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mHealth apps delivering early Intervention to support parents of children with autism: a scoping review protocol

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5 **mHealth apps delivering early Intervention to support parents of children with autism: a**
6 **scoping review protocol**
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Author contributions

U wrote the original draft. RB-U-PK contributed to the conception of the study and substantively revised the protocol. RB and U planned the initial search strategy and carried out the pilot. SN and TY developed the data extraction form. All authors RB, U, SN, TY and PK have contributed to the scoping review protocol, methodology for screening, final analysis and interpretation of the papers and read and approved the final version.

Conflicts of interest

The authors declare no conflict of interest.

mHealth apps delivering early Intervention to support parents of children with autism: a scoping review protocol

Abstract

Objective: This review aims to identify the mhealth apps delivering early intervention to support parents of children with autism spectrum disorders (ASD). We aim to explore the concept, context and methodology of implementation i.e., theoretical framework, feasibility, quality of evidence, for such apps.

Background: To improve outcomes for children with autism, early intervention has been found to be promising. parental training, parent psychoeducation and parent mediated intervention is regarded as the gold standard, to achieve early childhood development goals. Digital health technologies like tele-health, web-based services, have been used to deliver this at reduced cost. There is little evidence about their use and efficacy in empowering parents of children with ASD.

Inclusion criteria: The studies reporting the use of mhealth apps to support parents of children with ASD, in community settings, school settings, special schools, clinics, hospitals, or child development centers. There will be no exclusion based on region, or gender, or socio-cultural factors. The types of studies included will be quantitative, qualitative, mixed-methods study designs, case reports, grey literature, systematic reviews, clinical trials, and the studies reporting feasibility of digital mhealth applications.

Method: Using the NICE Healthcare Databases Advanced Search we will search the following databases with MEDLINE, PUBMED, CINAHL, EMBASE, PsycINFO, Cochrane Library, EbscoHost, Sabinet, SAGE Journals, Directory of Open Access Journals, BioMed Central, Scopus, ScienceDirect. Furthermore, grey literature will be searched through Google Scholar, ShodhGanga, JSTOR, CORE, EBSCO, DOAJ, BASE.

The searches will be limited to the age range of children between 2 to 6 years with ASD, and the date range is from the inception of the database to the current date. The terms for the autism spectrum disorder will be combined with terms for parent, early intervention and digital mhealth to identify eligible studies.

Word count: 289

What is already known on this topic?

1. Increasing prevalence of autism spectrum disorder can be attributed to the increased awareness.
2. Early intervention and supporting parents is regarded as the gold standard to help parents in understanding the treatment and prevention of their child's various behavioral problems.

What does this study hope to add?

1. This scoping review will identify what mhealth apps are available to support parents in early intervention, including their methodology, theoretical framework, quality of evidence and what outcomes measures have been evaluated.
2. This study will help identify the current gaps and future development of mhealth apps for parents of children with autism between 2 to 6 years.

Introduction

Autism spectrum disorder (ASD) refers to a group of lifelong neurodevelopmental disorders that can cause significant social, communication and behavioral difficulties.^{1,2,3} The symptoms are present from early childhood and affect daily functioning, posing a greater challenge for parents and carers of children with ASD.⁴ With continuously increasing prevalence, there are about 52 million people with autism across the globe, affecting 1%-2% of the world's population.^{5,6} This could be attributed to increased awareness among parents, carers, and professionals, and early identification. Resulting in increased demand for services, and highly unaddressed needs pre and post post-diagnosis for 70% of the children with ASD.^{7,8,9,10}

Although there is no cure for ASD, research shows that early intervention (EI) services can improve a child's development, behaviour and reduce symptoms.^{11,12,13,14} Thus imposing an increased need for dissemination and implementation of early interventions, to support children with ASD and their families.^{15,16,17,18} Early Intervention has been defined as "the term used to describe the services and supports that are available to babies and young children with developmental delays and disabilities, who are at risk of poor outcome and their families".^{19,20} The early intervention's primary purpose has been to help in the acquisition and generalization of critical developmental skills, to the possible extent, and achieve independent functioning across environments. The time period from birth up to six years is considered to be the most crucial for the brain development,¹ and intervening during this will help children reach their individual learning and developmental goals.²¹ Direct benefits of EI include improvement in outcomes like physical, cognitive, behavioral, and social and emotional development, parent efficiency, mental health and understanding of their child.^{19,22} Other reported benefits included increment in verbal and non-verbal abilities of children with ASD, along with improved parents and caregivers' efficacy and understanding of their child's needs.^{23,24}

To achieve these outcomes and support, various theoretical models like Developmental Systems Model, Unified Theory Approach, and Integrated Framework Model, have been used for implementation of early intervention.^{25,26,27} Although there is no fixed approach to implementation of early intervention, it has been reported to be an amalgam of various theories and approaches.²⁸

Community-based early intervention through parents or carers, based on an integrated framework theory, is reported to be helpful in building a solid base for the developing brain during the most crucial period of infancy and early childhood.^{29,30} Parent education and training (PET), is emphasized to be the priority during early intervention and care for their children with ASD,³¹ and have resulted in significantly improving the children's desirable and undesirable behaviors, increasing children's language/communication and cognitive abilities, reducing autism symptoms.^{32,33,34,35,36,37} PET programs along with parent mediated early intervention have since rapidly increased, focusing on imparting knowledge of child development, supporting parenting self-efficacy, to improve communication skills, cognitive and behaviour improvements. behavior management.^{38,39,40,41,42}

Despite reported effectiveness of early intervention programs at community level, in schools, parent group based and home based, limiting factors such as lack of trained professionals, lack of such services in remote areas, time factor, and cost effectiveness were

¹ For a detailed brain development process refer to Human brain development. Charles A. Nelson, University of Minnesota.

