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Design, development and pilot  
evaluation of *POD Adventures*, a digital  
game-based intervention to improve  
adolescent mental health in schools in  
India

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Submitted in total fulfilment of the requirements of the degree of Doctor of Philosophy

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School of Psychology

University of Sussex

## Declaration

I, Pattie P Gonsalves, declare that my thesis is my own work. The research reported in this thesis was conducted in accordance with the principles for the ethical treatment of human participants, and due acknowledgments have been made in text to all the materials used. The thesis conforms to an ‘article format’ in which the middle chapters consist of discrete articles written in a style that is appropriate for publication in peer-reviewed journals in the field. The first and final chapters present synthetic overviews and discussions of the field and the research undertaken. Portions of the thesis have also been published in the journals listed below.

Chapter 2 is published in *Frontiers in Public Health* as:

Gonsalves, P.P., Hodgson, E., Kumar, A., Aurora, T., Chandak, Y., Sharma, R.,  
\*Michelson, D. and \*Patel, V., [\*joint senior authors] (2019). Design and Development  
of the “POD Adventures” Smartphone Game: A Blended Problem-Solving Intervention  
for Adolescent Mental Health in India. *Frontiers in Public Health*, 7. doi:  
10.3389/fpubh.2019.00238

The author contributions are as follows:

- Pattie P Gonsalves (PhD candidate) was responsible for leading study conception and design; preparing data collection tools; directing the local research team; data collection via focus-group discussion, co-design workshops and user-testing sessions with adolescents in New Delhi and Goa; data analysis; and writing of the manuscript.
- Eleanor Hodgson and Rhea Sharma were responsible for some aspects of data collection, data analysis and providing feedback on the manuscript.

- Tiara Aurora, Yash Chandak and Avinash Kumar were collectively responsible for technology design.
- Dr Daniel Michelson and Prof Vikram Patel were responsible for providing feedback on study design, data analysis and corrections to the manuscript.

Chapter 3 is published in *Evidence Based Mental Health* as:

Gonsalves, P.P., Hodgson, E., Bhat, B., Sharma, R., Jambhale, A., \*Michelson, D. and \*Patel, V. [\*joint senior authors] (2020). App-based guided problem-solving intervention for adolescent mental health: a pilot cohort study in Indian schools. *Evidence Based Mental Health*, 24(1), 11-18. doi: 10.1136/ebmental-2020-300194

The author contributions are as follows:

- Pattie P Gonsalves (PhD candidate) was responsible for leading study conception and design; preparing the study protocol; directing and training the local research team; conducting qualitative interviews with study participants; data analysis; and writing of the manuscript.
- Eleanor Hodgson, Rhea Sharma and Abhijeet Jambhale were responsible for training and supervising lay counsellors and field researchers; and contributing to qualitative data analysis.
- Bhargav Bhat was responsible for data management and data analysis.
- Dr Daniel Michelson and Prof Vikram Patel were responsible for providing feedback on study design, data analysis and corrections to the manuscript.

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The author contributions are as follows:

- Pattie P Gonsalves (PhD candidate) was responsible for leading study conception and design; preparing the trial protocol; directing and training the local research team; data analysis; and writing of the manuscripts.
- Rhea Sharma and Abhijeet Jambhale were responsible for training and supervising lay counsellors and field researchers; and contributing to qualitative data analysis.
- Bhargav Bhat was responsible for data management and data analysis.
- Prof Christopher Fairburn, Prof Pim Cuijpers, Dr Kate Cavanagh, Eleanor Hodgson and Dr Helen Weiss were responsible for providing feedback on study design and data analysis.
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The author contributions are as follows:

- Pattie P Gonsalves (PhD candidate) was responsible for leading study conception and design; preparing the trial protocol; directing and training the local research team; data analysis; and writing of the manuscript.
- Rhea Sharma, Abhijeet Jambhale, Mamta Verma and Bindiya Chodankar were responsible for intervention delivery.
- Bhargav Bhat was responsible for data management and data analysis.
- Prof Christopher Fairburn, Prof Pim Cuijpers, Dr Kate Cavanagh, Eleanor Hodgson, Baptiste Leurent and Dr Helen Weiss were responsible for providing feedback on study design and data analysis.
- Dr Daniel Michelson and Prof Vikram Patel were responsible for providing feedback on study design and data analysis.

I hereby declare that this thesis has not been and will not be, submitted in whole or in part to another university for the award of any other degree.

Signature.....

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## **Abstract**

Mental disorders are a leading cause of disability among adolescents worldwide. Despite growing evidence for effectiveness psychosocial interventions, most adolescents do not receive appropriate mental health support, especially in low-and-middle-income countries (LMICs). Digital mental health interventions are increasingly being promoted as an important platform to deliver and scale up mental health care for adolescents with the potential to increase reach and reduce stigma and costs as compared with clinic-based service models, especially in low-resource settings. The present thesis incorporated three studies aimed at developing and evaluating ‘POD Adventures’, a smartphone-delivered digital intervention for common adolescent mental health problems in India.

Study 1 comprised participatory qualitative research (N=118 adolescents; N=8 service providers) intended to co-design a game-based problem-solving intervention for school-going adolescents with or at risk of experiencing anxiety, depression and/or conduct difficulties. Results informed the specifications of ‘POD Adventures’ as an open-access, smartphone-enabled, low-intensity intervention for adolescents with a felt need for psychological support. Delivery was endorsed in a guided format, i.e., the POD Adventures app accompanied by brief lay counsellor guidance.

Study 2 used a mixed-methods pre-post cohort design (N=248) to evaluate the feasibility and acceptability of the POD Adventures intervention, and to explore the effects of the intervention on self-reported mental health symptoms, prioritised problems, stress, and well-being. Results showed high completion and satisfaction rates and that the intervention was associated with large improvements in problem severity and mental health symptom severity. Findings also showed

that POD Adventures was feasible to deliver with guidance from lay counsellors and that the participants were satisfied with the guidance provided.

Study 3 was originally planned as a full-scale randomised controlled trial (RCT) but was modified due to local COVID-19 school closures. The modified study comprised a pilot feasibility RCT of POD Adventures (N=11) when remotely delivered with telephone guidance from counsellors. The study aimed to assess whether the feasibility and acceptability of POD Adventures would be replicated when delivered online with remote telephone-based support. The study also aimed to generate preliminary effect size estimates for use in designing a full-scale trial. Despite modifications made to conduct the study online, this format of intervention delivery was not feasible in the study context. It was concluded that the biggest barriers may have included difficulties accessing the online research procedures, the remotely delivered intervention delivery or a combination of both, which may have been exacerbated by the ongoing COVID-19 pandemic conditions at the time.

Overall, results across the three studies illustrate the role and opportunity that context-specific digital interventions offer in providing early intervention support to school-going adolescents with a felt need for psychological support in low-resource settings.

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## **LIST OF ABBREVIATIONS**

CSQ-8: Client Satisfaction Questionnaire

DMHI: Digital mental health intervention

DSMC: Data and Safety Monitoring Committee

ICMR: Indian Council of Medical Research

LMIC: Low-and-middle-income country

PRIDE: PremIum for aDoLEscents research programme in India

PSS: Perceived Stress Scale

RCADS-25: Revised Child Anxiety and Depression Scale–Short Version

RCT: Randomised controlled trial

SD: Standard deviation

SDQ: Strengths and Difficulties Questionnaire

SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials

SWEMWBS: Short Warwick-Edinburgh Mental Well-Being Scale

TSC: Trial Steering Committee

YTP: Youth Top Problems

## 1. INTRODUCTION

### 1.1. Introductory remarks

Mental disorders are a leading cause of disability among adolescents worldwide [1]. More than half of all individuals living with mental health problems present their initial symptoms by adolescence [2]. Taken together, the most common mental health problems in early life, namely anxiety, depression and conduct difficulties, account for over 75% of the global burden of adolescent mental disorders [3]. Although there is a growing body of evidence for effective psychosocial interventions, most adolescents are unable to access appropriate mental health support [4]. The treatment gap is particularly wide in low- and middle-income countries (LMICs), which are home to 90% of the world's youth population but contain only a small fraction of the world's mental health service resources [1, 5-7].

Evidence from diverse low-resource settings shows that adolescents adopt new technologies and use mobile devices and the internet more frequently than individuals from older age groups, including for the purpose of accessing health-related information [8]. In this regard, digital technologies are increasingly being promoted as an important platform for delivering and scaling up mental healthcare for young people [9, 10] with the potential to increase reach, reduce stigma and lower costs as compared with conventional clinic-based service models [11-13].

Notwithstanding varied access and gaps in connectivity, especially in rural areas, digital technologies offer unparalleled opportunities for transforming the delivery and use of mental health interventions in low-resource settings [14, 15]. Recent research on digital mental health interventions for adolescents highlights promising findings for feasibility, acceptability, and engagement [16-20]. Most recently, COVID-19 disruptions have accelerated the transition to

online delivery of mental health care globally [12, 21]. The gap between the potential that these interventions offer and their reach and uptake, particularly in LMICs, continues to be a critical challenge that requires investment and rigorous research [22].

Mental health interventions that use ‘gamified’ approaches have emerged more recently. Often referred to as ‘serious games’, these game-based interventions variously use game mechanics and aesthetics to change experience or behaviour patterns, and as therapeutic tools in treating anxiety, depression, autism, post-traumatic stress disorder (PTSD), attention-deficit/hyperactivity disorder (ADHD) and alcohol use [13, 16, 23]. Game-based interventions have shown promising evidence for promoting improved memory, attention span, problem-solving, emotion management and socialization, while supporting behaviour change [23]. However, robust research on uptake, engagement and effectiveness of such interventions is scarce, especially in LMICs [24-26].

## **1.2. Thesis overview**

The overall aim of this thesis was to develop and explore the acceptability, feasibility and potential impacts of ‘POD Adventures’, a context-specific digital intervention for common adolescent mental health problems in India. This thesis is presented with four manuscripts (three accepted for publication and the fourth one under review at the time of this thesis submission), corresponding to three studies that incorporate a combination of quantitative and qualitative methods. Data collection for Study 1 was completed in April 2019 prior to the PhD registration start date, while Study 2 and Study 3 were conducted entirely during the period after registration from September 2019 to August 2022.

Study 1 comprised participatory qualitative research activities conducted over 18 months from July 2017 - April 2019. These were intended to shape the development of ‘POD Adventures’ as a smartphone-enabled low-intensity transdiagnostic intervention for school-going adolescents with a felt need for mental health support and without a requirement to meet clinical case thresholds for eligibility. Study 1 has been published as a journal article in *Frontiers in Public Health* and the accepted manuscript is presented in Chapter 2.

Study 2 was conducted from July 2019 to March 2020. The aims were to evaluate the feasibility and acceptability of POD Adventures and to explore the impacts of the intervention on self-reported mental health symptoms, prioritised problems, stress and well-being in a sample of adolescents with a felt need for psychological support. The study used a mixed-methods pre-post cohort design. Participants were self-referred from two coeducational government-aided secondary schools in Goa, India. The intervention was delivered in two formats: ‘mixed’ (comprising individual and small group sessions) and ‘group’ (small group sessions only). Study 2 has been published as a journal article in *Evidence Based Mental Health* and the accepted manuscript is presented in Chapter 3.

Study 3 was originally planned as a full-scale randomised controlled trial designed to evaluate the effectiveness of POD Adventures. However, the advent of the COVID-19 pandemic required protocol modifications to fit around extended school closures, which were initiated in India from March 2020 and remained in place for nearly two years. The aims of Study 3 were thus modified to assess whether the feasibility and acceptability of POD Adventures would be replicated when delivered online and with remote telephone-based support. The intervention maintained all the

elements of the pre-existing digital specification, although modifications were made for internet-based recruitment and remotely delivered telephone guidance from counsellors. Study 3 was conducted over December 2020 - May 2021. The study protocol for Study 3 has been published as a journal article in *Journal of Medical Internet Research (JMIR) Protocols* and the accepted manuscript is presented in Chapter 4. The results of Study 3 have been written up in a journal manuscript, which is currently under review by *BJPsych Open*. The submitted manuscript is presented in Chapter 5. Finally, Chapter 6 provides an integrative discussion about the findings and implications of the current thesis.

The remainder of the current chapter (Chapter 1) introduces the significance of adolescent mental health with a focus on LMICs and the context in India where this thesis is situated. It also provides a literature review of digital mental health interventions, research on their impacts from LMIC settings and considerations for co-designing interventions with adolescents. Finally, the chapter provides a high-level description of the methods used in the three studies. It also includes further details about the candidate's contribution to the thesis.

### **1.3. Why focus on adolescents?**

#### **1.3.1. Why is adolescent mental health so important?**

Adolescents are defined as individuals aged between 10 and 19 years [27, 28] and comprise a quarter of the world's population [29]. The period of adolescence is characterised by dynamic brain development in which a young person's interaction with their social environment shapes the capabilities they take forward into adult life [30]. Adolescence is a crucial developmental phase, particularly for acquiring emotional and cognitive abilities, educational and vocational

skills, financial independence, civic engagement and the formation of lifelong relationships. Achieving these developmental milestones determines the lifelong health trajectory of a young person [31].

Promoting adolescent wellbeing is key to a sustainable future and “the best chance to achieve radical change for a prosperous, healthy and sustainable world” [32]. The transition from childhood to adolescence has become more complex than ever before [33]. On the one hand, population mobility, global communications, and economic development are setting the course for this generation. On the other hand, major threats to adolescent health and wellbeing are posed by negative trends promoting unhealthy lifestyles, the crisis of youth unemployment, reduced family stability, climate change, armed conflict, and mass migration [31].

Mental health problems now account for over a third of the total burden of disease in adolescents, with depressive, anxiety and conduct disorders together accounting for over 75% of this burden [3, 27, 29, 34]. Most mental disorders first emerge by the age of 14 and it is estimated that globally one in seven (14%) 10–19-year-olds experience mental health conditions. Further, most mental health problems remain largely unrecognised and untreated [20, 35, 36]. Evidence shows that most adolescents (up to 90%) who have a diagnosable mental disorder do not seek help or receive evidence-based care in a timely manner. This means that much of the burden of mental illness, while preventable, is not addressed and can result in chronic, persistent, and disabling illness across the productive decades of adult life, causing enormous suffering and weakening economies and societies [33, 35, 37].

The more risk factors to which adolescents are exposed, the greater the potential impact on their mental health. The World Health Organisation (WHO) has listed a wide range of stressors that contribute to mental health problems during adolescence. These include exposure to adversity, pressures to conform with peers and discrimination based on identity. Media influence and gender norms can exacerbate the disparity between an adolescent's lived reality and their perceptions or aspirations for the future [34]. Other stressors include the quality of home life and relationships with peers. Violence (especially sexual violence and bullying), harsh parenting and socioeconomic problems such as low parental education or low household income are also recognized risks to mental health [38]. These risks are compounded further for adolescents who are living in humanitarian and fragile settings; adolescents with chronic illness, neurodevelopmental disorders, pregnant adolescents, adolescent parents, or those in early or forced marriages; orphans; and adolescents from minority ethnic or sexual backgrounds or other discriminated groups are at greater risk [34].

Poor mental health in adolescence increases the risk of poverty, long-term social disability, and other adverse economic outcomes in adulthood [39-41]. Compared to their peers, young people with mental health problems are nearly twice as likely to not be in education, employment, or training, thereby reducing the workforce [42]. A declining youth workforce is likely to increase the burden on the working population, raise expenditure on long-term health care and reduce economic growth [33, 43]. The World Economic Forum has estimated that by 2030 mental ill-health alone would account for a loss of US\$16 trillion in global economic output [44].

### **1.3.2. Adolescent mental health in low-and-middle-income countries (LMICs)**

Mental health is inequitably distributed both in terms of resources and research in LMICs.

LMICs are home to 90% of the global population of young people aged 10-24 years [1]. Poverty, armed conflict, violence, and environmental stressors and disasters tend to be endemic in these countries and contribute to significant psychiatric morbidity, particularly depression, anxiety, and conduct-related difficulties. Availability and access to adolescent mental health services are grossly inadequate [45, 46]. LMICs are characterised by low rates of recognition of mental health disorders and lack data on the prevalence of mental disorders [47-50]. Further, LMICs are culturally, socio-economically, and linguistically diverse regions making it very challenging to identify strategies that are culturally sensitive and contextually relevant [51, 52].

Numerous barriers exist for both the supply and demand of mental health care in LMICs. In terms of resources, LMICs tend to be characterised by constraints such as inadequate funding and/or limited spending on mental health, a paucity of mental health care workers and poorly integrated health systems which contribute to inaccessible mental health care especially for adolescents [7, 49, 51, 53, 54]. Zhou et al. in a recent review of child and adolescent mental health policies in LMICs identified numerous challenges related to policy development and implementation in these countries. These included poor public awareness and low political willingness, stigma against mental health, cultural biases against children and adolescents, lack of child and adolescent mental health data, shortage of resources and international support resulting in decreased local responsibility and unsustainable programmes [55]. As a result of these challenges fewer people seek professional help in LMICs as compared to high-income settings and where they do, there are long delays with variable pathways to accessing care [56].



Adolescent mental health advocates maintain that in no other mental health area is the treatment gap as acute as it is in child and adolescent mental health [52, 54, 57], and that this area urgently requires prioritisation for scaling up services [58, 59].

Finally, there is a real paucity of research on effective interventions for adolescents in LMIC settings. Very few mental health trials carried out worldwide are carried out in LMICs and even fewer address adolescent mental health needs. For example, out of all the mental health trials conducted worldwide by 2007, only about one tenth (~1521 studies) had been conducted in LMICs and of these fewer than 1% addressed child or adolescent mental health problems. This means that less than 0.1% of global trials in mental health specifically addressed the needs of adolescents in LMICs [60, 61].

### **1.3.3. Context in India**

India is home to the world's largest population adolescents, estimated at over 250 million, placing the country at the centre of global efforts to improve mental health care for this group [1]. India's most recent National Mental Health Survey (2015–2016) reported a 7% prevalence of psychiatric disorders among 13–17-year-olds [62] and that psychiatric disorders among school-going adolescents were more than 23% [63]. India also has the highest youth suicide rate globally, and suicide is the leading cause of mortality for 15–29-year-olds [40, 64]. The overall treatment gap for mental health disorders for the general population is 90% [62], and this gap is likely to be as high as 99% for children and adolescents [65].

A review by Aggarwal et. al. on the evolution of adolescent mental health in India over the past decade identified a range of socioeconomic factors that appear to be contributing to a rise in the

prevalence of behavioural and emotional disorders among adolescents. These factors include rapid urbanisation, gender-related discrimination, academic pressures, parental conflict and strained familial relationships, school absenteeism and dropout [66]. Unfortunately, most research on mental health of Indian adolescents provides little by way of in-depth exploration of key stressors, impacts or mitigating strategies across different ages, genders or localities. Additionally, most studies are based on small and non-representative samples [67].

In 2014 India recognised mental health care provision as part of integrated primary care through the National Mental Health Programme (NHMP) [68, 69] and national adolescent health initiative (‘Rashtriya Kishor Swasthya Karyakram’) (RKSK) [70] which includes a mental health priority area [71]. Despite these policy developments, there continues to be a huge gap in addressing the mental health needs of adolescents and there is no standalone policy for child and adolescent mental health [72].

Findings from a recent scoping review of mental health prevention and treatment programmes in India found that most interventions were based in schools. Specifically, coping skills and resilience-focused curricula showed improvements in depressive symptoms, problem solving, academic stress, and overall well-being. The authors recommended school-based programmes as a helpful entry point and highlighted the paucity of digital interventions addressing adolescents [73].

#### **1.3.4. The role of schools**

Early intervention is now widely recognised as a key principle of public mental health approaches, with schools offering a key setting [33, 57, 74]. A recent review of comprehensive

school mental health programmes by Hoover et. al., showed that early intervention efforts (i.e., strategies designed to address mental health concerns for students experiencing mild distress or functional impairment or those at risk for a given problem) delivered in schools can reduce mental health symptoms in the short and longer term. There is also mounting evidence of positive impacts on academic indicators, including test scores, attendance, and grades [75].

In LMIC settings in particular, schools may provide one of the only platforms to reach the significant number of adolescents experiencing mental health problems [53, 57, 76]. In India, school-based mental health programmes for adolescents have been implemented on a limited and fragmented scale [67]. Most interventions have been conducted in urban private schools with little replication of findings in a different setting (e.g., semi-urban/rural settings, government schools, etc.) making it difficult to generalise findings [66]. Where available, school-mental health programmes have focused on health-promotion or school environments and fostering life skills with limited evidence on selective interventions for help-seeking adolescents [6, 73, 76-78].

### **1.3.5. Impacts of the COVID-19 pandemic**

The COVID-19 pandemic disproportionately impacted mental health outcomes for adolescents [79]. Many studies have shown that adolescents of varying backgrounds experienced higher rates of anxiety, depression and stress during the pandemic [80-83]. Lockdowns and prolonged school closures have been highlighted as key factors that have impacted mental health of adolescents globally. Mental health interventions that would have otherwise been delivered through school counsellors or student health services were disrupted or completely halted because of widespread school closures [84]. In this regard, intervention foci such as problem-solving skills, stigma

reduction and resilience building have been recommended in the context of ‘building back better’ after the pandemic, especially via educational settings [6].

#### **1.4. Digital mental health interventions (DMHIs) for adolescents**

##### **1.4.1. Introduction**

Digital mental health interventions (DMHIs) provide new opportunities for delivering mental health support to adolescents at scale [85]. Emerging economies are now characterised by rapid growth of smartphone adoption, especially among younger generations, although this growth is often uneven and skewed by age and gender [86]. India, for example, accounts for one-fifth of global youth mobile phone ownership but access to phones and the internet is highly gendered with 71% of males who own mobile devices as compared with 38% females [87]. Despite access gaps, research from LMICs shows that adolescents adopt new technologies and use mobile devices and the internet more frequently than individuals from older age groups, including for the purpose of accessing health-related information [14]. Digital technology platforms offer new avenues to reach vulnerable adolescents at scale and potentially overcome many of the barriers that exist around conventional service provision [14, 88]. DMHIs have received particular attention in the context of the COVID-19 pandemic due to their ability to provide remotely delivered alternatives to face-to-face treatments. Studies have shown their potential to offer timely and effective solutions for treatment, managing symptoms and preventing relapse in a variety of delivery modes, including using mobile apps with guidance, text messaging, moderated forums, web-based or computer-based programmes [12, 89].

### 1.4.2. Types of DMHIs

DMHIs can vary in design (for example, website-based or delivered via smartphone applications), and include a range of digital elements (e.g., games, online activities and chatbots) which help personalise and better meet the range of needs and preferences of users [90, 91]. Some DMHIs are fully automated and delivered without any human support (i.e., self-guided or unguided) while others may be ‘blended’ (i.e., accompanied by human support provided by a healthcare provider or other professional in ‘real time’ (for example, therapy provided face-to-face or telephone or via videoconferencing)) [91-95].

Banos et. al., summarised DMHIs into three groups: (1) internet-based interventions (IBIs), (2) smartphone applications and (3) mixed reality. Internet-based interventions (IBIs) are the most widely researched and refer to therapeutic programmes with specific objectives which are conveyed through modules or lessons and delivered via the internet by computer or mobile phone [90]. Studies show that IBIs can be as effective as face-to-face therapy for a range of mental disorders and can also prevent psychological problems [96, 97]. The second category, smartphone apps, are designed for smartphones and other wearable devices. There are more than 10,000 mental health apps available for public download [98] which cater to improving well-being and mental health and are available for a wide range of uses including prevention, diagnosis, treatment, and relapse prevention [8, 99]. The third category, mixed reality, refers to sophisticated tools such as virtual reality and augmented reality which allow high levels of interactivity, often in real-time, and combine the real world with virtual elements. Although initially designed for the treatment of phobias, the use of virtual reality in phobic disorders has expanded to other mental health disorders such as posttraumatic stress disorder, substance-

related disorders, eating disorders, psychosis and autism spectrum disorder showing successful results [100].

Another important and emerging category of digital interventions are ‘serious games’ and those using gamified approaches [101, 102]. Systematic reviews highlight that game-based interventions can expand the reach of online mental health programmes to those who might not otherwise use them. They can improve engagement and motivation through gaming features and may be effective for reducing mental health symptoms, especially for adolescents [17, 23, 101].

Reviews of DMHIs including game based DMHIs for adolescents have shown that there is more support for technologies for depression and anxiety than for other problems and across the spectrum of symptom severity [13, 16, 23, 103].

#### **1.4.3. Co-design of DMHIs**

Guidance on development of complex health interventions, especially for digital health [104, 105] emphasises the importance of user input at each stage of development [106, 107]. ‘Co-design’ in the context of DMHIs has been defined as the active collaboration between researchers, designers, developers, and users to develop and evaluate interventions. Co-design necessitates a shift from expert-led development work where interventions are designed ‘for’ users, to a user-centred approach which seeks to understand and apply lived experience to understand which problems need to be addressed. It is distinct from co-creation which typically refers to any act of collective creativity. Co-design involves more than participants simply ‘saying’ what they want from mental health services or interventions but refers to the joint exploration of needs and ‘making’ of solutions. Most co-design processes begin with

understanding the current needs and behaviours of users, developing concepts that are tested in simple, fast, and low-cost ways before being improved through an iterative process [108, 109].

Co-design is understood alongside the growing acknowledgement that adolescents have expert knowledge of their own lives and that their participation in intervention design and delivery. Co-design methods have been highlighted as essential to ensuring that interventions designed are accessible, appropriate, and effective [18, 110-112].

In terms of DMHI design and development, systematic reviews from both high- and low-income settings recommend the involvement of stakeholders such as prospective users, peers, family members and frontline workers to ensure that new interventions are contextually relevant and to facilitate integration into existing community mental health services [91, 113-115]. Jones et. al., in a practitioner review of co-design of digital mental health technologies with children and young people [18] describe how co-design can involve all aspects of the digital intervention such as its content, look and feel, accessibility, usability, data management or security and integration and implementation into users' everyday lives. They identify a variety of interactive methods such as 'design studios' (intensive development sessions) [116]; 'design charrettes' (large meetings to storyboard or sketch ideas) [109]; 'design jams' (small sessions to develop multiple iterations of user experiences) [109]; 'hackathons' (digital events with large groups to propose ideas for new technologies) [117]; writing, storytelling, creating videos and animations or physical products [101]; and focus-group discussions or individual interviews to identify the breadth of issues and new ideas. To further enhance the co-design process, rapid iterative testing

has been suggested as a way of helping move research from the ‘lab’ to different settings more quickly [104, 118-120].

#### **1.4.4. Evidence for DMHIs**

##### ***1.4.4.1. Impacts***

Many studies have documented the benefits of DMHIs in improving a range of mental health outcomes for adolescents including anxiety, depression, stress, eating disorders, psychosis, attention-deficit/hyperactivity disorder, autism spectrum disorder, suicide prevention and sleep problems [24]. Cognitive behavioural therapy (CBT) interventions have shown particularly promising findings [121, 122] which have even been included in routine care settings in high-income countries. For example, in 2019, the UK’s National Institute for Health and Care Excellence (NICE) guidelines recommended digital cognitive behavioural therapy (CBT) as a first-line treatment for mild depression in children and young people [123]. Three exemplar CBT technologies suggested by NICE were game-based DMHIs, namely SPARX [124], Stressbusters [125] and Grasp the Opportunity [126].

A recent umbrella review by Lehtimäki et. al., of 18 systematic reviews and meta-analyses of DMHIs for adolescents and youth found evidence on the benefits of DMHIs for anxiety, depression and stress when compared to nonactive controls (i.e., groups to which no treatment was provided or those put on a waitlist). Most studies showed an improvement in mental health outcomes (e.g., symptoms, disorders) at least in the short term, in those using the DMHIs (compared with controls) or the technologies performed at least as well as face-to-face approaches [24]. Evidence of long-term effects of DMHIs on adolescent mental health outcomes



is presently limited [16, 85, 127-131]. A key criticism of many studies of DMHIs is that potential harms or adverse effects of DMHIs are largely unaddressed [23, 91].

Evidence related to the use of DMHIs for adolescents in LMIC settings is scarce [19, 24]. For example, a recent systematic review of the effectiveness of DMHIs for children and young people found 83 studies of which only one study was from an LMIC country [19]. There is currently no systematic review for DMHIs for adolescents in LMIC settings.

#### ***1.4.4.2. Design elements of DMHIs***

Studies of DMHIs have highlighted specific design elements which are valuable for adolescents. These include privacy, safety, and discretion [16, 121, 132]; anonymity [16, 132]; credibility of design, visual appearance, and information and resources provided [13, 121, 132]; interactive tools [13, 121] and concise and interesting information [13, 16, 121, 132]. Interventions should be aesthetically attractive [13, 132]; provide reminders to use [121]; allow for personalization [121] and should have relatable situations, characters, or avatars [13]. The need to reflect local and cultural differences and needs has also been highlighted as an importance design consideration [13, 126, 133, 134]. For example, SPARX was created by a game company in New Zealand to treat mild-to-moderate depression in young people, including Māori youth who are an important indigenous group within the population. The development work was led by a Māori director and included co-design work facilitated by a Māori clinician with local adolescents and overseen by a Kaumātua (respected Māori elder) as well as a cultural advisory group. The Māori designs from the SPARX game were found to be appropriate and useful, and the ability to customize the SPARX characters with Māori designs appeared to enhance cultural identity for young users [133].

#### **1.4.4.3. *Delivery of DMHIs***

Studies of DMHIs have shown that interventions may only be of clinical significance when completed in a supervised settings such as schools or clinics. Further, several reviews and meta-analyses have demonstrated that DMHIs with an in-person element (for example, a therapist, parent and peer) were more effective than those that were fully automatized or self-administered. Multiple reviews have reported that participants found it useful to be in contact with professionals [13, 16, 121, 122]. In-person support has also been associated with higher intervention adherence and lower dropout rates in studies [16, 85].

#### **1.4.5. Gaps in the literature**

Although a growing body of evidence suggests that DMHIs may be effective and useful tools for providing psychological support to adolescents, several limitations must be considered.

First, although many DMHIs show promising results for feasibility and acceptability, there are few that have been tested using methodologically robust RCTs [13, 14, 16, 23, 122, 135]. Even adolescent-focused interventions that are recommended by NICE have limited evidence [125]. Relatedly, an important consideration is the unprecedented increase in the number of available commercial mental health apps and technologies which have not been accompanied by high-quality evidence to support their use [135-137]. For example, while there are more than 10,000 mental health apps available for download in commercial app stores, a small minority have been evaluated in published studies [138-140].

Second, the vast majority of DMHIs studied, including those focused on adolescents, have been developed in high-income contexts which may bias study conclusions and limit their

generalizability to LMICs [14, 19, 24-26]. Further, there are few studies on cultural adaptations of DMHIs in LMIC settings [141].

Third, engagement is a concern, varying across studies, and is usually lower in real-world settings as compared with research contexts [142]. For example, a significant percentage of users (20-50% or higher) stop using DMHIs or drop out of treatment programmes before completing them [13, 143-145]. A review of 41 DMHIs for anxiety and depression for adolescents and young people by Garrido et. al., found that DMHIs often failed to engage participants due to non-appealing aesthetic interfaces, frequent technical glitches or material that seemed too juvenile [13].

Fourth, there is limited evidence that DMHIs can be successfully implemented outside the research context in routine healthcare settings, even in higher income settings [104, 146].

Relatedly, a key difficulty identified in Mohr et. al., is the assumption that technologies themselves are the main agent of change during DMHI design, while paying less attention to the ecosystem and context surrounding that technology such as therapeutic support. To this end, they suggest that following a robust co-design approach allows for assumptions to be tested early and for stakeholders' expertise to be incorporated in the domains in which they will use the DMHI in practice [104, 147].

Fifth, there is a lack of regulation of DMHIs within the commercial sector [148] raising ethical questions with regards to how data are collected and used [149]. Further, there are risks that

DMHIs may even cause harm, particularly in the absence of rigorous evaluation or data on safety by independent research groups [91].

