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A Realist Evaluation of the development of a set of guidelines for technological interventions made for children and young people with ADHD to self-manage their condition

Lauren Powell, Jack Parker, Val Harpin, Susan Mawson
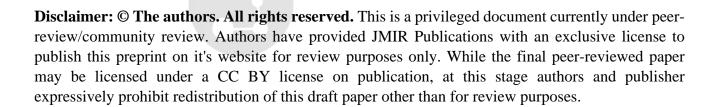
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Abstract

Background: Attention Deficit Hyperactivity Disorder (ADHD) is a complex neurodevelopmental disorder characterised by inattention, hyperactivity and impulsivity. ADHD can affect the individual, their family and the community. ADHD is managed using pharmacological and non-pharmacological treatments, which principally involves others helping children and young people (CAYP) manage their ADHD rather than learning self-management strategies themselves. Over recent years, technological developments have meant that technology has been harnessed to create interventions to facilitate the self-management of ADHD in CAYP. Despite a clear potential to improve the effectiveness and personalisation of interventions, there are currently no guidelines based on existing evidence or theories to underpin the development of technologies that aim to help CAYP self-manage their ADHD.

Objective: To create evidence-based guidelines with key stakeholders that will provide recommendations for the future development of technological interventions, which aim to facilitate the self-management of ADHD.

Methods: A realist evaluation approach was adopted in five phases. Phase one involved identifying propositions (or hypotheses) outlining what could work for such an intervention. Phase two involved the identification of middle-range theories of behaviour change to underpin the propositions. Phase three involved the identification and development of Context Mechanism Outcome Configurations (CMOCs), which essentially state, which elements of the intervention could be effected by which contexts and what the outcome of these could be. Phase four involved the validation and refinement of the propositions via interviews with key stakeholders (CAYP with ADHD, their parents and specialist clinicians). Phase five involved the development of the guidelines based on the identified middle-range theories and interview data.

Results: Six specialist clinicians, eight parents and seven CAYP were recruited to this study. Seven key themes were identified 1) Positive rewarding feedback, 2) Downloadable gaming resources, 3) Personalisable and adaptable components, 4) Psychoeducation component, 5) Integration of self-management strategies, 6) Goal setting and 7) Context (environmental and personal).
The identified mechanisms interacted with the variable contexts a complex technological intervention of this nature could be delivered in.

Conclusions: Complex intervention development for complex populations such as CAYP with ADHD should adopt various methodologies and methods such as realist evaluation and user-centered design that involves developing the intervention with key stakeholders to increase the likelihood that the intervention will succeed. The guidelines we describe can be used for the future development of technologies that aim to facilitate self-managed ADHD for CAYP.

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Original Manuscript

Original Paper

A Realist Evaluation of the development of a set of guidelines for technological interventions made for children and young people with ADHD to self-manage their condition

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Abstract

Background: Attention Deficit Hyperactivity Disorder (ADHD) is a complex neurodevelopmental

disorder characterised by inattention, hyperactivity and impulsivity. ADHD can affect the individual, their family and the community. ADHD is managed using pharmacological and non-pharmacological treatments, which principally involves others helping children and young people (CAYP) manage their ADHD rather than learning self-management strategies themselves. Over recent years, technological developments have meant that technology has been harnessed to create interventions to facilitate the self-management of ADHD in CAYP. Despite a clear potential to improve the effectiveness and personalisation of interventions, there are currently no guidelines based on existing evidence or theories to underpin the development of technologies that aim to help CAYP self-manage their ADHD.

Objective: To create evidence-based guidelines with key stakeholders that will provide recommendations for the future development of technological interventions, which aim to specifically facilitate the self-management of ADHD.

Methods: A realist evaluation approach was adopted over five phases. Phase one involved identifying propositions (or hypotheses) outlining what could work for such an intervention. Phase two involved the identification of existing middle-range theories of behaviour change to underpin the propositions. Phase three involved the identification and development of Context Mechanism Outcome Configurations (CMOCs), which essentially state, which elements of the intervention could be effected by which contexts and what the outcome of these could be. Phase four involved the validation and refinement of the propositions, from phase one, via interviews with key stakeholders (CAYP with ADHD, their parents and specialist clinicians). Phase five involved using information gathered during phases one-four to develop the guidelines.

Results: Six specialist clinicians, eight parents and seven CAYP were recruited to this study. Seven key themes were identified 1) Positive rewarding feedback, 2) Downloadable gaming resources, 3) Personalisable and adaptable components, 4) Psychoeducation component, 5) Integration of self-management strategies, 6) Goal setting and 7) Context (environmental and personal). The identified mechanisms interacted with the variable contexts a complex technological intervention of this nature could be delivered in.

Conclusions: Complex intervention development for complex populations such as CAYP with ADHD should adopt methods such as realist evaluation, to account for the context it is delivered in, and co-design, that involves developing the intervention in partnership with key stakeholders to increase the likelihood that the intervention will succeed. The development of the guidelines outlined in this paper could be used for the future development of technologies that aim to facilitate self-management in CAYP with ADHD.

Keywords: Attention Deficit Disorder with Hyperactivity, Realist Evaluation, Technology, Co-design

Introduction

ADHD, Prevalence and Management

Attention Deficit Hyperactivity Disorder (ADHD) is a highly comorbid [1] neurodevelopmental disorder, defined by three core symptoms; inattention, hyperactivity and impulsivity. It has a

worldwide prevalence of 3 to 5% in school age children [2] and children and young people (CAYP) are most likely to be diagnosed with ADHD in the UK when they are at primary school [3]. This amounts to approximately 26 million children and adolescents and this figure is rising globally [4]. Over the last 30 years, the number of people treated for ADHD in the UK has risen from 0.5 per 1000 to 30 per 1000 [3] and the annual healthcare costs for young people with ADHD in the UK are estimated at £670 million. CAYP with ADHD experience a number of ADHD related difficulties including poor academic attainment, poor social relationships increased likelihood of being suspended or expelled from school and leaving school earlier than their peers [5]. Additionally, genetic and contextual circumstances can also impact on the prevalence of the condition. ADHD is highly heritable [6] and those who are more socially disadvantaged are more likely to be diagnosed with ADHD [7, 8]. Moreover, ADHD often continues to affect individuals into adult life [1, 9].