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5 found.^{43,44} With the emergence of E-health services, early interventions programs' reach
6 expanded, and training programs like Triple-P, IMPACT Online, emerged with the aim of
7 delivering interventions to parents individually or in group settings.^{45,46}
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9 The web-based E-Health revolution digitized the early intervention services and
10 increased the reach of these programs.⁴⁷ However, people depended on immobile devices such
11 as desktop computers, network access, web cameras, to access these services.^{48,49} There are
12 studies which found tele-health to be an effective method for promoting children's healthy
13 behaviors and supporting parents.^{50,51} In a recent systematic review done by Ferguson et al.
14 (2019) they concluded while telehealth can be used for both diagnosis and treatment for ASD,
15 still due to methodological problems telehealth didn't meet the criteria for being considered a
16 true evidence-based treatment, and suggested the need for more research on to determine the
17 efficacy of telehealth as a treatment model.⁵²
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19 A little more than a decade ago, the term 'mobile health' (mhealth) was coined to
20 describe a subset of eHealth that uses mobile technologies, including advancements in
21 innovative applications to address health priorities.⁵³ Although this term has been in use since
22 2003, few experts in the field agree on its scope and definition. According to the WHO Global
23 Observatory for eHealth, mhealth is a "medical and public health practice supported by mobile
24 devices(MD), such as mobile phones, patient monitoring devices, personal digital assistants
25 (PDAs), and other wireless devices."⁵⁴ In addition to the MDs mentioned in this definition,
26 smartphones, portable media players, and tablet personal computers (tablet PCs) have essential
27 applications in mhealth.⁵⁵ With the emergence of smartphones, and reported efficacy and
28 feasibility of tele-health program, there has been seen a shift from e-health to mhealth.⁵⁶
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31 While the use of mHealth has been reported to improve health services in many medical
32 conditions for over a decade, evidence on its use in delivering early intervention to support
33 parents of children with ASD is limited.⁵⁷ For example, the mhealth app has been used to
34 facilitate the easier identification of autism diagnosis.^{58,59} mHealth has been used to deliver CBT
35 among typically developing and children and adolescents with ASD, for practicing and
36 improving communication skills, toilet training, improving sleep routine, for training parents to
37 reduce maltreatment and abuse.^{60,61,62,63}
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39 With an increasing prevalence and improving technological platforms, the reach of early
40 intervention programs can be increased by identifying and reporting these mhealth
41 applications. Little or no evidence of research on usability, feasibility, methodological aspects of
42 key components of such mhealth applications for parents have been found. Therefore, the
43 objective will be to conduct a scoping review of mHealth applications, their concept, and context
44 of implementation, methodological framework and evidence quality. This paper also aimed to
45 identify gaps in the literature to provide recommendations for future research. Based on the
46 findings and scope of the current evidence, the findings of this review will also lay the
47 foundation for development of an early intervention app to support parents.
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50 Following the Joanna Briggs Institute Scoping Review (JBI) Methodology, this scoping
51 review will map the available evidence related to the concept and context of the mhealth app
52 and report any gaps.⁶⁴ To address the research objective, we conducted an initial search of
53 PROSPERO, MEDLINE, the Cochrane Database of Systematic Reviews, and the JBI Evidence
54 Synthesis on 10, Nov 2021. We found no ongoing scoping or systematic reviews on our topic of
55 interest.
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Review questions:

- 1) What mhealth apps exist for supporting parents of children with suspected, or under diagnosis of ASD between 2 to 6 years of age.
- 2) Classification of the mhealth applications using NICE Evidence standards framework for digital health technologies.⁶⁵
- 3) Type of intervention, context, and outcome reported if any based using TiDieR Checklist.⁶⁶
- 4) What Theoretical framework has been used and reported for the development of the app?
- 5) What methodology for feasibility, evaluation and implementation has been used?
- 6) Quality and Level of Evidence will be reported using Evidence Based Practice (EBP) tool developed by Center for Evidence-Based Practice.⁶⁷

Inclusion and exclusion criteria

The studies will be selected and excluded specifically related to the following Population, Concept, and Context criteria presented in table 1.

Table 1: Predefined Inclusion and Exclusion criteria for identifying eligible studies

	Inclusion Criteria	Exclusion Criteria
Population/ Participants	Studies that include parents and carer of children with autism spectrum between the age of 1 year to 6 years will be included. As we are interested in reviewing the apps supporting parents in early years, therefore the age range has been restricted. In our review, we define parents as biological parents, birth parents, carer or foster parents who have children with ASD between 2 to 6 years.	Studies reporting mhealth apps for children above the age of 6 years or adolescents will be excluded.
Concept	According to the WHO Global Observatory for eHealth, mhealth is a "medical and public health practice supported by MDs, such as mobile phones, patient monitoring devices, PDAs, and other wireless devices." ⁵⁴ We define mhealth applications (apps) as applications developed for use on mobiles or smartphones, tablets, or i-pads that can be easily downloaded from the Play Store or App Store. This review will consider mhealth apps that support parents during early intervention.	Web/internet-based programs, or computer dependent programs will be excluded.
Type of Study	This scoping review will consider quantitative, qualitative, mixed-methods study designs, case reports, grey literature, systematic reviews, clinical trials, and feasibility studies of mhealth applications.	Any study not reporting the use of mhealth will be excluded.
Context	This review will consider studies conducted or implemented for parents of children with ASD to provide support in community settings, school settings, special schools, clinics, hospitals, or child development centers. There will be no exclusion based on region, or gender, or socio-cultural, or language factors.	No restriction on context
Note: § ASD- Autism Spectrum Disorder, mhealth- mobile health, World Health Organization- WHO, personal digital assistants -PDAs		