Finally, significant gaps in internet and mobile phone access continue to persist in many LMIC regions, especially for adolescents [150, 151]. For example, findings from the implementation of remote learning approaches in schools in LMICs during COVID-19 showed even lower rates of smartphone and internet access for adolescents than previously thought. These ranged from 2-6% of adolescents with access at home [152, 153].

## **1.5. About the current thesis**

### **1.5.1. Research context**

This thesis was funded by a School of Psychology Scholarship awarded to the PhD Candidate, Pattie Pramila Gonsalves. The included studies involved data collection that was nested within the Wellcome Trust-funded PRIDE (Premium for aDolEscents) programme in India (Principal Investigator: Prof. Vikram Patel, Harvard Medical School; Co-Investigator and PhD Supervisor: Dr Daniel Michelson, University of Sussex). PRIDE is the largest adolescent mental health research programme ever undertaken in a developing country, and was implemented from 2016-2022 by Sangath, an Indian mental health NGO, at secondary school sites in New Delhi and Goa. PRIDE aimed to develop and evaluate a suite of transdiagnostic interventions arranged around a stepped-care model and targeting common mental health problems among urban school-going adolescents in India.

PRIDE incorporated three key design innovations: (i) a core set of practice elements which were systematically identified by matching evidence-based practices to common adolescent problems in the local context [154]; (ii) delivery by lay counsellors in line with evidence for the cost-effectiveness of task sharing in mental health care in diverse low-resource settings [114]; and (iii) stepped care architecture [155] for further resource efficiency such that a broadly applicable problem-solving intervention ('Step 1') was delivered as a brief first-line intervention, followed by a more tailored, higher-intensity second step ('Step 2') for non-responders [156].

Initially PRIDE developed and evaluated Step 1, a brief first-line counsellor-led problem-solving intervention in secondary schools across New Delhi and Goa in India [157-159]. This intervention was accompanied by structured classroom-based sensitisation activities to generate awareness and referrals [160]. A randomised controlled trial compared the counsellor-led problem-solving intervention with problem-solving booklets alone and found that the counsellor-led format had significant effects on adolescents' prioritised problems at the primary endpoint at 6 weeks. No evidence was found that the two formats differed on outcomes related to mental health symptom severity and similar reductions were observed within both trial arms at 6 weeks. A 12-month follow-up study showed small but sustained effects on multiple outcome domains, including mental health symptoms, adolescent's prioritised problems, functional impairment and perceived stress. These findings are noteworthy as most of the existing evidence for longer-term effectiveness of adolescent mental health interventions is based on lengthy, disorder-specific treatment protocols and intensive interventions delivered by specialists. The findings suggest that this intervention has strong potential for scale up in India and potentially, in other low-resource settings [158].

PRIDE studies revealed that there was a high demand for psychological support among students, even though most self-referred students did not meet clinical thresholds for mental disorders and therefore did not meet intervention eligibility criteria. This prompted questions about optimal delivery formats for first-line problem-solving and other options for catering to this wider group such as through the deployment of a DMHI. Considering these questions, ‘POD Adventures’ was initially conceptualised as a digitally delivered, open-access, early intervention to promote adaptive coping and to mitigate risks for developing more severe and socially disabling mental health problems in the longer term. It aimed to enhance a student’s ability to cope with stressors and thereby prevent or improve mental health problems [161], in line with stress-coping theory [162]. In terms of delivery, POD Adventures adopted a blended approach that deployed low-intensity non-specialist support in tandem with a smartphone-delivered game, potentially reducing the resource demands of conventional face-to-face counselling.

### **1.5.2. The current thesis**

This thesis is specifically concerned with the acceptability, feasibility and potential impacts of ‘POD Adventures’, a context-specific smartphone-delivered digital intervention for common adolescent mental health problems in India. It is anticipated that the findings of the linked research studies will contribute to the otherwise scant evidence base for digital and game-based interventions for adolescent mental health problems, with potential applications to other LMIC settings. The findings could also provide important insights into the role of digital interventions in bridging the care gap for adolescents in India and in other similar contexts. An outline of the thesis is illustrated in **Figure 1.1**.

### ***1.5.2.1. Study 1***

The aim of Study 1 was to co-design a game-based problem-solving intervention for school-going adolescents with or at risk of experiencing anxiety, depression and/or conduct difficulties.

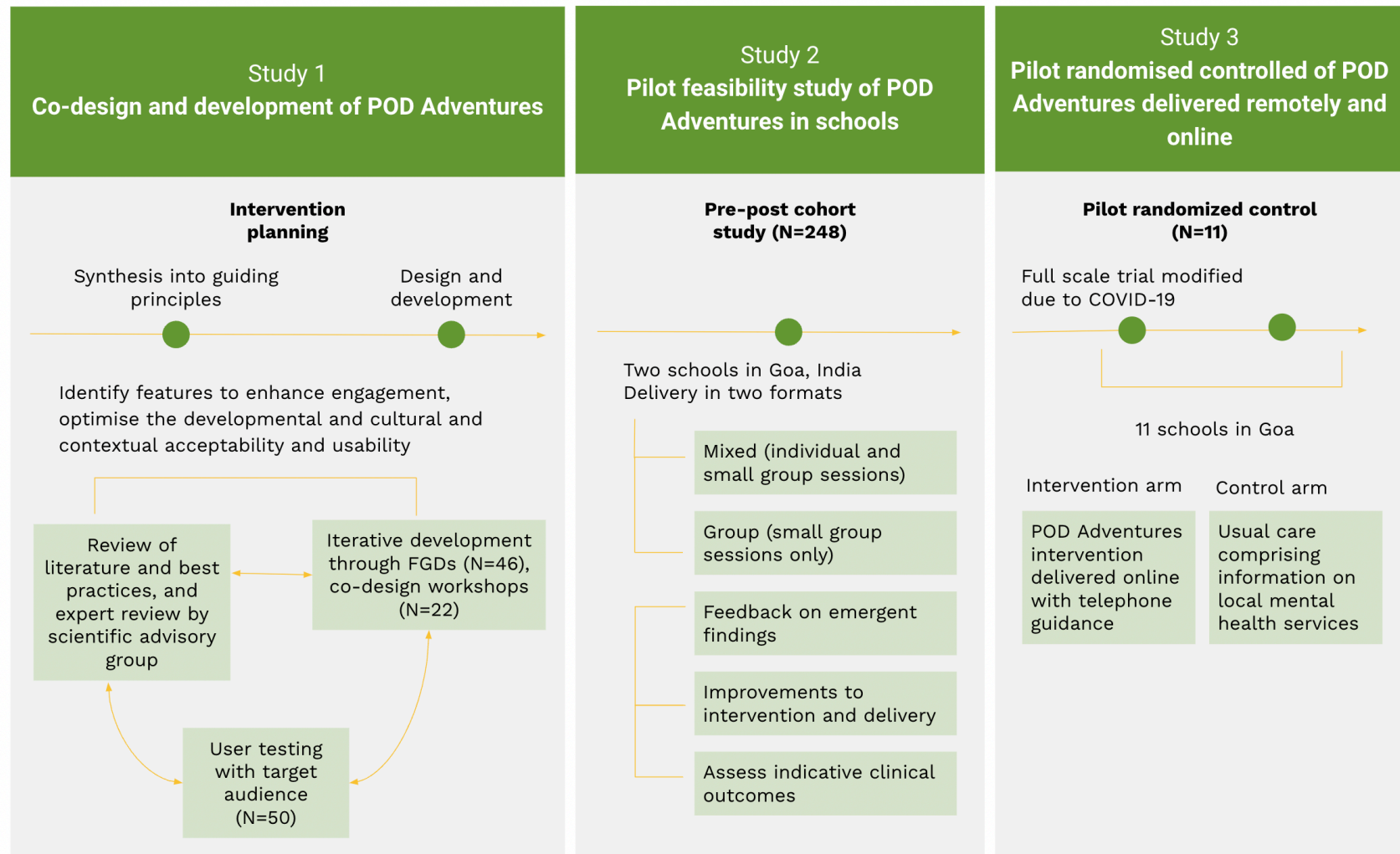
The specific objectives of Study 1 were to understand:

1. access to a digital intervention for adolescents in schools in India
2. appropriateness of a digital intervention
3. features to enhance engagement with the problem-solving content of the intervention
4. features to optimise the developmental and cultural acceptability of the intervention
5. features to optimise usability of the intervention
6. features to optimise feasibility of intervention delivery

### ***1.5.2.2. Study 2***

The aims of Study 2 were to test the feasibility and acceptability of POD Adventures for adolescents with a felt need for psychological support, and to evaluate indicative clinical impacts of the intervention on adolescents' self-reported mental health symptoms, prioritised problems, stress and well-being. The intervention was delivered in school settings in Goa, India, using two formats, namely, 'mixed' (comprising individual and small group sessions) and 'group' (small group sessions only). The specific objectives of Study 2 were to:

1. test the feasibility, acceptability, and potential impacts of POD Adventures as a guided app-based intervention for adolescents with a felt need for psychological support irrespective of assessed clinical severity.
2. identify refinements of the intervention based on these findings and in preparation for a rigorous evaluation through a randomised controlled trial.

**Figure 1.1:** Studies included in this thesis



### **1.5.2.3. Study 3**

Study 3 was originally intended to be a full-scale randomised controlled trial (RCT) of the POD Adventures intervention delivered in schools by lay counsellors. However, the timing of the COVID-19 pandemic coincided with the planned start date of the trial and this study had to be modified to fit around extended school closures, which were initiated in India from March 2020 onwards and remained in place for nearly two years. These circumstances required a pragmatic trial design that examined feasibility parameters related to the remote delivery and evaluation of POD adventures specifically as well as offering insights into more general issues related to optimising recruitment and sustaining engagement in internet-based trials and interventions.

The specific objectives of Study 3 were therefore modified to assess whether the feasibility and acceptability of POD Adventures would be replicated when delivered online and with remote telephone-based support in the context of COVID-19 restrictions. The intervention maintained all the elements of the pre-existing digital specification although modifications were made for internet-based recruitment and remotely delivered telephone guidance from counsellors. Study 3 aimed also to generate preliminary estimates of the effectiveness of the intervention to inform sample size calculations for a full-scale trial.

## **1.5.3. Research design and methodology**

### **1.5.3.1. Introduction**

The current research was premised on an epistemological framework that viewed adolescents as actors in their own right and recognised that research must be undertaken *with* them rather than *on* them [163]. This underscored the use of participatory elements, creating space for the voices

and perspectives of adolescents to emerge in a less structured way while engaging adolescents in shaping the content and direction of the research and intervention (such as through co-design and user-testing activities and intervention content which drew directly on participant experiences) [164].

The selection of mixed methods was also informed by conceptual frameworks and theoretical models related to mental health service design [105, 165-167]. These emphasise research designs that use quantitative and qualitative data collection and analysis to better understand a research problem than is possible with the use of either methodological approach alone. In the context of adolescents in LMICs, research has highlighted the utility of mixed methods in allowing for deeper exploration of diverse and nuanced contextual factors that impact adolescents [168-171].

The methods used in this thesis are also aligned with international guidelines for the design and evaluation of complex interventions which outline principles on how to develop service solutions for real world practice [118] [172]. Further, these guidelines are aligned with the principles of a ‘person-based approach’ [105] to intervention development which suggests strong and early engagement with potential service users and practitioners and evaluating acceptability, feasibility, and effectiveness. They also recommend a focus on understanding how interventions interact with their context [118, 172].

#### ***1.5.3.2. Design***

Study characteristics of the three included studies are summarised in **Table 1.1**.

**Table 1.1:** Summary of study characteristics

<i>Study</i>	<i>Location</i>	<i>Design</i>	<i>Participants</i>	<i>Location</i>
Study 1: Co-design and development of POD Adventures	New Delhi and Goa	Qualitative study comprising co-design workshops, focus-group discussions (FGDs) and user-testing sessions	Participants were aged 12–17 years and recruited from local schools in New Delhi and Goa, including a subgroup with self-identified mental health needs.	In schools
Study 2: Pilot feasibility study of POD Adventures in schools	Goa	Mixed methods pre-post cohort study	N=248 participants from grades 9-12 from two co-educational schools	In schools
Study 3: Pilot randomised controlled trial of POD Adventures delivered remotely online during COVID-19	Goa	Pilot randomised controlled trial (RCT)	N=11 participants from grades 9-12 from 11 co-educational schools	Online

Study 1 involved intervention development and followed a person-centred approach [105] consisting of four iterative activities: (i) review of recent context-specific evidence on mental health needs and preferences for the target population of school-going Indian adolescents, including a multiple stakeholder analysis of school counselling priorities and pilot studies of a brief problem-solving intervention; (ii) new focus group discussions with student participants and service providers; (iii) co-design workshops with student participants and service providers; and (iv) user-testing with student participants.

Study 2 used a pre-post cohort study and iterative mixed methods design with concurrent data collection and analysis aligned with guidance for complex evaluations [161]. This enabled rapid feedback of emergent findings and concurrent refinements to the intervention and its delivery. Indicative clinical outcomes were assessed at four and 12 weeks after entry into the study. The

study was conducted in two coeducational, government-aided, English-medium secondary schools in Goa, India, without established counselling services. The intervention was delivered in two formats, 'mixed' (comprising individual and small group sessions) and 'group' (small group sessions only).

Study 3 was originally designed as a full-scale trial intended to take place in-person from June 2020, however due to COVID-19 lockdowns in India the original study protocol was modified prior to trial registration or participant enrolment. Study 3 was redesigned as a parallel, two-arm, individually randomised pilot-controlled trial with 11 secondary schools in Goa, India. Participants received either the POD Adventures intervention delivered over four weeks or usual care comprising information about local mental health services and national helplines. Outcomes were assessed at two timepoints: baseline and six weeks post randomization.

#### ***1.5.3.3. Participants***

Participants in the three included studies are summarised in **Table 1.1**.

Study 1 comprised 118 adolescents from six schools (n=4 schools in Goa; n=2 schools in New Delhi). Participants were drawn from grades 8-11 and ranged in age from 12 to 16 years. They were recruited through a combination of classroom announcements and teacher nominations. No specific eligibility criteria were used to select adolescents based on current/prior experiences of mental health problems. In addition, eight service providers (n=5 from Goa; n=3 from New Delhi) participated in the study.

Study 2 comprised 248 participants from grades 9–12 (aged 13–19 years) from two coeducational schools in Goa who self-referred for psychological help with perceived stress.

Study 3 was conducted remotely and comprised 11 participants who were enrolled in grades 9-12 (ages 13-19 years) from 11 collaborating schools. They were required to have access to an internet-enabled Android smartphone with a valid phone number for the duration of the study which was conducted during intermittent COVID-19 school closures and lockdowns.

Participants were recruited through a brief sensitization session delivered to individual classes either online (via virtual classrooms) or, where social distancing policies allowed, in school, and where feasible, through distribution of a printed or downloadable flyer via school-moderated email/WhatsApp groups. Inclusion and exclusion criteria, and the final samples for each of the studies of the current thesis are explained separately in Chapters 2-5.

#### ***1.5.3.4. Measures***

Measures used in each of the studies have been explained in detail in each paper (Chapters 2-5).

An overview is provided in **Table 1.2** below.

**Table 1.2:** Measures used across included studies

<i>Measure</i>	<i>Tools</i>	<i>Description</i>	<i>Timepoints</i>	<i>Study</i>
<i>Feasibility</i>				
Feasibility of research procedures	Referral logs; logs of eligibility, assent, and consent; completion of outcome assessments	Feasibility of research procedures was assessed using routinely logged frequencies and proportions of eligible/ineligible self-referrals, assenting/consenting participants, randomised participants (Study 3), and completed outcome assessments.	Throughout study period	Study 2, Study 3
Feasibility of	Attendance logs at	Feasibility of intervention delivery	Throughout	Study 2,

intervention delivery	sessions (in person/online), app use analytics, intervention fidelity ratings of on-boarding and review discussions with counsellor	was assessed using routinely logged frequencies and proportions of participants who logged into the app at least once, completed individual sections of the app, and completed the intervention overall (i.e., attended both the on-boarding and review session/telephone calls and completed both app sections). Participants' use of the app was recorded using integrated analytics software. Exploratory variables of interest included knowledge of problem-solving assessed through multiple-choice quizzes, and self-reported use of problem solving in real-world situations.	study period	Study 3
<i>Acceptability</i>				
Acceptability of the intervention	Qualitative interviews	Semi-structured qualitative interviews to understand acceptability of attending school-based sessions, preferences for intervention features, usability, and helpfulness.	Upon intervention completion	Study 2
User satisfaction	Client Satisfaction Questionnaire-8 (CSQ-8) and four additional questions about the POD Adventures app	User satisfaction was assessed using the Client Satisfaction Questionnaire-8 (CSQ-8) [173]. Four additional items were added to obtain insights about the POD Adventures app. The items were: (1) The game has increased my ability to cope with problems on my own; (2) The game was easy to use; (3) The information in the game was easy to understand; (4) The game was fun and interesting to use. These were obtained to understand user ratings of helpfulness, usability, ease of understanding and enjoyment.	Baseline, 4 weeks and 12 weeks (Study 2)  Baseline (pre-randomisation) and 6 weeks post randomisation	Study 2  Study 3
<i>Clinical outcomes</i>				
Indicative clinical outcomes	1) Youth Top Problems (YTP)	The YTP is a brief, idiographic measure on which the respondent identifies, prioritises, and rates three main problems. Each of the three problems is scored from 0 to 10 according to perceived problem severity (with higher scores indicating greater severity). A mean severity score is calculated by summing individual problem scores and then	Baseline, 4 weeks and 12 weeks  Baseline (pre-randomisation) and 6 weeks post randomisation	Study 2  Study 3

		dividing by the number of nominated problems [174]. The YTP was translated into Hindi for PRIDE studies, where it was found to be highly sensitive to change over the course of the problem-solving intervention [157, 159].	n	
	2) Strengths and Difficulties Questionnaire (SDQ)	The SDQ is a widely used measure for psychopathology in children and adolescents globally. It has been used in numerous research studies in India and has been translated into Hindi and several other Indian languages [76, 175-177]. A Total Difficulties scale score is derived by summing items from four problem subscales (emotional, conduct, hyperactivity/inattention, and peer relationship), while a fifth subscale measures prosocial functioning and does not contribute to the overall severity score. Individual problem scale items are scored from 0 to 2 (with higher scores indicating greater problem severity), giving a range of 0–40.	Baseline, 4 weeks and 12 weeks	Study 2
	3) Perceived Stress Scale (PSS)	The PSS-4 measures perceptions of stress, reflecting the degree to which situations are appraised as stressful during the preceding month. It has been translated into Hindi and used in several surveys and as an outcome measure in trials globally. This brief instrument uses a five-point scale (0 = never, 1 = almost never, 2 sometimes, 3 = fairly often, 4 = very often) to assess how often the respondent has experienced primary appraisals of events as stressful. Total scores range between 0 and 16, with higher scores indicating a stronger tendency towards stressful appraisals. A study of secondary students in Hyderabad, India reported high internal consistency (Cronbach's alpha = 0.84) and test-retest reliability (0.85) for the longer 14-item form of the PSS [178].	Baseline, 4 weeks and 12 weeks	Study 2
	4) Short Warwick-Edinburgh Mental Well-Being Scale (SWEMWBS)	The SWEMWBS is a commonly used measure for mental well-being. The SWEMWBS is a unidimensional scale that comprises seven items	Baseline, 4 weeks and 12 weeks	Study 2

		scored on a five-point scale (1=none of the time, 2=rarely, 3=some of the time, 4 = often and 5 = all the time) with a total range from 7 to 35, where higher scores indicate more positive mental wellbeing [179]. Strong internal consistency has been previously reported in adolescent samples [180].		
	5) Revised Child Anxiety and Depression Scale– Short Version (RCADS-25)	The Revised Child Anxiety and Depression Scale (RCADS) is a 47-item, youth self-report questionnaire. It yields a Total Anxiety Scale (sum of the 5 anxiety subscales) and a Total Internalising Scale (sum of all 6 subscales). Items are rated on a 4-point Likert-scale from 0 (“never”) to 3 (“always”) [181]. A 25-item version has been developed to reduce the burden on respondents and speed up completion time [182]. Although this measure has not been used in many Indian studies [183] a reliability generalisation meta-analysis showed that the RCADS is a reliable instrument for cross-cultural use [184].	Baseline (pre-randomisation) and 6 weeks post randomisation	Study 3

#### *1.5.3.5. Analytic methods*

The current thesis used mixed quantitative and qualitative analytic methods.

Study 1 comprised focus group discussions (FGDs), co-design workshops and user-testing. Data were analysed and triangulated around the research objectives using an integrated inductive-deductive approach to content analysis and through thematic and mapping techniques [105, 185].

In Study 2, quantitative process indicators were analysed and described using frequencies, means, standard deviations (SDs) and proportions. Analysis of clinical outcome measures involved comparisons of pre-post scores using paired t-tests. Subgroup analyses were conducted



by clinical severity to examine the impact of the intervention separately for those in the subthreshold and case severity ranges and for each delivery format (mixed and group). Qualitative interviews were analysed using an integrated inductive-deductive approach to thematic analysis [185].

The statistical analysis for Study 3 was descriptive, aiming to provide estimates of key feasibility and acceptability parameters and indicative clinical outcomes. The outcome measures were summarised at baseline and at six-week follow up by trial arm. These were summarised by mean (SD), median (IQR), or n (%) values overall and stratified by age, gender and baseline outcome score.

### **1.6. Candidates' contribution to the thesis**

The PhD candidate was based full-time at the Sangath NGO in New Delhi and Goa, India, where they led data collection and research management activities from 2017 - 2022. The candidate's contributions across the three included studies involved: leading the design of the research; obtaining ethics approvals from the host and collaborating institutions for each study; directing the local research team; designing and implementing paper and digital data collection tools; recruiting, training and supervising field researchers who implemented data collection activities; conducting some data collection activities including focus-group discussions, co-design workshops, qualitative interviews for Study 1 and Study 2; data analysis and writing of the manuscripts. Involvement of the candidate and each author for each study is described in the Declaration section of this thesis (see page 2).

## 2. DESIGN AND DEVELOPMENT OF THE ‘POD ADVENTURES’ SMARTPHONE GAME: A BLENDED PROBLEM-SOLVING INTERVENTION FOR ADOLESCENT MENTAL HEALTH IN INDIA (STUDY 1)

### 2.1. Abstract

**Introduction:** Digital technology platforms offer unparalleled opportunities to reach vulnerable adolescents at scale and overcome many barriers that exist around conventional service provision. This paper describes the design and development of *POD Adventures*, a blended problem-solving game-based intervention for adolescents with or at risk of anxiety, depression and conduct difficulties in India. This intervention was developed as part of the PRIDE research programme, which aims to establish a suite of transdiagnostic psychological interventions organised around a stepped care system in Indian secondary schools.

**Methods:** Intervention development followed a person-centred approach consisting of four iterative activities: (i) review of recent context-specific evidence on mental health needs and preferences for the target population of school-going Indian adolescents, including a multiple stakeholder analysis of school counselling priorities and pilot studies of a brief problem-solving intervention; (ii) new focus group discussions with N=46 student participants and N=8 service providers; (iii) co-design workshops with N=22 student participants and N=8 service providers; and (iv) user-testing with N=50 student participants. Participants were aged 12-17 years and recruited from local schools in New Delhi and Goa, including a subgroup with self-identified mental health needs (N=6).

Results: Formative data from existing primary sources, new focus groups and co-design workshops supported a blended format for delivering a brief problem-solving intervention, with counsellors supporting use of a game-based app on ‘offline’ smartphones. User-testing with prototypes identified a need for simplification of language, use of concrete examples of concepts and practice elements to enhance engagement. There were also indications that participants most valued relatability and interactivity within real-world stories with judicious support from an in-app guide. The final prototype comprised a set of interactive and gamified vignettes and a structured set of problem-solving questions to consolidate and generalise learning while encouraging real-world application.

Discussion: Findings shaped the design of *POD Adventures* and its delivery as an open-access blended intervention for secondary school students with a felt need for psychological support, consistent with an early intervention paradigm. A randomised controlled trial is planned to evaluate processes and impacts of *POD Adventures* when delivered for help-seeking students in low-resource school settings.

## **2.2. Introduction**

Mental health problems account for over a third of the total burden of disease in adolescents [3], with depressive, anxiety and conduct disorders together accounting for over 75% of this burden [7]. India is home to the world’s largest population of adolescents, placing the country at the centre of global efforts to improve mental health care for this age group. At the same time, fewer than 10% of young Indians have access to formal mental health services [60]. The negative impacts of adolescent mental problems are starkly reflected in the strong association between

poor mental health and long-term social disability, while suicide is the leading cause of death for 15–24-year-olds in India [11, 40, 41].

The large mental health care gap in India and other low-and middle-income countries (LMICs) coincides with a rapid boom in telecommunications and internet access. Evidence from diverse low-resource settings shows that young people aged 10-24 years adopt new technologies and use mobile devices and the internet more frequently than individuals from older age groups, including for the purpose of accessing health-related information [14]. India has 90% mobile phone penetration, more than 225 million smartphone subscribers, and rapidly increasing rates of internet and social media usage [186]. Despite varied access and gaps in connectivity, especially in rural areas, digital technology platforms offer unparalleled opportunities to reach vulnerable adolescents at scale and overcome many of the barriers that exist around conventional service provision [14, 88].

Since the initial description of ‘e-health’ by Eysenbach [187], the nature of such digital provision has evolved considerably. Static content delivered via personal computers (PCs) or laptops has been superseded by more advanced technology that allows for greater functionality and adaptability. This increasingly involves delivery of interventions through applications (‘apps’) designed for smartphones and other wearable digital devices [188]. There are now more than 10,000 publicly available mental health apps [146], of which a growing number make use of “serious games,” i.e. games that are designed to educate, train, or change behaviour as they entertain players [102]. However, few serious games to date have been tested and reported in the

scientific literature; the available reports are based almost entirely on desktop-computer formats rather than mobile apps [17].

Meta-analyses and systematic reviews of mental health apps for adolescent populations highlight promising findings for feasibility and acceptability [16, 121, 122, 189, 190]. Game-based approaches offer specific characteristics that can help make learning more meaningful, engaging, visual and interactive [17]. However, evidence of efficacy remains limited, especially for apps evaluated in LMICs and for those focused specifically on adolescent mental health [14, 24]. A recent review of digital technology for treating and preventing mental health problems in LMICs identified 49 studies, including only four studies with adolescents or youth [14].

In this paper, we describe the design of *POD Adventures*, a blended problem-solving game-based intervention for adolescents with or at risk of anxiety, depression and conduct difficulties in India. *POD Adventures* was developed as part of the PREmium for ADolEscents (PRIDE) research programme (2016-2020), which aims to establish a suite of transdiagnostic psychological interventions organised around a stepped care system in Indian secondary schools [157, 159]. PRIDE has also developed and evaluated a counsellor-led problem-solving intervention in secondary schools across New Delhi and Goa in India. The counsellor-led problem-solving intervention and associated sensitisation activities (aimed at generating self-referrals) have been evaluated in randomised controlled trials at the New Delhi site. *POD Adventures* was originally conceptualised as a digital counterpart to the PRIDE counsellor-led problem-solving intervention, with both aiming to enhance a participant's ability to cope with stressors and thereby prevent/improve mental health problems [161], in line with stress-coping

theory [162]. In terms of delivery, *POD Adventures* follows a blended approach that deploys low-intensity human support in tandem with a smartphone-delivered game, potentially reducing the resource demands of conventional face-to-face counselling. Thus, we aimed to develop an intervention specification that could bridge the gap between the high prevalence of anxiety, depression and conduct difficulties and low capacity of the public mental health system in India and potentially other similar settings [191].

## 2.3. Methods

### 2.3.1. Research design

An iterative approach was taken to intervention design following established design guidelines including the person-centred approach by Yardley et. al. [105] and World Health Organisation (WHO) guidelines on monitoring and evaluating digital health interventions [192]. The research design also incorporated insights from linked research activities related to the development and evaluation of PRIDE's counsellor-led problem-solving intervention. The primary objectives of the current study were to:

- i. understand access to and appropriateness of a digital intervention for adolescents in schools in India
- ii. identify features to enhance engagement with, the problem-solving content of the intervention
- iii. identify features to optimise the developmental and cultural acceptability and usability of the intervention
- iv. identify features to optimise contextual acceptability and feasibility of intervention delivery

### **2.3.2. Setting**

Intervention development was initiated in July 2017 at sites in New Delhi (north India) and Goa (southern India). These sites were selected for the current study as services, staff and school relationships were pre-existing in these two regions. Goa and Delhi are among India's most highly urbanised states and offered opportunities to evaluate the roll out of a technology-enabled intervention. Primary data collection was conducted in two same-sex government-run, Hindi medium secondary schools in New Delhi (one all-girls and one all-boys) and six co-educational government-aided secondary schools in Goa.

### **2.3.3. Ethical approvals**

Approvals for PRIDE's formative research activities, including the current study, were obtained from the Indian Council of Medical Research (ICMR) and institutional review boards of Sangath (the implementing organization in India) and London School of Hygiene and Tropical Medicine (a collaborating academic partner in the UK). Local approvals were also obtained from the relevant school boards in New Delhi and Goa. Informed written assent and consent was obtained from participating adolescents and their parents/guardians. Detailed information sheets providing information about the PRIDE programme, focus group discussion and co-design workshops were included, along with assent/consent forms that were developed in English, Hindi, and Konkani (the local languages). Participants were provided with certificates of participation for their time and contributions.

### **2.3.4. Data collection**

Intervention design consisted of four main activities: (i) review of previous formative work; (ii) focus group discussions (FGDs); (iii) co-design workshops; and (iv) user-testing. Insights from

(i), (ii) and (iii) were used to define the intervention “guiding principles” [105] leading to the specification of an initial prototype. Insights from (iv) helped to refine iterative prototypes following from emergent findings on feasibility, acceptability, and usability

### *Previous formative research*

A review of the previous formative research consisting of qualitative studies [67, 72] and pilot studies [157] contributed to intervention planning activities. Two qualitative studies were conducted [67, 72] that consisted of focus group discussions with multiple stakeholders including school-going adolescents from low-and middle-income communities, parents, teachers, school counsellors and service providers at the two research sites in New Delhi and Goa. An iterative phased approach was then used to model and then test successive prototypes of the intervention in two linked pilot studies [157] at the New Delhi site using a prospective cohort design. The studies evaluated the acceptability and feasibility of the intervention delivery and potential for impact to refine the intervention.

### *Focus group discussions*

#### Participants

Forty-six adolescents (n=23 in Delhi; n=23 in Goa; 21 female: 25 male) participated in six FGDs (one per school at four schools in Goa; one per school at two schools in Delhi) (see **Table 2.1**). Participants were drawn from grades 8-11 and ranged in age from 12-16 years (mean 14.0), with recruitment carried out through a combination of classroom announcements and teacher nominations. To capture different perspectives, we tried to approximate equal quotas with regards to age and gender. No specific eligibility criteria were used to select adolescents based



on current/prior experiences of mental health problems, although participants were required to be proficient in English, Hindi, or Konkani, and to provide informed assent and parental consent. In addition, we conducted two FGDs at each site drawing on a group of eight service providers (n=3 in Delhi; n=5 in Goa) with experience of delivering the PRIDE counsellor-led problem-solving intervention in the collaborating schools (see [157] for further details of service providers).

### Topics

Participant FGDs consisted of questions about the use and preferences for different digital media; access to smartphones; and nature of use, location of use and experience playing games and apps. Service provider FGDs consisted of questions regarding the appropriateness of a digital mental health intervention in school settings. This included reflections on successes and challenges faced in delivering a brief problem-solving intervention in a conventional face-to-face individual format. Each FGD lasted 60-90 minutes and was conducted jointly by the first author and representatives from a partner design agency. FGDs were audio-recorded and documented through written notes and photographs of group work.