ADHD management includes a combination of behavioural and pharmacological interventions [1]. There is strong evidence that pharmacological treatment and non-pharmacological interventions, such as psychoeducation programmes, behavioural interventions and cognitive behavioural therapy, have a major beneficial effect on the core symptoms of ADHD in approximately 80% of cases, at least in the short term [1, 10]. ADHD can affect every aspect of an individual's life and support from professionals and family members are limited. There is some evidence of short-term efficacy in managing the core ADHD symptoms, conduct disorders, social skills, self-efficacy and emotional outcomes. CAYP, however, often rely on clinicians and parents to manage their condition young people are often unwilling to engage in treatment [11] which limits ADHD self-management into adulthood [12]. Therefore, In order to attempt the prevention of the individual falling into crisis when they reach adulthood, it is essential that the target population learn how to self-manage their condition through co-designed interventions [13, 14]. This includes exploring contemporary, innovative, interactive methods of engaging CAYP with ADHD such as the use of technology may improve their motivation and adherence to treatment. However, methodological limitations make it difficult to draw definitive conclusions from clinical trials [15].

Self-management in CAYP with ADHD and behavior change theories

People with long-term conditions (including ADHD) spend around 1% of their time interacting with a clinician leaving 99% of their lives managing it themselves [16]. However, in order to self-manage a condition, behavior change is required. A number of theories have attempted to breakdown aspects of behavior that requires change. For example, the Chronic Care Model (CCM) [17] identifies six elements [18] that are important factors for successful chronic care and prevention management that have previously been applied to the care of CAYP with ADHD [19, 20]. These include and are not limited to:

- The promotion of safe quality care; any self-management intervention for CAYP with ADHD will need to adhere to quality standards to ensure the content is reliable and appropriate,

- Support should be based on evidence and what the patient's needs and preferences are; if the intervention does not adhere to what the patient wants or needs, they maybe less likely to engage with it,

- Self-management support should be provided to help patients manage their health and care; CAYP with ADHD should self-manage their condition to decrease the likelihood that they fall into crisis later in life,

- Community resources should be available to improve access; resources should be available to facilitate and support the self-management of ADHD in CAYP.

Similarly, the Behaviour Change Wheel (BCW) [21] provides a framework specifically for behavior change interventions and involves the "COM-B" model, which refers to the interactions between "Capability", "Opportunity", "Motivation" and "Behaviour". Capability refers to the psychological and physical ability to engage with an activity, Opportunity refers to factors outside of the individual to ensure behaviour change is possible and Motivation refers to brain processes that "energise and direct behavior". The COMB-B model provides a useful framework of elements that influence behaviour change and can indeed be applied to self-management. For example in order to self-manage a condition, the individual's behaviour will need to change. In order to do this, they should be motivated and have the capability to change their behaviour and be in the correct environment for the change to occur.

Further, the Health Foundation states that people with long-term conditions need to have the knowledge, skills and confidence in order to manage their condition "effectively in the context of... everyday life" [22]. These underlying principles of self-management and the principles from the CCM and the BCW are important for all long-term condition self-management, including ADHD in CAYP.

Technology interventions for ADHD Self-Management in CAYP

Technology has been shown to have large potential to improve the effectiveness and personalisation of mental health interventions [15]. A number of attempts have been made to harness technology to engage CAYP in self-managing their ADHD [23-41]. Examples include a handheld organisational device [37], computer games [25, 27, 34, 39, 41], and programmes [29, 30, 40], an augmented reality serious game [23] and mobile applications to improve reading speed [33], executive functioning [35] and healthy sleep habits [38].

The results of these interventions have found increased ability to remain on task at school [32], improved organisational skills [37], ADHD symptoms and sleep [38]. It must also be noted that although a number of these studies have found positive results, it is unclear if these effects are maintained over a longer time period [24, 31, 33-36].

However, not all of these studies show positive or significant results. ADHD is a highly complex comorbid condition and it is therefore difficult to control for contextual differences using randomized controlled trial (RCT) methodologies. It is also possible that the uptake of each intervention between participants may vary [15]. Others may use the interventions in different contexts to one another with variable distractions [42, 43].

Evaluating Complex Conditions

It is now understood that the steps taken for increasing evidence in complex conditions is no longer linear and the updated Medical Research Council (MRC) Framework (2008) [44] places greater attention to the context in which interventions take place.

Figure 1. Outlining the MRC model of complex intervention development [44].

Please insert Figure 1 here.

Three key components for the development of these complex interventions are outlined below:

1. Interventions should be clearly underpinned by existing theories. Theories that are based on existing knowledge can offer a clear way to underpin a rationale, which can assist with communication with stakeholders [45, 46];
2. Interventions should be developed in partnership with key stakeholders [46-48];
3. Intervention developers should account for the context by which the intervention is developed in by identifying what works for whom and under what circumstances. This means the intervention is more likely to be a success [42, 43, 49].

Other evaluation study designs such as RCTs and quasi-experimental only answer the question "What works?" and do no capture the complexity of complex conditions and interventions or the characteristics of the context the intervention is delivered in [50]. This is important as the context, content and outcomes of a complex intervention can involve a high degree of variance [50]. Therefore, if technological interventions are designed to be used with complex conditions such as ADHD in various contexts, it is imperative they are underpinned by theory and they consider the contexts in which the intervention will be delivered [44]. A previous attempt to develop a complex intervention went beyond the question "What works?" and this involved a realist review that explored the question *"what works for whom, under which circumstances and respects"* [51]. However, to our knowledge, a Realist Evaluation (RE) has never been used to develop guidelines for the development of interventions.