Methods

Due to the nature of the research question, a scoping review design was chosen to identify what mhealth apps are available for supporting parents with early intervention in children with ASD between 2 to 6 years of age. This scoping review will be conducted per the JBI methodology and the PRISMA extension for scoping reviews (PRISMA-ScR) checklist and flow diagram to identify and report the findings of the scoping review.^{64,68}

Data extraction and findings of the summary table based on TiDier checklist will be used to summarize the findings as per the review questions. We will use the Evidence Standards Framework for Digital Health Technologies developed by National Institute for Health and Care

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5 Excellence (NICE) to report the functional classification of the final mhealth apps selected for
6 review.
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8 **Search strategy**

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10 An initial limited search of MEDLINE and PsycInfo was undertaken to identify keywords, articles
11 on the topic. The text words in the titles, abstracts, and keywords used to describe the articles
12 helped develop a complete search strategy adapted for included databases (see Appendix I).
13

14
15 The search will include peer-reviewed articles in quantitative, qualitative, mixed-methods study
16 designs, case reports, grey literature, systematic reviews, clinical trials, and feasibility studies. In
17 addition, only studies reporting the use of mhealth apps for parents of children limited to the
18 following age groups between two to six years will be included.
19

20 The NICE Healthcare Databases Advanced Search will search the following databases with
21 MEDLINE, PUBMED, CINAHL, EMBASE, PsycINFO, Cochrane Library, EbscoHost, Sabinet, SAGE
22 Journals, Directory of Open Access Journals, BioMed Central, Scopus, ScienceDirect. Furthermore,
23 grey literature will be searched through Google Scholar, ShodhGanga, JSTOR, CORE, EBSCO, DOAJ,
24 BASE.
25

26 **Study selection**

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29 Following the search, all identified records will be uploaded into a data screening sheet
30 developed on google sheet and searched for duplicates. Following this, titles and abstracts will
31 then be screened by two reviewers independently for assessment against the inclusion criteria.
32 Potentially relevant papers will be retrieved in full and screened against the population,
33 concept, and context to adhere to the inclusion criteria. The screening of the reference lists of
34 articles selected for full-text review will be done for additional papers. The scoping review will
35 record and report reasons for the exclusion of full-text papers that do not meet the inclusion
36 criteria.
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38 **Patient and Public Involvement**

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41 The review will also consider studies reporting involvement of parents and carer. We aim to
42 involve parents, carer and guardian of children with ASD in dissemination of the findings of this
43 review. Based on the findings we will conduct a focus group interview involving parents and
44 carers to inform the development of the app.
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48 **Data extraction**

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51 Data after review of the full paper will be collated using the data extraction instrument
52 (Appendix II: Data extraction instrument). The table will include specific details about the
53 author of the study, purpose of the study, year, origin, methodology of study including
54 population and sample size, context, concept, and target population, outcome variables with
55 measures, and key findings that relate to the scoping review question, major strengths and
56 limitations, the parental views/ feedbacks and feasibility, the theoretical framework used and
57 reported if any.
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5 A summary of the finding table based on all the included studies will present information as per
6 the TiDier Checklist and will report quality and level of evidence.

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8 The draft data extraction tool will be modified and revised as necessary while extracting data
9 from each included paper. Modifications will be detailed in the full scoping review. Any
10 disagreements that arise between the reviewers will be resolved through discussion or with a
11 third reviewer. Authors of papers will be contacted to request missing or additional data, where
12 required.

13 14 **Data analysis and presentation**

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17 Results will be presented visually and descriptively in tables based on the data extraction tool
18 (Appendix II) and summary of findings for included papers (Appendix III). The discussion and
19 conclusions will also address potential areas for evidence synthesis and identified research
20 gaps.

21 22 **Ethics and dissemination:**

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25 Ethical approval not required; final scoping review paper will be published in a peer reviewed
26 journal.

