**From theory to practice: Insights into intervention development of the NON-STOP app for children with Perthes’ Disease**

Abstract

The development of interventions in healthcare often lacks a robust theoretical basis, which may contribute to sub-optimal engagement and effectiveness. This paper provides insights 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-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 are summarised, providing practical actions for clinicians and researchers in orthopaedics.

Background

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 [1], aim to optimise 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 amongst the clinical community to perform a randomised controlled trial, though there was no uniformity concerning ‘best-practice’ in the non-surgical group. A set of consensus recommendations were made to optimise 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 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 [1]. 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 optimising 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 emphasises 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

Figure 1 – The MRC framework for developing and evaluating complex intervention

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 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 [7] ISRCTN ref: ISRCTN83315571.

The NON-STOP app is divided into four key elements, which align to the intervention development processes described (Table 1) 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.

Table 1 – Key elements of NON-STOP app with methodological relationship

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| --- | --- | --- |
| **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] |
| **Customisable Avatar** | Bobby the bone, a customisable avatar that users personalised as they continued to engage with the app |

Intervention development elements to consider

The MRC framework provides guidance on the key elements for consideration in intervention development. In Table 2 key areas of the intervention development process are outlined. 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.

Figure 2 – Example views of the NON-STOP app components

Table 2 – Considerations and challenges during development and future considerations

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| --- | --- | --- | --- |
| **Key elements** | **Considerations and challenges** | **NON-STOP examples** | **Practical considerations** |
| **Planning the process** | 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 3-4 months. App development time is similar. | Seek advice/guidance from those with experience when planning resources |
| Costings for PPIE and EDI are required and need specialist input [8] | External (NIHR) funding secured to support | Seek guidance from relevant parties e.g. NIHR EDI toolkit [9] and PPIE advice |
| **Developing the content** | 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 the intervention may be used in |
| Theoretical underpinning maximises 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 team** | 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, with decisions made as a team are important | 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 customisation options | Consider the refinement-related time-implications and plan accordingly |
| **Considering the implementation** | Training needs of clinicians and users is 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 the intervention development process |
| 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 |

Summary

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 (EDI) to ensure content is suitable for people from diverse backgrounds, which will in turn maximise 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 optimising engagement.

**References**

1. Skivington, K., et al., *A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance.* BMJ, 2021. **374**: p. n2061.

2. Galloway, A.M., et al., *A case review to describe variation in care following diagnosis of Perthes’ Disease.* Bone & Joint Open, 2020. **1**(11): p. 691-695.

3. Mair, J.L., et al., *Effective Behavior Change Techniques in Digital Health Interventions for the Prevention or Management of Noncommunicable Diseases: An Umbrella Review.* Annals of Behavioral Medicine, 2023. **57**(10): p. 817-835.

4. Teixeira, P.J., et al., *Exercise, physical activity, and self-determination theory: A systematic review.* International Journal of Behavioral Nutrition and Physical Activity, 2012. **9**(1): p. 78.

5. Galloway, A.M., et al., *Clinical consensus recommendations for the non-surgical treatment of children with Perthes’ Disease in the UK.* The Bone & Joint Journal, 2024. **106-B**(5): p. 501-507.

6. Galloway, A.M., et al., *“Waiting for the best day of your life”. A qualitative interview study of patients’ and clinicians’ experiences of Perthes’ Disease.* Bone & Joint Open, 2023. **4**(10): p. 735-741.

7. ISRCTN. *Operative or non-surgical treatment of Perthes’ Disease*. 2024 [cited 2024 21/11/2024]; Available from: <https://www.isrctn.com/ISRCTN83315571>.

8. Research, N.I.f.H.a.C. *Inclusive research design to become an NIHR condition of funding*. 2024 [cited 2024 13/12/2024]; Available from: <https://www.nihr.ac.uk/inclusive-research-design-become-nihr-condition-funding>.

9. Research, N.I.f.H.a.C. *Equality, Diversity and Inclusion Toolkit*. 2024 [cited 2024 13/11/2024]; Available from: <https://www.rssleicesterresources.org.uk/edi-toolkit?tags=EDI>.