Therefore, this study aims to utilise a RE methodology [52] and involve key stakeholders (CAYP with ADHD, their parents/carers and specialist clinicians) in the development of a theory and evidence based guidelines. The guidelines developed may help the future development of technological interventions that aim to help primary school aged CAYP with ADHD self-manage their condition more effectively. Primary school aged CAYP have been chosen as this is when the most common age to be diagnosed with ADHD in the UK. RE aims to go beyond the "what works" question and answer the question *"what works for whom, under which circumstances and respects"*. RE also takes into account the complexities of the condition, the intervention and the context by which it is delivered [52]. The use of underpinning behaviour change middle-range theories (See Table 1 for definition) will improve the generalisabiliy of the guidelines to more than one context. There is a need for these guidelines because existing frameworks are useful in terms of generalisation to many conditions whereas CAYP with ADHD have complex needs that need addressing separately to ensure future interventions are suitable for them.

Methodology

Principles of Realist Evaluation

RE has been shown as an effective framework for evaluating complex health interventions [43]. The aim of RE is to explore how a mechanism may cause a different outcome when in different contexts (see Table 1 for definitions) [52]. The process adopted for this study is outlined in Figure 2. The RE approach outlined in this article has been guided by Realist And Meta-narrative Evidence Synthesis: Evolving Standards (RAMESES) II reporting standards for RE [53] and has been followed the process stipulated in Pawson and Tilley, 1997 [52].

Table 1. Definitions of Context, mechanism and outcomes [52].

Term	Definition
Middle-range Theories (MRT)	A theory that can be used to explain specific parts of an intervention. MRTs are identified at the beginning of this process and examined throughout the process and for this study, during data collection.
Context	The environment or "backdrop" of an intervention. Context can change over time, which could reflect aspects of change whilst an intervention is implemented [54]. The context may limit or allow the mechanisms.
Mechanism	This refers to aspects ("resources") that are as a result of the intervention and the response to those resources e.g. cognitive, motivational, emotional [54].
Outcome(s)	Outcomes (intended or unintended) refer to what may happen as a result of an intervention. E.g. variable context may create an unintended outcome, which could be vital to intervention delivery.

Figure 2. Outlining the process of generating, validating and refining propositions and CMOCs. This process lasted between May and September 2018.

Please insert Figure 2 here.

Stage 1: Identifying propositions

Propositions are comparable to that of hypotheses that predict what is believed to occur in a given situation or within research. Developing the propositions for this study involved authors LP and JP exploring theoretical concepts from the literature that derive from behavior change and human computer interaction theories (see Table 2) that could underpin a technological intervention that aims to help CAYP with ADHD self-manage their condition. Agreement of these concepts was reached through discussion between all the authors. The product of Stage 1 was a list of propositions.

Stage 2: Identifying a theoretical framework

Using the principles of RE [43] a theoretical framework was formed to underpin the development of the intervention guidelines. That is, concepts within identified theories could underpin specific components (or "mechanisms") of an intervention. The theoretical framework was based upon theories that can be applied to educating CAYP with ADHD and human computer interaction (see Table 2) and was constructed by authors LP and JP.

Table 2. Product of Stage 2: Demonstrating how MRTs underpin the intervention guidelines.

Middle-range theories	Ingredients and Middle-range theory link	How intervention could incorporate the ingredients
Classical Conditioning (CC)[a], Operant Conditioning (OC)[b],	Reward (OC, CC, DD, SDT, BCW)	Immediate rewards for all correct responses to engage and motivate the user.

Optimal Stimulation Theory (OST)[c], Social Learning Theory (SLT)[d], Social Regulation Theory (SRT)[e], Executive Dysfunction (ED)f, Dynamic Developmental Theory (DDT)[g], Experiential Learning Theory (ELT)[h], Social Cognitive Theory (SCT)[i], Self Determination Theory[j] Organismic Integration Theory[k], Behaviour Change Wheel[k] (BCW), Chronic Care Model[L] (CCM)	Stimulation (OST, ED)	User can move on to different available sections of the intervention and previous work will be saved to return to later. User to have the choice to carry out intervention activities electronically or on paper.
	Sequential learning (ED)	All "sections" of intervention to not be available at once (preventing overstimulation). Different sections to become "unlocked" once others are completed.
	Self-efficacy (SLT, SCT)	Intervention will provide the user with the opportunity to self-evaluate their performance, by receiving feedback from the intervention (e.g. stars, coins) and from others (verbal persuasion/encouragement).
	Learning (ELT)	Paper based activities will be available for those with limited access to a device (e.g. sharing with siblings, limited device access at bedtime) and/or Internet.
	Independent practice (SLT)	Used in the absence of a clinician.
	Social regulation (SRT, CCM)	Section that teaches user techniques to self-manage ADHD e.g. anger management.
	Social Learning (SLT)	Intervention should provide scenarios of social situations where the user can make appropriate decisions (reinforced with immediate rewards).
	Social cognition (SCT)	Setting short-term, meaningful and relevant goals to the user to motivate them to engage with the intervention.
Co-Design (CD), User Interface Design (UID), CCM	Stakeholder involvement in design (CD, UID, CCM)	Stakeholders should be involved in the design and development of the intervention to increase intervention success.
CC, OC, OST, SLT, SRT, ED, DDT, Experiential Learning Theory (ELT).	Self-monitoring	User monitors their performance independently.
	Reinforcement	Intervention should provide positive feedback where applicable and they can share this with others.
	Self-management	Intervention should give the user opportunities to problem solve, make decisions and take action in real life scenarios based on what they have learned.
	ADHD Knowledge and understanding	Intervention should provide the user with accessible information to help them better understand ADHD so they can more optimally self-manage it.