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Appendix I: Search strategy

#MEDLINE (NICE Healthcare Databases Advanced Search). Search conducted on 06 August 2021

Search	The search strategy used in MEDLINE (NICE Healthcare Databases Advanced Search)	Records retrieved
#1	Digit* OR exp TECHNOLOGY/ OR exp ELECTRONICS/ OR exp "DIGITAL TECHNOLOGY"/ OR exp "ANALOG-DIGITAL CONVERSION"/ OR digitisa* OR digitiza* OR onlin* OR technolog* OR computeriz* OR digitaliz* OR cell phone* OR mhealth* OR mobile technology* OR smartphone* OR mHealth apps* OR digital health intervention* OR digital health technology* OR e-health* OR telehealth* OR telemedicine*	2,263,054
#2	paren* OR exp PERSONS/ OR paren*or guardi* OR famil* OR Parent training* OR psychoeducation* OR parent education* OR Parent Education Programmes* OR Parent Education Groups* OR Parent Psychoeducation* OR Parent Education Training*	178,797
#3	"AUTISM SPECTRUM DISORDER"/ OR "AUTISTIC DISORDER"/ OR "PDD"/ OR "ASPERGER"/ OR "NEURODIS"/ OR "AUTISM SPECTRUM CONDITIONS"/ OR "AUTISTIC SPECTRUM CONDITIONS"/ OR "AUTISM"/ OR "COMPLEX AUTISTIC SPECTRUM"/ OR "SOCIAL COMMUNICATION DISORDERS"/ OR "NEURODISABILITY"/ OR "AUTISTIC DISORDER"/ OR "AUTISTIC CONDITION"/ OR "ASPERGER SYNDROME"/ OR "SPECTRUM"	461,50
#4	CHILD HEALTH SERVICES"/ OR "PREVENTIVE HEALTH SERVICES"/ OR "EARLY INTERVENTION, EDUCATIONAL"	88604
#5	COMBINED- (1 AND 2 AND 3 AND 4)	879

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Appendix II: Data extraction instrument												
<i>Author (s) (Year)</i>	<i>Purpose of study/paper</i>	<i>Origin</i>	<i>Population and sample size</i>	<i>Methodology</i>	<i>Context</i>	<i>Concept</i>	<i>Classification as per the NICE Evidence standards framework for digital health technologies</i>	<i>Outcome variables with Measures</i>	<i>Key findings that relate to the scoping review question</i>	<i>Major strengths and limitations</i>	<i>Parental views/feedbacks</i>	<i>Theoretical framework</i>

Appendix III: Summary of Finding Table reporting mHealth app-based Interventions as per TIDieR Checklist

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	<i>BRIEF NAME</i>	<i>WHY</i>	<i>WHAT</i>		<i>WHO PROVIDED</i>	<i>HOW</i>	<i>WHERE</i>	<i>WHEN and HOW</i>	<i>TAILORING</i>	<i>MODIFICATIONS</i>	<i>HOW WELL</i>		<i>Quality & Level of Evidence</i>
Title	1. Provide the name or a phrase that describes the intervention.	2. Describe any rationale, theory, or goal of the elements essential to the intervention	3. Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	4. Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	5. For each category of intervention provider (e.g., psychologist, nursing assistant), describe their expertise, background and any specific training given.	6. Describe the modes of delivery (e.g., face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	7. Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	MUCH 8. Describe the number of times the intervention was delivered and over what period including the number of sessions, their schedule, and their duration, intensity or dose.	9. If the intervention was planned to be personalized, titrated, or adapted, then describe what, why, when, and how.	10. If the intervention was modified during the study, describe the changes (what, when, and how).	11. Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	

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Appendix I: Search strategy

#MEDLINE (NICE Healthcare Databases Advanced Search). Search conducted on 06 August 2021

Search	The search strategy used in MEDLINE (NICE Healthcare Databases Advanced Search)	Records retrieved
#1	Digit* OR exp TECHNOLOGY/ OR exp ELECTRONICS/ OR exp "DIGITAL TECHNOLOGY"/ OR exp "ANALOG-DIGITAL CONVERSION"/ OR digitisa* OR digitiza* OR onlin* OR technolog* OR computeriz* OR digitaliz* OR cell phone* OR mhealth* OR mobile technology* OR smartphone* OR mHealth apps* OR digital health intervention* OR digital health technology* OR e-health* OR telehealth* OR telemedicine*	2,263,054
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#3	"AUTISM SPECTRUM DISORDER"/ OR "AUTISTIC DISORDER"/ OR "PDD"/ OR "ASPERGER"/ OR "NEURODIS"/ OR "AUTISM SPECTRUM CONDITIONS"/ OR "AUTISTIC SPECTRUM CONDITIONS"/ OR "AUTISM"/ OR "COMPLEX AUTISTIC SPECTRUM"/ OR "SOCIAL COMMUNICATION DISORDERS"/ OR "NEURODISABILITY"/ OR "AUTISTIC DISORDER"/ OR "AUTISTIC CONDITION"/ OR "ASPERGER SYNDROME"/ OR "SPECTRUM"	461,50
#4	CHILD HEALTH SERVICES"/ OR "PREVENTIVE HEALTH SERVICES"/ OR "EARLY INTERVENTION, EDUCATIONAL"	88604
#5	COMBINED- (1 AND 2 AND 3 AND 4)	879

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Appendix II: Data extraction instrument												
<i>Author (s) (Year)</i>	<i>Purpose of study/paper</i>	<i>Origin</i>	<i>Population and sample size</i>	<i>Methodology</i>	<i>Context</i>	<i>Concept</i>	<i>Classification as per the NICE Evidence standards framework for digital health technologies</i>	<i>Outcome variables with Measures</i>	<i>Key findings that relate to the scoping review question</i>	<i>Major strengths and limitations</i>	<i>Parental views/feedbacks</i>	<i>Theoretical framework</i>

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Appendix III: Summary of Finding Table reporting mHealth app-based Interventions as per TIDieR Checklist