### ***Co-design workshops***

#### Participants

Twenty-two participants (n=13 in Delhi; n=9 in Goa; 4 female: 18 male) participated in one co-design workshop each conducted at the participating schools at the two research sites (see **Table 2.1**). The mean age of adolescents was 14 years (range 13.0-15.0 years) from grades 8-10.

Eligibility criteria and recruitment procedures were the same as in the FGDs. The same group of eight service providers participated in one design workshop at each site.

### Topics

Co-design workshop activities with participants included: (i) exploring a selection of popular games and apps such as Temple Run, Candy Crush, Tekken, Horizon Chase, and *Kaun Banega Crorepati?* (an Indian version of *Who Wants to be a Millionaire?*) on smartphones; (ii) story building to create personas and problem scenarios; (iii) paper prototyping of game components and characters; and (iv) discussion about prototype ideas presented by participants. Workshops with providers focused on: (i) prototype contents; (ii) identifying narratives for the game and how to emphasize the key problem-solving features; and (iii) suggestions for making the game easier to understand and navigate for users. Each workshop lasted 90-120 minutes and was conducted jointly by the first author and team members from the partner design agency.

Workshops were documented through photographs of group work and were audio-recorded and transcribed.

### ***User-testing***

#### Participants

Fifty participants (28 female: 22 male) from six schools took part in 22 user-testing sessions over nine months at the Goa site (see **Table 2.2**). The mean age of participants was 14.5 years (range 12-17 years) from grades 8-12. Participants were recruited in three ways: (i) classroom announcements; (ii) teacher referral of participants representing a mix of age and gender within

their classes; and (iii) participants with prior experience of school counselling who were invited to volunteer.

### Topics

User-testing sessions consisted of researcher-supported gameplay, paper-prototyping, and discussion-based feedback to provide insights on intervention acceptability and usability.

Participants were asked about their views about the gameplay contents and concepts; characters; gamified components such as rewards, quizzes, missions, etc., as well as on ease of use, game bugs and points in the game when external support was required. Feedback was also sought on human support and intervention delivery options in schools such as small group delivery.

Gameplay was observed and notes taken by supervising researchers. Discussions were documented through photographs and were audio-recorded and transcribed.

**Table 2.1:** Participant characteristics FGDs and co-design workshops

<i>Activity</i>	<i>Location</i>	<i>Participants (N)</i>	<i>Number of sessions</i>	<i>Age range (years)</i>	<i>Female(N):Male (N)</i>
Focus group discussions (FGDs)	Goa	Students (23)	4	12-16	11:12
	Delhi	Students (23)	2	14-16	10:13
	Goa	Service providers (5)	2	-	5:0
	Delhi	Service providers (3)	2	-	3:0
Co-design workshops	Goa	Students (9)	1	14-15	4:5
	Delhi	Students (13)	1	13	0:13
	Goa	Service providers (5)	1	26-35	7:5

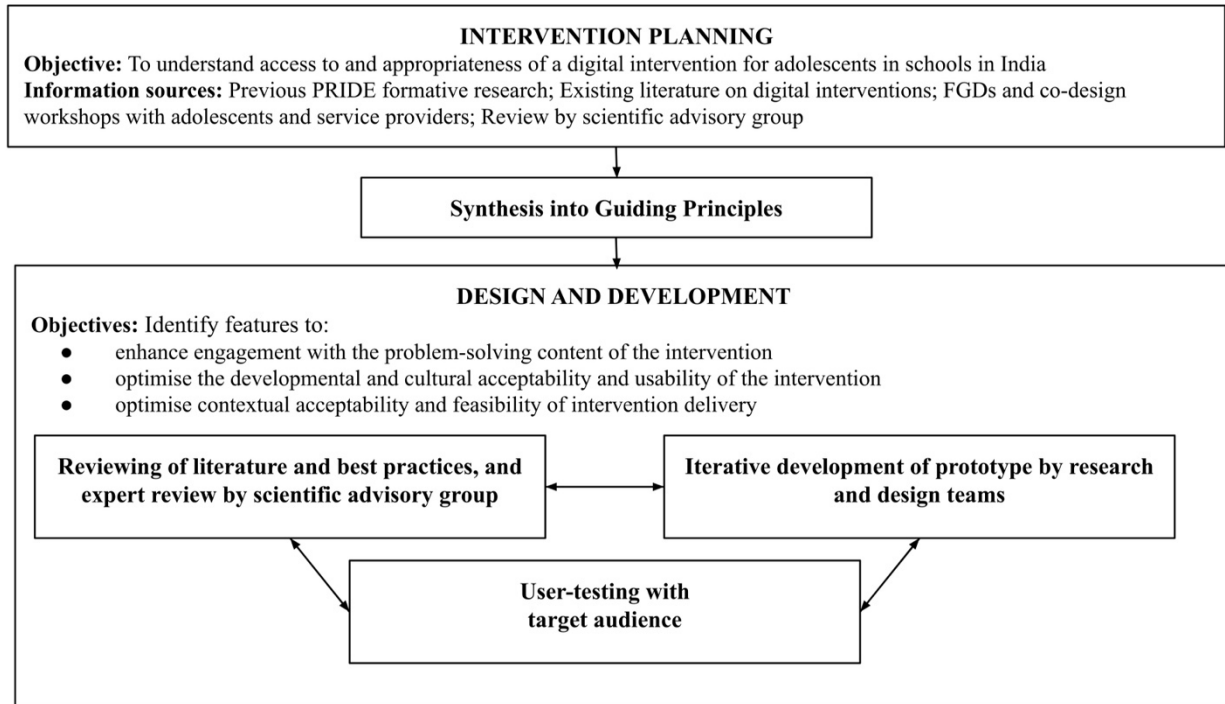
**Table 2.2:** Participant characteristics - user testing

<i>Student Group</i>	<i>Participants (N)</i>	<i>Age (range in years)</i>	<i>Gender Female(N):Male (N)</i>	<i>Source of recruitment</i>	<i>Number of sessions</i>
School 1	6	13-15 years	4:2	Teacher	1
School 2	6	12-15 years	3:3	Teacher	4
School 3	8	12-15 years	4:4	Volunteers	7
School 4	12	15-17 years	6:6	Teacher	2
School 5	12	12-15 years	8:4	Teacher	5
School 6*	6	15-17 years	3:3	Teacher	3
Total	50	12-17 years	28:22	-	22

\*Prior experience of PRIDE face to face counselling programme

### 2.3.5. Data Analysis

Analysis followed an iterative and recursive process which was led by an intervention working group (PPG, EH, RS) with oversight from the senior investigators (DM and VP) and an independent Scientific Advisory Group (see Acknowledgements). Insights from the parallel PRIDE formative research activities [67, 72, 157], new FGDs, co-design workshops and user-testing were analysed and triangulated around the four research objectives using an integrated inductive-deductive approach to content analysis and through thematic and mapping techniques (see Figure 2.1) [185]. This resulted in a set of “guiding principles” that summarized the intervention objectives and distinctive features necessary to meet these objectives, in alignment with key information about the target population and its context. During prototype development, the formative data sources were revisited regularly and reviewed alongside the wider literature on digital interventions for adolescent mental health, insights from user-testing and from implementation of the counsellor-led intervention that was being conducted in parallel.

**Figure 2.1: Research design process**

## 2.4. Results

### *Accessibility and appropriateness of digital interventions*

#### Context of self-help

Self-help was suggested early in the formative PRIDE research [157, 193] as a scalable format however consultations with stakeholders and service provider FGDs highlighted that ‘self-help’ was not a culturally-congruent concept for most Indian adolescents [67]. Service provider and participant FGDs revealed norms around seeking or receiving direct instruction from parents, teachers, and other elders. Both groups felt that support from a counsellor would be necessary for an intervention to be effective. Service providers also reported that students they had previously provided counselling services to had difficulties understanding abstract concepts. This was linked to the emphasis on rote learning over critical thinking in the Indian schooling system. The

game was therefore designed to incorporate a combination of teaching methods including direct instruction, modelling, and practice to accommodate different learning styles and to emphasise self-efficacy [194].

#### Accessibility and compatibility of technology

Most participants in the FGDs reported having easy access to smartphones, albeit through devices that usually belonged to a parent (mainly fathers). The primary use was to play offline games, while internet access was restricted by limited data packs. Participants navigated a variety of digital and app-based games with minimal help, lending support to the acceptability and usability of a gamified format. Formative work revealed that digital interventions were broadly appealing to adolescents [67, 193]. More specifically, participants and service providers felt that a digital delivery format might offer more opportunities for personalisation and engagement in the context of self-help, thereby addressing limitations raised about the usefulness of this modality. Moreover, FGDs indicated that typing into a smartphone may be preferred by many participants to writing on paper. On the other hand, service providers highlighted potential concerns arising from parents and teachers regarding the amount of time that adolescents spend on phones. Based on these learnings, the decision was taken to restrict delivery to counsellor-supported use of smartphones during dedicated school-based sessions, and for functionality to be independent of internet access (i.e., work offline).

#### Ensuring privacy

The importance of providing participants with clear assurances about privacy and confidentiality emerged strongly in the preliminary formative work [193]. In line with best practice guidelines

for other mental health apps [194], an adolescent-friendly privacy policy was drafted in simple language and included in the game prototype. This policy contained details about how information would be collected, used, and stored and under what circumstances it would be shared (i.e., in the case of risk to self or others).

### Shift to open-access delivery

Piloting of the PRIDE counsellor-led problem-solving intervention generated high demand, including most self-referred adolescents who scored below thresholds for clinical caseness [157]. Considering this finding and supported by feedback from participant FGDs and user-testing that problem solving would be a useful and valued skill for all adolescents (not just those experiencing ongoing mental health difficulties), *POD Adventures* was re-conceptualised as an open-access intervention for adolescents with a felt need for psychological support. This decision was consistent with evidence for problem solving as an effective prevention strategy for adolescents with emotional problems [195-197] as well as wider evidence and emerging service models for early intervention for adolescent mental health problems [198].

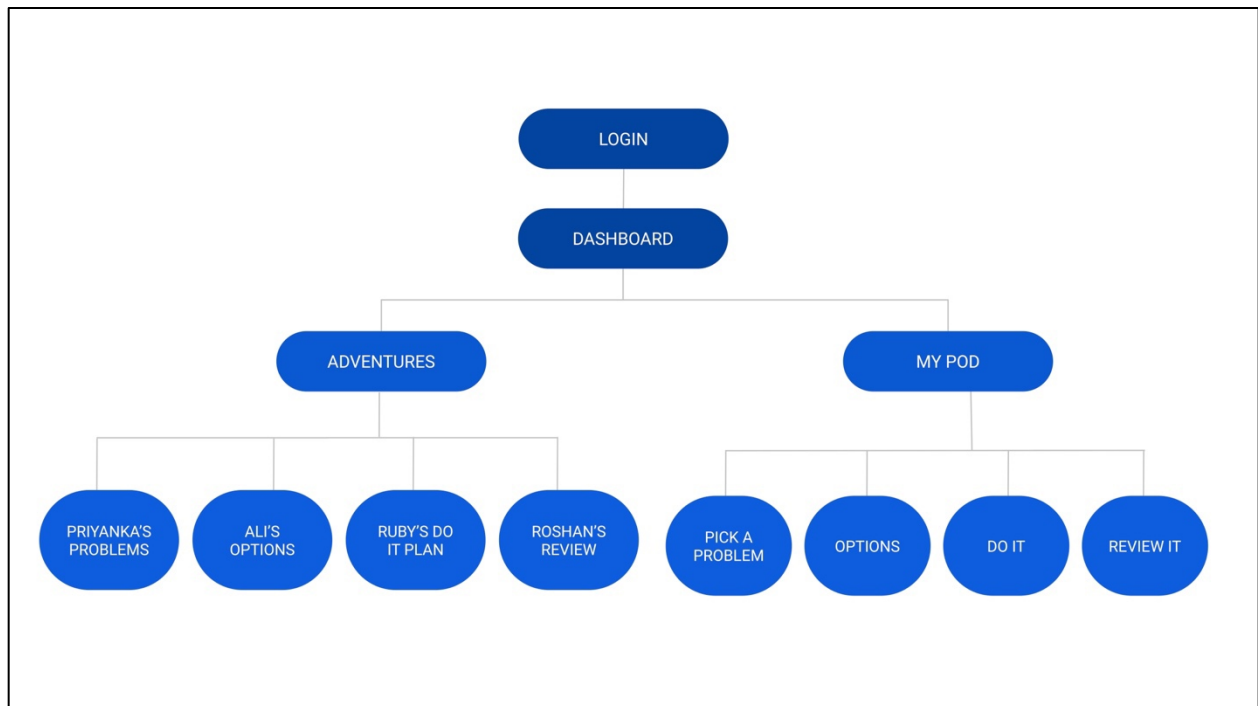
### ***Problem-solving contents***

#### Format and structure

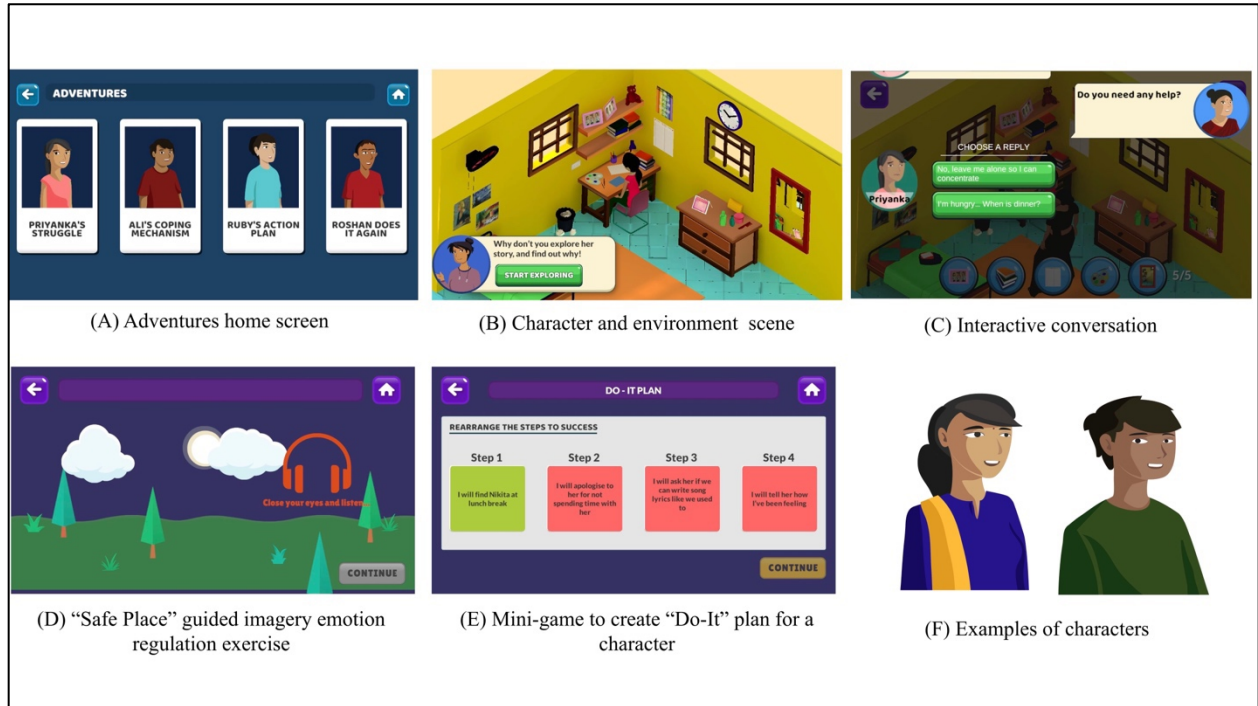
Piloting of the counsellor-led intervention supported a simplified three step problem-solving procedure with the memorable acronym, “POD” (identifying “Problems”, generating “Options” and creating a “Do it” plan) [157] and this was adopted in development of the game. Also consistent with the counsellor-led intervention that used printed comic booklets to illustrate problem solving, both participants and service providers suggested that a narrative format would

be optimal for the game. The prototype structure comprised two main sections, adventures, and My-POD (see **Figure 2.2**), with navigation within and between sections supported by a guide character. The adventures section contained short vignette-based stories exploring different adolescent characters and their problem-solving journeys while emphasising the steps of problem solving (see **Figure 2.3**). The My-POD section was designed to help generalise and consolidate learning of the previous steps through real-world application. This section presented participants with a series of forced-choice and open-text questions in which they were guided through the steps of problem solving for their own problems (see **Figure 2.4**).

**Figure 2.2:** Intervention prototype structure





**Figure 2.3:** Adventures section screenshots

### Common problems and stress reactions

PRIDE formative work [67, 72, 193], FGDs and co-design workshops identified common social stressors including academic pressure, bullying, difficulties in romantic relationships, negotiating parental and peer influences, and exposure to violence and other threats to personal safety. Stress reactions were commonly described using the catch-all term 'tension,' while more specific references to anger, rumination, and loss of concentration were also prominent in adolescents' narratives. The four character-based vignettes in the game were scripted to reflect some of these common problems and stress reactions. During user-testing, participants consistently reported that the vignettes were relatable but that they would like more character details and more vignettes. In response, game scripts were revised to include more detail for the central characters (e.g., more 'thought bubbles' which shared a character's thoughts and feelings; see **Figure 2.3**).

However due to the brief nature of the intervention a decision was made to limit the number of vignettes to four.

### Concepts

User-testing sessions highlighted that while specific problem-solving behaviours were learned with relative ease, conceptual learning intended to address problem orientation was limited. My-POD questions were revised to provide concrete examples wherever possible (for example, the Options section provided the instruction, ‘Write down some good things about this option’ and was supplemented by help text saying, ‘For example, a good thing might be that the option would be easy for you to do, or that it would make a BIG difference to your problem’).

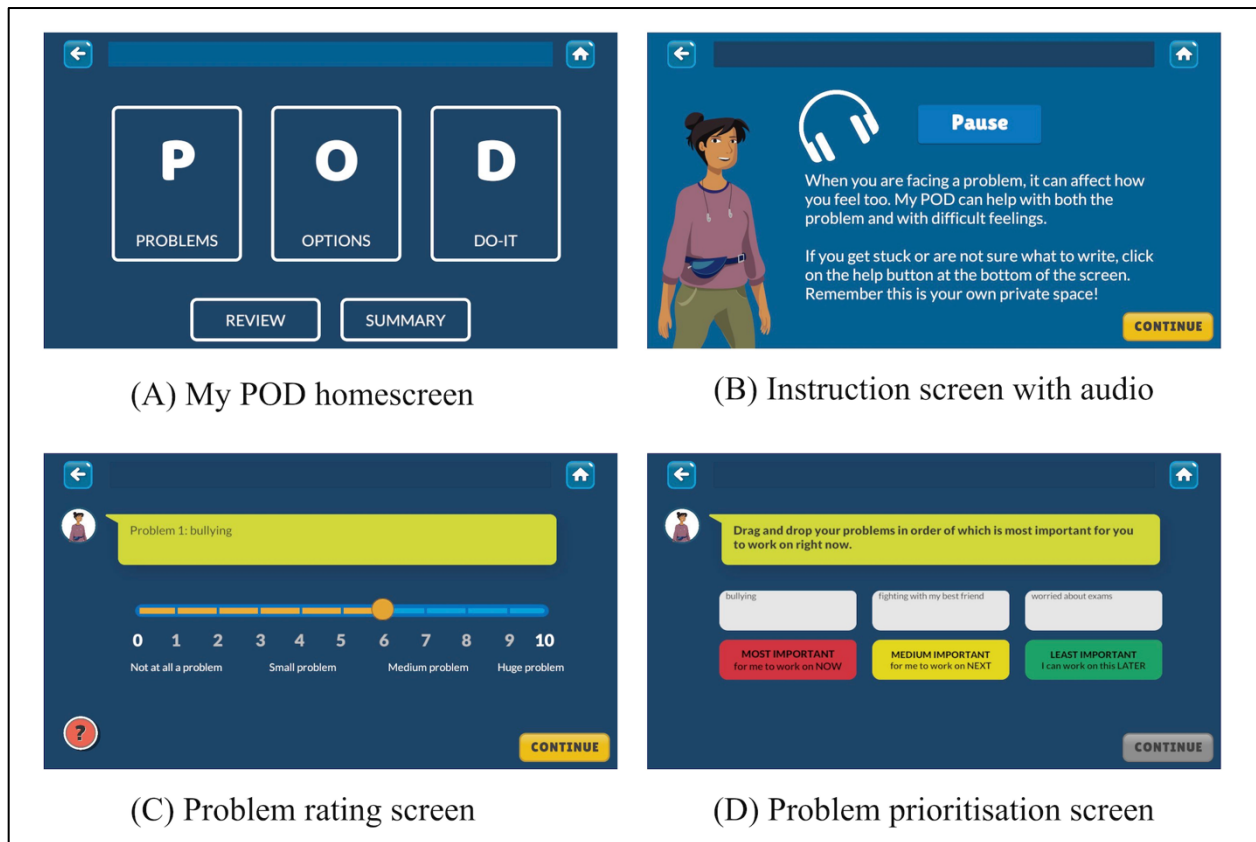
Additionally, an introductory animated video explaining the overarching stress-coping model and concepts of problem solving was incorporated into the game opening. These concepts were reinforced repeatedly at key points throughout the game.

Early versions of My-POD contained a high proportion of incomplete or inaccurately filled fields. Participants reported that some of the activities in this section, particularly related to option generation and selection (for example, weighing pros and cons) were difficult. Instruction screens containing text and audio information were added (see **Figure 2.4**), free-text questions were supplemented with sliding scale responses (see **Figure 2.4**), and a summary section was added to easily view action planning progress. These enhancements resulted in greatly improved completion of this section.

Participants also expressed a desire to access more directive tips and specific suggestions about

ways to solve problems. In response, an interactive “Options Bank” was designed around different life domains (for example, problems faced at school, at home, in their neighbourhood, emotion-focused problems, etc.).

**Figure 2.4:** My-POD section screenshots



### Emotion regulation activities

Formative PRIDE work indicated adolescents employed avoidance more frequently than active coping when faced with stressful situations [157]. A key component of effective treatment therefore was in helping participants understand and manage emotions, also supported by findings from the service provider FGDs [67]. To address this, emotion regulation exercises were embedded in the Adventures section of the game. These exercises were designed based on an abbreviated form of Nezu et. al. ‘Stop, Slow down, Think, Act’ method [161], and included guided imagery, breathing and muscle relaxation exercises (see Figure 2.3). In user-testing,

participants reported that the early iterations of these activities were too long, and these were subsequently revised to be kept under two-minutes to minimise boredom and disengagement.

### ***Developmental and cultural acceptability***

#### Media preferences

During FGDs and co-design workshops, participants expressed a preference for games with stories set in varied real-world environments and offering choices which could be explored. In response, gameplay was organized around a set of interactive vignettes located in age-appropriate settings (for example, at school, home, playground, etc.; see **Figure 2.3**). The three-dimensional immersive design of the game was based on photographs taken by game developers at the schools and surrounding localities and the design aesthetic was informed by participants' media preferences. Special care was taken to ensure a cast of culturally relatable characters representing a mix of genders, ages, body shapes, social classes, and common names.

The overall tone of the game was designed to be non-directive with multiple features providing user-choice [199, 200]. Some differences in media preferences were noted between girls and boys, such that boys appeared to prefer immersive games and girls favoured puzzle-platform games. The prototype was therefore designed to include both narrative and puzzle elements. In user-testing, participants strongly endorsed elements of user-control and interactive content and expressed a desire for more features of this type. In response, additional user-controlled decision points such as options to select conversational responses were added (see **Figure 2.3**). The game was designed to be available in the two most spoken languages (English and Hindi) and a vernacular language spoken at the Goa site (Konkani).

### Literacy

Formative PRIDE research revealed widespread literacy difficulties among students in Government-run and Government-aided schools, which limited the use of text-heavy printed problem-solving materials [157]. User-testing also highlighted the need for more concrete and specific language, particularly around problem-solving concepts. This led to several changes in phrasing, for example, “Do you think you will face any challenges?” was revised to “What might stop you?” The lexicon of emotion words was also reduced and paired with illustrated “smileys” to aid comprehension.

### Gamification

Participants co-design workshops highlighted several gameplay features with the potential to enhance motivation. Participants created mock games that included quizzes, obstacles and fighting elements, reflecting preferences for elements of competition and rewards. Consequently, vignettes were designed to include ‘missions’ in which users completed a series of tasks to progress through the vignette (for example, clicking on objects in a room to discover a character’s worries represented by that object). ‘Mini-games’ were also incorporated to model, practice and reinforce specific problem-solving behaviours (for example, rearranging the steps to make a Do-It plan for a character; see **Figure 2.3**). Quizzes were also incorporated to assess recall at the end of every vignette. During user-testing, the mini-games were among the most popular features. However, virtual “badges”, originally introduced to reward completion of mini-games, were poorly understood and generally disliked in favour of more targeted verbal

encouragement. In response, the badges were replaced with motivational feedback from the guide character and points awarded for correct quiz responses.

### ***Intervention delivery***

#### **In-game support**

Participants endorsed both relational and instructional functions provided by face-to-face contacts with school counsellors [193]. Service provider FGDs suggested that a guide character within the game could provide some of these functions. The game guide character was designed to provide instructions, information (psychoeducation and teaching the problem-solving method) and support (praise, encouragement, and motivational statements) throughout the game. They were conceptualised as a warm and knowledgeable older peer, intended to enhance dialogue support and social support features in line with persuasive systems design [199, 201]. Contingent responses from the guide were programmed wherever possible. For instance, if participants rated their mood as negative, the guide would respond with a sympathetic and encouraging message. User-testing indicated that the guide character was generally liked by participants. However, users of early prototypes felt that the guide appeared too often and that some of their comments were unnecessary. The guide feature was subsequently revised to appear less frequently during the Adventures section and their script was revised to focus on reinforcing key learning about the problem-solving method. During user-testing some participants reported that they felt supported by the game itself (rather than specifically by the guide) and that they enjoyed and felt safe in sharing their problem within the game.

### Human support

Most spontaneous requests for help during user-testing were made when participants required troubleshooting of game mechanics (e.g., which button to press next). Difficulties in understanding content emerged in discussions following gameplay but were not immediately apparent. Participants expressed mixed views about relational functions of human support. Some participants reported that the game was better than meeting with a person because “*the game always listens to you*”. Others felt that it was important to meet with someone because they “*understand what you say*”. Participants who had previously received a face-to-face counselling intervention suggested that the game may be sufficient on its own for some participants, but others with more severe problems might also require counsellor support. The human support for the game was subsequently conceptualised to offer both instruction and personalised support at onboarding and completion of the game, with the counsellor available to help when needed throughout the rest of the intervention.

### Managing risk

Service provider FGDs highlighted concerns about ensuring appropriate provisions for risk assessment and management within the intervention. In response, a mood rating system was incorporated into the digital login procedure. This was linked to a risk assessment question that would be triggered for participants who reported very low mood. As the game was designed to work offline, a real-time alert was not possible. Instead, a positive response to the risk assessment question diverted the participant to a locked screen containing a message about approaching the supporting school counsellor. A counsellor would then undertake further

assessment and management, after which the participant would potentially resume the intervention by the counsellor using a code to unlock the screen.

### Group delivery

Participants in user-testing sessions were not specifically concerned about the prospect of peers knowing about their engagement with the game, although concerns were voiced about other participants observing their gameplay. Some participants expressed that group sessions may be advantageous to encourage a sense of togetherness among intervention users. It was suggested private gameplay could still be achieved in a group setting if participants were able to sit at a distance from each other.

## **2.5. Discussion**

### **Principal findings and relevance to prior work**

This paper describes the collaborative design and development of *POD Adventures*, a blended gamified smartphone intervention for school-going adolescents with or at risk of anxiety, depression and conduct difficulties in India. The study aimed to understand access and appropriateness of digital interventions for adolescents and identify features to optimise: engagement with the problem-solving content, developmental and cultural acceptability and usability and contextual acceptability and feasibility of delivery.

This study found that a digital blended self-help format was acceptable to school-going adolescents in this context. The game prototype was designed to work offline and with provision of direct counsellor supervision and support during school hours in response to concerns from teachers and parents about inappropriate/unguided use of smartphones, and limited internet



access at schools and participants' homes. Local infrastructural limitations, particularly the lack of online functionality, limited design decisions that might harness the full range of benefits of mobile health interventions for this population, such as 'on-the-go' use to facilitate practice [124, 202] or the ability to connect with other users [146]. However, the design allows for further development of the game to include enhanced interactivity or online functionality in the future.

The gamified and narrative formats were found to be engaging by participants. Comprehension of problem-solving concepts was improved by revisions to the game contents wherein principles were made more explicit and concrete and supported by additional explanation, illustration, and repetition.

Gamified features such as user-choice, rewards and quizzes were found to be key aspects that participants endorsed and that enhanced their enjoyment of and engagement with the game. This is a consistent finding across the existing global mobile health (mHealth) literature and suggests these features may be universal components of an engaging design [194, 199, 202]. Design preferences in this study bear a number of similarities to SPARX [124], a CD-Rom and downloadable app-based game delivering cognitive-behavioural therapy (CBT) to adolescents for depression. SPARX is also set in three-dimensional worlds and included characters, avatars and gamification, levels, modules, and a "guide" character. Given the universality of these features, although regional translations and cultural adaptations would be necessary, it is hoped that the basic design would be acceptable across states in India.

Instructional and relationship support were found to be valued by participants. Aspects of these support functions were shared across the in-game guide and the supporting counsellor.

Participants also reported feeling supported by the game itself, consistent with studies from other countries examining therapeutic alliance with digital interventions [203]. It is important to note, however, that throughout the intervention planning and development process, participants and service providers also highlighted limitations of pure digital self-help to meet adolescents' needs in full. The intervention was therefore designed as blended with limited support from a counsellor [203, 204]. This is consistent with other global research which has found that some human support increases satisfaction [85] and adherence [205] with digital interventions for mental health.

The reconceptualization of this intervention as an open-access intervention for all help-seeking students fits with a broader move towards early interventions and selective or indicated prevention for adolescent mental health problems [33, 197, 198]. It is also aligned with evidence on problem solving as an effective strategy for emotional problems [195, 196] and recent research showing positive effects of skill-based digital mental health promotion interventions for young people with depression and anxiety [206].

## **Strengths**

A key strength of this study was the emphasis on user-centred design, following the guidance for design of complex interventions and principles of the person-based approach to intervention development [105, 192]. The iterative methodology enabled participants to guide the development and provide their inputs at each stage. Sensitivity of the researchers and design

team to local and cultural context, language, participant media preferences and digital access helped focus on user needs and formed important considerations for the prototype design. These have also been described in detail in this paper as they could inform the development of other similar kinds of programmes in the future. Another important strength is the grounding of intervention contents in relevant theory, clinical evidence, and past research. Participants were balanced with regard to age, grade, and gender across the different activities as much as possible. The number of adolescent participants across two diverse research sites as well as service providers that consisted of both clinical psychologists and lay counsellors also strengthened the study. Participants with previous mental health problems who had utilized counselling services in the past were also included.

### **Limitations**

Researcher or design team personal views may have influenced the process of development and interpretation of results. However, the relatively large number of adolescent participants and service providers who were consulted may have helped minimize bias. Parent and caregiver perspectives could not be included and would be a valuable addition to future work.

The research methods used, i.e., focus groups, co-design workshops and user-testing have limitations. Both teacher nominated referrals and self-selection may have introduced bias. However, the number of participants was large (N=46 for FGDs, N=22 for co-design workshops and N=50 for user-testing sessions) and ideas and feedback began to be repeated as activities progressed indicating saturation might have been reached. Working with a larger number of participants who had experienced mental health difficulties or experienced counselling may have strengthened the prototype development. Although this study took place in two different

urbanized regions in India, further work would be needed to confirm the generalizability to other settings such as semi-urban or rural settings.