[a]CC: Classical Conditioning [55]; [b]OC: Operant Conditioning [56]; [c]OST: Optimal Stimulation Theory [57]; [d]SLT: Social Learning Theory [58]; [e]SRT: Social Regulation Theory [59]; [f]ED: Executive Dysfunction [60]; [g]DDT: Dynamic Developmental Theory [61]; [h]ELT: Experiential Learning Theory [62]; [i]SCT: Social Cognitive Theory [63]; [j]SDT: Self Determination Theory [64], [k]BCW: Behaviour Change Wheel [21], [L]CCM: Chronic Care Model [17], [M]Co-design [13, 14].

Stage 3: CMOC generation

After the propositions (Stage 1) and the theoretical framework (Stage 2) were developed, they were set out as context-mechanism-outcome-configurations (CMOCs) during Stage 3 of this process.

Authors LP and JP generated the CMOCs. Table 3 outlines some examples of the CMOCs generated during Stage 3.

Table 3. Product of Stage 3: CMOC examples.

CMOCs	Plausible mechanism "What"	Contexts: "for whom" and "in what circumstances"	Possible outcomes
CMOC 1	Receiving feedback from the intervention might improve the users confidence by confirming performance.	Internet and intervention accessible at home, used independently of clinician.	Development of self-efficacy
CMOC 2	Positive reinforcement (reward) may motivate the user to use the intervention	Intervention should give positive rewarding feedback to the user.	Increased understanding of condition and self-management

Stage 4: Validation and Refinement of New and Existing CMOCs

CMOCs were then validated and refined by conducting interviews with CAYP with ADHD, their parents/carers and specialist clinicians. Author LP conducted the interviews and they were conducted at the participant's convenience. Clinician interviews were undertaken at their workplace and young person and parent interviews took place in their homes.

Participants

Participants were recruited to adhere to the sampling frame below:

CAYP with ADHD and their parents/carers:
- Males and females
- CAYP with Autism Spectrum Disorder (ASD) and without ASD
- Families who live in the 10% of most and least deprived areas of the UK [65]
- CAYP with ADHD aged 8 – 11 years.

Clinicians:
- A sample that includes ADHD specialist nurses, a paediatrician and psychiatrist.
- Clinicians who work at Child and Adolescent Mental Health services (CAMHS) and paediatric neurodisability services.

Recruitment

CAYP with ADHD and parents/carers were recruited via a database held by the research team. Clinicians were recruited via the NHS in the South Yorkshire region. Participants were recruited until data saturation was achieved [66]. The eligibility criteria for CAYP with ADHD were (1) Aged 8-11 years, (2) Diagnosed with ADHD. Parents/carer (1) must have been a parent/carer of a young person with a confirmed ADHD diagnoses and (2) must have been able to provide details of the ADHD medication the young person was prescribed. Clinicians had to be employed by a service that treats CAYP with ADHD and have experience of working with this population.

Procedure

Semi-structured interviews focused on initial propositions that were tested and refined. CAYP with

ADHD, their parents/carers and clinicians provided interview data to test the propositions. The study received ethical approval from the University of Sheffield's School of Health and Related Research Ethics Committee (Ref: 021203), NHS Health Research Authority and Research and Development local approvals. Interviews took place in the CAYP/parents/carer's home and clinician's workplaces. All participants provided written informed consent or assent (CAYP only).

Participants were asked (age appropriate) questions that were derived from the propositions. Questions included:

- What type of feedback do you think your child would like and why? (parent/carer)
- What do you think the role of friends and family could be for supporting CAYP with ADHD with a technological intervention? (clinicians/parent/carer)
- If you play a computer game, do you like to collect things like coins, stars, points? (CAYP with ADHD)

Parents/carers provided ADHD medication details for their child (where applicable) and completed a Swanson Nolan and Pelham (SNAP IV) questionnaire to provide a measure of their child's current ADHD symptoms.

Data Analysis

Analysis focused on refining and generating new CMOCs. Principles of thematic and framework analysis were adopted [67, 68]. Guidelines were identified based on existing CMOCs (framework analysis approach) and when data did not fit with existing CMOCs, new CMOCs were generated (thematic analysis approach) [43].

Stage 5: Development of Guidelines

This was based on the refined and newly generated CMOCs from Stage 4. The final guidelines aim to provide a set of recommendations for designing a complex technological intervention that aim to help CAYP with ADHD self-manage their condition. The guidelines also provide advice regarding the environment the intervention should be delivered in. The CMOCs refined during Stage 4 were used to form the content of the guidelines. The guidelines can be found in Multimedia appendix 1. Author LP initially put the guidelines together and then discussed the guidelines with the rest of the research team (authors JP, VH and SM) and refined them accordingly.

Validation Results

Participant characteristics

21 participants (7 CAYP, 8 parents, 6 clinicians) were recruited from July to October 2018. Participant demographic information is included in Table 4 (CAYP), Table 5 (parents) and Table 6 (clinicians). All parents were able to provide information regarding their child's ADHD medication. All interviews were transcribed verbatim. During analysis, agreement between the two primary coders was high.

Table 4. Demographic information of CAYP with ADHD.

Study ID	Gender (F[b]/ M[c])	Age (yrs)	Other diagnosis	ADHD medication	Medicated during interview? ([e]Y/[f]N)	SDI[a]	Inattention [g]SNAP Score	Hyperactivity/ Impulsivity SNAP Score	Connors Index
YP1	F	11	ASD[d]	Concerta	Y	820	2	1.66	1.8
YP2	M	9	N/A	N/A	N	13513	2.55	2.89	2.5
YP3	F	8	ASD	Usually 27mg Delmosart	N	17403	3	3	2.7
YP4	M	10	N/A	Delmosart 36mg	Y	23954	1.78	2	2.6
YP5	M	11	N/A	Delmosart 36mg+27mg	Y	4913	[h]1.56	2.22	2.4
YP6	M	9	N/A	Delmosart 36mg	Y	1318	1.78	2.56	2.2
YP7	M	8	Attachment disorder	Elvanse, 40mg	Y	32596	1.67	1.88	1.9

[a]SDI: 1 is indicative of the most deprived area in the UK and 32844 is the most affluent area in the UK.
[b]F: Female; [c]M: Male; Yrs: Years; [d]ASD: Autism Spectrum Disorder; [e]Y: Yes, [f]N; No; SDI: Social Deprivation Index; [g]SNAP: Swanson, Nolan and Pelham Questionnaire.
SNAP Scores: Scores indicative of ADHD are as follows: Inattention: 1.78 and above; Hyperactivity/Impulsivity: 1.44 and above; Connors Index: 1.67 and above; Combined score: 1.63 and above.
[h]Please note YP6 does not meet the threshold for one SNAP component. They did meet the criteria for all other SNAP domains.
*Average score across Inattention, Hyperactivity/Impulsivity and Connors Index subsections.