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BRIEF NAME	WHY	WHAT	WHO PROVIDE D	HOW	WHERE	WHEN and HOW	TAILORI NG	MODIFIC ATIONS	HOW WELL	Quality & Level of Evidence
1. Provide the name or a phrase that describes the intervention.	2. Describe any rationale, theory, or goal of the elements essential to the intervention	3. Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	4: Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	5. For each category of intervention provider (e.g., psychologist, nursing assistant), describe their expertise, background and any specific training given.	6. Describe the modes of delivery (e.g., face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	7. Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	8. Describe the number of times the intervention was delivered and over what period including the number of sessions, their schedule, and their duration, intensity or dose.	9. If the intervention was planned to be personalized, titrated, or adapted, then describe what, why, when, and how.	10. If the intervention was modified during the study, describe the changes what, why, when, and how). 11. Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them. Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	

BMJ Paediatrics Open

mHealth apps delivering early Intervention to support parents of children with autism: a scoping review protocol

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Manuscript ID	bmjpo-2021-001358.R1
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Date Submitted by the Author:	15-Feb-2022
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Keywords:	Qualitative research, Technology, Psychology

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5 **mHealth apps delivering early intervention to support parents of children with autism: a**
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Keywords: early digital intervention; mhealth; autism spectrum; digital technology; mobile application-based support

Word count – 2430

References Count: 68

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Author contributions

U wrote the original draft. RB-U-PK contributed to the conception of the study and substantively revised the protocol. RB and U planned the initial search strategy and carried out the pilot. SN and TY developed the data extraction form. All authors RB, U, SN, TY and PK have contributed to the scoping review protocol, methodology for screening, final analysis and interpretation of the papers and read and approved the final version.

Conflicts of interest

The authors declare no conflict of interest.

mHealth apps delivering early Intervention to support parents of children with autism: a scoping review protocol

Abstract

Objective: This review aims to identify the mhealth apps delivering early intervention to support parents of children with autism spectrum disorders (ASD). We aim to explore the concept, context and methodology of implementation i.e., theoretical framework, feasibility, quality of evidence, for such apps.

Background: To improve outcomes for children with autism, early intervention has been found to be promising. parental training, parent psychoeducation and parent-mediated intervention is regarded as the gold standard, to achieve early childhood development goals. Digital health technologies like tele-health, web-based services, have been used to deliver this at a reduced cost. There is little evidence about their use and efficacy in empowering parents of children with ASD.

Inclusion criteria: The studies reporting the use of mhealth apps to support parents of children with ASD, in community settings, school settings, special schools, clinics, hospitals, or child development centers. There will be no exclusion based on region, gender, or socio-cultural factors. The types of studies included will be quantitative, qualitative, mixed-methods study designs, case reports, grey literature, systematic reviews, clinical trials, and studies reporting feasibility of digital mhealth applications.

Method: Using the NICE Healthcare Databases Advanced Search we will search the following databases: MEDLINE, PUBMED, CINAHL, EMBASE, PsycINFO, Cochrane Library, EbscoHost, Sabinet, SAGE Journals, Directory of Open Access Journals, BioMed Central, Scopus, ScienceDirect. Furthermore, grey literature will be searched through Google Scholar, ShodhGanga, JSTOR, CORE, EBSCO, DOAJ, BASE.

The searches will be limited to the age range of children between 2 to 6 years with ASD, and the date range is from the inception of the database to the current date. The terms for the autism spectrum disorder will be combined with terms for parent, early intervention and digital mhealth to identify eligible studies.

Word count: 289

What is already known about this topic?

1. The increasing prevalence of autism spectrum disorder can be attributed to increased awareness.
2. Early intervention and supporting parents are regarded as the gold standard to help parents in understanding the treatment and prevention of their child's various behavioural problems.

What does this study hope to add?

1. This scoping review will identify what mhealth apps are available to support parents in early intervention, including their methodology, theoretical framework, quality of evidence and what outcomes measures have been evaluated.
2. This study will help identify the current gaps and future development of mhealth apps for parents of children with autism between 2 to 6 years.

Introduction

“Autism spectrum disorder (ASD) is characterized by persistent deficits in social communication and social interaction across multiple contexts, including deficits in social reciprocity, nonverbal communicative behaviours used for social interaction, and skills in developing, maintaining, and understanding relationships. (The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5))”¹ The symptoms are present from early childhood and affect daily functioning, posing a greater challenge for parents and carers of children with ASD.² With continuously increasing prevalence, there are about 52 million people with autism across the globe, affecting 1%-2% of the world’s population.^{3,4} This could be attributed to increased awareness among parents, carers, and professionals, and early identification. Resulting in increased demand for services, and highly unaddressed needs pre and post diagnosis for 70% of the children with ASD.^{5,6,7,8}

Autism research suggests that early detection and appropriate early intervention is the best way to help children with ASD.^{9,10} Early intervention can lead to improved development, behaviour and reduced symptoms.^{11,12} Thus imposing an increased need for dissemination and implementation of early interventions, to support children with ASD and their families.^{13,14,15,16} Early Intervention has been defined as “the term used to describe the services and supports that are available during early years to babies and young children with developmental delays and disabilities, who are at risk of poor outcomes and their families”.^{17,18} Its primary goal has been to facilitate the acquisition of critical developmental skills and allow children to achieve independence across different environments. The time period from birth up to six years is considered to be the most crucial for brain development.¹ By intervening during this period, children will be able to meet their individual developmental and learning goals.¹⁹ Direct benefits of EI include improvement in child’s outcomes like physical, cognitive, behavioural, and social and emotional development.^{17,20} Other reported benefits included increment in verbal and non-verbal abilities of children with ASD, along with improved parents and caregivers’ ability to manage and understand their child’s needs.^{21,22}