### **Implications for research and practice**

There are relatively few digital interventions for adolescents or in LMICs, particularly smartphones apps that have been rigorously designed and evaluated or are available in local languages [14, 19, 24]. *POD Adventures* could help fill this gap, especially considering the challenges of delivering accessible and timely mental health support to adolescents in LMIC settings where mental health services are under-resourced and overstretched.

In India in particular, rapidly growing penetration of mobile devices, internet and social media is increasing opportunities for wider accessibility of these kinds of interventions [186]. *POD Adventures* could be adapted to settings where there is increased access to smartphones amongst adolescents or where it can be integrated into existing services (for example, as part of school counselling provision or as part of broader-based health promotion activities) at lower levels of the stepped care approach [41, 130]. As blended self-help intended to be delivered with some human support *POD Adventures* is potentially more cost effective and easier to disseminate [16, 203, 207, 208]. In the future, this support could be delivered through teachers, older peers or non-specialists with appropriate training, thereby also contributing to interventions that can be delivered in settings that have limited skilled alternative interventions or approaches, especially in LMICs [209].

**Next steps**

Future plans include the evaluation of POD Adventures through a randomised controlled trial in 2020 to evaluate effectiveness for help seeking students. A key focus of this work will include understanding optimal methods of delivery, frequency and nature of human support required and implications for scaling up in low resource settings.

### **3. AN APP-BASED GUIDED PROBLEM-SOLVING INTERVENTION FOR ADOLESCENT MENTAL HEALTH: A PILOT COHORT STUDY IN INDIAN SCHOOLS (STUDY 2)**

#### **3.1. Abstract**

**Introduction:** This paper describes the pilot evaluation of ‘POD Adventures’, a lay counsellor guided problem-solving intervention delivered via a smartphone app in Indian secondary schools. To test the feasibility and acceptability of POD Adventures for adolescents with a felt need for psychological support, and to explore the intervention’s effects on self-reported mental health symptoms, prioritized problems, stress, and wellbeing.

**Methods:** We used a mixed-methods pre-post cohort design. Participants were self-referred from grades 9-12 in two co-educational government-aided secondary schools in Goa, India. The intervention was delivered in two formats, ‘mixed’ (comprising individual and small group sessions) and ‘group’ (small group sessions only).

**Findings:** 248 participants enrolled in the study and 230 (92.7%) completed the intervention.

**Outcomes** at 4-weeks showed significant improvements on all measures that were maintained at 12 weeks. Large effects were observed on problem severity scores (4 weeks,  $d=1.47$ ; 12 weeks,  $d=1.53$ ) while small to moderate effects were seen on mental health symptoms, stress, and wellbeing. 22 students completed qualitative interviews about their experience of the intervention. Participants found POD Adventures easy to use, engaging and helpful in solving their problems. They were satisfied with the guidance provided by the counsellor irrespective of delivery format.

Discussion: POD Adventures was feasible to deliver with guidance from lay counsellors in Indian schools, acceptable to participants, and associated with large improvements in problem severity and mental health symptom severity. POD Adventures has promise as an early intervention for adolescents with a felt need for psychological support in low-resource settings.

### **3.2. Introduction**

Mental health problems account for nearly half of the burden of disease in adolescents, with depressive, anxiety and conduct disorders together accounting for over 75% of this burden [210, 211]. The impact of youth mental health problems falls most heavily on low- and middle-income countries (LMICs) [212]. India alone contains 20% of the global adolescent population, amounting to some 250 million 10–19-year-olds. At the same time, fewer than 10% of young Indians have access to formal mental health services [60]. The large mental health care gap in India and other LMICs coincides with a rapid boom in telecommunications and internet access [213]. Young people typically adopt new technologies and use mobile devices and the internet more frequently than older age groups, including for the purpose of accessing health-related information. Digital technologies have therefore been advocated as an important platform for scaling up youth mental health care [214], with the potential to increase reach, reduce stigma and lower costs compared with conventional clinic-based service models [11, 13, 16].

Notwithstanding varied access and gaps in access or connectivity, especially in rural areas, digital technologies offer unparalleled opportunities for transforming the delivery and use of mental health interventions in low-resource settings [213]. Recent systematic reviews of mental health apps and game-based approaches for adolescents highlight promising findings for

feasibility, acceptability, and engagement [13, 16-19, 121, 190, 215]. However, evidence of efficacy is scarce, particularly in low-resource settings [17, 213, 216].

This paper describes the pilot evaluation of ‘POD Adventures’, a problem-solving app intervention delivered in Indian secondary schools with guidance provided by lay counsellors. This approach integrates face-to-face contact with self-guided digital content and is consistent with findings that human facilitation can optimise engagement with and outcomes of digital interventions [122, 215]. POD Adventures is part of the PRIDE research program (2016-2021) that has been developing and evaluating transdiagnostic psychological interventions for common adolescent mental health problems in India [67]. Previous PRIDE studies [157, 159] revealed a high demand for psychological support among secondary school pupils, the majority of whom did not meet conventional clinical thresholds for mental disorders. Keeping this wider group in mind, POD Adventures was conceptualised as an open-access, early intervention to promote adaptive coping and to mitigate risks for developing more severe and socially disabling mental health problems in the longer-term. The app was collaboratively designed with adolescents through an iterative and person-centred approach, incorporating insights from a range of user consultations across a period of 18 months prior to conducting this study [217].

The aim of the current study was to test the feasibility, acceptability, and potential effects of POD Adventures as a guided app-based intervention for adolescents with a felt need for psychological support irrespective of assessed clinical severity. Our goal was to refine the intervention based on these findings in preparation for a rigorous evaluation through a randomised controlled trial.



### **3.3. Methods**

#### **3.3.1. Setting**

The study was conducted in two co-educational, government-aided, English-medium secondary schools in Goa, India, without established counselling services. Goa is one of India's most highly urbanized states and offered a relevant context in which to evaluate a technology-enabled intervention intended for low-resource settings. The schools comprised adolescents from both centrally located urban and remote rural areas of the state.

#### **3.3.2. Design**

A pre-post cohort study used an iterative mixed-methods design with concurrent data collection and analysis aligned with guidance for complex evaluations [118]. This enabled rapid feedback of emergent findings and concurrent refinements to the intervention and its delivery. A secondary objective was to assess indicative outcomes at 4 and 12 weeks after entry into the study.

#### **3.3.3. Ethics**

Approvals were obtained from the Indian Council of Medical Research, Archdiocese Board of Education in Goa, institutional review boards of Sangath (the implementing organization in India) and Harvard Medical School (the sponsor). Written assent (or consent for individuals aged 18 years or older) was obtained from all participating adolescents. Written consent was additionally sought from a parent or guardian for adolescents aged less than 18 years.

### **3.3.4. Participants**

#### *Eligibility*

Eligible participants were students in grades 9-12 (aged 13-19 years) who self-referred for psychological help with perceived stress and were proficient in written and spoken English or Konkani (as needed to participate fully in study procedures and the intervention). Participants were excluded if there was an elevated risk of self-harm or suicide requiring external referral. Risk was identified using a brief screening questionnaire followed by a structured interview-based assessment where indicated.

#### *Recruitment*

The sampling frame consisted of all students from the eligible classes in the two participating schools. Recruitment involved a brief 20–30-minute sensitisation session, delivered to individual classes, which promoted the intervention as a ‘stress reduction and problem-solving program’. These one-off sessions were conducted by a counsellor using a digital slideshow to support discussion about commonly experienced stressful problems and to provide a brief description of the intervention and referral process. Students were invited to self-refer by any one of three methods: (i) completing and returning a referral form at the classroom session; (ii) using a ‘drop-box’ for referral forms at other times; or (iii) approaching a member of the study team during school hours. Recruitment remained open from July 2019 until January 2020.

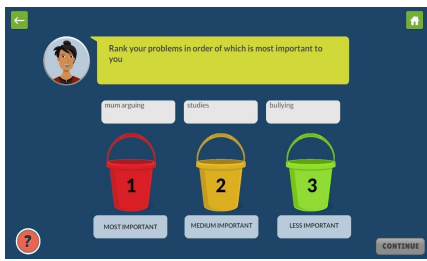

### **3.3.5. Intervention**

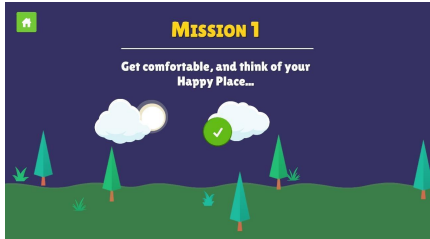

#### *Content*

The intervention comprised a smartphone app, ‘POD Adventures’, guided by a lay counsellor. The app was built around three problem-solving steps that had been developed and evaluated for

use in non-digital intervention formats through the PRIDE program [157, 159]: (i) ‘Problem identification; (ii) ‘Option generation’; and (iii) creating a ‘Do it’ plan. The app content was organised in two sections: (i) *Adventures*, in which problem-solving concepts and methods were taught through gamified stories along with guided practice of emotion regulation strategies; and (ii) *My POD*, in which a series of questions scaffolded the participant through step-by-step problem solving for their own problems (see Table 3.1).

**Table 3.1:** Intervention structure, content and delivery

	<i>App Content</i>	<i>Delivery and guidance</i>	
		<i>Mixed format</i>	<i>Group format</i>
Session 1	<p>‘P’ step of problem identification and prioritisation; practice of emotion regulation exercise of ‘colour breathing’, a guided breathing exercise with visualisation.</p>  <p>Problem prioritisation in ‘My POD’</p>	<p><b>Individual</b></p> <p>1:1 onboarding to orient the student to the app and build rapport.</p> <p>Independent gameplay of the app with support and troubleshooting as required.</p>	<p><b>Group</b></p> <p>Group onboarding to orient students to the app and build rapport.</p> <p>Independent gameplay of the app with support and troubleshooting as required.</p>
Session 2	<p>‘O’ step of option generation, weighing pros and cons and selecting the best option; practice of emotion regulation exercise of mindful stretching.</p>  <p>Minigame teaching option generation</p>	<p><b>Group</b></p> <p>Independent gameplay of the app with support and troubleshooting as required.</p>	<p><b>Group</b></p> <p>Independent gameplay of the app with support and troubleshooting as required.</p>

Session 3	‘D’ step of making a ‘do it’ plan for selected option; practice of emotion regulation exercise of ‘happy place’ guided imagery exercise of imagining a place they feel happy, safe and calm.	 <p>Happy place guided imagery exercise</p>	Group	Group
Session 4	Review the outcome of the ‘do it’ plan and make a revised plan where necessary; practice of emotion regulation exercise of the participant’s choice.	 <p>Conversation teaching review skills</p>	Individual	Group

### *Delivery*

POD Adventures was delivered during school hours in school-allotted rooms and on devices provided by the study team. Participants could not access the app outside these sessions. The app was designed to function offline (i.e., no internet connectivity required when in use) due to the lack of reliable internet connectivity in Goa. The app was offered in English with Konkani (local language) voiceover. The intervention delivery schedule consisted of four 30–40-minute sessions over 2-3 weeks. The first session included an ‘onboarding’ that provided an overview of the programme and introduction to the app (see **Table 3.1**). The fourth session concluded with a ‘review’ of students’ progress to consolidate learning. The onboarding and review lasted approximately 10 minutes each and were implemented by counsellors according to detailed scripts. For the remainder of the sessions, participants used the app independently with

counsellor guidance provided as and when required. Guidance entailed explanation and troubleshooting of any app content or technical issues.

To understand efficiency of delivery (as part of feasibility assessment), the intervention was delivered through two delivery formats (see **Table 3.1**), the order of which was randomly chosen. In the first instance, a ‘mixed’ delivery format was offered to all eligible study participants over a period of two months. This format comprised individual sessions at the beginning and end (sessions 1 and 4), while sessions 2 and 3 were conducted in groups of up to six participants in which participants used the app independently while a counsellor was available for support as required. For the remaining five-month period of the study, we used a ‘group’ format for all sessions. Scripts for the onboarding and review were adapted to each delivery format but covered the same overall content.

### *Counsellors*

Guidance was provided by four bilingual English and Konkani-speaking lay-counsellors. They were college graduates with two years of experience in delivering a face-to-face variant of the same problem-solving intervention [157] but no prior experience of delivering a digital intervention. Counsellors received a 4-day office-based training built around a printed intervention manual. Supervision consisted of weekly peer group supervision meetings (lasting approximately one hour), moderated by a clinical psychologist. In each meeting, counsellors rated and discussed selected audio-recorded sessions using a session fidelity scale.

### 3.3.6. Measures and collection procedures

Feasibility of research procedures was assessed through routinely logged rates of referrals, eligibility, assent and consent, and completion of outcome assessments. Feasibility of the intervention was assessed using data on session attendance, session duration and intervention completion (i.e., attendance at all four sessions) and fidelity ratings of onboarding and review discussions.

User satisfaction was assessed using the Client Satisfaction Questionnaire-8 [173] and four additional questions about the app ((i) The game has increased my ability to cope with problems on my own; (ii) The game was easy to use; (iii) The information in the game was easy to understand; (iv) The game was fun and interesting to use)) which obtained user ratings of helpfulness, usability, ease of understanding and enjoyment. Semi-structured qualitative interviews were conducted by three study authors (PPG, RS and AJ) with a purposively selected sample of students (n=22) who completed the intervention. We aimed to approximate equal quotas with regards to age, gender, and delivery format. Questions covered acceptability of attending school-based sessions, using the allocated smartphone, preferences for specific app features, game usability, helpfulness of the app content, and experiences of counsellor guidance. Interviews were conducted by two study authors (PPG & RS) and audio-recorded, transcribed verbatim and translated to English where necessary.

Clinical outcomes were assessed using four validated self-report questionnaires that measured psychosocial problem severity (Youth Top Problems (YTP))[218], mental health symptoms (Strengths and Difficulties Questionnaire (SDQ)) [219], perceived stress (Perceived Stress Scale

(PSS)) [178] and wellbeing (Short Warwick-Edinburgh Mental Wellbeing Scale (SWEMWBS)) [220]. All measures have been used in previous PRIDE studies [157, 159]. Outcomes were collected at baseline, 4 weeks, and 12 weeks after baseline.

### **3.3.7. Analysis**

Quantitative process indicators were described using frequencies, means, SDs and proportions.

Analysis of clinical outcome measures involved comparisons of pre-post scores using paired t-tests and was restricted to participants who completed baseline and end-point assessments.

Outcome measures were compared between baseline and the 4 and 12 week end-points.

Subgroup analyses were conducted by baseline SDQ severity to examine the impact of the intervention separately for those in the sub-threshold and case severity ranges using Indian SDQ cut-offs of 19 for girls and 20 for boys [175]. Subgroup analyses were also conducted for each delivery format (mixed and group).

Student interviews were analysed using an integrated inductive-deductive approach to thematic analysis [185]. Familiarisation with the data set was followed by line-by-line coding of a subset of manuscripts by two co-authors (PPG & RS). This created an initial list of categories and codes. An iterative process of coding additional manuscripts, reviewing, and revising the coding framework was followed before arriving at a final set of themes, categories, and codes. Interview transcripts were analysed using NVivo 12.

### 3.4. Results

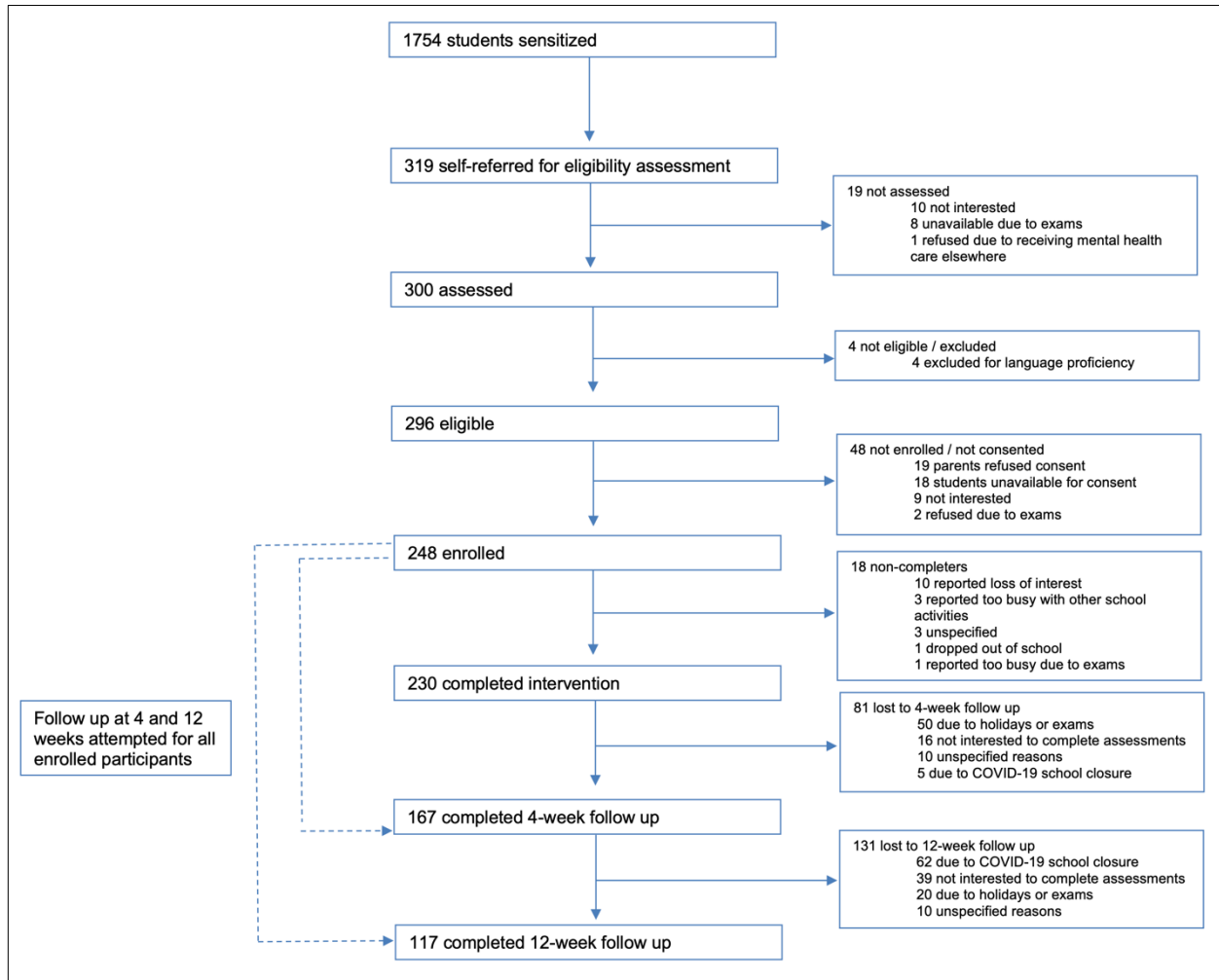
#### *Uptake*

Sensitisation sessions were conducted in 36 classrooms with 1754 students, from which n=319 (18.2%) referrals were generated (all self-initiated by students). Most of these self-referrals were made at the end of classroom sessions (n=207); the remainder occurred when a student approached a researcher (n=61) or deposited a referral form in a drop box (n=51). Rates of referral differed by grade, with very few participants from grades 10 (n=8, 2.6%) and 12 (n=34, 10.7%), which are national examination grades. From the referred sample, n=4 students (1.4%) were excluded based on literacy, no students were excluded due to risk and n=248 (83.7%) provided assent and parental consent to participate in the study. Reasons for non-consent were mostly due to loss to follow up, lack of interest or exams (n=29) followed by parents declining consent (n=19) (**Figure 3.1**).

#### *Demographics*

Consenting participants were aged 13-19 years (mean 15.57 years; 124 male and 124 female). The SDQ Total Difficulties mean score at baseline for the entire sample (n=248) was 15.90, SD=5.66. 177 participants (71.4%) scored in the sub-threshold range (SDQ Total Difficulties mean=13.13, SD=3.77) while the remainder of the sample, n=71 (28.6%), were at or above the case severity cut-off score (SDQ Total Difficulties mean= 22.79, SD=3.17). 157 participants (63.3%) reported clinically significant functional impairment on the SDQ Impact Supplement (SDQ Impact Mean=3.16, SD=2.02).



**Figure 3.1: Participant flow**

### **Completion**

230 participants (92.7%) completed four sessions within the designated time frame of 2-3 weeks.

Non-completers tended to be slightly older (completer mean age=15.51 years; non-completer mean age=16.33 years;  $p=.009$ ), female (female non-completers,  $n=13$  (10.5%); male non-completers,  $n=5$  (4.0%);  $p=0.05$ ) and reported higher SDQ Total Difficulties scores at baseline (completer mean score=15.66,  $SD=5.46$ ; non-completer mean score=18.83,  $SD=7.37$ ;  $p=0.02$ ). Reasons for non-completion were loss of interest ( $n=10$ ), exams ( $n=1$ ), other school activities ( $n=3$ ), dropped out from school ( $n=1$ ) and unknown ( $n=3$ ).

### ***Delivery***

Most participants (n=173, 69.7%) received the group delivery format and n=57 (22.9%) took part in the mixed format. The group format was associated with less cumulative session time over the course of the intervention (group, mean=1 hour 36 mins; mixed n=57, mean=2 hours 15 mins) and less counsellor time per student (group, mean = 9.46mins; mixed, mean=24.49 mins). The mean number of participants that attended group sessions was 3 instead of the planned 5-6 students, largely due to classroom scheduling challenges. Fidelity ratings of 71 sessions revealed a high level of faithfulness to the scripts for the onboarding and review (mean 1.77; SD 0.20; inter-rater correlation of 0.67).

### ***Satisfaction***

Service satisfaction scores ranged from good to excellent on the CSQ-8 (CSQ-8: M=26.20; SD=3.20; range=18-32) and the four app-specific questions. The item-wise mean for the CSQ-8 was 3.28, SD=0.40 (maximum of 4) and the app-specific mean score was 3.66, SD=0.34 (maximum of 4). Nearly all respondents (n=157; 91.3%) felt that the program and app had helped them to deal more effectively with their problems. There was a trend towards higher satisfaction ratings among participants who received the mixed format (group, mean CSQ= 25.89 [SD=3.37]; mixed, mean CSQ = 26.96 [SD=2.60]; p=0.05). Analysis of satisfaction by age and gender revealed no significant associations.

### ***Clinical outcomes***

Follow-up assessments at 4 weeks were completed for n=167 (67.3%) of the sample. Missing assessments were due to timing constraints around exams or holidays (n=50), participants who

did not want to complete assessments (n=16), early school closure due to COVID-19 (n=5), and non-attendance for unspecified reasons (n=10). Follow-up assessments at 12 weeks were completed for n=117 (47.2%) of the sample. Missed assessments were due to early school closure due to COVID-19 (n=62), participants who did not want to complete assessments (n=39), holidays or exams (n=20) and unspecified reasons (n=10). No significant differences were found for baseline characteristics of age, gender, problem severity or mental health symptoms for those who did and did not complete end-line or follow-up assessments.

Compared with baseline, outcomes at 4-weeks showed significant improvements on all measures (**Table 3.2**). These improvements were maintained at 12 weeks. Large effects were observed on YTP scores at both endpoints relative to baseline (4 weeks,  $d=1.47$ ; 12 weeks,  $d=1.53$ ) while small to moderate effects were seen on the SDQ Total Difficulties, PSS-4 and SWEMWBS. Similar improvements were observed across outcomes for both delivery formats: mixed, YTP at 4 weeks  $d=1.3$ ,  $CI=0.91-1.67$ ; YTP at 12 weeks  $d=1.36$ ,  $CI=0.93-1.76$ ; SDQ Total Difficulties at 4 weeks  $d=0.50$ ,  $CI=0.20-0.79$ , SDQ Total Difficulties at 12 weeks  $d=0.64$ ,  $CI=0.31-0.96$  and group, YTP at 4 weeks  $d=1.56$ ,  $CI=1.29-1.83$ ; YTP at 12 weeks  $d=1.64$ ,  $CI=1.28-1.98$ ; SDQ Total Difficulties at 4 weeks  $d=0.56$ ,  $CI=0.36-0.75$ ; SDQ Total Difficulties at 12 weeks  $d=0.67$ ,  $CI=0.21-0.69$ . There were no significant differences in outcomes based on age or gender.

Sub-group analyses by SDQ Total Difficulties baseline score (sub-threshold or case severity range) showed statistically significant improvements at 4 weeks for both groups on the SDQ Total Difficulties scale (sub-threshold (n=122) baseline=13.15, 4-weeks=11.65,  $t=3.99$ ,  $p<.001$ ; case severity(n=45) baseline=22.67, 4-weeks =17.54,  $t=7.50$ ,  $p<.001$ ) and YTP (sub-threshold

(n=122) baseline=6.28, 4-weeks=3.14,  $t=14.69$ ,  $p<.001$ ; case severity (n=45) baseline=7.64, 4-weeks=3.60,  $t=12.88$ ,  $p<.001$ ).

**Table 3.2:** Clinical outcomes

		<i>YTP</i>	<i>SDQ</i>	<i>PSS-4</i>	<i>SWEMWBS</i>
4 week pre-post (N= 167)	Baseline Mean (SD)	6.63 (2.07)	15.71 (5.56)	7.62 (2.66)	22.21 (4.35)
	4 weeks Mean (SD)	3.27 (1.72)	13.23 (5.40)	6.32 (2.47)	23.80 (4.48)
	Mean Difference CI	3.36 (3.01 - 3.71)	2.48 (1.78 - 3.17)	1.30 (0.82 - 1.78)	-1.59 (-2.37 - -0.80)
	P Value	<0.001	$p<0.001$	$p<0.001$	$p<0.001$
	Effect size (CI)	$d=1.47$ (1.25 – 1.69)	$d=0.54$ (0.38 – 0.70)	$d=0.41$ (0.25 – 0.56)	$d= 0.31$ (0.15 – 0.46)
12 week pre-post (N= 117)	Baseline Mean (SD)	6.62 (2.08)	15.93 (5.42)	7.66 (2.41)	21.74 (4.06)
	12 weeks Mean (SD)	2.93 (1.65)	12.60 (5.65)	6.19 (2.52)	23.23 (5.02)
	Mean Difference CI	3.70 (3.25 - 4.14)	3.33 (2.41 - 4.26)	1.47 (0.90 - 2.04)	-1.49 (-2.42 - -0.56)
	P Value	$p<0.001$	$p<0.000$	$p<0.001$	$p<0.002$
	Effect size (CI)	$d=1.53$ (1.26 – 1.79)	$d=0.66$ (0.45 – 0.85)	$d=0.47$ (0.28 – 0.66)	$d= 0.29$ (0.10 – 0.47)

### ***Intervention experience: participant interviews***

Exit interviews were conducted with 22 students who completed the intervention (aged 13-17 years; 11 male: 11 female). Three themes emerged from the interviews: (i) experiences of digital content; (ii) interactions with peers and counsellors; and (iii) impacts (**Table 3.3**).

*Digital content:* Participants highlighted the overall novelty of using a smartphone to learn skills that they could apply in their everyday lives. The level of privacy and ability to work independently were also mentioned favourably. Learning through characters' stories was a highly valued feature and a larger bank of stories was noted by several participants as a potential improvement. The app was generally considered easy to use but a few participants identified certain confusing game mechanics (e.g., 'drag and drop') and issues related to typing and difficult login passwords.

*Interactions:* Participation in the intervention was found to be socially acceptable with participants noting the positive influence of seeing other students signing up. Participants denied any difficulties related to teasing or stigma while leaving class to join sessions. Participants felt adequately supported by the counsellor's input and commented positively on counsellor qualities such as helpfulness and friendliness. Those participants who experienced the mixed delivery format did not show a clear preference for either the group or individual session options. Moreover, those who received only group sessions were pleased with the level of guidance available and did not believe that an individual session option would have been preferable. One participant expressed that the guidance from the counsellor was more helpful in making them feel better than the content of the app.

*Impacts:* Nearly all participants felt that the programme had positively impacted their prioritized problem. Some participants specifically mentioned more generalized benefits results from enhanced coping skills (e.g., time management and techniques for emotion regulation) and indicated on-going practice of these skills.

**Table 3.3:** Illustrative quotes from exit interviews with participants

<b>Experiences of digital content</b>	
Look and feel	<p><b>Engagement</b> <i>It was more visually attractive and better when it's visual rather than the normal books and all.</i></p> <p><b>Novelty</b> <i>I would say it was quite helpful, it was innovative, like something new, something different.</i></p> <p><b>Privacy</b> <i>The game has a nice quality, it keeps information private with headphones. This helps in maintaining privacy.</i></p>
Valued features	<p><b>Learning through relatable stories</b> <i>After seeing the story I came to know what was happening with me too, that it was the same thing, almost the same situation that was happening related to bullying and all. I had the same problem, so I figured out how to get help and so everything has become good now.</i></p> <p><b>Relaxation and emotion regulation</b> <i>Breathing out and breathing in. That is the thing I learnt a lot. That's what made my problem go down a bit. My friends would ask me what are you doing, "you just kept quiet suddenly" but I am practicing it.</i></p>
Usability	<p><b>Game mechanics and typing difficulties</b> <i>I had no real difficulties, but sometimes while putting in passwords it was difficult and the teacher would handle it.</i></p> <p><b>Easy to use</b> <i>Initially I was thinking that when we use the mobile to play the game it will be difficult but when I used it, it was easy.</i></p>
Improvements	<p><b>Improvements to Adventures</b> <i>More stories... stories feel like how lessons are. If the lesson is good so then we go to the end of the lesson, but if the lesson is boring then we don't, so those are the kinds of stories, like the stories were interesting</i></p> <p><b>Improvements to My-POD</b> <i>The same question was asked but in two different ways. I had to give the same answers, so I didn't really understand why, I had to write it twice.</i></p>
<b>Interactions with peers and counsellors</b>	
Social acceptability	<p><b>Influence of other students joining program</b> <i>"We all signed up together and it was good... We even recommended it to people from other schools but they were not from your group..."</i></p> <p><b>Leaving class for mental health support</b> <i>Initially when I was called from class to go to a session my friends used to ask me where I am going. I am not ashamed to tell them that I am going to the counsellor. It's OK, everyone needs help! Maybe it's just in a different way. The first time I just kept my mouth</i></p>

	<i>shut and didn't say, but when I went down for interval my friends asked me again, and I didn't want to avoid them or make it look like I was hiding stuff. I just said that I was with the counsellor. I thought I would get a very bad reaction but they actually asked me what happened! They were concerned about me.</i>
Guidance and delivery	<p>Comparisons with face-to-face counselling  <i>The game was really good, better than talking to someone.  Sometimes you don't like sharing or talking to someone.  In the game you are by yourself, you can put in what you want. You don't have to worry about another person.</i></p> <p><i>The app helps with its stress relieving methods but what comes from the person is much better than that. I wouldn't suggest it as much as talking to the person. That's much better, it makes you feel better. At least in my case it made me feel much better.</i></p> <p>Preference for individual or group sessions  <i>It felt good in the group. When I am individually doing it I get bored because nobody is there, if there is some movement of others then it feels a little good.</i></p> <p>Counsellor guidance valued  <i>It was very encouraging. It was very helpful to have someone encouraging you to go through with your solutions.</i></p> <p><i>Counsellors would also help in the middle if we needed. They were like friends and telling them our problems or problem solving wasn't scary. They would do it nicely.</i></p>
<b>Impacts</b>	
Direct problem resolution	<i>The problems I wrote are not affecting me in my life anymore, so now if I get a problem I think of myself as a POD master! I realised that there are options in life and we have gone through that...to test one of them and which is the best so we can just try out them.</i>
Ongoing practice	<i>Now I am doing regular practice sometimes because of which I feel relaxed and also getting less distraction so now I can give attention.</i>
Increase in knowledge and skills	<i>The top most thing I learned was about the time table, and to make my own.</i>
Future use of learning	<i>When I myself or any friends or even if my family has any problem then I can tell them this idea.</i>

### 3.5. Discussion

This study assessed the feasibility, acceptability, and indicative outcomes of an app-based, guided problem-solving intervention for adolescents ahead of a future trial. Overall, participants expressed a high degree of satisfaction with the experience of using the app and with the associated guidance provided by the supporting counsellors. Moreover, nearly one in every five students who attended classroom sensitization sessions about the app decided to self-refer,

suggesting a high degree of social acceptability that was corroborated by participant interviews. The high demand for the intervention is an important finding given the evidence that stigma can serve as a major barrier to uptake of school-based mental health interventions [221]. It is notable that adolescents highlighted privacy as one of the preferred features of the app and this aspect was also emphasized as part of the sensitization sessions. Even though the intervention was delivered in a group format for at least some of the sessions, adolescents were not required to disclose personal information to peers or directly to counsellors. More generally, our findings contribute to the evidence that digital formats may be appealing to adolescents regardless of exposure and access to technology, although most of the previous research in this area originates from high-income countries [16, 121, 190].