Table 5. Demographic information of parents of CAYP with ADHD.

Participant ID	Comorbid condition	Age of child (yrs)
P1	ASD	11
P2	N/A	9
[a]P3	ASD	8
P4	N/A	10
P5	N/A	11
P6	N/A	9
P7	Attachment disorder	8
[a]P8	ASD	8

[a]P3 and P8 are the parents of the same child and were interviewed together.

Table 6. Demographic information of clinicians, demonstrating 8months to 18.5years of experience of working with CAYP with ADHD with a mean of a total of 6.9 years of experience.

Participant ID	Gender	Job Title	Clinical experience with CAYP with ADHD (yrs, months)
C1	M	Registrar Psychiatrist	2y
C2	F	Consultant Paediatrician	4y 6m
C3	F	Nurse Clinical Specialist	18y 6m
C4	F	Nurse Prescriber	8m
C5	F	Consultant Community Paediatrician	10y
C6	F	Consultant Community Paediatrician	6y

Initial propositions

Nine propositions were identified by author LP and checked for accuracy by author JP. They were then tested against the interview data and refined:

1. If the user receives feedback from the intervention, then the user's confidence may be improved.
2. If the user can access downloadable resources from the intervention, then they may generate a deeper understanding of the concepts covered within the intervention.
3. If the user can choose personalisable characters and a variety of modules within the intervention, then this may enable them to maintain stimulation to carry out the task.
4. If the user receives positive reinforcement (reward) from the intervention, then this may motivate them to use the intervention.
5. If the user engages with social scenarios within the intervention, then they may make more appropriate social decisions in the future, which may help enhance social relationships.
6. If the user engages with the intervention, then they may gain a better understanding of their ADHD.
7. If the user engages with the intervention, then improved self-management of their ADHD may improve relationships with friends and family.
8. If the user gains encouragement from friends/relatives to use the intervention, then this could reinforce the user's engagement with the intervention.
9. If short-term meaningful goals are set for the user via the intervention, then this could encourage them to engage with the intervention.

Testing the propositions

Seven themes were identified: 1) Positive rewarding feedback, 2) Downloadable gaming resources, 3) Personalisable and adaptable components, 4) Psychoeducation component, 5) Integration of self-management strategies, 6) Goal setting and 7) Context (personal and environmental). These themes focussed on testing the nine initial propositions.

Positive Rewarding Feedback (proposition 1 and 4)

All participants expressed a wish for immediate positive reward when the user may select a correct response. One participant said that when they get a reward e.g. a sticker at school, it makes them feel "proud" (YP5). Examples of instant reward could be auditory confirmation of a correct response and collecting items such as coins, stars, diamonds of trophies. The reward (and the intervention itself) should also be visually attractive.

> "I think that (instant positive reward) will really help his self-confidence." (P4)

> "I think a lot of the games nowadays build up points and it makes sense... having reward builds up their self esteem.... And just makes them feel happier" (C4)

Additionally, all 21 participants suggested that the instant positive reward component would motivate the user to engage with the intervention. They also felt that additional motivation to

engage with the intervention could involve personalising the reward (n=12). That is, the user can choose their rewards (e.g. coins, trophies, stars) because CAYP with ADHD *"tend to get bored quite quickly"* (C2).

Eleven participants stated reward could also be given by providing different levels where the use could "level up" or open "new areas" once a previous level is "completed". Most of the CAYP (n=5) and two parents wanted these levels to increase in difficulty.

> *"I like harder and harder cos if you do harder and harder you get better and better at it."* (YP7)

However two CAYP (YP3, YP6), one parent (P7) and two clinicians believed that if levels were too challenging for the user, this could cause frustration and demotivate their engagment with the intervention. Therefore, one clinician suggested that there could still be levels and areas to create choice, allowing the user to feel they are progressing, but these levels could have an option to make them easier;

> *"...simplify the challenge so you could make the challenges harder ...but there could be a simplify option that the kids could use and so the kids that do get frustrated can simplify it and get it done."* (C1)

Downloadable Gaming Resources (proposition 2)

If applicable, the option of using downloadable resources could be made available for when the intervention may not be accessible, for example if the child/young person has to share a device with siblings, has limited screen time (e.g. before bed time) or is away from home (e.g. in the car or on holiday). Participants wanted downloadable resources to have a gaming component including quizzes, mazes, word searches, crosswords, colouring in or origami activities (n=5 CAYP, 3 parents, 2 clinicians).