To achieve these outcomes and support, various theoretical models like Developmental Systems Model, Unified Theory Approach, and Integrated Framework Model, have been used for the implementation of early intervention.^{23,24,25} The developmental systems model is a framework for implementing community-based early intervention services. It supports children and families by addressing potential stressors related to risk and disability conditions. This allows parents to engage in positive parent-child interactions, which in turn helps children develop skills and abilities. A unified theory approach looks at the broader contexts in which families and programs exist. As families and homes are primary nurturing contexts, strengthening relationships (parent-child, child-child, parent-practitioner, etc.) is crucial to early childhood intervention. This approach emphasizes the importance of adults providing children with positive experiences so that they may learn by both acting on and observing their environment. Early childhood intervention practices informed by the unified theory approach are therefore individually and dynamically tailored to meet the unique needs of each child and family. The later; integrated framework model, not just focuses on parents, but on combining independent interventions, programs and theories, into one, at different levels like in social setting, school setting, and home to maximize intervention exposure, resulting in improving the

¹ For a detailed brain development process refer to Human brain development. Charles A. Nelson, University of Minnesota.

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5 targeted outcome in children. Although there is no fixed approach to the implementation of
6 early intervention, it has been reported to be an amalgam of various theories and approaches.²⁶
7 Community-based early intervention through parents or carers, based on an integrated
8 framework theory, is reported to be helpful in building a solid base for the developing brain
9 during the most crucial period of infancy and early childhood.^{27,28} Parent education and training
10 (PET), is emphasized to be the priority during the early intervention and care for their children
11 with ASD,²⁹ and has resulted in significantly improving the children's desirable behaviours,
12 increasing children's language/communication and cognitive abilities, and reducing autism
13 symptoms.^{30,31,32,33,34,35} PET programs along with parent-mediated early intervention have since
14 rapidly increased, focusing on imparting knowledge of child development, supporting parenting
15 self-efficacy, improving communication skills, cognitive and behaviour improvements.^{36,37,38,39,40}
16

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18 Despite the reported effectiveness of early intervention programs at the community
19 level, in schools and parent-based groups, it was found that there were still limitations such as a
20 lack of trained professionals, unavailability of such services in remote areas, the time factor,
21 cost-effectiveness etc.^{41,42} With recent advancements made through information technologies
22 like E-Health Services, early interventions programs' reach expanded and training programs
23 like Triple-P, IMPACT Online, etc. emerged.^{43,44} These web-based programs helped by delivering
24 these workshops individually or together, providing more personalized care while also cutting
25 down costs due to reduced needless time spent travelling between locations.⁴⁵
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28 However, people depended on immobile devices such as desktop computers, network
29 access, web cameras, to access these services.^{46,47} There are studies that found telehealth to be
30 an effective method for promoting children's healthy behaviours and supporting parents.^{48,49} In
31 a recent systematic review done by Ferguson et al. (2019) they concluded while telehealth can
32 be used for both diagnosis and treatment for ASD, still due to methodological problems
33 telehealth didn't meet the criteria for being considered a true evidence-based treatment and
34 suggested the need for more research to determine the efficacy of telehealth as a treatment
35 model.⁵⁰
36

37
38 A little more than a decade ago, the term 'mobile health' (mhealth) was coined to
39 describe a subset of eHealth that uses mobile technologies, including advancements in
40 innovative applications also called mhealth apps to address health priorities.⁵¹ Although this
41 term has been in use since 2003, few experts in the field agree on its scope and definition.
42 According to the WHO Global Observatory for eHealth, mhealth is a "medical and public health
43 practice supported by mobile devices (MD), such as mobile phones, patient monitoring devices,
44 personal digital assistants (PDAs), and other wireless devices."⁵² In addition to the MDs
45 mentioned in this definition, smartphones, portable media players, and tablet personal
46 computers (tablet PCs) have essential applications in mhealth.⁵³ With the emergence of
47 smartphones, and reported efficacy and feasibility of telehealth programs, there has been seen a
48 shift from e-health or web-based programs to mhealth apps.⁵⁴
49

50
51 While the use of mHealth apps has been reported to improve health services in many
52 medical conditions for over a decade, evidence on its use in delivering early intervention to
53 support parents of children with ASD is limited.⁵⁵ Studies have reported the use of mobile
54 technology in supporting clinicians and professionals to facilitate the easier identification of
55 autism diagnosis.^{56,57} It has been used to deliver intervention directly to individuals with ASD,
56 for example to deliver CBT, for improving functional communication skills, toilet training, turn-
57 taking, improving sleep routine, as a speech-generating device, for video modeling to train for
58 transitional behaviors in schools, vocational and daily living skills, multiple-step job
59 performance, is documented.^{58,59,60,61,62,63,64} All the apps, which have been documented are
60 delivering a targeted intervention, to be mostly used by individual, and adolescents with ASD.