The intervention completion rate (92%) is noteworthy as low levels of adherence are frequently reported in digital adolescent mental health interventions, including in school settings [13, 16, 18, 19]. In line with our observations, the literature suggests that interventions involving regular interactions with a therapist or that are completed in a supervised setting tend to be more acceptable and effective and have higher rates of engagement and completion [13, 215]. The use of a person-centred approach in the app's development, entailing adolescent co-design activities and extensive user-testing, may also have enhanced overall acceptability [217]. Although rates of non-completion were low, it is notable that female and older participants with higher SDQ scores were more likely to discontinue. There were no significant differences in satisfaction according to age or gender suggesting that this might not reflect broader trends in acceptability, and it will be important to monitor these differential effects in future evaluations.



Participants valued guidance from the counsellors, whether it was provided individually or in small groups. Though satisfaction scores showed a trend in favour of the mixed delivery format, there were also indications that the group format provided a helpful normalizing context in which participants drew encouragement from seeing peers engaged in the program. Further, both formats of the intervention produced similar improvements across outcome measures. Given that group delivery was demonstrably more efficient than the mixed format (requiring less counsellor guidance time per individual student), there is a compelling argument for the group format being the default option for future studies.

POD Adventures showed potential for clinical impact across several outcome domains. Problem severity, mental health symptoms, stress and wellbeing were significantly improved at 4 weeks and these gains maintained at 12-week follow-up. Interviews corroborated these improvements, particularly with respect to resolution of focal problems. Participants also spoke about ongoing practice and recognized opportunities for future use of newly learned skills, suggesting that the intervention may help to build resilience to future problems despite its brief delivery schedule. We also note that similar effects on problem severity and mental health symptoms were observed irrespective of participants' baseline symptom severity. This is particularly relevant in India where previous PRIDE studies have demonstrated high demand for counselling from students who do not meet clinical thresholds [67, 157, 159] and where early interventions for emerging mental health problems are scarcely available [60].

In deciding on potential intervention modifications, we considered findings from this study as well as overall programme aims and resources required to make the changes. The resulting

changes consisted of: (i) *content changes*: revisions to text and story components to enhance acceptability; (ii) *user-interface and gamification changes*: updating of the colour scheme to make it more visually appealing and adding additional instruction screens; and (iii) ‘*back end*’ *technical changes*: use of simpler passwords and building online functionality allowing for real-time data syncing and remote delivery of the intervention. Finally, group delivery was selected as the optimal modality for a future evaluation.

### **Strengths and limitations**

The study did not use a control group so we cannot rule out the possibility of regression to the mean or improved outcomes due to factors other than the specific effects of the intervention. In addition, outcomes were assessed via self-report and so it is possible that participants may have reported more favourable responses because they were in regular contact with the counsellors and researchers. Follow up at both endpoints was impacted by participants who did not want to complete assessments and poor follow up at 12 weeks due to early school closures which may have biased our results and further limits conclusions about potential impacts which should be interpreted with caution. We will therefore consider briefer and more engaging methods to collect participant outcomes and follow them up for the future study. On the other hand, and in line with guidance for formative evaluations of complex interventions [217], we supplemented quantitative data with in-depth qualitative interviews to generate rich descriptions of intervention acceptability, feasibility, and impacts.

**Conclusions**

This mixed-methods evaluation found that POD Adventures was feasible, acceptable, and potentially effective at improving mental health symptoms and associated outcomes among help-seeking adolescents in a low-resource context. POD Adventures might be especially helpful when adolescents first begin to experience distress. The app can be delivered efficiently in schools – and possibly other settings - using a low-intensity group format that requires minimal guidance. Especially considering COVID-19, exploring remote digital delivery of such an intervention either independently or with remote guidance may be of special relevance.

## **4. A GUIDED INTERNET-BASED PROBLEM-SOLVING INTERVENTION DELIVERED THROUGH SMARTPHONES FOR SECONDARY SCHOOL PUPILS DURING THE COVID-19 PANDEMIC IN INDIA: PROTOCOL FOR A PILOT RANDOMIZED CONTROLLED TRIAL (STUDY 3)**

### **4.1. Abstract**

Introduction: “POD Adventures” is a gamified mental health intervention delivered via a smartphone app and supported by counsellors for a target population of secondary school students in India. This paper describes the protocol for a pilot randomized controlled trial of a remotely delivered version of the intervention in the context of COVID-19 restrictions. Our objectives are to assess the feasibility of research procedures and intervention delivery and to generate preliminary estimates of the effectiveness of the intervention to inform the sample size calculation of a full-scale trial.

Methods: We will conduct a parallel, 2-arm, individually randomized pilot-controlled trial in 11 secondary schools in Goa, India. This pilot trial aims to recruit 70 participants with a felt need for psychological support. Participants will receive either the POD Adventures intervention delivered over 4 weeks or usual care comprising information about local mental health services and national helplines. Outcomes will be assessed at two timepoints: baseline and 6 weeks post randomization.

Results: The first participant was enrolled on January 28, 2021, and 6-week assessment completed on April 4, 2021. Owing to a second wave of the COVID-19 pandemic in India,

schools in Goa were closed on April 22, 2021. Trial participants are currently receiving the intervention or completing follow-up assessments.

**Conclusion:** This pilot trial will help understand the feasibility of implementing and evaluating a remotely delivered digital mental health intervention in a low-resource setting. Our findings will be used to design future trials that can address difficulties of accessing psychosocial support in-person and support wider efforts to scale up evidence-based mental health interventions for young people.

**Trial Registration:** ClinicalTrials.gov NCT04672486;

<https://clinicaltrials.gov/ct2/show/NCT04672486?term=NCT04672486&draw=2&rank=1>

## **4.2. Introduction**

Globally, 10-20% of adolescents experience mental health conditions that a, but the majority of them do not seek help or receive care [210, 222]. The COVID-19 pandemic has increased the incidence of some youth mental disorders and exacerbated existing mental health problems [79, 81, 82, 223, 224], with worsening mental health outcomes linked to social isolation, disrupted education and worries about the future [225].

The pandemic has also led to rapid and large-scale changes in service provision, particularly in the transition to online delivery of care [12, 21]. At the same time, reviews of digital mental health interventions consistently raise concerns about the accessibility of digital technologies among disadvantaged groups [150] and difficulties keeping users engaged even among groups

with access to technology [13]. Though promising gamified approaches have recently emerged [13, 16] evidence from low-resource settings is especially scarce [19, 24].

The current protocol describes a pilot feasibility trial of ‘POD Adventures’, a novel gamified intervention delivered via a smartphone app and supported remotely by counsellors for a target population of secondary school students in India. Although the intervention was developed prior to the COVID-19 pandemic, the timing of the COVID-19 outbreak meant that the trial was launched during lockdowns and extended school closures. This required a pragmatic trial design that examined feasibility parameters related to the remote delivery and evaluation of POD adventures specifically, as well as offering insights into more general issues related to optimizing recruitment and sustaining engagement in online trials and interventions.

POD Adventures is part of the PRIDE research programme (2016–2022) that was conceived to address the scarcity of evidence-based interventions for common adolescent mental health problems in India and low-resource settings more broadly. This has involved developing and evaluating a suite of transdiagnostic psychological interventions that can be delivered by non-specialist (“lay”) counsellors in under-resourced school settings [157, 159, 226]. POD Adventures was conceptualized as an open-access, early intervention to promote adaptive coping and mitigate risks for developing more severe and socially disabling mental health problems in the longer term. The app was collaboratively designed with adolescents using a person-centred approach [217]. The intervention integrates brief guidance from a lay counsellor with self-guided digital content from an app, in line with findings that human facilitation can enhance engagement with and outcomes of digital mental health interventions [13, 122]. Co-design workshops with

young people and iterative piloting suggested that the optimal delivery mode for POD Adventures involved small group sessions with up to six students working independently on smartphones under the supervision of a counsellor. This offline, school-based format was evaluated in 2019-20 as part of an uncontrolled cohort study (N=248), with findings suggesting that the intervention was acceptable, engaging and feasible to deliver in school settings [226].

The current paper describes the protocol for a pilot randomised controlled trial of POD Adventures delivered in an alternative online format, necessitated by COVID-19-related school closures in 2020-21. School disruptions led us to reposition the intervention to be online and remotely delivered for students to use at home. The intervention maintains all elements of the pre-existing digital specification although modifications have been made for online recruitment and remotely delivered guidance from counsellors. The specific objectives are to assess the feasibility of research procedures and intervention delivery and generate preliminary estimates of the effectiveness of the intervention to inform the sample size calculation for a full-scale trial.

### **4.3. Methods**

#### **4.3.1. Design**

This protocol adheres to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 guidelines [227]. The study uses a parallel, two-arm, individually randomized controlled trial design. Outcomes will be assessed at two timepoints: baseline and 6 weeks post-randomisation.

#### **4.3.2. Setting**

The trial will be conducted in partnership with 11 co-educational, Government-aided, English-medium secondary schools in Goa, India with an overall sampling frame of approximately 2500 students. Schools are relatively small with an average of 230 students within grades 9-12, which will be targeted in the current study. Goa is one of India's most urbanized states and offers a relevant context in which to evaluate a technology-enabled intervention intended for low-resource settings. The schools comprise adolescents from both centrally located urban and remote rural areas of the state.

#### **4.3.3. Eligibility criteria**

Eligible participants will (i) be enrolled in grades 9-12 (ages 13-19 years) in collaborating schools; (ii) have access to an internet-enabled Android smartphone with a valid phone number for the duration of the pilot; (iii) be able to read and understand English; and (iv) provide their assent and parental consent (for participants under 18 years). We will exclude students who (i) are unable to understand intervention materials (for example, due to a reading or hearing disability or inability to comprehend English); and (ii) are identified as having an elevated risk of self-harm or suicide and requiring external referral, based on a brief screening questionnaire and follow-up structured interview.

#### **4.3.4. Interventions**

##### ***Intervention arm***

##### **Content**

POD Adventures is grounded in stress-coping theory [162], with a mechanistic focus on problem solving. The content of the POD Adventures app comprises two sections: 'Adventures' which



teaches problem-solving concepts and methods through contextually appropriate games; and ‘My POD’ which scaffolds the student through the application of step-by-step problem-solving procedures to their own prioritized problems. This is built around the acronym ‘POD’ which corresponds to three problem-solving steps: (i) identify one or more current distressing or impairing problems (‘Problem identification’); (ii) identify ways of modifying the chosen problem or the accompanying emotional response and select the most promising option (‘Option generation’); and (iii) implement the chosen solution and evaluate the outcome (‘Do it’) (**Table 4.1**). These problem-solving steps were originally refined and evaluated for use in non-digital intervention formats through earlier PRIDE studies [157]. The app will be provided in English with Konkani or Hindi (local language) voice-over options.

**Table 4.1:** Intervention overview

<i>Content sections</i>	<i>Description</i>	<i>Delivery</i>
Problem identification	Problem identification and prioritisation. This section includes practising an emotion regulation exercise of ‘colour breathing’, a guided breathing exercise with visualisation.	Individual telephone onboarding to orient the student to the app and build rapport. Independent gameplay of the app with support and troubleshooting as required.
Option generation	Generating options to solve the identified problems, learning to weigh pros and cons and selecting the best option. This section includes practising mindful stretching.	Independent gameplay of the app with support and troubleshooting as required.
“Do it” plan	Making a ‘do it’ plan for selected option(s); practising an emotion regulation exercise of ‘happy place’, a guided imagery exercise of imagining a place the participant feels happy, safe and calm.	Independent gameplay of the app with support and troubleshooting as required.
Review	Reviewing the outcomes of the ‘do it’ plan and making a revised plan where necessary; practising	Individual telephone review of student’s progress and understanding of POD steps.

	any emotion regulation exercise of the participant's choice.	Independent gameplay of the app with support and troubleshooting as required.
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### Delivery

The intervention is delivered individually through a combination of 1:1 telephone guidance and app use in the participants' own time. In the first instance, participants will be directed to a dedicated study website to watch a two-minute video that provides an overview of the app and how to use it. They will then attend a 1:1 brief telephone 'on-boarding' session with a counsellor in which the counsellor offers an overview of the intervention and explores the participant's prioritized problem(s). The counsellor will also provide the participant with a 4-digit app download password to download the app from the study website onto their own/shared family device. The app will be offered to participants for use in their own time over 4 weeks for a suggested minimum duration of 30 minutes per week. The app guides participants through the Adventures and My-POD sections and participants can choose to work on one or more self-nominated problems. They are encouraged to work at their own pace through the Adventures content, and with respect to at least one prioritized problem in My-POD, over 4 weeks.

For the duration of the study period, participants will receive a weekly reminder SMS containing messages of encouragement to use the app. They will also receive a notification to use the app if they do not log in for five consecutive days. On-demand telephone support from a counsellor will be available for addressing technical problems and clarifying app content throughout the study. A troubleshooting guide on app installation, resetting passwords, internet problems and how to get in touch with the study team will be available for participants to access on the study website.

Each participant's progress through the app will be visible to their allocated counsellor via a secure web portal. During the fourth week of the intervention or on completing the app contents, whichever is first, a brief 'review' call will be arranged between the counsellor and participant via text message or phone call to discuss the participant's progress, overall learning, and their plan for managing future problems. Participants who want additional help after the completion of the intervention will be provided with a self-referral sheet containing information about local and national mental health services.

### Counsellors

Guidance will be provided by two bilingual English and Konkani-speaking lay counsellors. They have two years of experience in delivering a face-to-face (analogue) problem-solving intervention [159] and one year of experience in facilitating use of the POD Adventures app in school-based group sessions [226]. Although college graduates, the counsellors do not possess formal training in psychotherapy or experience beyond the scope of low-intensity problem solving. The counsellors have received an initial four-day office-based training built around a structured intervention manual.

Counsellors will offer individual guidance to each participant, comprising the scheduled onboarding and review calls. In addition, counsellors will proactively make telephone calls to participants who do not use the app despite reminders.

Supervision will consist of weekly peer group supervision meetings (lasting approximately 1 hour), moderated by a psychologist. In each meeting, the counsellors will discuss progress of individual participants, review fidelity checklists of on-boarding and review sessions and identify areas where troubleshooting or support might be required by any participants.

### ***Control arm***

Through the study website, participants will be sent a digital flyer consisting of information and contact details about local mental health service providers and two recently established government provided/affiliated helplines [228, 229].

## **4.3.5. Measures**

### ***Participant characteristics***

At baseline we will collect descriptive socio-demographic data about the selected school populations and adolescents registering for the study. Students will provide their name, phone number, gender (male or female), date of birth, email address (optional), grade, home address, parent/guardian contact information, school name and how they learned about the study. Enrolled participants will also be asked to respond to four questions about their mobile phone and internet use relating to ownership and frequency of use.

### ***Feasibility outcomes***

Feasibility of research procedures will be assessed through routinely logged numbers and proportions of eligible/ineligible self-referrals (with reasons for ineligibility), assenting/consenting participants (with reasons for not assenting/consenting), randomised

participants (with reasons for not randomizing), and completed outcome assessments (with reasons for non-completion).

Feasibility of the intervention delivery will be assessed using data on attendance, intervention completion (i.e., attendance at on-boarding and review telephone calls and use of the POD Adventures app) and counsellor-completed fidelity checklists of onboarding and review discussions.

Intervention processes will be assessed through the number and duration of contacts with counsellors, number of days between on-boarding and review sessions, amount of app content completion, and reasons for non-completion. Data about participants' use of the app will also be captured securely from integrated analytics software. Key indicators will include login and logout timestamps, knowledge of problem solving assessed by multiple-choice quizzes, and self-reported use of problem solving in real-world situations.

User satisfaction data will be obtained from participants in the intervention arm at 6 weeks using an eight-item service satisfaction questionnaire [173] with four appended forced-choice items that ask specifically about the experience of using the POD Adventures app.

After the follow-up assessment, semi-structured qualitative interviews will be conducted with around 10-15 participants sampled purposively according to sex and age from both study arms; the exact number of interview participants will depend on thematic saturation. Interviews will be carried out over the phone by a researcher who has not been involved in intervention delivery.

Participants will be asked about their experiences of online research procedures such as recruitment, use of the study website, consent, and assessment procedures. Intervention arm participants will be asked additional questions about acceptability of using the intervention online, their experiences of guidance from counsellors, usability and utility of app features, and potential harms. Interviews will be audio-recorded and transcribed by a member of the study team.

### ***Clinical outcomes***

Clinical outcomes will be assessed using two validated self-report questionnaires that measure psychosocial problem severity (Youth Top Problems (YTP)) [174] and self-reported depression and anxiety (Revised Child Anxiety and Depression Scale – Short Version (RCADS-25) [230]. Assessments will be carried out at two timepoints: pre-randomisation at baseline and post-intervention follow up (six weeks after randomisation). Measures will be collected online through the study website.

#### **4.3.6. Sample size**

We used a confidence interval approach for the calculation of sample sizes for external pilot randomised controlled trials [231] which recommend a sample size of at least  $n=70$  participants (35 per arm) to estimate the standard deviation for a continuous outcome with good precision for a pilot RCT.

#### **4.3.7. Recruitment and consent procedures**

The participant flow diagram is shown in **Figure 1**. The sampling frame consists of all students from relevant classes in the participating schools. Recruitment will be initiated using (i) a brief

20–30-minute sensitization session, delivered to individual classes either online (via virtual classrooms) or, where social distancing policies allow, in school using a slideshow and brief video containing information about the study; and (ii) distribution of an electronic or printed information flyer via school moderated email/WhatsApp groups explaining the study and how to participate.

Interested students will be invited to visit the study website ([www.pod.sangath.in](http://www.pod.sangath.in)) where they will first be required to complete an eligibility assessment based on the study inclusion criteria. If the student is eligible, they will be able to watch an animated video about the study and read information about what study participation will entail. Ineligible students will be provided with a digital information flyer that includes details about local and national services and helplines. This will be provided in a language of their choice (English, Hindi, or Konkani).

As part of the study registration process, eligible participants will be asked to provide basic demographic details and create a password for their use of the study website. Following registration, we will obtain digital consent from participants above 18 years and assent from participants below 18 years. Parent /guardian (“caregiver”) consent will also be obtained for participants below 18 years. Prospective participants and caregivers (if the index adolescent is aged under 18 years) will be presented with information in writing, supported by an audio soundtrack in a preferred language, on the study website. The information will be followed by a series of “yes” and “no” questions to establish understanding and willingness to enrol in the research and verified by a digital signature. For assenting participants below 18 years, digital

parental consent will be followed by a confirmatory telephone call to the parent/guardian from the study team within two working days.

A toll-free helpline will also be made available for prospective participants to ask specific questions and seek technical support for registration.

#### **4.3.8. Allocation and randomisation**

Each participant will be allocated a unique, anonymized ID number after registering on the study website. Upon completion of consent, a notification will be sent to the study data manager via a secure web portal designed for the study data collection. Randomisation will be performed by the data manager on this platform and the outcome of allocation will be communicated to the participants through a telephone call from a researcher and through an SMS alert, both of which will inform the participant to log in to the study website for information about their allocation. The study website will create a personalized dashboard that directs the participant to their next step.

The randomisation algorithm will be computer-generated and stratified by school grade using randomly sized blocks of four, six, and eight. Participants and counsellors will not be blinded to the allocation assignment. However, other members of the research team (the Principal Investigator, trial statistician and researchers) will remain blind to participation allocation status.



#### **4.3.9. Data collection**

##### ***Screening and initial assessments***

The schedule for enrolment, interventions and assessments is summarized in **Table 4.2**.

Participants will complete a self-screen for eligibility and then register on the study website.

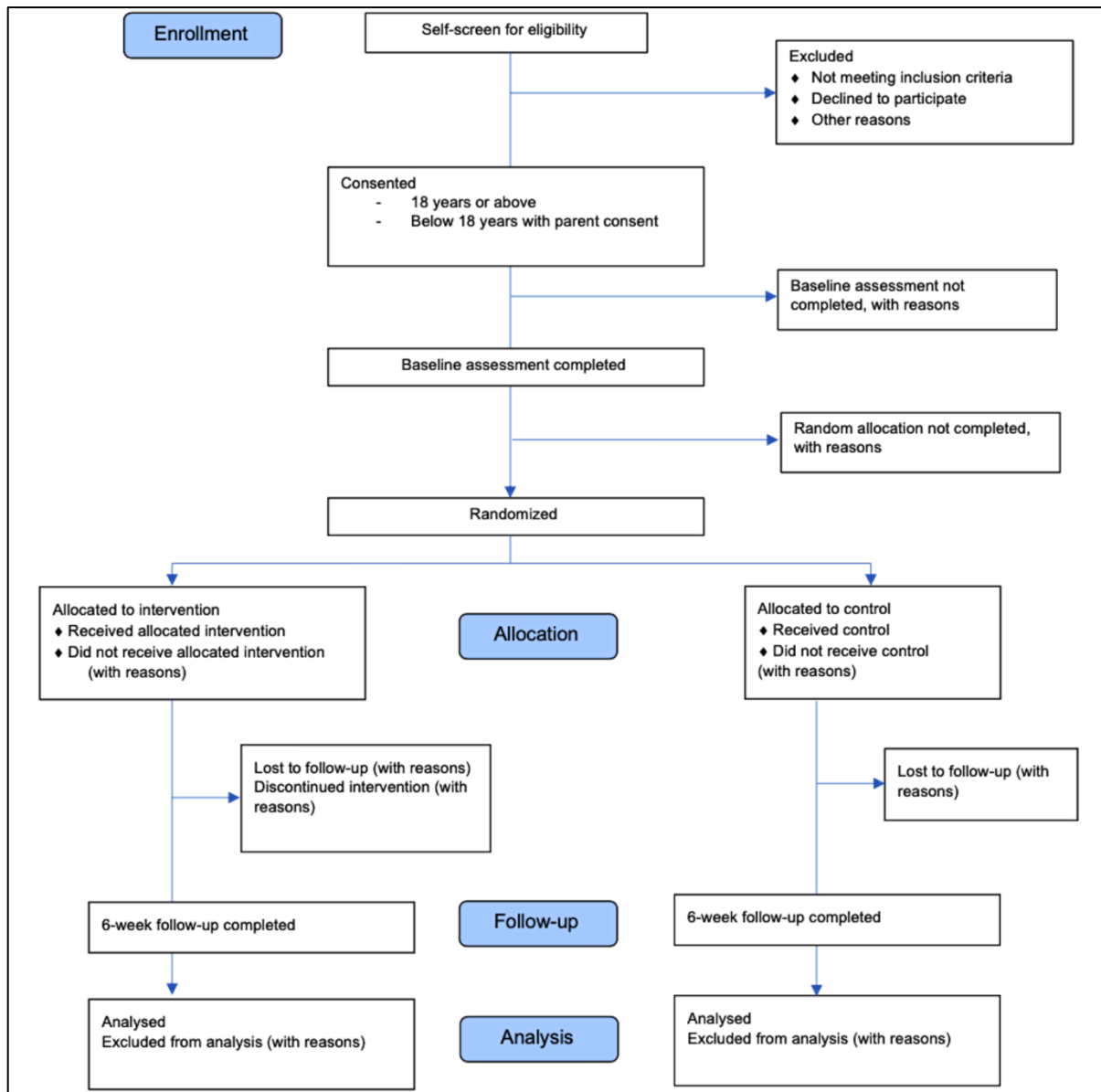
They will receive an automated SMS alert to complete the baseline assessment once assent/consent is received. A researcher will make contact by telephone to remind the participant if the baseline assessment has not been completed two days after this. The measures take approximately 15-20 minutes to complete online. Researchers will make up to four telephone attempts over the subsequent two weeks.

##### ***Follow-up assessment***

Participants will receive an SMS reminder 42 days (i.e., 6 weeks) post-randomisation to complete the follow-up assessment on the study website. This will be accompanied by a telephone call from the researcher using a standardised script that asks participants to complete the assessment. Automated SMS reminders will be sent to the participants every three days over the next two weeks or until the follow-up assessment is completed on the study website.

Researchers will make up to four telephone attempts following this due date, with a maximum allowance of two weeks.

**Figure 4.1:** Consolidated Standards of Reporting Trials (CONSORT) flow diagram that will be used to illustrate participation throughout the phases of the POD Adventures pilot trial



**Table 4.2:** Schedule for enrolment, interventions, and assessments

Timepoint	Enrolment	Allocation	Follow up at 6 weeks post randomisation
	7 working days	0 weeks	At 6 weeks
<b>ENROLMENT</b>			
Self-screener for eligibility	X		
Informed assent (participant) and consent (parent/guardian)	X		
Allocation			
<b>INTERVENTIONS</b>			
POD Adventures		X	
Usual care information		X	
<b>ASSESSMENTS</b>			
Demographic information	X		
Outcome assessments (self-reported) > Youth Top Problems (YTP) > RCADS-25	X		X
Process evaluation > Service satisfaction questionnaire > App process data (intervention arm) > Qualitative interviews > Research and intervention process data	X	X	X

### ***Qualitative interviews***

Within two weeks of completing the follow-up assessment, a subsample of participants, purposively selected from both trial arms, will be invited by telephone to take part in an interview.

***Strategies for promoting participant compliance, retention and completing follow-up***

Intervention participants' attendance at scheduled telephone sessions will be logged by counsellors. We will also undertake the following activities to support adherence to study procedures in both trial arms:

- i. All participants will receive an SMS instruction to complete their baseline and follow-up assessments, along with SMS notification once this is completed
- ii. All participants will receive a telephone call from a researcher two days after the first SMS alert with an invitation to complete the baseline assessment, and as soon as their follow-up assessment is due
- iii. If a participant cannot be reached by telephone after four consecutive attempts, they will be sent an SMS text message and asked to opt in for any further contact
- iv. Participants in the intervention arm will receive an SMS reminder one day prior to on-boarding and review telephone sessions
- v. All telephone calls and text messages, successful and unsuccessful, will be documented

**4.3.10. Data security and management**

The study will be hosted on the servers of Sangath, the implementing organization based in Goa, India. These servers will be encrypted, with data backups occurring daily. The study web portal and its associated data will be accessible only to authorized and approved personnel. When registering, participants will create password-protected accounts and the platform allocates a unique trial IDs to participants. For analyses, data will be de-identified by removing names, contact information and any other personal identifiers. Students who withdraw from the study

will have their data removed and a withdrawal confirmation notification will be sent from the research team by phone or email. All data will be stored securely for 10 years.

#### **4.3.11. Monitoring and safety**

##### Data monitoring

Monitoring and governance for the pilot trial will be provided by a Trial Steering Committee (TSC; comprising senior investigators and independent subject experts) and Data and Safety Monitoring Committee (DSMC; a fully independent group with relevant clinical and trials expertise). Any study protocol amendments will be agreed and formulated in conjunction with the TSC and DSMC and submitted to relevant institutional review boards for approval.

##### Harms

The study team will continuously monitor for any participant safeguarding concerns. At baseline, all participants will be screened for risk of self-harm or suicide. Risk will be identified using a brief screening questionnaire followed by a telephone-based structured assessment where indicated. If a participant reports the presence of any thoughts of self-harm or suicide during the baseline assessment or during on-boarding or review phone calls (intervention arm participants), a risk management session will be provided to the participant within 24 hours along with information about support services will be immediately provided by the counsellor. If deemed appropriate by the clinical supervisor, the participant will also be referred to an independent mental health specialist for further assessment/treatment. At the 6-week follow up assessment, all participants will be asked about any negative effects of using the intervention or participation in the study more generally.

### COVID-19 precautions

The research team will implement the pilot trial in line with local and national public health guidance and make every effort to minimize in-person visits to schools unless specifically requested by schools. Health and safety measures outlined in local government guidelines for school reopening will be strictly followed by research staff who may visit schools as part of any recruitment activities. In addition, fieldwork safety training will be provided to all study team members. Study team members will employ measures to maintain physical distancing and use of personal protective equipment such as masks in line with local health and safety protocols.

### **4.3.12. Analysis**

#### Statistical analysis

The statistical analysis for this pilot trial will be mainly descriptive in nature, aiming to provide estimates of key trial parameters and to inform power calculations for a future trial. The outcome measures will be summarized at baseline and at six-week follow up by trial arm. These will be summarized by means (standard deviation), medians (interquartile range), or numbers and proportions as appropriate to relevant subgroups (defined by age, gender and baseline outcome score). For continuous outcomes, histograms will also be plotted within each arm to assess normality and whether any transformation is required. Analyses will be conducted to examine the effect of the intervention in normal and clinical subgroups (as measured by the RCADS-25).

#### Qualitative analysis

Qualitative interviews will be transcribed verbatim and downloaded to NVivo V.12. Thematic coding frameworks will be constructed to allocate codes to emergent themes within the data, facilitating their identification and organization. Transcripts will be independently coded to

enable discrepancies to be identified and consensus reached about the interpretation and application of the coding framework. Data that do not fit the initial coding framework will lead to the generation of new themes and framework revision. Data will then be consistently classified, indexed and subject to thematic analysis using the refined coding framework.

#### **4.3.13. Ethics and safety**

Institutional Review Board approvals have been obtained from the Indian Council of Medical Research (ICMR); Sangath (the implementing organization in India); Harvard Medical School, USA (the sponsor), London School of Hygiene and Tropical Medicine, UK (collaborator) and the University of Sussex (collaborator). Individual school permissions have also been obtained for all participating schools. The Principal Investigator (PI) will act as custodian of the data in accordance with legislation of the research sponsor (Harvard Medical School) and funder (Wellcome Trust, UK).

#### **4.3.14. Dissemination plan**

School reports, consisting of the mean aggregate scores for the measures, will be prepared and shared with the school at completion of the data collection period. The study results will be prepared for academic publication in open-access mode.

### **4.4. Results**

Student sensitization sessions began online and in-person on January 11, 2021. The first participant was enrolled on January 28, 2021 and their 6-week assessment was completed on April 4, 2021. Due to a second wave of COVID-19 in India, schools in Goa were closed on 22<sup>nd</sup>

April. At the time of manuscript submission, trial participants are receiving the intervention or completing follow-up assessments, with all activities carried out remotely.

#### **4.5. Discussion**

This paper describes the POD Adventures pilot trial, which aims to assess the feasibility of conducting a future large-scale trial of a gamified mental health intervention for secondary school students in India. Designed as an early intervention for common youth mental health problems, POD Adventures is intended to meet the growing need for mental health support among secondary school students in India [232]. All intervention and research activities have been moved online in the context of COVID-19 restrictions. The results will therefore offer specific insights into the viability of delivering and evaluating psychosocial interventions under conditions of social distancing and school closures.

An individually randomised design was chosen for this study due to the relatively small number of available schools, which ruled out an alternative cluster-randomised design. Risks of contamination are minimized through remote online delivery, which limits potential for communication between participants that might ordinarily occur in school settings. Additionally, the choice of a usual care control, consisting of information about other services and helplines, rules out the possibility of contamination due to the same counsellors interacting with both trial arms [233].