> *"Including quizzes cos I like quizzes."* (YP1)

Personalisable and adaptable components (proposition 3)

Five CAYP, four parents and all six clinicians requested that the technology should be personalisable and include adaptable avatars; that is, characters they can personalise by changing hair/eye colour, gender, clothing, skin colour that can be adapted as and when they wish. Four clinicians believed this was so that the user could "relate" to the intervention and it's content:

> *"That it's (the language) not too clinical and that they can actually relate to it... It's the relating to it really that's most important. ...you have to be really careful that its not so generalised that they can't relate to it."* (C3)

One parent (P4), one young person (YP4) and one clinician (C4) emphasised the importance of having the correct amount of stimulation to ensure they are not over or under stimulated:

> *"You don't want to over-stimulate them, but you want them to have that draw, I think its finding the right balance between overload and sort of retaining err concentration."* (P4)

Psychoeducation component (proposition 6)

Five CAYP, five parents and all six clinicians believed it was an important aim for the user to have a good understanding of their ADHD. It was also considered important by two clinicians (C2, C3) that the positive aspects of ADHD should be highlighted through examples of others who have ADHD and have been successful such as celebrities as they believed there was a lot of negativity surrounding the condition. One clinician believed this could be "life changing" (C1);

> *"Because I want to know about ADHD, what it does and what it effects in your body."* (YP5)

> *"Knowledge is power and just giving her the confidence, increased self-esteem."* (P3)

> *"I think it could be massive for them across the board it could help them at school, help them learn, help them make friends, help with their relationships with others…"* (C1)

Five clinicians wanted interventions for CAYP to self-manage their ADHD to be more positive whilst not "glossing over" some of the difficulties. All six clinicians expanded on the above and stated that when CAYP with ADHD act incorrectly or impulsively, they often feel bad about themselves and having knowledge about their condition could help prevent this. Three CAYP, four parents and four clinicians emphasised the importance of understanding their ADHD so the user can explain it to their friends.

> *"Cos if I know more I can tell people more about the like what I've got (ADHD) so they know what it means."* (YP4)

Integration of Self-management Strategies (propositions 5 and 7)

Five CAYP, four parents and all six clinicians believed an intervention should include strategies to help the child self-manage their ADHD such as anger management strategies, One participant stated that he counts to forty, three times to calm down (YP7).

> *"He can learn sort of techniques you know sort of self-management techniques trying to calm himself down."* (P4)

Another self-management strategy discussed was animated "social scenarios" with alternate endings for the user to choose from to help them understand what acceptable behaviour is and is not in social situations. This idea was favoured by clinicians (n=5), CAYP with ADHD (n=3) and parents (n=3). Two clinicians (C5, C6) stated this could be beneficial because similar "social stories" are already used with CAYP with ASD, which is comorbid in many CAPY with ADHD.

> *"She seems to learn a lot through like watching videos… if she wants to know how to do something, she goes on YouTube."* (P1)

> *"I really like the idea of scenario-based teaching."* (C2)

> *"(Social scenarios) sound like a similar principle to the social stories we use with the children with autism we see. I think that could be useful as it could help the children to reflect on what they might do in a situation before they are in the heat of the moment."* (C5)

Goal Setting (proposition 9)

Six parents liked the idea of goal setting within a technological intervention. They liked the idea of short-term goals due to poor working memory in CAYP with ADHD, which means they may find it challenging to process longer-term goals.

Context (propositions 6 and 8)

It was found that the variable context an intervention is delivered in could affect the outcome it may have and these contexts could be divided into environmental and personal:

Personal contexts

One parent (P3) and one clinician (C5) stated some CAYP with ADHD also have dyslexia and may struggle to read text therefore the background colour to any included text should be adaptable. This is because some people with dyslexia find it easier to read text on specific background colours. This could enable the user to access the information more easily. One parent (P1) and all six clinicians also believed it is important for information presented should be developmental age appropriate and the language should be suitable to ensure the user can understand the material provided.

> *"A whole variety of those different (background) colours then that would make it much more accessible. It would make it easier for them (CAYP with dyslexia as well as ADHD) to read, it could stop the words and the letters moving, it makes it so they can actually read what's written rather than it being a sea of text they can't access. There's a huge overlap between lots of condition like dyspraxia, dyslexia, ADHD, Autism."* (C5)

Environmental contexts

Thirteen participants (n=3 CAYP, n=4 parents, n=6 clinicians) believed they would be more motivated to engage with a technological intervention if they had encouragement and support from close friends or relatives. One young person (YP1) stated that her family and her dog could get in the way if she was to use an intervention of this nature, which could affect the effect the outcome intervention has on the user.

> *"I think it will be good for them to do on their own but I think it will be good for other people to know what they have looked at so they can reinforce if they have any questions."* (C3)

Six parents believed that supporting their child with an intervention that helps them self-manage their ADHD could help build their relationship with their child.

Stage 4: CMOC Refinement

As a result of validating CMOCs with key stakeholders, existing CMOCs have been refined (see Table 7 for examples) and two more CMOCs have been developed (Table 8). All CMOCs can be found in Multimedia appendix 2.

Table 7. Refined CMOC examples that support initial propositions (See Appendix 2 for final list of refined CMOCs).

CMOCs	Plausible mechanism "What"	Contexts: "for whom" and "in what circumstances"
CMOC 1	Receiving **positive rewarding** feedback from	Internet and intervention accessible at home and

		the intervention might improve the users confidence by confirming performance.	used independently of clinician. **Intervention should be colourful and not too text heavy.**
CMOC 3		Enabling the user to choose **personalisable and adaptable** characters **of majority and minority groups** and **a limited number of** "modules" will maintain stimulation to carry out the task.	The intervention will give positive and rewarding feedback to the user. **Users will also have their own user area so they can return to previous work and carry on where they left off.**

Table 8. Additional CMOCs generated from CMOC validation with key stakeholders.

CMOCs	Plausible mechanism "What"	Contexts: "for whom" and "in what circumstances"
CMOC 10	User will have a better understanding of their ADHD so they can explain it to others (friends/ family)	The intervention will provide age appropriate information to improve the user's knowledge and understanding of their ADHD and provide suggestions of how to explain their ADHD to others.
CMOC 11	An indication of improvement/progress such as leveling up will motivate adherence	The intervention will provide the user with varying game levels to keep them engaged and motivated to use the intervention. A "simplify option" will also be available to keep frustration levels down where applicable.