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5 There is a lack of research reporting apps for parents to be used in a community setting as a
6 part of integrated early intervention.
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8 With an increasing prevalence and improving technological platforms, the reach of early
9 intervention programs can be increased by identifying and reporting these mhealth apps. This
10 review is part of a wider study that focuses on the development, use and feasibility of autism
11 early intervention apps for parents. With limited evidence and very few studies on the usability,
12 feasibility, methodological aspects of key components of such mhealth applications there is a
13 need for this review. Therefore, the objective will be to conduct a scoping review of mHealth
14 applications, their concept, and context of implementation, methodological framework and
15 evidence quality. This paper also aimed to identify gaps in the literature to provide
16 recommendations for future research. Based on the findings and scope of the current evidence,
17 the findings of this review will also lay the foundation for the development of an early
18 intervention app to support parents.
19

20 Following the Joanna Briggs Institute Scoping Review (JBI) Methodology, this scoping
21 review will map the available evidence related to the concept and context of the mhealth app
22 and report any gaps.⁶⁵ To address the research objective, we conducted an initial search of
23 PROSPERO, MEDLINE, the Cochrane Database of Systematic Reviews, and the JBI Evidence
24 Synthesis on 10, Nov 2021. We found no ongoing scoping or systematic reviews on our topic of
25 interest.
26

27 **Review questions:**

- 28
- 29 1) What mhealth apps exist for supporting parents of children with suspected, or under-
30 diagnosis of ASD between 2 to 6 years of age?
 - 31 2) Classification of the mhealth applications using NICE Evidence standards framework for
32 digital health technologies.⁶⁶
 - 33 3) What type of intervention, context, and outcomes are reported, and to summarize them
34 using TiDieR Checklist.⁶⁷
 - 35 4) What theoretical framework has been used and reported for the development of the
36 app?
 - 37 5) What methodology for feasibility, evaluation and implementation has been used?
 - 38 6) Quality and Level of Evidence will be reported using the Evidence-Based Practice (EBP)
39 tool developed by the Center for Evidence-Based Practice.⁶⁸
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42 **Inclusion and exclusion criteria**

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44 The studies will be selected and excluded specifically related to the following Population,
45 Concept, and Context criteria presented in table 1.
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Table 1: Predefined Inclusion and Exclusion criteria for identifying eligible studies

	Inclusion Criteria	Exclusion Criteria
Population/ Participants	Studies that include parents and carer of children with autism spectrum disorder between the ages of 2 years to 6 years will be included. As we are interested in reviewing the apps supporting parents in the early years, therefore the age range has been restricted. In our review, we define parents as biological parents, birth parents, carer or foster parents who have children with ASD between 2 to 6 years.	Studies reporting mhealth apps for children above the age of 6 years or adolescents will be excluded.
Concept	We define mhealth applications (apps) as applications developed for use on mobiles or smartphones, tablets, or I pads that can be easily downloaded from the Play Store or App Store. This review will consider mhealth apps that support parents during early intervention.	Web/internet-based programs or computer-dependent programs will be excluded.
Type of Study	This scoping review will consider quantitative, qualitative, mixed-methods study designs, case reports, grey literature, systematic reviews, clinical trials, and feasibility studies of mhealth applications.	Any study not reporting the use of mhealth will be excluded.
Context	This review will consider studies conducted or implemented for parents of children with ASD to provide support during the early intervention in community settings, school settings, special schools, clinics, hospitals, at home a child development centres. There will be no exclusion based on region, gender, socio-cultural, or language factors.	No restriction on context
Note: § ASD- autism spectrum disorder, mhealth- mobile health, World Health Organization- WHO, personal digital assistants -PDAs		

Methods

Due to the nature of the research question, a scoping review design was chosen to identify what mhealth apps are available for supporting parents with early intervention in children with ASD between 2 to 6 years of age. This scoping review will be conducted per the JBI methodology and the PRISMA extension for scoping reviews (PRISMA-ScR) checklist and flow diagram to identify and report the findings of the scoping review.^{65,69}

Data extraction and findings of the summary table based on TiDieR checklist will be used to summarize the findings as per the review questions. We will use the the Evidence Standards

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5 Framework for Digital Health Technologies developed by National Institute for Health and Care
6 Excellence (NICE) to report the functional classification of the final mhealth apps selected for
7 review.
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9 10 **Search strategy**

11 An initial limited search of MEDLINE and PsycInfo was undertaken to identify keywords, articles
12 on the topic. The text words in the titles, abstracts, and keywords used to describe the articles
13 helped develop a complete search strategy adapted for included databases (see Appendix I).
14

15 The search will include peer-reviewed articles in quantitative, qualitative, mixed-methods study
16 designs, case reports, grey literature, systematic reviews, clinical trials, and feasibility studies. In
17 addition, only studies reporting the use of mhealth apps for parents of children limited to the
18 following age groups between two to six years will be included.
19

20 The NICE Healthcare Databases Advanced Search will search the following databases with
21 MEDLINE, PUBMED, CINAHL, EMBASE, PsycINFO, Cochrane Library, EbscoHost, Sabinet, SAGE
22 Journals, Directory of Open Access Journals, BioMed Central, Scopus, ScienceDirect. Furthermore,
23 grey literature will be searched through Google Scholar, ShodhGanga, JSTOR, CORE, EBSCO, DOAJ,
24 BASE.
25