Key challenges of this study may be uptake and adherence. Despite the compulsory shift to online education for students across India, there is still varied access in smartphone ownership and internet connectivity [234]. Young people from high-income settings have reported many



challenges impacting on their engagement with online interventions, such as limited access and technical issues, lack of time, doubts regarding the perceived helpfulness of the programme, and preferences for face-to-face help [13]. Further, delivery of self-directed digital programmes for youth at home and in other relatively un-monitored settings has been associated with relatively poor adherence [42]. A recent review of studies from Latin America showed similar challenges [141]. Low mental health literacy in our demographic may be another factor which may negatively impact uptake [235]. In anticipation of these challenges, the study uses a broad range of recruitment strategies aligned with existing best practice [19], such as in-person classroom sensitization (where possible), use of explanatory videos and flyers, and use of a toll-free telephone number for queries.

Competing demands for time may be another engagement barrier and has been previously observed in PRIDE studies conducted in Indian schools [157, 226]. Counsellor guidance and reminders via SMS or app notifications offered to participants in the intervention arm may positively impact retention [121]. Looking beyond the immediate context of this study, potential implementation barriers include a shortage of suitably trained, supervised, and motivated school counsellors. To address this concern, a separate component of the wider PRIDE research programme will examine the effects of a digital training curriculum on competences of prospective school counsellors to deliver an evidence-based problem-solving intervention.

The strengths of this pragmatic pilot trial include the novelty of the intervention and its pivot from in-person to online delivery in a low-resource setting. Outcomes will be assessed via self-report, thereby lowering the risk of bias due to unblinded outcome assessments. The study should

offer useful insights about the feasibility of remotely delivered mental health interventions for adolescents in similar contexts.

## **5. PILOT RANDOMISED CONTROLLED TRIAL OF A REMOTELY DELIVERED ONLINE INTERVENTION FOR ADOLESCENT MENTAL HEALTH PROBLEMS IN INDIA: LESSONS LEARNED ABOUT LOW ACCEPTABILITY AND FEASIBILITY DURING THE COVID-19 PANDEMIC (STUDY 3)**

### **5.1. Abstract**

**Introduction:** “POD Adventures” is a gamified problem-solving intervention delivered via a smartphone app and supported by lay counsellors for a target population of secondary school students in India during the COVID-19 pandemic. We aimed to evaluate the feasibility and acceptability of undertaking a randomized controlled trial of POD Adventures when delivered online with telephone support from counsellors.

**Methods:** We conducted a parallel, two-arm, individually randomized pilot-controlled trial with 11 secondary schools in Goa, India. Participants received either the POD Adventures intervention delivered over four weeks or usual care comprising information about local mental health services and national helplines. Outcomes were assessed at two timepoints: baseline and six weeks post randomization.

**Results:** 79 classroom sensitisation sessions reaching a total of 1575 students were conducted. 92 self-initiated study referrals (5.8%) were received, however only 11 participants enrolled in the study. No intervention arm participants completed the intervention. Outcomes at six weeks were not available for intervention arm participants (n=5) and only four control arm participants completed outcomes. No qualitative interviews or user satisfaction measures were completed as participants could not be reached by the study team.

Discussion: Despite modifications to address barriers arising from COVID-19 restrictions, online delivery was not feasible in the study context. Low recruitment and missing feasibility and acceptability data make it difficult to draw conclusions about intervention engagement and indicative clinical outcomes. Prior findings that showed high uptake, adherence and engagement with POD Adventures when delivered in a school-based context suggest that an online study and delivery posed the biggest barriers to study participation and engagement.

## **5.2. Introduction**

Mental disorders are a leading cause of disability among young people worldwide [1]. Most mental health problems begin by the age of 14, and one in five adolescents experiences a mental health disorder each year [1, 31, 236]. Despite growing evidence for effective psychosocial interventions, most young people do not receive appropriate help, particularly in low-and middle-income countries (LMICs) which contain 90% of the world's population aged under 25 years [4, 49].

Public health measures such as lockdowns and school closures, have severely impacted many adolescents during the COVID-19 pandemic, despite relatively little mortality and morbidity arising directly from infection [153, 237-239]. Schools were partially or fully closed for extended periods in many LMICs, coinciding with disrupted service provision more generally (e.g., to social care and specialist mental health services). There have been considerable psychosocial impacts linked to suspended routines and recreation, and rising concerns for family income and health [1]. The pandemic has also been linked with rising incidence of some mental

disorders among adolescents and exacerbations in pre-existing mental health problems [79, 81, 82].

COVID-19 disruptions have accelerated the transition to online delivery of mental health care [12, 21]. Reviews of digital mental health interventions have consistently raised concerns about the accessibility and reach of digital technologies especially among disadvantaged groups [150], and difficulties keeping users engaged irrespective of social background [13]. Promising engagement approaches have recently emerged (e.g., “gamified” interventions that offer game-like feel and relatable, interactive content [13, 16]). However, evidence is scarce on effectiveness and uptake especially in LMICs. A recent review of 18 systematic reviews and meta-analyses of digital mental health interventions for adolescents found no studies from low-resource settings [24]. Another comprehensive review of 83 studies of digital mental health interventions for children and young people found only one report from an LMIC [19].

The current study describes a pilot feasibility and acceptability trial of “POD Adventures”—a gamified problem-solving intervention delivered via a smartphone app and supported by lay counsellors. The intervention was aimed at a target population of secondary school students in India during the COVID-19 pandemic. POD Adventures is part of the PRIDE research programme (2016-2022), which was designed to address the scarcity of evidence-based interventions for common adolescent mental health problems in India and low-resource settings more broadly. PRIDE involved the development and evaluation of a suite of transdiagnostic psychological interventions to be delivered by non-specialist (“lay”) counsellors in under-resourced school settings [154, 159, 217].

POD Adventures is grounded in stress-coping theory [162] with a mechanistic focus on problem solving. It was conceptualized as an open-access, early intervention to promote adaptive coping for psychosocial problems and thus mitigate risks for developing more severe and socially disabling mental health problems in the longer term. The app was designed with adolescents using a person-centred approach [217]. The intervention integrates brief guidance from a lay counsellor with self-guided digital content from an app, in line with findings that human facilitation can enhance engagement with and outcomes of digital mental health interventions [13, 121, 122]. Co-design workshops with young people and iterative piloting suggested that the optimal delivery mode for POD Adventures was small group sessions with up to six students working independently on smartphones under the supervision of a counsellor [217]. This offline, school-based format was evaluated in 2019-2020 as part of an uncontrolled cohort study (N=248). Findings showed that the intervention was highly acceptable, engaging, and feasible to deliver in school settings. Indicative clinical outcomes showed significant reduction in problem severity and mental health symptoms after four and 12 weeks [226].

The timing of the COVID-19 outbreak meant that a planned randomized controlled trial designed to evaluate this offline in-school mode of delivery of POD Adventures had to be modified to fit around extended school closures, which were instigated in India from March 2020 onwards (and remained in place for nearly two years). The specific objectives of this modified trial were to assess whether the feasibility and acceptability of POD Adventures would be replicated when delivered online and with remote telephone-based support.

### 5.3. Methods

#### 5.3.1. Trial design

We conducted a parallel, two-arm, individually randomized controlled pilot trial with outcomes assessed at two timepoints: baseline and six weeks post-randomisation. Originally designed as a full-scale trial intended to take place in-person from June 2020, we modified the original protocol into a remotely delivered online pilot trial prior to trial registration or any participants enrolling in the original trial. The pilot trial protocol was approved by the Institutional Review Boards of Sangath (the implementing organization in India), Harvard Medical School (the sponsor), London School of Hygiene and Tropical Medicine (collaborator), and the University of Sussex (collaborator), and was registered at ClinicalTrials.gov (NCT04672486). Additional permissions were obtained from all participating schools. The pilot protocol has been previously published [240]. Trial findings have been reported according to CONSERVE-CONSORT guidelines for trials modified due to COVID-19 [241].

#### *Key modifications*

**Table 5.1** summarises key protocol modifications to accommodate online delivery. These modifications were agreed in consultation with the Trial Steering Committee.

**Table 5.1:** Modifications for online delivery

	<i>Protocol item</i>	<i>Original protocol</i>	<i>Modifications due to COVID-19</i>
1	Methods of recruitment	<ul style="list-style-type: none"> <li>- Sensitisation sessions conducted for school staff and students in-person</li> <li>- The process of study enrolment was in person via the researcher in the school</li> </ul>	<ul style="list-style-type: none"> <li>- Sensitisation sessions conducted for school staff and students, either in-person or remotely via virtual classroom</li> <li>- The process of study enrolment was online</li> </ul>
2	Intervention delivery	<ul style="list-style-type: none"> <li>- The POD Adventures app offered on researcher-provided</li> </ul>	<ul style="list-style-type: none"> <li>- The POD Adventures app made available for remote online</li> </ul>

		smartphones on school premises during designated times - Intervention on-boarding (at intervention start) and review (at completion of the intervention) conducted either individually or in small groups - On-hand troubleshooting help for technical or content issues available during intervention sessions in school - No usage reminders to students as intervention provided in school and on researcher device - No tailored in-app encouragement offered	download on participant's personal device - Intervention on-boarding, and review sessions conducted individually via telephone with the use of onboarding and review videos available on the study website. - Troubleshooting guides available on the POD website for troubleshooting the app, troubleshooting the POD website and for game installation - Toll free number and counsellor number for any other help needed- telephonic help - Notifications and reminders for download, weekly usage reminder and reminder for no log in for 5 days programmed - Automated weekly push notifications to offer in-app encouragement and motivation
3	Study design	- Planned as a fully powered randomized controlled trial with N=522 participants, to be conducted on school premises	- Modified to reflect a pilot trial design. Study objectives relate to testing acceptability and feasibility of online delivery of the intervention

### 5.3.2. Setting and participants

#### *Setting*

The trial was conducted during partial (comprising optional attendance in person at school on 50% basis as decided by students/parents) and complete COVID-19 school closures between December 2020 – May 2021 in 11 co-educational, government-aided, English-medium secondary schools in Goa, India, with an overall sampling frame of approximately 2500 students. Schools had an average of 230 students within grades 9-12. Goa is one of India's most urbanized states and offered a suitable context in which to evaluate an online intervention intended for low-resource settings. Goa was also the setting of an earlier uncontrolled evaluation of the offline



version of POD Adventures [226]. The schools comprised adolescents from both centrally located urban and remote rural areas of the state.

### ***Participants***

We recruited participants who were: (1) enrolled in grades 9-12 (ages 13-19 years) in collaborating schools; (2) had access to an internet-enabled Android smartphone with a valid phone number for the duration of the pilot trial; (3) were able to read and understand English as a primary language; and (4) willing to provide written assent/consent (including from a parent/guardian [“caregiver”] for participants aged <18 years). We excluded students who were unable to comprehend the intervention materials (e.g., owing to a reading or hearing disability or inability to comprehend English) or were identified as having an elevated risk of self-harm or suicide and requiring external referral, based on a brief screening questionnaire and follow-up structured interview during study enrolment.

### ***Recruitment***

Recruitment involved: (1) a brief 20-30-minute sensitization session delivered to individual classes either online (via virtual classrooms) or, where social distancing policies allowed, in school using a slideshow and brief video containing information about the study; and (2) where feasible, distribution of a downloadable or printed information flyer via school-moderated email/WhatsApp groups to enrolled students explaining the study and how to participate.

***Enrolment***

Interested students were directed to visit the study website from their homes and using their own or borrowed devices. The website could be accessed in a language of their choice (English, Hindi, or Konkani). Students first completed a short eligibility assessment consisting of questions related to their age, class, and language. Eligible students were then prompted to watch an animated video and/or read information about what study participation entailed. Ineligible students were provided with a downloadable information flyer containing details about local and national services and helplines.

Potential participants were guided through a brief online registration process, and asked to provide basic demographic details, a phone number, and to create a password for their use of the study website. This information was sought to be able to contact potential participants to obtain assent or caregiver/parental consent. Following registration, assent/consent was obtained through a web-based consent form via the study website which was e-signed and dated by participants and the caregiver/parent. Consent was obtained from participants aged  $\geq 18$  years and assent from those aged  $< 18$  years. For participants aged  $< 18$  years, web-based caregiver/parental consent was followed by a confirmatory telephone call from the study team within two working days. A toll-free telephone helpline was also made available for prospective participants to ask questions or seek technical support for registration.

### ***COVID-19 precautions***

The research team implemented the study in line with local and national public health guidance and made every effort to minimise in-person visits to schools unless specifically requested by the school authorities. Fieldwork safety training was provided to all study team members.

### **5.3.3. Interventions**

#### ***Intervention arm***

The POD Adventures intervention comprised an app and brief counsellor guidance via telephone. Participants also received information about local mental health service providers and government provided/affiliated helplines (i.e., enhanced usual care as offered in the control arm; see below).

The content of the POD Adventures app comprises two sections: (1) “Adventures” teaches problem-solving concepts and methods through contextually appropriate stories and games; and (2) “My POD” guides a user through the application of step-by-step problem-solving procedures for their own prioritized problem(s). The description of the app has been published elsewhere [217]. The app was offered in English text with English, Konkani, or Hindi voice-over options. Guidance was offered in a language of the participants’ choice.

The intervention was initiated by watching a one-minute pre-recorded orientation video via the study website and a brief 10-15 minute “on-boarding” telephone call with a counsellor in which the counsellor offered an overview of the intervention and worked with the participant to identify and prioritise a target problem(s). The counsellor also provided the participant with app download instructions, and participants were expected to download the app from the study

website. Participants were then encouraged to work at their own pace through the Adventures content, and apply the steps of problem solving to their own prioritised problem(s) in the My POD section of the app. During the fourth week of the intervention or after completing both sections of the app, whichever was first, a brief review call was scheduled between the counsellor and participant via text message or a telephone call. The purpose was to discuss the participant's progress, overall learning, and their plan for managing future problems.

For the duration of the study, each participant received a weekly reminder via text message containing encouragements to use the app. They also received a notification reminder to use the app if they did not log in for five consecutive days. In addition, counsellors proactively made telephone calls to participants who did not use the app despite reminders. On-demand telephone support from a counsellor was offered for addressing technical problems and clarifying app content throughout the study. A troubleshooting guide about installing the app, resetting passwords and online connectivity problems was made available for participants on the study website.

Guidance was provided by multi-lingual lay counsellors. Counsellors had two years of experience in delivering a face-to-face (analogue) problem-solving intervention [157] and one year of experience in facilitating use of the POD Adventures app in school-based group sessions [226]. The counsellors' supervision consisted of weekly peer group supervision meetings (lasting approximately one hour), moderated by a psychologist. In each meeting, counsellors discussed progress of individual participants, reviewed fidelity checklists from the telephone sessions, and identified areas where troubleshooting or support might be required by participants.

### ***Control arm***

Control arm participants received enhanced usual care, comprising a digital flyer with information about and contact details for local mental health service providers and government-provided and -affiliated mental health helplines.

### **5.3.4. Measures**

#### ***Participant characteristics***

We collected descriptive sociodemographic data about the selected school populations and adolescents registering for the study. Enrolled participants were also asked to respond to four questions about their mobile phone and internet ownership and use.

#### ***Feasibility***

Feasibility of research procedures was assessed using routinely logged frequencies and proportions of eligible/ineligible self-referrals (with reasons for ineligibility), assenting/consenting participants (with reasons for not assenting/consenting), randomised participants (with reasons for not randomizing), and completed outcome assessments (with reasons for non-completion).

Feasibility of intervention delivery was assessed using routinely logged frequencies and proportions of participants who logged into the app at least once, completed individual sections of the app, and completed the intervention overall (i.e., attended both the on-boarding and review telephone calls and completed both app sections). Granular data on participants' use of the app was also recorded using integrated analytics software. Exploratory variables of interest included

knowledge of problem-solving assessed through multiple-choice quizzes, and self-reported use of problem solving in real-world situations (extracted from the My-POD section of the app).

### *Acceptability*

User satisfaction data was intended to be collected from participants in the intervention arm at 6 weeks using an adapted eight-item user satisfaction measure that had been used in previous PRIDE studies [157], with four additional forced-choice items that asked specifically about the experience of using the POD Adventures app. Qualitative interviews were also planned to investigate participants' experiences of online research procedures in both trial arms, with additional questions planned about the acceptability of the POD Adventures app and counsellors' inputs for intervention arm participants. Interviews were to be conducted via telephone within two weeks of completing the follow-up assessment with a subsample of participants, purposively selected from both trial arms.

### *Clinical outcomes*

Indicative clinical outcomes were assessed using two validated self-report questionnaires that measure psychosocial problem severity (Youth Top Problems [YTP]) [174] and self-reported depression and anxiety (Revised Child Anxiety and Depression Scale–Short Version [RCADS-25]) [230]. Assessments were carried out at two timepoints: baseline (pre-randomization) and post-intervention follow up (six weeks after randomization).

#### **5.3.5. Sample size**

We used a confidence interval approach for the calculation of sample sizes for external pilot randomized controlled trials [231], which recommended a sample size of 70 participants (35 per

arm) to estimate the standard deviation for a continuous outcome with adequate precision for a pilot RCT.

#### **5.3.6. Randomization and blinding**

Each participant was allocated a unique, anonymized ID number after registering on the study website. Upon completion of consent, a notification was sent to the study data manager via a secure web portal designed for the study data collection.

The randomisation algorithm was computer-generated and stratified by school grade using randomly sized blocks of 4, 6, and 8. Randomization was performed by the data manager on this platform, and the outcome of allocation was communicated to the participants through a telephone call from a researcher and through an SMS text message alert, both of which informed the participant to log in to the study website for information about their allocation. The study website consisted of a personalized dashboard that directed the participant to their next step.

Participants and counsellors were not blinded to allocation status. However, other members of the research team (the principal investigator, trial statistician, and researchers) remained blind to participation allocation status.

#### **5.3.7. Data collection**

Baseline data was collected via the study website. Participants received an automated SMS alert to initiate the baseline assessment after completing the above-mentioned assent/consent procedures. A researcher additionally contacted participants by telephone to remind them to complete the baseline assessment if it had not been completed within two days.

The follow-up assessment was initiated by SMS text message invitation exactly 6 weeks after randomization. This message was followed up by a telephone call from a researcher using a standardized script that asked participants to complete the assessment. Automated SMS text message reminders were sent to participants every 3 days over the next 2 weeks or until the follow-up assessment was completed on the study website. Researchers made a minimum of 4 telephone attempts following the due date, with a maximum allowance of 2 weeks.

### ***Data security and management***

The study was hosted on the servers of Sangath, the implementing organization based in Goa, India. These servers were encrypted, with data backups occurring daily. The study web portal and its associated data were accessible only to authorized and approved personnel.

### **5.3.8. Statistical analysis**

The statistical analysis was mainly descriptive in nature, aiming to provide estimates of key feasibility and acceptability parameters and indicative clinical outcomes. The outcome measures were summarized at baseline and at 6-week follow up by trial arm. These were summarized by mean (SD), median (IQR), or n (%) values overall and stratified by age, gender, and baseline outcome score.

## **5.4. Results**

### **Feasibility of research procedures**

Overall, 79 sensitisation sessions (12 online; 67 in person) were conducted, reaching a total of 1575 students. From the sensitised sample, 92 referrals (5.8%) were received, all self-initiated by



students. Most referrals (n=69, 75%) originated from in-person sensitisation sessions, followed by referral forms via drop boxes placed in schools (n=18, 19.5%). Only five referrals (5.4%) were made through the toll-free helpline following online sensitisation.

From the referred sample, 38 students (41.3%) completed the online eligibility self-screener. One student was excluded because of literacy difficulties, and three were excluded due to no access to a smartphone (n=3). No students were excluded due to risk. Of the 34 eligible referrals, 16 (45%) completed consent procedures while the remaining 18 referrals did not enrol. Reasons for non-participation included students who were uncontactable (n=9), unable to access a phone/internet (n=4), exams (n=2), problem resolved (n=2), and parent consent denied (n=1). The mean time taken from referral to randomisation was 6.8 days (SD= 8.8).

Overall, 11 participants completed the baseline assessment and were randomized. Five participants were allocated to the intervention arm and six participants were allocated to the control arm.

### **Participant characteristics**

Randomized participants were aged 13–19 years (mean 15.3 years, SD= 1.0; 4 male and 7 female) (**Table 5.2**). All participants had RCADS scores in the normal range (RCADS T-score mean for anxiety and depression was 50.7, SD=7.8) (**Table 5.3**). Baseline demographic and clinical characteristics were similar across the two study groups. As part of the baseline assessment, participants also completed a brief technology exposure survey. Seven participants (63.3%) reported owning a personal mobile phone and four participants (36.4%) reported having

access to a family/shared phone. Ten participants (90.9%) reported using a smartphone and the internet nearly every day and one participant reported use every 3-4 days.

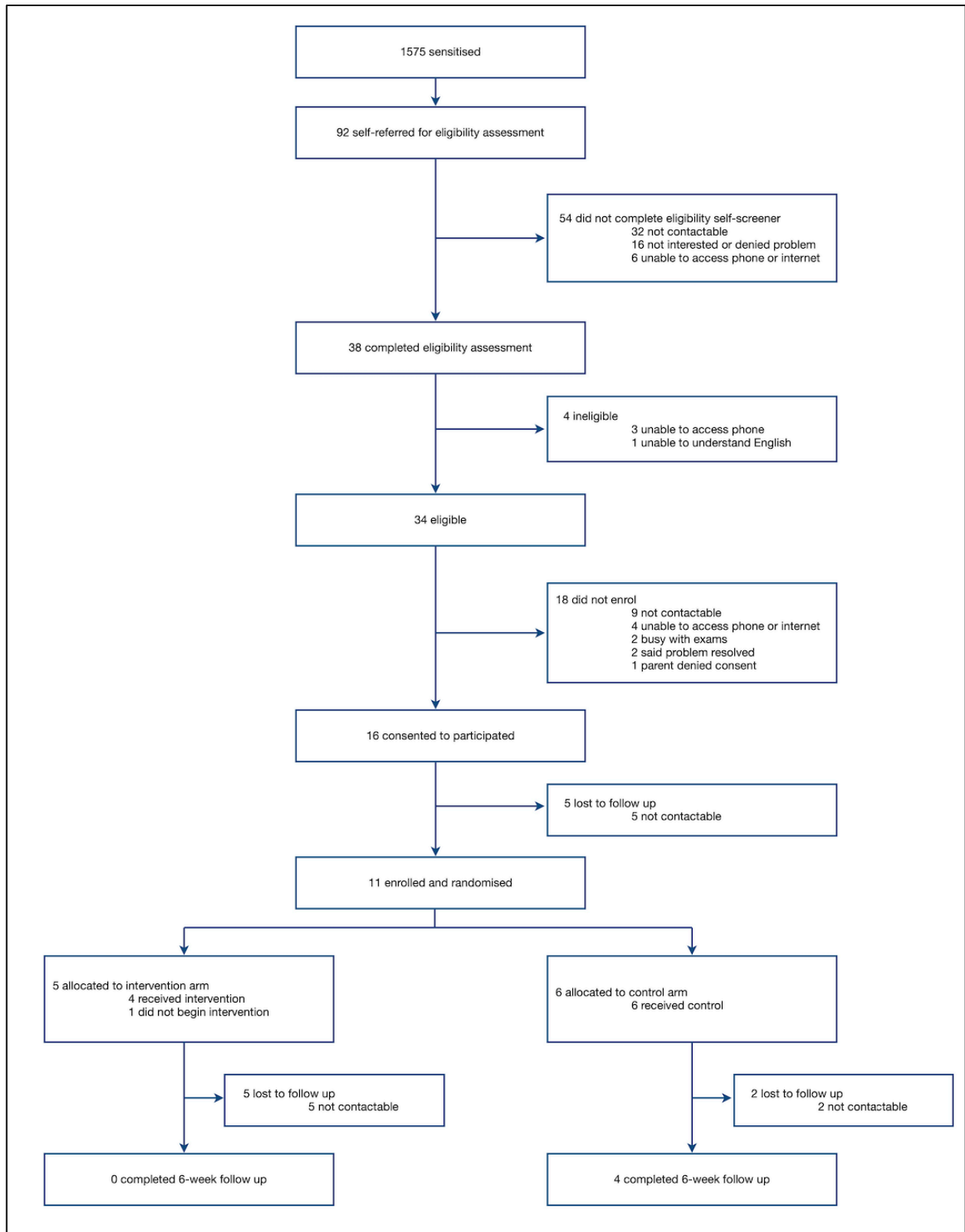
**Table 5.2:** Participant characteristics

		<i>Intervention arm (n=5)</i>	<i>Control arm (n=6)</i>	<i>Total (n=11)</i>
Sex	Female	3 (60.0%)	4 (66.7%)	6 (54.5%)
	Male	2 (40.0%)	2 (33.3%)	5 (45.5%)
Mean age (years), SD		15.0 (SD=0.5)	15.5 (SD=1.3)	15.3 (SD=1.0)
Grade	9	4 (80.0%)	3 (50.0%)	7 (63.6%)
	10	1 (20.0%)	2 (33.3%)	3 (27.3%)
	11	0 (0.0%)	0 (0.0%)	0 (0.0%)
	12	0 (0.0%)	1 (16.7%)	1 (9.1%)
Referral source	At classroom sensitisation session	5 (40.0%)	6 (60.0%)	11 (100%)

**Table 5.3:** Participant baseline characteristics

		<i>Baseline profile (N=11) Mean (SD)</i>	<i>Intervention arm (N=5) Mean (SD)</i>	<i>Control arm (N=6) Mean (SD)</i>
Youth Top Problem (YTP) total score		6.5 (1.7)	6.6 (2.1)	6.5 (1.4)
RCADS T Score	Total depression	49.3 (7.6)	46.8 (3.8)	51.3 (9.6)
	Total anxiety	52.0 (8.9)	50.6 (4.2)	53.2 (11.9)
	Total anxiety and depression	50.7 (7.8)	48.6 (2.9)	52.5 (10.4)

(YTP=Youth Top Problems measure; RCADS= Revised Child Anxiety and Depression Scale–Short Version)

**Figure 5.1: Participant flow**

### Feasibility and acceptability of intervention delivery

Process indicators for the intervention group are summarised in **Table 5.4**. Two participants did not begin the intervention (i.e., did not attend the on-boarding call with the counsellor or use the app), and no participants completed the intervention. Only one participant completed the first section of the app. Reasons for non-completion were unspecified as participants could not be reached by the study team. For the same reason, no qualitative interviews or user satisfaction measures were completed.

Data about participants' use of the app captured via an integrated analytics software was excluded from this analysis due to very low completion of the app and non-completion of sections such as multiple-choice quizzes, or self-reported use of problem solving in real-world situations.

**Table 5.4:** Intervention use indicators

<i>Intervention indicators</i>	<i>N=5</i>
Intervention orientation video watched on study website	4 (80%)
On-boarding session with counsellor completed via telephone	3 (60%)
First section of POD Adventures app completed	1 (20%)
Second section of POD Adventures app completed	0 (0%)
Third section of POD Adventures app completed	0 (0%)
Fourth section of POD Adventures app completed	0 (0%)

### Indicative clinical outcomes

No outcome data were available for intervention arm participants, none of whom could be reached to complete assessments.

### 5.5. Discussion

This study aimed to evaluate the feasibility and acceptability of POD Adventures, an app-based adolescent mental health intervention, when delivered online accompanied by telephone support from counsellors during the COVID-19 pandemic in India. Despite a range of modifications to address barriers arising from COVID-19 restrictions, online remote delivery was found to not be acceptable or feasible for the target population in the study context.

The current results contrast remarkably with feasibility and acceptability findings from a large school-based cohort study (N=248) of POD Adventures which was delivered offline on school premises prior to the COVID-19 pandemic. The latter study had comparatively higher rates of self-referral (18.2% versus 5.6% in the current study) and intervention completion (93% versus no completers in this study). Qualitative interviews with participants further showed that the app was easy to use, engaging and helpful in solving their problems when used offline, while the brief guidance provided by counsellors was experienced as adequate and helpful whether provided individually or in small groups [226].

In the current study, we additionally found that a very small proportion of self-referred students ultimately completed assent/consent procedures, and no participants in the intervention arm completed the intervention or outcome assessments despite the motivators for the intervention and the efforts by the research team. The absence of qualitative data about barriers to study participation and intervention use make it difficult to identify the extent to which participation challenges resulted from difficulties with smartphone or internet access, specific concerns about accessing a mental health intervention online (e.g., related to privacy or helpfulness), and/or the

timing of the study. In the latter regard, it is notable that the research took place during the especially severe second COVID-19 wave in India, which included widespread lockdowns and school closures in the context of overwhelmed health systems [1, 153]. Potential participants may have been concerned about their own physical health or illness affecting family members.

The findings of this study are broadly aligned with research related to the non-adoption or scale up of many promising technological innovations in health care [242]. Greenhalgh et. al., in three reviews of technology diffusion and implementation [242-244] have shown that the implementation of a new technology as part of changes to health care services is inherently very challenging. These reviews highlight that those innovations requiring changes in organisations, or the wider care system have a poor track record of adoption due to the dual challenge of non-adoption by individual users and difficulties with spread or scale up. They further emphasise that it is not only individual factors that make or break a technology implementation effort but the dynamic interplay between these factors. The more complex an innovation or the setting in which it is introduced, the less likely it is to be successfully adopted or scaled up. They also emphasize that methodologically robust RCTs alone will not elucidate these complex interactions and emphasise the need for more studies that are interdisciplinary, nondeterministic, locally situated, and designed to examine the recursive relationship between human action and the wider system context [245]. Further, findings from this study are consistent with those from recent reviews which show that digital interventions may achieve greater uptake and sustained engagement when delivered in structured and guided settings, such as schools or clinics [13, 19, 24]. Furthermore, these reviews have concluded that interventions which involved educational programmes completed in the participant's own time (i.e., at home without supervision) are not

effective. Li et. al., found that prior experiences of accessing mental health counselling may make students more open to online services [246], a finding that was not relevant to the present sample as they had limited experiences of in-person mental health services. Given the prior findings that showed high uptake, adherence and engagement with POD Adventures when delivered in schools [226], it seems likely that an online study and remote delivery rather than the app content were the biggest barriers to study participation and engagement. Relatedly, a systematic review by Garrido et. al. found that study dropout rates for digital interventions for depression and anxiety with young people tended to relate more to recruitment methods, especially in the case studies completed by participants at home/in their own time, than to non-engagement of the interventions themselves [13].

Findings from the implementation of remote learning approaches in schools in LMICs around the world have revealed extremely low rates of smartphone and internet access, ranging from 2-6% of young people with access at home. This has impeded learning and school participation throughout the COVID-19 pandemic [152]. In the current study, self-referring students who were unable to enrol in the study reported lack of access to a smartphone or internet as the most common reason for non-participation. Even among those participants who did enrol in the study, it is possible that they faced recurring or intermittent difficulties with accessing a smartphone and/or internet connectivity. For intervention arm participants in particular, telephone guidance and text messages may not have been readily accessible due to sporadic phone access.

Another key barrier may have been limited sensitization in a sample with little to no prior experiences of formal mental health interventions. It is possible that the brief classroom

sensitization session provided as part of recruitment was insufficient in building an understanding of the intervention features or potential benefits when delivered online.

Recent research shows that enhancing mental health literacy and addressing concerns about the implications of making use of online help-seeking (such as concerns about privacy, that it may be too impersonal, or that the help would be unreliable and untrustworthy) may help build demand from young people [132, 246, 247].

### **Implications**

This study suggests there may be a gap between the potential that online digital interventions offer and the reach and uptake of these technologies, especially for adolescents from LMICs [22], emphasising the ongoing need for in-person-delivered interventions as well as the development and evaluation of technologies that are context-specific. For example, use of web browser-based rather than app-based interventions as they do not require downloading or regular updates or work on any smartphone device [12, 22].

There is also a pressing need to distinguish digital mental health interventions by their content characteristics and their delivery characteristics. Findings from this pilot trial suggest that online delivery of POD Adventures was not feasible, despite earlier evidence that the content of the app was useful, appropriate, and potentially effective in the same population. Furthermore, distinct adaptations that account for population-specific needs of adolescents (e.g., technology ability and access, literacy levels, media, and language preferences) are needed [22]. Interventions which explicitly aim to reduce demographic disparities related to intervention retention (e.g., the use of very brief digital interventions such as single session rather than multiple sessions) should be



evaluated [248, 249]. Finally, judicious use of technology for trial procedures and the use of hybrid approaches, which include in-person interaction at school may help conduct evaluations [250].