Discussion

Principal Results

This study aimed to present a RE approach to develop guidelines that may help the future development of technological interventions, which aim to help CAYP with ADHD self-manage their condition more effectively. Seven key themes emerged from the interviews with key stakeholders; 1) Positive rewarding feedback, 2) Downloadable gaming resources, 3) Personalisable and adaptable components, 4) Psychoeducation component, 5) Integration of self-management strategies, 6) Goal setting and 7) Context (environmental and personal). Importance was placed on the variable environmental and personal context such an intervention could be delivered in and how these contexts could affect the outcomes of the interventions.

Comparison with Prior Work

Positive Rewarding Feedback

All participants identified the need for instant positive reward within a technological intervention for CAYP with ADHD. This is supported by behaviour change middle-range theories such as classical conditioning, which states that unconscious behaviour will change when a stimulus is repeatedly paired with a particular response such as rewards [55]. Similarly, Operant Conditioning is when an individual repeatedly makes an association with a stimulus such as reward or punishment [56]. These theories explain why the administration of reward can change behaviour. Dynamic Developmental theory states CAYP with ADHD have a shorter "window" between behaviour and a reward response in order for them to make the association between the behaviour and the positive response [61]. This explains why the reward should be immediate. Bandura theory of self-efficacy

also states that gaining confidence by achieving and accomplishing a task can increase an individual's self-efficacy. This is referred to as "Mastery Experiences" [69]. The BCW states that the individual needs to be motivated in order for behaviour to change [21] and reward could motivate a child with ADHD to engage with an intervention.

Downloadable Gaming Resources

Some participants (n=5 CAYP, 3 parents, 2 clinicians) liked the idea of having the option of being able to print off resources that complement the technological intervention in the event that technology is not available (e.g. before bedtime, away from the home). This could be important as CAYP with ADHD are overrepresented in socially deprived areas [7, 8], and may not have access to technology. It would also provide the user the opportunity to have an experience away from a screen and could help supplement learning by conducting a physical action. The latter claim is supported by John Dewey's Experiential Learning Theory [62].

Personalisable and adaptable components

Previous evidence suggests that CAYP with ADHD would like a mobile application to be personalisable [47]. It well documented that CAYP with ADHD need to be optimally stimulated in order to maintain engagement with a task [70-72]. As advised by study participants (n=5 CAYP, 4 parents, all clinicians), personalisable avatars that are able to be constantly adapted as and when the user would like to could provide them with the stimulation and motivation to remain engaged with the intervention. CAYP with ADHD have also been reported to want to adapt avatars so that they can relate to them [47]. Four clinicians emphasised the importance of the CAYP being able to relate to the intervention. Support for this can come from a "mini theory" Organismic Integration Theory (OIT), derived from Self Determination Theory. OIT emphasises the importance of relatedness in order to motivate an individual to behave in a certain way [64].

Psychoeducation Component

Participants (n=5 CAYP, 5 parents, all 6 clinicians) wanted CAYP to know more about their ADHD so that they could self-manage it more effectively and so the CAYP could explain what ADHD means to their peers. This concurs with existing literature where emphasis has been placed on the value of psychoeducation for CAYP with ADHD and their families as an expert understanding of their condition could lead to more positive individual choices [49, 73]. The Health Foundation reports that educating people about their long-term condition can support self-management [74], Public Heath England [75] and the Mental Health Taskforce's Five Year Forward View for Mental Health [76] states that early intervention avoids CAYP falling into crisis and expensive longer-term interventions into adulthood. This evidence suggests that psychoeducation for CAYP with ADHD as early as possible is vital to help them understand and self-manage their condition. Despite this favourable evidence base for psychoeducation, CAYP with ADHD often do not have access to appropriate psychoeducation and their understanding of the condition is frequently poor and likely to lower self-esteem.

Integration of Self-Management Strategies

Five CAYP, four parents and all six clinicians believed the availability of self-management strategies for ADHD could be useful for CAYP with ADHD. Social learning theory states that individuals can learn by imitating others [58]. Animated social scenarios whereby the user can choose alternate endings could enable the user to learn about acceptable behaviour in social situations. Bandura's self-efficacy theory states that "Modelling" can increase self-efficacy [69].

Two clinicians recognised that "social stories" are an effective way to teach CAYP with ASD how to behave appropriately in social situations and are often used in clinical practice. [77, 78]. They therefore believed the proposed animated social scenarios and could work well with many CAYP with ADHD especially those CAYP have a comorbid social skills difficulties.

Furthermore, "interpreting physiological signs" is also a stream of Banduras theory of self-efficacy [69]. This could have applied to ADHD in CAYP as if the young person can identify when they are likely to feel angry or frustrated, this could be when they apply some self-management strategies to control their behaviour, which could lead to an improvement in their self-efficacy.

As CAYP with ADHD can be impulsive, it was requested that interventions should involve a component to help them when they wish to behave impulsively for example when they are angry. Support from this may come from the Social Regulation Theory that states CAYP with ADHD lack self-control, which can affect their working memory [59]. This theme is also supported by the CCM, which states that patients should receive support to self-manage their condition [17].

Goal Setting

Six parents liked the idea of short-term goal setting within an intervention. Executive dysfunction theory has been applied to ADHD [60] and states that CAYP with ADHD commonly experience working memory deficits. This is supportive of the fact that goals should be short rather than longer-term as their working memory capacities may not enable them to remember requirements to achieve a long-term goal.

Context: environmental

In accordance with the MRC framework and the ICF, this research found that variable contexts an intervention could be delivered in could be divided into personal and environmental factors [79]. Figure 3 displays identified environmental and personal contexts as having the potential to change intervention outcomes.

One example of an environmental context is support from others. Thirteen participants believed there was value in CAYP with ADHD having support and encouragement (to use an intervention) from their close friends and families. This concurs with the theory of self-efficacy that states that "feedback and persuasion" from significant others, such as family members, can increase one's self-efficacy [69, 80]. Therefore, the support from a close friend or relative when completing such an intervention could help increase the user's self-efficacy.

