeholder engagement. This led to the development of a digital self-management intervention for children with Perthes' disease that has been tested to a preliminary feasibility stage. It has been refined, in line with the MRC framework, and is prepared for further implementation and evaluation. This paper has provided meaningful insights from the development process. The hope is that it may facilitate future intervention development by clinicians and researchers in orthopaedic research, reducing resource waste and optimizing engagement.

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Data sharing

The data that support the findings for this study are available to other researchers from the corresponding author upon reasonable request.

Ethical review statement

Ethical review was not required for this piece of work.

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