26 27 28 **Study selection**

29 Following the search, all identified records will be uploaded into a data screening sheet
30 developed on google sheet and searched for duplicates. Following this, titles and abstracts will
31 then be screened by two reviewers independently for assessment against the inclusion criteria.
32 Potentially relevant papers will be retrieved in full and screened against the population,
33 concept, and context to adhere to the inclusion criteria. The screening of the reference lists of
34 articles selected for full-text review will be done for additional papers. The scoping review will
35 record and report reasons for the exclusion of full-text papers that do not meet the inclusion
36 criteria.
37
38

39 40 **Patient and Public Involvement**

41 The review will also consider studies reporting the involvement of parents and carers. We aim
42 to involve parents, carers and guardians of children with ASD in the dissemination of the
43 findings of this review. Based on the findings we will conduct a focus group interview involving
44 parents and carers to inform the development of the app.
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49 50 **Data extraction**

51 Data after review of the full paper will be collated using the data extraction instrument
52 (Appendix II: Data extraction instrument). The table will include specific details about the
53 author of the study, purpose of the study, year, origin, methodology of study including
54 population and sample size, context, concept, and target population, outcome variables with
55 measures, and key findings that relate to the scoping review question, major strengths and
56 limitations, the parental views/ feedbacks and feasibility, the theoretical framework used and
57 reported if any.
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5 A summary of the finding table based on all the included studies will present information as per
6 the TiDier Checklist and will report quality and level of evidence.

7
8 The draft data extraction tool will be modified and revised as necessary while extracting data
9 from each included paper. Modifications will be detailed in the full scoping review. Any
10 disagreements that arise between the reviewers will be resolved through discussion or with a
11 third reviewer. Authors of papers will be contacted to request missing or additional data, where
12 required.

13 14 **Data analysis and presentation**

15
16 Results will be presented visually and descriptively in tables based on the data extraction tool
17 (Appendix II) and a summary of findings for included papers (Appendix III). The discussion and
18 conclusions will also address potential areas for evidence synthesis and identified research
19 gaps.
20

21 22 **Ethics and dissemination:**

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24 Ethical approval is not required; the final scoping review paper will be published in a peer-
25 reviewed journal.
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Appendix I: Search strategy

#MEDLINE (NICE Healthcare Databases Advanced Search). Search conducted on 06 August 2021

Search	The search strategy used in MEDLINE (NICE Healthcare Databases Advanced Search)	Records retrieved
#1	Digit* OR exp TECHNOLOGY/ OR exp ELECTRONICS/ OR exp "DIGITAL TECHNOLOGY"/ OR exp "ANALOG-DIGITAL CONVERSION"/ OR digitisa* OR digitiza* OR onlin* OR technolog* OR computeriz* OR digitaliz* OR cell phone* OR mhealth* OR mobile technology* OR smartphone* OR mHealth apps* OR digital health intervention* OR digital health technology* OR e-health* OR telehealth* OR telemedicine*	2,263,054
#2	paren* OR exp PERSONS/ OR paren*or guardi* OR famil* OR Parent training* OR psychoeducation* OR parent education* OR Parent Education Programmes* OR Parent Education Groups* OR Parent Psychoeducation* OR Parent Education Training*	178,797
#3	"AUTISM SPECTRUM DISORDER"/ OR "AUTISTIC DISORDER"/ OR "PDD"/ OR "ASPERGER"/ OR "NEURODIS"/ OR "AUTISM SPECTRUM CONDITIONS"/ OR "AUTISTIC SPECTRUM CONDITIONS"/ OR "AUTISM"/ OR "COMPLEX AUTISTIC SPECTRUM"/ OR "SOCIAL COMMUNICATION DISORDERS"/ OR "NEURODISABILITY"/ OR "AUTISTIC DISORDER"/ OR "AUTISTIC CONDITION"/ OR "ASPERGER SYNDROME"/ OR "SPECTRUM"	461,50
#4	CHILD HEALTH SERVICES"/ OR "PREVENTIVE HEALTH SERVICES"/ OR "EARLY INTERVENTION, EDUCATIONAL"	88604
#5	COMBINED- (1 AND 2 AND 3 AND 4)	879

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Appendix II: Data extraction instrument

<i>Author (s) (Year)</i>	<i>Purpose of study/paper</i>	<i>Origin</i>	<i>Population and sample size</i>	<i>Methodology</i>	<i>Context</i>	<i>Concept</i>	<i>Classification as per the NICE Evidence standards framework for digital health technologies</i>	<i>Outcome variables with Measures</i>	<i>Key findings that relate to the scoping review question</i>	<i>Major strengths and limitations</i>	<i>Parental views/feedbacks</i>	<i>Theoretical framework</i>

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Appendix III: Summary of Finding Table reporting mHealth app-based Interventions as per TIDieR Checklist

	BRIEF NAME	WHY	WHAT		WHO PROVIDED	HOW	WHERE	WHEN and HOW	TAILORING	MODIFICATIONS	HOW WELL		Quality & Level of Evidence
Title	1. Provide the name or a phrase that describes the intervention.	2. Describe any rationale, theory, or goal of the elements essential to the intervention	3. Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	4: Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	5. For each category of intervention provider (e.g., psychologist, nursing assistant), describe their expertise, background and any specific training given.	6. Describe the modes of delivery (e.g., face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	7. Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	8. Describe the number of times the intervention was delivered and over what period including the number of sessions, their schedule, and their duration, intensity or dose.	9. If the intervention was planned to be personalized, titrated, or adapted, then describe what, why, when, and how.	10. If the intervention was modified during the study, describe the changes what, why, when, and how).	11. Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	

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