Context: personal

One participant acknowledged that ADHD is a highlight comorbid disorder [81], which includes other conditions such as dyslexia and one provision that could be made is giving users the option to change text background colour to aid reading. Additionally, optimal stimulation Theory states that CAYP with ADHD need to be optimally stimulated to maintain their attention. Therefore it is important that information and language presented is both age appropriate and interesting to look at e.g. by the use of bright colours.

Figure 3. Outlines identified environmental and personal contextual factors that could affect the effect (outcome) an intervention has on a user.

Please insert Figure 3 here.

Strengths, limitations and recommendations

This study has highlighted the importance on considering the variable context in which interventions take place [44]. If research does not consider factors such as the context the intervention is delivered in and the variety in the population, the results could lack reliability and depth [82]. Therefore, this study has provided initial guidelines to assist future technology developers with this process. Furthermore, MRTs were used to underpin the guidelines to help increase its generalisability to more than one context. Future research into complex intervention development for any population may wish to adapt the methodology of this study to assist with building an evidence base for their intervention.

Existing evidence is supportive of a psychoeducation component for such interventions [49, 73-76] therefore future technology should include this component if appropriate.

Additionally, the BCW [21] provides a framework for behavior change interventions and the CCM [17] for the care of chronic conditions. During the production of these guidelines, the National Institute for Health and Care Excellence (NICE) have released their Digital Health Intervention (DHI) Framework [83]. This is an excellent framework that makes a number of detailed recommendations for the development of complex DHIs. Where these models, and the NICE DHI framework, are valuable for behaviour change, chronic care and complex intervention development respectively, they are generic models that can be applied to many conditions, not only ADHD. Where the guidelines developed in this instance are partially based upon generic theories such as these, they are also condition specific. This is important for a population with complex needs such as CAYP with ADHD as they have needs that cannot be applied to the many conditions the BCW, CCM and NICE DHI framework target.

Whilst a sampling frame was adhered to, ensuring a representative sample of this complex population, the qualitative nature of this research meant that the CMOCs for this study were validated and refined using interview data from a small number of participants (n=21). ADHD is a highly complex neurological condition therefore one intervention will not suit all CAYP with ADHD or all families and future technological interventions will need to account for this. In addition, for some, these guidelines and subsequent technology development may still not meet their need for personable one-to-one interaction. Furthermore, this study was limited to the views and opinions of CAYP with ADHD, their parents and specialist clinicians. Game designers and platform developers were not consulted as it was outside the aims and objectives of this study. Future research may benefit from incorporating the views and opinions of these individuals.

Complex interventions for ADHD self-management run the inevitable risk of variable uptake of the intervention among participants [15], therefore future attempts should account for this. These guidelines were designed in 2018. Technology is constantly changing and alongside this, so are consumer expectations [43] therefore it is important for these guidelines to be reviewed regularly and for future projects to develop complex interventions to be aware of technological developments at the time. Although these guidelines may need reviewing, contexts that complex interventions are delivered in will always be variable therefore the methodology adopted for this study could be used beyond the lifetime of the guidelines developed.

Conclusions

This study has adopted the principles of RE [52] to design a set of guidelines that can be used when developing complex, technological interventions that aim to help CAYP aged 8-11 with ADHD self-manage their condition. The guidelines propose helping CAYP aged 8-11 years with ADHD

understand their condition and to help provide them with tools to self-manage if more effectively. This concurs with the Health Foundations guide to self-management of long-term conditions [22]. It is anticipated that these guidelines will become a Research Derived Actionable Tool [84] in the future for designers to use and maximise the impact they have on the development of technological interventions for this population in the future. It is recommended that a co-design approach should be adopted when designing complex interventions to increase the likelihood of acceptance of the intervention and engagement with it [13, 14]. The methodology presented could also be used to stimulate a wide range of stakeholders (service users, clinicians, researchers, policy makers) to think differently about how interventions for this population, and other populations and age groups, is designed. Beyond the use of these guidelines, future research evaluating the effectiveness of such an intervention must contain large sample sizes and account for the variable contexts interventions are delivered in to ensure findings are generalisable. A follow up period is also essential to evaluate if intervention effects persist over longer periods of time [15, 49]. Although these guidelines provides a good theory and evidence basis for the development of a future complex intervention of this nature, it must be acknowledged that it is vital that complex interventions should be coproduced in partnership with key stakeholders to increase the likelihood that the intervention is to be accepted by the intended users [46-48].

Acknowledgments

Conflicts of Interest

None declared

Abbreviations

ADHD: Attention Deficit Hyperactivity Disorder
BCW: Behaviour Change Wheel
CAYP: Children and young people
CAMHS: Child and Adolescent Mental Health Service
COM-B: Capability Opportunity Motivation-Behaviour
CCM: Chronic Care Model
RE: Realist Evaluation
CMOC: Context Mechanism Outcome Configuration
CC: Classical Conditioning
DHI: Digital Health Intervention
NICE: National Institute of Health and Care Excellence
OC: Operant Conditioning
OST: Optimal Stimulation Theory
SLT: Social Learning Theory
SRT: Social Regulation Theory
ED: Executive Dysfunction
DDT: Dynamic Developmental Theory

ELT: Experiential Learning Theory
SCT: Social Cognitive Theory
ASD: Autism Spectrum disorder
M: Male
F: Female
NHS: National Health Service
OIT: Organismic Integration Theory
RAMESES: Realist and Meta-narrative Evidence synthesis: Evolving standards
SDT: Self Determination Theory
SNAP: Swanson, Nowlan and Pelham Questionnaire
Yrs: Years

Multimedia appendix 1: The guidelines for the development of technological interventions for CAYP with ADHD.

Please insert multimedia appendix 1 here.

Multimedia appendix Two: Refined CMOCs.

Please insert multimedia appendix 2 here.

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