## **Conclusion**

Findings from this pilot trial are inconclusive about whether the key barriers to adolescent participation were due to difficulties accessing online research procedures, intervention delivery, or a combination of both, which may have been exacerbated by COVID-19 pandemic conditions. More studies with this age group and in similar settings are needed to establish the generalisability of these findings.

## 6. DISCUSSION

### 6.1. Introduction

This thesis has described the co-design process and formative evaluation of *POD Adventures*, a digital game-based intervention aimed at improving adolescent mental health in schools in India. This thesis incorporated three studies that were embedded within the PRIDE adolescent mental health research programme [156-160]. Together, findings from these studies extend the current evidence base on the acceptability and feasibility of digital mental health interventions (DMHIs) for school-going adolescents in India and similar LMIC contexts. This chapter provides a concluding summary and discussion of the findings of the three studies within the context of existing literature. It also outlines strengths and limitations of this thesis and provides recommendations for future practice and research.

### 6.2. Summary of findings

The findings from the three studies represent, to the best of our knowledge, insights from the only counsellor-guided game-based DMHI designed for school-going adolescents in India or an LMIC [23, 24, 73]. Study 1 involved co-design activities which were aimed at identifying features that would optimise engagement, cultural and contextual acceptability, ease of use and feasibility of a game-based problem-solving intervention in low-resource schools. The co-design process followed a person-centred approach to digital intervention design [105]. We used iterative in-depth qualitative research to understand the first-hand context and perspectives from potential providers and end users. The final prototype of the POD Adventures app comprised a set of interactive and gamified vignettes and a structured set of problem-solving questions to consolidate and generalise learning while encouraging real-world application. Delivery was

endorsed in a guided format wherein lay counsellors provided brief on-boarding and progress review support at the beginning and end of the intervention. Findings also supported delivery in an open-access format i.e., open to all help-seeking students irrespective of clinical case thresholds for eligibility, consistent with early intervention paradigms.

Study 2 tested the acceptability and feasibility of guided delivery of POD Adventures to adolescents in school settings. This study was additionally aimed at understanding the potential impacts of the intervention on self-reported mental health symptoms, prioritised problems, stress and well-being. The intervention was delivered in two formats, 'mixed' (comprising individual and small group sessions) and 'group' (small group sessions only). Findings showed high completion and satisfaction rates and that the intervention was associated with large improvements in problem severity and mental health symptom severity. Findings indicated that POD Adventures was feasible to deliver with guidance from lay counsellors and that participants were satisfied with the guidance provided irrespective of delivery in an individual or group format. We concluded that delivery via a group format would be an efficient strategy for delivery in schools.

Study 3 was originally planned as a full-scale randomised controlled trial (RCT) but was modified due to COVID-19 school closures and lockdowns. The modified study comprised a pilot feasibility RCT of POD Adventures when remotely delivered with telephone guidance from counsellors. This study aimed to assess whether the feasibility and acceptability of POD Adventures would be replicated when delivered online and with remote telephone-based support in the context of COVID-19 restrictions. It also aimed to generate preliminary effect size

estimates for use in designing a full-scale trial. Despite modifications made to conduct the study online with remote support, this format of the intervention was not feasible. It was concluded that the biggest barriers may have included difficulties accessing online research procedures, remote intervention delivery or a combination of both, which may have been exacerbated by the ongoing COVID-19 pandemic conditions at the time. It is noteworthy that findings from this study contrasted with the prior findings of Study 2, which showed high uptake, adherence and engagement with the intervention when delivered in person in schools.

Overall, the findings of this thesis show that POD Adventures was acceptable and feasible to deliver in-person in school settings and was helpful for adolescents wanting psychological support in line with research that supports the potential integration of digital games into mental health services [17, 23, 101, 103]. The findings are also consistent with insights from systematic reviews, albeit primarily of studies from high-income settings [13, 24, 91], which show that DMHIs have greater uptake and engagement when they are delivered in structured and guided settings such as schools. Finally, the findings lend support to the value of problem-solving as a possible first-line intervention in school settings [251] while underscoring the need to address critical questions about delivery via an online format in settings outside school [242, 252].

### **6.3. Strengths and limitations**

#### **Strengths**

A key strength of the current thesis was the use of mixed methods research designs which were informed by established conceptual frameworks for mental health service design and participatory research [105, 118, 172, 192, 253]. The explicit focus on co-design and involvement of student inputs at each stage of design and development further helped to capture

adolescents' preferences and insights first-hand and was a related strength. Sensitivity of the researchers and the design team to the adolescents' local and cultural context, language, media preferences and digital access strengthened the intervention design. In fact, a recent systematic review of game-based interventions for young people's mental health promotion and treatment by Ferrari et. al., [23] gave the highest service user involvement ratings to the approach used to design POD Adventures in Study 1 as compared with 30 other international game based interventions [217]. This review scored stakeholder involvement on the following categories: partnership and collaboration in game development, consultation and feedback on the game, game testing/study data collection on game experience or acceptability, and gameplay by youth study participants.

The use of diverse samples for Study 1 and Study 2 which were balanced with regard to age, grade and gender across the different activities provided us more confidence in the results. Further, the inclusion of participants with previous mental health problems who had previously utilised counselling services (Study 1) may have increased the appropriateness and quality of the intervention [254, 255]. A related strength was the inclusion of qualitative feedback from service providers (Study 1) and adolescents (Study 1 and Study 2). The collection of qualitative data from participants has been shown to be an ideal method for eliciting the perspectives of potential or current service users, and to contextualise learnings especially during the early stages of research on areas where there is little previous work [256].

Another important strength was that the content of the POD Adventures intervention itself was grounded in relevant theory and clinical evidence. Past research endorses problem solving as a

widely applicable therapeutic approach for emotional problems and for a range of psychosocial stressors [55, 257-259]. Evidence from two recent comprehensive systematic reviews [251, 260] has highlighted the versatility, practicality, simplicity, and flexibility of problem solving for depression and anxiety. Findings from Michelson et. al., further suggest that problem solving may be most appropriate during earlier clinical stages and potentially as part of primary prevention, and generalisable across diverse contexts notwithstanding implementation challenges that may be faced in schools or structural inequalities [251].

### **Limitations**

The current thesis has some limitations. Although a robust co-design process was attempted, the methods employed had drawbacks. First, adolescent involvement throughout the entire research lifecycle was missing. Researchers from the fields of participatory research, (for example, [261-264]) and digital mental health intervention design [13, 18, 265] recommend that end-users be involved at all stages of design, from problem identification to evaluation, to maximise acceptability and effectiveness of interventions [105]. While this thesis included consultation and collaboration via FGDs, co-design activities and user-testing with adolescents, we did not engage adolescents in activities where they directed or led research activities. Further, we were unable to undertake any co-design activities prior to Study 3 due to COVID-19 restrictions. It is possible that some feasibility and acceptability issues may have been detected if these activities were conducted. Involving end users in research has been shown to ensure the research remains grounded in the service-user perspective and therefore is more practical and relevant. In fact, studies involving end-users as co-researchers have been found to have higher recruitment and retention rates and improved quality of data [266]. Second, we did not collect any feedback on

the experience of co-design itself. This may have been a missed opportunity for participants to reflect on and learn from their own experiences as well as to share valuable insights about experiences of participatory research for other projects wishing to conduct similar design and development activities [265]. Third, the use of a reporting tool such as the Guidance for Reporting Involvement of Patients and the Public (GRIPP) guidelines would have complemented this thesis. GRIPP provides a checklist to report involvement of people in research and helps document aspects of involvement that went well, as well as those that did not, to ensure that subsequent studies can build on the user-involvement experiences [267]. Fourth, it is possible that issues related to a power imbalance between the research team and adolescents involved as research participants impacted our findings. This challenge has been found to be potentially amplified in LMICs as compared with high-income countries where mental health is often less stigmatised and young people's opinions are more commonly sought [110, 268]. While robust assent and consent procedures were followed, and co-design activities included techniques to build rapport and create a comfortable environment, researchers may have been viewed as authority figures which led to apprehensions to provide honest or critical feedback. Fifth, while service providers were involved in Study 1, we did not systematically collect their feedback in Study 2 or Study 3. In addition to this, views of parents/caregivers and teachers could not be included in this thesis due to practical constraints of the study setting and schools involved in the studies. Inclusion of their perspectives about adolescent experiences, symptoms, supports and enabling structural factors may have strengthened the POD Adventures intervention and delivery model [269, 270].

It is possible that self-selection occurred in participants who volunteered to take part in the research activities. They may have been more likely to have an interest in mental health research or have lower levels of stigma or hesitation about help-seeking although they may still be representative of proposed end-users [132, 271-274].

Concerns about the cost and timeframe of the pipeline from development to implementation of digital interventions have been regularly raised, particularly the need for faster application of findings into community settings [18, 25, 108, 109]. In the case of POD Adventures, the timescale from design to pilot evaluation was approximately four years. Given the fast pace of evolving digital technology and culture, it is possible that participant preferences for POD Adventures changed over the course of the thesis period [275, 276]. Although refinements to POD Adventures were made over the course of Study 1, Study 2 and Study 3, these may not have been sufficient to sustain engagement.

Another important limitation of the studies included in this thesis is that they did not consider potential harms of the intervention in detail. While Study 3 included a single qualitative question about any negative effects experienced, this may not have been sufficient to understand possible harms. Most studies of DMHIs, especially game-based interventions, have not yet explicitly addressed harms such as stigma [221] or gaming disorders in their studies [23]. Ferrari et. al., suggest that a partial explanation for the lack of attention to possible negative effects or even addiction in applied games for mental health relates to their serious therapeutic purposes (i.e., symptom reduction, treatment facilitation or support or education) or that they are now considered part of everyday life and no more addictive than other daily activities or hobbies [23].



Finally, the absence of a control group further limits the generalisability of the findings of this thesis.

#### **6.4. Implications for research and practice**

Future studies of POD Adventures should aim to understand the enablers and barriers to intervention adoption and scale up. For this purpose, the use of frameworks such as ‘NASSS’ (‘non-adoption, abandonment, scale-up, spread and sustainability’) by Greenhalgh et. al., [242] may help identify factors which limit the chance of achieving large-scale or sustained adoption of the intervention. Future studies should additionally focus on gaps highlighted by the wider literature on DMHIs. These include limited insights about putative mechanisms of the intervention in achieving clinically meaningful outcomes [25]; the relationship between user engagement and outcomes [277]; in which settings (for example, schools, clinics, online, etc.) and contexts (for example, mode of delivery, delivery agent, etc.) POD Adventures is most effective [12, 13, 22]; and potential harms [23]. Studies should also collect data and report differential effects for gender, age groups, socioeconomic status, and geographic settings [29]. When conducting studies, researchers should make judicious use of digital technology for research procedures. While on the surface it may seem appealing to rely only on online methods for delivery of both interventions and collection of outcome measures, studies suggest that research staff continue to play an important role in promoting good recruitment and retention rates [250].

Future adaptations of POD Adventures should consider population-specific needs of adolescents which account for their technology ability and access, literacy levels, media, or language

preferences [22]. These may include changes made to illustrate relatable situations (e.g., diverse young persons, different types of activities, etc.), showcase different risk factors for poor mental health (e.g., migration, war, discrimination, low socio-economic status, etc.) and to address help-seeking related challenges (e.g., low mental health literacy and corresponding distrust, or limited access to treatment). Adaptations could also be made to content or procedural components (e.g., reduced text or reading), functionality (e.g., consideration of a potentially bad internet connection), design and aesthetics (e.g., the amount or design of pictures) and guidance (e.g., type or amount of guidance) [278]. Incorporation of new experimental interventions such as the ‘STARS’ chatbot (Sustainable Technology for Adolescents and youth to Reduce Stress (STARS)) [279], a World Health Organisation (WHO) transdiagnostic chatbot under development for distressed youth might enhance the appeal and impacts of POD Adventures.

Future studies should examine the cost-effectiveness of delivering POD Adventures in schools with non-specialists as this type of intervention could play an important role in providing low-cost mental health support and thereby strengthening community health systems [26].

Finally, in view of the positive acceptability and feasibility findings in school settings, future work on POD Adventures should strategically consider the wider delivery context of schools in India and similar contexts and delivery by lay counsellors important factors in implementation and potential scale up.

## **6.5. Conclusion**

While DMHIs have proven to be a promising option for delivering support to adolescents [25] and amidst policy makers’ calls for rapid technology implementation at scale [242], the field is

now at a crucial inflection point. It is imperative to deal with the multiple complexities of healthcare to move from proof-of-concept projects to interventions which can be scaled up [242, 252]. The direction that research and development take will determine the scope, reach and impacts that DMHIs have on the global burden of mental health problems for adolescents in the years to come [252]. To this end, it is vital to build a concerted and strategic focus on LMICs, which are home to the majority of the world's adolescents, to ensure DMHIs do not have a paradoxical effect in amplifying healthcare inequalities, but instead create meaningful and lasting impact [63, 252, 280].

POD Adventures offers a unique opportunity to deploy and scale up a digital intervention to support adolescent mental health in India and similar LMIC settings, especially amid growing psychosocial problems most recently provoked by the COVID-19 pandemic. This intervention could be offered to adolescents from at-risk groups or those with suspected mental health problems in the early stages of a stepped-care approach [23] and thereby meaningfully contribute to and accelerate efforts to integrate context-specific mental health support into under-resourced health systems.

## REFERENCES

1. UNICEF, *The State of the World's Children 2021: On My Mind – Promoting, protecting and caring for children's mental health*. 2021, UNICEF: New York.
2. Bruha, L., et al., *Global child and adolescent mental health: challenges and advances*, in *London J Prim Care (Abingdon)*. 2018, © 2018 The Author(s). Published by Informa UK Limited, trading as Taylor & Francis Group. p. 108-9.
3. Gore, F.M., et al., *Global burden of disease in young people aged 10-24 years: a systematic analysis*. *Lancet*, 2011. **377**(9783): p. 2093-102.
4. Patel, V., et al., *Improving access to care for children with mental disorders: a global perspective*. *Archives of disease in childhood*, 2013. **98**(5): p. 323-327.
5. Juengsiragulwit, D., *Opportunities and obstacles in child and adolescent mental health services in low- and middle-income countries: a review of the literature*. *WHO South East Asia J Public Health*, 2015. **4**(2): p. 110-122.
6. Kumar, D., *School mental health program in India: Need to shift from a piecemeal approach to a long-term comprehensive approach with strong intersectoral coordination*. *Indian J Psychiatry*, 2021. **63**(1): p. 91-96.
7. Saraceno, B., et al., *Barriers to improvement of mental health services in low-income and middle-income countries*. *Lancet*, 2007. **370**(9593): p. 1164-74.
8. Bakker, M.J., et al., *Practitioner Review: Psychological treatments for children and adolescents with conduct disorder problems - a systematic review and meta-analysis*. *J Child Psychol Psychiatry*, 2017. **58**(1): p. 4-18.
9. Dea, B., et al., *A cross-sectional exploration of the clinical characteristics of disengaged (NEET) young people in primary mental healthcare*. *BMJ Open*, 2014. **4**(12): p. e006378.
10. Uhlhaas, P. and J. Torous, *Digital tools for youth mental health*. *npj Digital Medicine*, 2019. **2**(1): p. 104.
11. Firth, J., et al., *The efficacy of smartphone-based mental health interventions for depressive symptoms: a meta-analysis of randomized controlled trials*. *World Psychiatry*, 2017. **16**(3): p. 287-298.
12. Torous, J., et al., *Digital Mental Health and COVID-19: Using Technology Today to Accelerate the Curve on Access and Quality Tomorrow*. *JMIR mental health*, 2020. **7**(3): p. e18848-e18848.
13. Garrido, S., et al., *What Works and What Doesn't Work? A Systematic Review of Digital Mental Health Interventions for Depression and Anxiety in Young People*. *Frontiers in Psychiatry*, 2019. **10**(759).
14. Naslund, J.A., et al., *Digital technology for treating and preventing mental disorders in low-income and middle-income countries: a narrative review of the literature*. *Lancet Psychiatry*, 2017. **4**(6): p. 486-500.
15. Waller, G., et al., *Cognitive-behavioral therapy in the time of coronavirus: Clinician tips for working with eating disorders via telehealth when face-to-face meetings are not possible*. *Int J Eat Disord*, 2020. **53**(7): p. 1132-1141.
16. Hollis, C., et al., *Annual Research Review: Digital health interventions for children and young people with mental health problems – a systematic and meta-review*. *Journal of Child Psychology and Psychiatry*, 2017. **58**(4): p. 474-503.
17. Lau, H.M., et al., *Serious Games for Mental Health: Are They Accessible, Feasible, and Effective? A Systematic Review and Meta-analysis*. *Frontiers in Psychiatry*, 2017. **7**(209).

18. Bevan Jones, R., et al., *Practitioner review: Co-design of digital mental health technologies with children and young people*. Journal of Child Psychology and Psychiatry, 2020.
19. Liverpool, S., et al., *Engaging Children and Young People in Digital Mental Health Interventions: Systematic Review of Modes of Delivery, Facilitators, and Barriers*. J Med Internet Res, 2020. **22**(6): p. e16317.
20. Solmi, M., et al., *Age at onset of mental disorders worldwide: large-scale meta-analysis of 192 epidemiological studies*. Molecular Psychiatry, 2021.
21. Moreno, C., et al., *How mental health care should change as a consequence of the COVID-19 pandemic*. The Lancet Psychiatry, 2020. **7**(9): p. 813-824.
22. Figueroa, C.A. and A. Aguilera, *The Need for a Mental Health Technology Revolution in the COVID-19 Pandemic*. Front Psychiatry, 2020. **11**: p. 523.
23. Ferrari, M., et al., *Gaming My Way to Recovery: A Systematic Scoping Review of Digital Game Interventions for Young People's Mental Health Treatment and Promotion*. Frontiers in Digital Health, 2022. **4**: p. 814248.
24. Lehtimäki, S., et al., *Evidence on Digital Mental Health Interventions for Adolescents and Young People: Systematic Overview*. JMIR Ment Health, 2021. **8**(4): p. e25847.
25. Carter, H., et al., *The emergence of digital mental health in low-income and middle-income countries: A review of recent advances and implications for the treatment and prevention of mental disorders*. J Psychiatr Res, 2021. **133**: p. 223-246.
26. Fu, Z., et al., *Effectiveness of digital psychological interventions for mental health problems in low-income and middle-income countries: a systematic review and meta-analysis*. The Lancet Psychiatry, 2020. **7**(10): p. 851-864.
27. WHO. *Adolescent mental health factsheet*. 2021; Available from: <https://www.who.int/news-room/fact-sheets/detail/adolescent-mental-health>.
28. Sacks, D., *Age limits and adolescents*. Paediatr Child Health, 2003. **8**(9): p. 577-8.
29. Das, J.K., et al., *Interventions for Adolescent Mental Health: An Overview of Systematic Reviews*. The Journal of adolescent health : official publication of the Society for Adolescent Medicine, 2016. **59**(4S): p. S49-S60.
30. Blakemore, S.J. and K.L. Mills, *Is adolescence a sensitive period for sociocultural processing?* Annu Rev Psychol, 2014. **65**: p. 187-207.
31. Patton, G.C., et al., *Our future: a Lancet commission on adolescent health and wellbeing*. Lancet, 2016. **387**(10036): p. 2423-78.
32. Kleinert, S. and R. Horton, *Adolescent health and wellbeing: a key to a sustainable future*. Lancet, 2016. **387**(10036): p. 2355-6.
33. McGorry, P.D., et al., *Designing and scaling up integrated youth mental health care*. World Psychiatry, 2022. **21**(1): p. 61-76.
34. (WHO), W.H.O. *Adolescent mental health: Fact sheet 2022*; Available from: <https://www.who.int/news-room/fact-sheets/detail/adolescent-mental-health>.
35. Vos, T., et al., *Global burden of 369 diseases and injuries in 204 countries and territories, 1990&#x2013;2019: a systematic analysis for the Global Burden of Disease Study 2019*. The Lancet, 2020. **396**(10258): p. 1204-1222.
36. Kessler, R.C., et al., *Lifetime prevalence and age-of-onset distributions of DSM-IV disorders in the National Comorbidity Survey Replication*. Arch Gen Psychiatry, 2005. **62**(6): p. 593-602.

37. Reiner, R.C., *Diseases, Injuries, and Risk Factors in Child and Adolescent Health, 1990 to 2017: Findings From the Global Burden of Diseases, Injuries, and Risk Factors 2017 Study*. JAMA Pediatrics, 2019. **173**(6): p. e190337-e190337.
38. Reiss, F., et al., *Socioeconomic status, stressful life situations and mental health problems in children and adolescents: Results of the German BELLA cohort-study*. PLoS One, 2019. **14**(3): p. e0213700.
39. Jenkins, R., et al., *Debt, income and mental disorder in the general population*. Psychol Med, 2008. **38**(10): p. 1485-93.
40. Patel, V., et al., *Suicide mortality in India: a nationally representative survey*. Lancet, 2012. **379**(9834): p. 2343-51.
41. Patel, V., et al., *The Lancet Commission on global mental health and sustainable development*. The Lancet, 2018. **392**(10157): p. 1553-1598.
42. Achilles, M.R., et al., *Adherence to e-mental health among youth: Considerations for intervention development and research design*. Digital health, 2020. **6**: p. 2055207620926064-2055207620926064.
43. Rechel, B., et al., *How Can Health Systems Respond to Population Ageing?* European Observatory on Health Systems and Policies, Policy Brief 10, 2009.
44. Bloom, D., E. Cafiero, and J.-L. E., *The global economic burden of non-communicable disease*. . 2011, World Economic Forum: Geneva.
45. Kessler, R.C., et al., *Age of onset of mental disorders: a review of recent literature*. Curr Opin Psychiatry, 2007. **20**(4): p. 359-64.
46. Kakuma, R., et al., *Human resources for mental health care: current situation and strategies for action*. The Lancet, 2011. **378**(9803): p. 1654-1663.
47. Carvajal, L., J.H. Requejo, and C.E. Irwin, *The Measurement of Mental Health Problems Among Adolescents and Young Adults Throughout the World*. J Adolesc Health, 2021. **69**(3): p. 361-362.
48. Thornicroft, G., et al., *Undertreatment of people with major depressive disorder in 21 countries*. Br J Psychiatry, 2017. **210**(2): p. 119-124.
49. Yatham, S., et al., *Depression, anxiety, and post-traumatic stress disorder among youth in low and middle income countries: A review of prevalence and treatment interventions*. Asian journal of psychiatry, 2018. **38**: p. 78-91.
50. Erskine, H.E., et al., *The global coverage of prevalence data for mental disorders in children and adolescents*. Epidemiol Psychiatr Sci, 2017. **26**(4): p. 395-402.
51. Simelane, S.R.N. and P.J. de Vries, *Child and adolescent mental health services and systems in low and middle-income countries: from mapping to strengthening*. Curr Opin Psychiatry, 2021. **34**(6): p. 608-616.
52. Patel, V., et al., *Promoting child and adolescent mental health in low and middle income countries*. J Child Psychol Psychiatry, 2008. **49**(3): p. 313-34.
53. Barry, M. and R. Jenkins, *Implementing Mental Health Promotion*. 2007.
54. Petagna, M., et al., *Mental Health Gap Action Programme intervention Guide (mhGAP-IG) for Child and Adolescent Mental Health in Low- and Middle-Income Countries (LMIC): A Systematic Review*. Community Mental Health Journal, 2022.
55. Zhou, W., et al., *Child and Adolescent Mental Health Policy in Low- and Middle-Income Countries: Challenges and Lessons for Policy Development and Implementation*. Front Psychiatry, 2020. **11**: p. 150.

56. Volpe, U., et al., *The pathways to mental healthcare worldwide: a systematic review*. Curr Opin Psychiatry, 2015. **28**(4): p. 299-306.
57. Kieling, C., et al., *Child and adolescent mental health worldwide: evidence for action*. Lancet, 2011. **378**(9801): p. 1515-25.
58. Patel, V. and A. Rahman, *Editorial Commentary: An agenda for global child mental health*. Child Adolesc Ment Health, 2015. **20**(1): p. 3-4.
59. Servili, C., *An international perspective on youth mental health: the role of primary health care and collaborative care models*. J Can Acad Child Adolesc Psychiatry, 2012. **21**(2): p. 127-9.
60. Patel, V., et al., *Mental health of young people: a global public-health challenge*. Lancet (London, England), 2007. **369**(9569): p. 1302-1313.
61. Klasen, H. and A.C. Crombag, *What works where? A systematic review of child and adolescent mental health interventions for low and middle income countries*. Soc Psychiatry Psychiatr Epidemiol, 2013. **48**(4): p. 595-611.
62. Gururaj G., V.M., Benegal V, N R, K P, Singh L., et al., *National Mental Health Survey of India, 2015-16: Prevalence, patterns and outcomes*. 2016: Bengaluru: National Institute of Mental Health and Neuro Sciences (NIMHANS).
63. Malhotra, S. and B.N. Patra, *Prevalence of child and adolescent psychiatric disorders in India: a systematic review and meta-analysis*. Child Adolesc Psychiatry Ment Health, 2014. **8**: p. 22.
64. Dandona, R., et al., *Gender differentials and state variations in suicide deaths in India: the Global Burden of Disease Study 1990-2013;2016*. The Lancet Public Health, 2018. **3**(10): p. e478-e489.
65. Shastri, P.C., *Promotion and prevention in child mental health*. Indian J Psychiatry, 2009. **51**(2): p. 88-95.
66. Agarwal, S., et al., *Evidence on feasibility and effective use of mHealth strategies by frontline health workers in developing countries: systematic review*. Trop Med Int Health, 2015. **20**(8): p. 1003-14.
67. Parikh, R., et al., *Priorities and preferences for school-based mental health services in India: a multi-stakeholder study with adolescents, parents, school staff, and mental health providers*. Global Mental Health, 2019. **6**: p. e18.
68. Gupta, S. and R. Sagar, *National Mental Health Programme-Optimism and Caution: A Narrative Review*. Indian J Psychol Med, 2018. **40**(6): p. 509-516.
69. Balamurugan, G., R. Govindan, and V. Rani, *Models and roles in National Mental Health Programme*. Indian Journal of Psychiatric Nursing, 2019. **16**: p. 52.
70. Ministry of Health and Family Welfare, G.o.I. *Rashtriya Kishor Swasthya Karyakram (RKSK)*. 2015; Available from: [https://www.nhp.gov.in/rashtriya-kishor-swasthya-karyakram-rksk\\_pg](https://www.nhp.gov.in/rashtriya-kishor-swasthya-karyakram-rksk_pg).
71. Srivastava, K., K. Chatterjee, and P.S. Bhat, *Mental health awareness: The Indian scenario*, in *Ind Psychiatry J*. 2016. p. 131-134.
72. Roy, K., et al., *India's response to adolescent mental health: a policy review and stakeholder analysis*. Social Psychiatry and Psychiatric Epidemiology, 2019. **54**(4): p. 405-414.
73. Mehra, D., et al., *Mental Health Interventions among Adolescents in India: A Scoping Review*. Healthcare (Basel), 2022. **10**(2).

74. Fusar-Poli, P., et al., *Preventive psychiatry: a blueprint for improving the mental health of young people*. World Psychiatry, 2021. **20**(2): p. 200-221.
75. Hoover, S. and J. Bostic, *Schools As a Vital Component of the Child and Adolescent Mental Health System*. Psychiatr Serv, 2021. **72**(1): p. 37-48.
76. Srikala, B. and K.K. Kishore, *Empowering adolescents with life skills education in schools - School mental health program: Does it work?* Indian J Psychiatry, 2010. **52**(4): p. 344-9.
77. Shinde, S., et al., *Promoting school climate and health outcomes with the SEHER multi-component secondary school intervention in Bihar, India: a cluster-randomised controlled trial*. Lancet, 2018. **392**(10163): p. 2465-2477.
78. Gujar, K. and V. Pingale, *School mental health programme in Maharashtra - Today and way ahead*. Annals of Indian Psychiatry, 2017. **1**(1): p. 4-7.
79. Jones, E.A.K., A.K. Mitra, and A.R. Bhuiyan, *Impact of COVID-19 on Mental Health in Adolescents: A Systematic Review*. International Journal of Environmental Research and Public Health, 2021. **18**(5).
80. Jones, N., et al., *Intersecting barriers to adolescents' educational access during COVID-19: Exploring the role of gender, disability and poverty*. International Journal of Educational Development, 2021. **85**: p. 102428.
81. Liang, L., et al., *The Effect of COVID-19 on Youth Mental Health*. Psychiatr Q, 2020. **91**(3): p. 841-852.
82. Serlachius, A., S.M. Badawy, and H. Thabrew, *Psychosocial Challenges and Opportunities for Youth With Chronic Health Conditions During the COVID-19 Pandemic*. JMIR pediatrics and parenting, 2020. **3**(2): p. e23057-e23057.
83. Czeisler, M., et al., *Mental Health, Substance Use, and Suicidal Ideation During the COVID-19 Pandemic - United States, June 24-30, 2020*. MMWR Morb Mortal Wkly Rep, 2020. **69**(32): p. 1049-1057.
84. Lee, J., *Mental health effects of school closures during COVID-19*. Lancet Child Adolesc Health, 2020. **4**(6): p. 421.
85. Clarke, A.M., T. Kuosmanen, and M.M. Barry, *A systematic review of online youth mental health promotion and prevention interventions*. J Youth Adolesc, 2015. **44**(1): p. 90-113.
86. Center, P.R., *Smartphone ownership is growing rapidly around the world, but not always equally*. 2019.
87. GSMA, *The Mobile Gender Gap Report 2021*. 2021.
88. Jones, S.P., et al., *How Google's 'ten Things We Know To Be True' could guide the development of mental health mobile apps*. Health Aff (Millwood), 2014. **33**(9): p. 1603-11.
89. Philippe, T.J., et al., *Digital Health Interventions for Delivery of Mental Health Care: Systematic and Comprehensive Meta-Review*. JMIR Ment Health, 2022. **9**(5): p. e35159.
90. Baños, R.M., R. Herrero, and M.D. Vara, *What is the Current and Future Status of Digital Mental Health Interventions?* The Spanish Journal of Psychology, 2022. **25**: p. e5.
91. Bevan Jones, R., et al., *Digital technologies to support adolescents with depression and anxiety: review*. BJPsych Advances, 2022: p. 1-15.



92. Williams, A., et al., *Internet-based interventions to support recovery and self-management: A scoping review of their use by mental health service users and providers together*. BMC Psychiatry, 2019. **19**(1): p. 191.
93. Gaebel, W., et al., *European Psychiatric Association (EPA) guidance on the quality of eMental health interventions in the treatment of psychotic disorders*. Eur Arch Psychiatry Clin Neurosci, 2016. **266**(2): p. 125-37.
94. Álvarez-Jiménez, M., et al., *Internet-based interventions for psychosis: a sneak-peek into the future*. Psychiatr Clin North Am, 2012. **35**(3): p. 735-47.
95. Naslund, J.A., et al., *Emerging mHealth and eHealth interventions for serious mental illness: a review of the literature*. J Ment Health, 2015. **24**(5): p. 321-32.
96. Carlbring, P., et al., *Internet-based vs. face-to-face cognitive behavior therapy for psychiatric and somatic disorders: an updated systematic review and meta-analysis*. Cogn Behav Ther, 2018. **47**(1): p. 1-18.
97. Baderol Allam, F.N., et al., *Web-Based Dietary and Physical Activity Intervention Programs for Patients With Hypertension: Scoping Review*. J Med Internet Res, 2021. **23**(3): p. e22465.
98. Torous, J. and L.W. Roberts, *Needed Innovation in Digital Health and Smartphone Applications for Mental Health: Transparency and Trust*. JAMA Psychiatry, 2017. **74**(5): p. 437-438.
99. Donker, T., et al., *Smartphones for smarter delivery of mental health programs: a systematic review*. J Med Internet Res, 2013. **15**(11): p. e247.
100. Emmelkamp, P.M.G. and K. Meyerbröker, *Virtual Reality Therapy in Mental Health*. Annu Rev Clin Psychol, 2021. **17**: p. 495-519.
101. Fleming, T.M., et al., *Serious Games and Gamification for Mental Health: Current Status and Promising Directions*. Front Psychiatry, 2016. **7**: p. 215.
102. Michael, D.R. and S. Chen. *Serious Games: Games That Educate, Train, and Inform*. 2005.
103. Barnes, S. and J. Prescott, *Empirical Evidence for the Outcomes of Therapeutic Video Games for Adolescents With Anxiety Disorders: Systematic Review*. JMIR Serious Games, 2018. **6**(1): p. e3.
104. Mohr, D.C., et al., *Accelerating Digital Mental Health Research From Early Design and Creation to Successful Implementation and Sustainment*. J Med Internet Res, 2017. **19**(5): p. e153.
105. Yardley, L., et al., *The Person-Based Approach to Intervention Development: Application to Digital Health-Related Behavior Change Interventions*. J Med Internet Res, 2015. **17**(1): p. e30.
106. Wight, D., et al., *Six steps in quality intervention development (6SQuID)*. J Epidemiol Community Health, 2016. **70**(5): p. 520-5.
107. Fleming, T., et al., *The Importance of User Segmentation for Designing Digital Therapy for Adolescent Mental Health: Findings From Scoping Processes*. JMIR Ment Health, 2019. **6**(5): p. e12656.
108. Thabrew, H., et al., *Co-design of eHealth Interventions With Children and Young People*. Front Psychiatry, 2018. **9**: p. 481.
109. Hodson, E., et al., *Co-design in mental health; Mellow: a self-help holistic crisis planning mobile application by youth, for youth*. The Design Journal, 2019. **22**: p. 1529-1542.

110. Sellars, E., et al., *Young people's advisory groups in health research: scoping review and mapping of practices*. Archives of Disease in Childhood, 2021. **106**(7): p. 698.
111. Palmer, V.J., et al., *The Participatory Zeitgeist: an explanatory theoretical model of change in an era of coproduction and codesign in healthcare improvement*. Med Humanit, 2019. **45**(3): p. 247-257.
112. Blanchard, M. and N. Fava, *Co-designing New Solutions to Support Young People's Mental Health and Wellbeing*, in *Future Directions in Well-Being: Education, Organizations and Policy*, M.A. White, G.R. Slemp, and A.S. Murray, Editors. 2017, Springer International Publishing: Cham. p. 197-201.
113. Muke, S.S., et al., *Digital Training for Non-Specialist Health Workers to Deliver a Brief Psychological Treatment for Depression in Primary Care in India: Findings from a Randomized Pilot Study*. Int J Environ Res Public Health, 2020. **17**(17).
114. Raviola, G., et al., *Innovative Models in Mental Health Delivery Systems: Task Sharing Care with Non-specialist Providers to Close the Mental Health Treatment Gap*. Curr Psychiatry Rep, 2019. **21**(6): p. 44.
115. Khan, A., et al., *Design and Development of a Digital Program for Training Non-Specialist Health Workers to Deliver an Evidence-Based Psychological Treatment for Depression in Primary Care in India*. J Technol Behav Sci, 2020. **5**(4): p. 402-415.
116. Huggett, D., et al., *Engaging Youth in a Mental Health System Improvement Initiative in Ontario: Developing the Be Safe Resource*. Canadian Journal of Community Mental Health, 2017. **36**(2): p. 121-131.
117. Wiljer, D., et al., *Thought Spot: Co-Creating Mental Health Solutions with Post-Secondary Students*. Stud Health Technol Inform, 2017. **234**: p. 370-375.
118. Craig, P., et al., *Developing and evaluating complex interventions: the new Medical Research Council guidance*. Bmj, 2008. **337**: p. a1655.
119. Merry, S.N., et al., *Debate: Supporting the mental health of school students in the COVID-19 pandemic in New Zealand - a digital ecosystem approach*. Child Adolesc Ment Health, 2020. **25**(4): p. 267-269.
120. Rice, S., et al., *Moderated online social therapy for depression relapse prevention in young people: pilot study of a 'next generation' online intervention*. Early Interv Psychiatry, 2018. **12**(4): p. 613-625.
121. Grist, R., J. Porter, and P. Stallard, *Mental Health Mobile Apps for Preadolescents and Adolescents: A Systematic Review*. Journal of Medical Internet Research, 2017. **19**: p. e176.
122. Grist, R., et al., *Technology Delivered Interventions for Depression and Anxiety in Children and Adolescents: A Systematic Review and Meta-analysis*. Clinical Child and Family Psychology Review, 2018. **22**.
123. (NICE), N.I.f.H.a.C.E., *Depression in children and young people: Identification and management (NG134)*. 2019: UK.
124. Merry, S., et al., *The effectiveness of SPARX, a computerised self help intervention for adolescents seeking help for depression: Randomised controlled non-inferiority trial*. BMJ (Clinical research ed.), 2012. **344**: p. e2598.
125. Wright, B., et al., *Computerised cognitive-behavioural therapy for depression in adolescents: 12-month outcomes of a UK randomised controlled trial pilot study*. BJPsych Open, 2019. **6**(1): p. e5.

126. Ip, P., et al., *Effectiveness of a culturally attuned Internet-based depression prevention program for Chinese adolescents: A randomized controlled trial*. Depression and Anxiety, 2016. **33**(12): p. 1123-1131.
127. Välimäki, M., et al., *Web-Based Interventions Supporting Adolescents and Young People With Depressive Symptoms: Systematic Review and Meta-Analysis*. JMIR Mhealth Uhealth, 2017. **5**(12): p. e180.
128. Podina, I.R., et al., *A Meta-Analysis on the Efficacy of Technology Mediated CBT for Anxious Children and Adolescents*. Journal of Rational-Emotive & Cognitive-Behavior Therapy, 2016. **34**(1): p. 31-50.
129. Ebert, D.D., et al., *Internet and Computer-Based Cognitive Behavioral Therapy for Anxiety and Depression in Youth: A Meta-Analysis of Randomized Controlled Outcome Trials*. PLOS ONE, 2015. **10**(3): p. e0119895.
130. Pennant, M.E., et al., *Computerised therapies for anxiety and depression in children and young people: A systematic review and meta-analysis*. Behaviour Research and Therapy, 2015. **67**: p. 1-18.
131. Ye, X., et al., *Effectiveness of internet-based interventions for children, youth, and young adults with anxiety and/or depression: a systematic review and meta-analysis*. BMC Health Services Research, 2014. **14**(1): p. 313.
132. Pretorius, C., D. Chambers, and D. Coyle, *Young People's Online Help-Seeking and Mental Health Difficulties: Systematic Narrative Review*. J Med Internet Res, 2019. **21**(11): p. e13873.
133. Shepherd, M., et al., *The design and relevance of a computerized gamified depression therapy program for indigenous māori adolescents*. JMIR Serious Games, 2015. **3**(1): p. e1.
134. Bansa, M., et al., *A Little Effort Can Withstand the Hardship: Fielding an Internet-Based Intervention to Prevent Depression among Urban Racial/Ethnic Minority Adolescents in a Primary Care Setting*. J Natl Med Assoc, 2018. **110**(2): p. 130-142.
135. Naslund, J.A., et al., *Digital Innovations for Global Mental Health: Opportunities for Data Science, Task Sharing, and Early Intervention*. Current Treatment Options in Psychiatry, 2019. **6**(4): p. 337-351.
136. Wasil, A.R., et al., *Estimating the real-world usage of mobile apps for mental health: development and application of two novel metrics*, in *World Psychiatry*. 2021. p. 137-138.
137. Wasil, A.R., et al., *A review of popular smartphone apps for depression and anxiety: Assessing the inclusion of evidence-based content*. Behaviour Research and Therapy, 2019. **123**: p. 103498.
138. Torous, J., et al., *Towards a consensus around standards for smartphone apps and digital mental health*. World Psychiatry, 2019. **18**(1): p. 97-98.
139. Larsen, M.E., et al., *Using science to sell apps: Evaluation of mental health app store quality claims*. npj Digital Medicine, 2019. **2**(1): p. 18.
140. Lau, N., et al., *Popular Evidence-Based Commercial Mental Health Apps: Analysis of Engagement, Functionality, Aesthetics, and Information Quality*. JMIR Mhealth Uhealth, 2021. **9**(7): p. e29689.
141. Jiménez-Molina, Á., et al., *Internet-Based Interventions for the Prevention and Treatment of Mental Disorders in Latin America: A Scoping Review*. Frontiers in psychiatry, 2019. **10**: p. 664-664.

142. Baumel, A., et al., *Objective User Engagement With Mental Health Apps: Systematic Search and Panel-Based Usage Analysis*. J Med Internet Res, 2019. **21**(9): p. e14567.
143. Lewis, C., et al., *Dropout from psychological therapies for post-traumatic stress disorder (PTSD) in adults: systematic review and meta-analysis*. Eur J Psychotraumatol, 2020. **11**(1): p. 1709709.
144. Richards, D. and T. Richardson, *Computer-based psychological treatments for depression: a systematic review and meta-analysis*. Clin Psychol Rev, 2012. **32**(4): p. 329-42.
145. Torous, J., et al., *Dropout rates in clinical trials of smartphone apps for depressive symptoms: A systematic review and meta-analysis*. J Affect Disord, 2020. **263**: p. 413-419.
146. Torous, J., et al., *Clinical review of user engagement with mental health smartphone apps: evidence, theory and improvements*. Evid Based Ment Health, 2018. **21**(3): p. 116-119.
147. Mohr, D.C., et al., *Three Problems With Current Digital Mental Health Research . . . and Three Things We Can Do About Them*. Psychiatr Serv, 2017. **68**(5): p. 427-429.
148. Cummins, N. and B.W. Schuller, *Five Crucial Challenges in Digital Health*. Front Digit Health, 2020. **2**: p. 536203.
149. Wykes, T., J. Lipshitz, and S.M. Schueller, *Towards the Design of Ethical Standards Related to Digital Mental Health and all Its Applications*. Current Treatment Options in Psychiatry, 2019. **6**(3): p. 232-242.
150. Taylor, C.B., E.E. Fitzsimmons-Craft, and A.K. Graham, *Digital technology can revolutionize mental health services delivery: The COVID-19 crisis as a catalyst for change*. Int J Eat Disord, 2020. **53**(7): p. 1155-1157.
151. Lutz, C., *Digital inequalities in the age of artificial intelligence and big data*. Human Behavior and Emerging Technologies, 2019. **1**(2): p. 141-148.
152. UNICEF, *How many children and young people have internet access at home? Estimating digital connectivity during the COVID-19 pandemic 2020*, UNICEF: New York.
153. UNICEF, *Rapid assessment of learning during school closures in the context of COVID*. 2021: New Delhi.
154. Chorpita, B.F., et al., *Design process and protocol description for a multi-problem mental health intervention within a stepped care approach for adolescents in India*. Behaviour Research and Therapy, 2020. **133**: p. 103698.
155. Bower, P. and S. Gilbody, *Stepped care in psychological therapies: access, effectiveness and efficiency. Narrative literature review*. Br J Psychiatry, 2005. **186**: p. 11-7.
156. Malik, K., et al., *Development of a transdiagnostic stepped care programme for common adolescent mental health problems in Indian secondary schools: lessons from a pilot study examining acceptability and feasibility*. Global Mental Health, 2022: p. 1-5.
157. Michelson, D., et al., *Development of a transdiagnostic, low-intensity, psychological intervention for common adolescent mental health problems in Indian secondary schools*. Behaviour Research and Therapy, 2020. **130**: p. 103439.
158. Malik, K., et al., *Effectiveness and costs associated with a lay counselor-delivered, brief problem-solving mental health intervention for adolescents in urban, low-income schools in India: 12-month outcomes of a randomized controlled trial*. PLoS Med, 2021. **18**(9): p. e1003778.

159. Michelson, D., et al., *Effectiveness of a brief lay counsellor-delivered, problem-solving intervention for adolescent mental health problems in urban, low-income schools in India: a randomised controlled trial*. The Lancet Child & Adolescent Health, 2020. **4**(8): p. 571-582.
160. Parikh, R., et al., *Increasing demand for school counselling through a lay counsellor-delivered classroom sensitisation intervention: a stepped-wedge cluster randomised controlled trial in New Delhi, India*. BMJ Global Health, 2021. **6**(6): p. e003902.
161. Nezu, A.M., C. Maguth Nezu, and T.J. D'Zurilla, *Problem-solving therapy: A treatment manual*. Problem-solving therapy: A treatment manual. 2013, New York, NY, US: Springer Publishing Co. x, 323-x, 323.
162. Lazarus, R. and S. Folkman, *Stress, Appraisal and Coping*. 1984, Springer New York.
163. James, A.M., *Principles of youth participation in mental health services*. Med J Aust, 2007. **187**(S7): p. S57-60.
164. Arnold, M.E. and M. Cater, *From Then to Now: Emerging Directions for Youth Program Evaluation*. Journal of Youth Development, 2011. **6**: p. 80-92.
165. Jensen, P.S., K. Hoagwood, and T. Petti, *Outcomes of Mental Health Care for Children and Adolescents: II. Literature Review and Application of a Comprehensive Model*. Journal of the American Academy of Child & Adolescent Psychiatry, 1996. **35**(8): p. 1064-1077.
166. Hohmann, A.A., *A Contextual Model for Clinical Mental Health Effectiveness Research*. Mental Health Services Research, 1999. **1**(2): p. 83-91.
167. Tashakkori, A. and J.W. Creswell, *Editorial: The New Era of Mixed Methods*. Journal of Mixed Methods Research, 2007. **1**(1): p. 3-7.
168. Baird, S., et al., *No One Left Behind: Using Mixed-Methods Research to Identify and Learn from Socially Marginalised Adolescents in Low- and Middle-Income Countries*. The European Journal of Development Research, 2021. **33**(5): p. 1163-1188.
169. Tilzey, S.E., et al., *Mixed Methods Adolescent Research*, in *The Encyclopedia of Child and Adolescent Development*. 2020. p. 1-14.
170. Palinkas, L.A., et al., *Mixed method designs in implementation research*. Adm Policy Ment Health, 2011. **38**(1): p. 44-53.
171. Onwuegbuzie, A.J. and K.M.T. Collins, *The Role of Sampling in Mixed Methods-Research*. KZfSS Kölner Zeitschrift für Soziologie und Sozialpsychologie, 2017. **69**(2): p. 133-156.
172. Skivington, K., et al., *A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance*. Bmj, 2021. **374**: p. n2061.
173. Attkisson, C., *The Client Satisfaction Questionnaire (CSQ) Scales*. 1996.
174. Weisz, J.R., et al., *Youth Top Problems: using idiographic, consumer-guided assessment to identify treatment needs and to track change during psychotherapy*. J Consult Clin Psychol, 2011. **79**(3): p. 369-80.
175. Bhola, P., et al., *Assessment of Self-Reported Emotional and Behavioral Difficulties Among Pre-University College Students in Bangalore, India*. Indian Journal of Community Medicine, 2016. **41**: p. 146-150.
176. Srinath, S., P. Kandasamy, and T.S. Golhar, *Epidemiology of child and adolescent mental health disorders in Asia*. Curr Opin Psychiatry, 2010. **23**(4): p. 330-6.
177. Singh, K., M. Junnarkar, and S. Sharma, *Anxiety, stress, depression, and psychosocial functioning of Indian adolescents*. Indian J Psychiatry, 2015. **57**(4): p. 367-74.

178. Cohen, S., T. Kamarck, and R. Mermelstein, *A Global Measure of Perceived Stress*. Journal of Health and Social Behavior, 1983. **24**(4): p. 385-396.
179. Goodman, R., et al., *Using the Strengths and Difficulties Questionnaire (SDQ) to screen for child psychiatric disorders in a community sample*. Br J Psychiatry, 2000. **177**: p. 534-9.
180. Clarke, A., et al., *Warwick-Edinburgh Mental Well-being Scale (WEMWBS): validated for teenage school students in England and Scotland. A mixed methods assessment*. BMC Public Health, 2011. **11**: p. 487.
181. Chorpita, B.F., C.E. Moffitt, and J. Gray, *Psychometric properties of the Revised Child Anxiety and Depression Scale in a clinical sample*. Behav Res Ther, 2005. **43**(3): p. 309-22.
182. Ebesutani, C., et al., *The Revised Child Anxiety and Depression Scale-Short Version: scale reduction via exploratory bifactor modeling of the broad anxiety factor*. Psychol Assess, 2012. **24**(4): p. 833-45.
183. Halder, K., *Adapting a Revised Child Anxiety and Depression Scale for rural India: a pilot, amenable to scale up*. 2016.
184. Piqueras, J.A., et al., *The Revised Child Anxiety and Depression Scale: A systematic review and reliability generalization meta-analysis*. J Affect Disord, 2017. **218**: p. 153-169.
185. Bradley, E.H., L.A. Curry, and K.J. Devers, *Qualitative Data Analysis for Health Services Research: Developing Taxonomy, Themes, and Theory*. Health Services Research, 2007. **42**(4): p. 1758-1772.
186. S., K., *Digital in 2018: World's Internet Users Pass the 4 Billion Mark - We Are Social*. . 2018.
187. Eysenbach, G., *What is e-health?* J Med Internet Res, 2001. **3**(2): p. e20.
188. Mandryk, R.L. and M.V. Birk, *Toward Game-Based Digital Mental Health Interventions: Player Habits and Preferences*. J Med Internet Res, 2017. **19**(4): p. e128.
189. Price, M., et al., *mHealth: a mechanism to deliver more accessible, more effective mental health care*. Clin Psychol Psychother, 2014. **21**(5): p. 427-36.
190. Archangeli, C., et al., *Mobile Health Interventions for Psychiatric Conditions in Children*. Child and Adolescent Psychiatric Clinics of North America, 2016. **26**.
191. van Os, J., et al., *The evidence-based group-level symptom-reduction model as the organizing principle for mental health care: time for change?* World Psychiatry, 2019. **18**(1): p. 88-96.
192. Organization, W.H., *Monitoring and Evaluating Digital Health Interventions*. . 2016, World Health Organization (WHO).
193. Parikh, R., et al., *"It is like a mind attack": stress and coping among urban school-going adolescents in India*. BMC Psychology, 2019. **7**(1): p. 31.
194. Perski, O., et al., *Conceptualising engagement with digital behaviour change interventions: a systematic review using principles from critical interpretive synthesis*. Translational Behavioral Medicine, 2017. **7**(2): p. 254-267.
195. Spence, S.H., J.K. Sheffield, and C.L. Donovan, *Preventing adolescent depression: an evaluation of the problem solving for life program* Journal of Consulting and Clinical Psychology, 2003. **71** (1) p. 3-13.
196. Heppner, P.P., G.W. Neal, and L.M. Larson, *Problem-Solving Training as Prevention with College Students*. The Personnel and Guidance Journal, 1984. **62**(9): p. 514-519.

197. Brown, J.S.L., et al., *School-based early intervention for anxiety and depression in older adolescents: A feasibility randomised controlled trial of a self-referral stress management workshop programme ("DISCOVER")*. Journal of Adolescence, 2019. **71**(1): p. 150-161.
198. McGorry, P.D. and C. Mei, *Early intervention in youth mental health: progress and future directions*. Evidence Based Mental Health, 2018. **21**(4): p. 182.
199. Cheek, C., et al., *Integrating Health Behavior Theory and Design Elements in Serious Games*. JMIR Mental Health, 2015. **2**(2): p. e11.
200. Stoll, R.D., et al., *Usability of a Smartphone Application to Support the Prevention and Early Intervention of Anxiety in Youth*. Cognitive and Behavioral Practice, 2017. **24**(4): p. 393-404.
201. Oinas-Kukkonen, H. and M. Harjumaa, *Persuasive Systems Design: Key Issues, Process Model, and System Features*. Communications of the Association for Information Systems, 2009. **24**.
202. Pramana, G., et al., *Using Mobile Health Gamification to Facilitate Cognitive Behavioral Therapy Skills Practice in Child Anxiety Treatment: Open Clinical Trial*. JMIR Serious Games, 2018. **6**(2): p. e9.
203. Neil, A.L., et al., *Predictors of adherence by adolescents to a cognitive behavior therapy website in school and community-based settings*. J Med Internet Res, 2009. **11**(1): p. e6.
204. Aardoom, J.J., et al., *Web-Based Fully Automated Self-Help With Different Levels of Therapist Support for Individuals With Eating Disorder Symptoms: A Randomized Controlled Trial*. J Med Internet Res, 2016. **18**(6): p. e159.
205. Mehrotra, S. and R. Tripathi, *Recent developments in the use of smartphone interventions for mental health*. Curr Opin Psychiatry, 2018. **31**(5): p. 379-388.
206. Ennis, L., et al., *Can't surf, won't surf: The digital divide in mental health*. Journal of Mental Health, 2012. **21**(4): p. 395-403.
207. Anderson, R.E., et al., *Working alliance in online cognitive behavior therapy for anxiety disorders in youth: comparison with clinic delivery and its role in predicting outcome*. J Med Internet Res, 2012. **14**(3): p. e88.
208. Colom, F., *Keeping therapies simple: psychoeducation in the prevention of relapse in affective disorders*. British Journal of Psychiatry, 2011. **198**(5): p. 338-340.
209. Bruckner, T.A., et al., *The mental health workforce gap in low- and middle-income countries: a needs-based approach*. Bull World Health Organ, 2011. **89**(3): p. 184-94.
210. Collaborators, G.C.a.A.H., *Diseases, Injuries, and Risk Factors in Child and Adolescent Health, 1990 to 2017: Findings From the Global Burden of Diseases, Injuries, and Risk Factors 2017 Study*. JAMA Pediatrics, 2019. **173**(6): p. e190337-e190337.
211. UNFPA, *The power of 1.8. billion adolescents, youth and the transformation of the future*. 2014.
212. Rathod, S., et al., *Mental Health Service Provision in Low- and Middle-Income Countries*. Health services insights, 2017. **10**: p. 1178632917694350-1178632917694350.
213. Naslund, J.A., et al., *Digital technology for treating and preventing mental disorders in low-income and middle-income countries: a narrative review of the literature*. The Lancet Psychiatry, 2017. **4**(6): p. 486-500.
214. Mei, C., et al., *Global research priorities for youth mental health*. Early Intervention in Psychiatry, 2020. **14**(1): p. 3-13.

215. Torous, J., et al., *Digital Mental Health and COVID-19: Using Technology Today to Accelerate the Curve on Access and Quality Tomorrow*. JMIR Ment Health, 2020. 7(3): p. e18848.
216. (NIMH), N.I.o.M.H., *Opportunities and Challenges of Developing Information Technologies on Behavioral and Social Science Clinical Research*. 2018.
217. Gonsalves, P.P., et al., *Design and Development of the "POD Adventures" Smartphone Game: A Blended Problem-Solving Intervention for Adolescent Mental Health in India*. Frontiers in Public Health, 2019. 7(238).
218. Weisz, J.R., et al., *Youth Top Problems: using idiographic, consumer-guided assessment to identify treatment needs and to track change during psychotherapy*. Journal of consulting and clinical psychology, 2011. 79 3: p. 369-80.
219. Mind, Y.i. *Strengths and Difficulties Questionnaire*. 26 August 2020]; Available from: <https://sdqinfo.org/>.
220. Clarke, A., et al., *Warwick-Edinburgh Mental Well-being Scale (WEMWBS): Validated for teenage school students in England and Scotland. A mixed methods assessment*. BMC Public Health, 2011. 11(1): p. 487.
221. Gronholm, P., E. Nye, and D. Michelson, *Stigma related to targeted school-based mental health interventions: A systematic review of qualitative evidence*. Journal of Affective Disorders, 2018. 240.
222. (WHO), W.H.O. *Adolescent mental health factsheet*. 2021; Available from: <https://www.who.int/news-room/fact-sheets/detail/adolescent-mental-health>.
223. Galea, S., R.M. Merchant, and N. Lurie, *The Mental Health Consequences of COVID-19 and Physical Distancing: The Need for Prevention and Early Intervention*. JAMA Intern Med, 2020. 180(6): p. 817-818.
224. Team, C.C.-R., *Severe Outcomes Among Patients with Coronavirus Disease 2019 (COVID-19) - United States, February 12-March 16, 2020*. MMWR Morb Mortal Wkly Rep, 2020. 69(12): p. 343-346.
225. Loades, M.E., et al., *Rapid Systematic Review: The Impact of Social Isolation and Loneliness on the Mental Health of Children and Adolescents in the Context of COVID-19*. J Am Acad Child Adolesc Psychiatry, 2020. 59(11): p. 1218-1239.e3.
226. Gonsalves, P., et al., *App-based guided problem-solving intervention for adolescent mental health: a pilot cohort study in Indian schools*. Evidence Based Mental Health, 2020. 24: p. ebmental-2020.
227. Chan, A.W., et al., *SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials*. Bmj, 2013. 346: p. e7586.
228. Ministry of Education, G.o.I. *Manodharpan*. 2020; Available from: <http://manodharpan.mhrd.gov.in/>.
229. (NIMHANS), N.I.o.M.H.a.N. *Psychosocial support and mental health services helpline 2020*; Available from: <https://nimhans.ac.in/pssmhs-helpline/>.
230. Klaufus, L., et al., *Psychometric evaluation of two short versions of the Revised Child Anxiety and Depression Scale*. BMC Psychiatry, 2020. 20(1): p. 47.
231. Hertzog, M.A., *Considerations in determining sample size for pilot studies*. Res Nurs Health, 2008. 31(2): p. 180-91.
232. Porter, C., et al., *Impact of the COVID-19 pandemic on anxiety and depression symptoms of young people in the global south: evidence from a four-country cohort study*. BMJ Open, 2021. 11(4): p. e049653.



233. Magill, N., et al., *A scoping review of the problems and solutions associated with contamination in trials of complex interventions in mental health*. BMC Med Res Methodol, 2019. **19**(1): p. 4.
234. Union, U.N.C.s.F.a.I.T., *How many children and young people have internet access at home? Estimating digital connectivity during the COVID-19 pandemic 2020*, UNICEF: New York.
235. Gaiha, S.M., et al., *Stigma associated with mental health problems among young people in India: a systematic review of magnitude, manifestations and recommendations*. BMC Psychiatry, 2020. **20**(1): p. 538.
236. (WHO), W.H.O. *Adolescent mental health*. 2020; Available from: <https://www.who.int/news-room/fact-sheets/detail/adolescent-mental-health>.
237. Hafstad, G.S. and E.-M. Augusti, *A lost generation? COVID-19 and adolescent mental health*. The Lancet Psychiatry, 2021. **8**(8): p. 640-641.
238. Viner, R.M., et al., *School closure and management practices during coronavirus outbreaks including COVID-19: a rapid systematic review*. Lancet Child Adolesc Health, 2020. **4**(5): p. 397-404.
239. Viner, R.M., et al., *Reopening schools during the COVID-19 pandemic: governments must balance the uncertainty and risks of reopening schools against the clear harms associated with prolonged closure*. Archives of Disease in Childhood, 2021. **106**(2): p. 111.
240. Gonsalves, P.P., et al., *A Guided Internet-Based Problem-Solving Intervention Delivered Through Smartphones for Secondary School Pupils During the COVID-19 Pandemic in India: Protocol for a Pilot Randomized Controlled Trial*. JMIR Res Protoc, 2021. **10**(10): p. e30339.
241. Orkin, A.M., et al., *Guidelines for Reporting Trial Protocols and Completed Trials Modified Due to the COVID-19 Pandemic and Other Extenuating Circumstances: The CONSERVE 2021 Statement*. JAMA, 2021. **326**(3): p. 257-265.
242. Greenhalgh, T., et al., *Beyond Adoption: A New Framework for Theorizing and Evaluating Nonadoption, Abandonment, and Challenges to the Scale-Up, Spread, and Sustainability of Health and Care Technologies*. J Med Internet Res, 2017. **19**(11): p. e367.
243. Greenhalgh, T., et al., *Diffusion of Innovations in Service Organizations: Systematic Review and Recommendations*. The Milbank Quarterly, 2004. **82**(4): p. 581-629.
244. Greenhalgh, T., et al., *Storylines of research in diffusion of innovation: a meta-narrative approach to systematic review*. Social Science & Medicine, 2005. **61**(2): p. 417-430.
245. Greenhalgh, T., et al., *SCALS: a fourth-generation study of assisted living technologies in their organisational, social, political and policy context*. BMJ Open, 2016. **6**(2): p. e010208.
246. Li, W., L.A. Denson, and D.S. Dorstyn, *Understanding Australian university students' mental health help-seeking: An empirical and theoretical investigation*. Australian Journal of Psychology, 2018. **70**(1): p. 30-40.
247. Upton, E., et al., *Changes in mental health and help-seeking among young Australian adults during the COVID-19 pandemic: a prospective cohort study*. Psychological Medicine, 2021: p. 1-9.

248. Cohen, K.A. and J.L. Schleider, *Adolescent dropout from brief digital mental health interventions within and beyond randomized trials*. Internet Interventions, 2022. **27**: p. 100496.
249. McDanal, R., et al., *Associations of LGBTQ+ Identities With Acceptability and Efficacy of Online Single-Session Youth Mental Health Interventions*. Behavior Therapy, 2022. **53**(2): p. 376-391.
250. Hall, C.L., et al., *Opportunities and challenges of delivering digital clinical trials: lessons learned from a randomised controlled trial of an online behavioural intervention for children and young people*. Trials, 2020. **21**(1): p. 1011.
251. Michelson, D., et al., *Problem Solving as an Active Ingredient in Indicated Prevention and Treatment of Youth Depression and Anxiety: An Integrative Review*. J Adolesc Health, 2022.
252. Ben-Zeev, D. and D.C. Atkins, *Bringing digital mental health to where it is needed most*. Nature Human Behaviour, 2017. **1**(12): p. 849-851.
253. Mohr, D.C., et al., *The behavioral intervention technology model: an integrated conceptual and technological framework for eHealth and mHealth interventions*. J Med Internet Res, 2014. **16**(6): p. e146.
254. Gradingier, F., et al., *Values associated with public involvement in health and social care research: a narrative review*. Health Expect, 2015. **18**(5): p. 661-75.
255. Vojtila, L., et al., *Engaging a person with lived experience of mental illness in a collaborative care model feasibility study*. Research Involvement and Engagement, 2021. **7**(1): p. 5.
256. Palinkas, L.A., *Qualitative and mixed methods in mental health services and implementation research*. J Clin Child Adolesc Psychol, 2014. **43**(6): p. 851-61.
257. Boustani, M.M., et al., *Common elements of adolescent prevention programs: minimizing burden while maximizing reach*. Adm Policy Ment Health, 2015. **42**(2): p. 209-19.
258. Chorpita, B.F. and E.L. Daleiden, *Mapping evidence-based treatments for children and adolescents: application of the distillation and matching model to 615 treatments from 322 randomized trials*. J Consult Clin Psychol, 2009. **77**(3): p. 566-79.
259. Rith-Najarian, L.R., M.M. Boustani, and B.F. Chorpita, *A systematic review of prevention programs targeting depression, anxiety, and stress in university students*. Journal of Affective Disorders, 2019. **257**: p. 568-584.
260. Krause, K.R., et al., *Problem-solving training as an active ingredient of treatment for youth depression: a scoping review and exploratory meta-analysis*. BMC Psychiatry, 2021. **21**(1): p. 397.
261. Faulkner, A., *The ethics of survivor research Guidelines for the ethical conduct of research carried out by mental health service users and survivors*. 2004, UK: The Policy Press.
262. Happell, B. and C. Roper, *Consumer participation in mental health research: articulating a model to guide practice*. Australas Psychiatry, 2007. **15**(3): p. 237-41.
263. Cargo, M. and S.L. Mercer, *The value and challenges of participatory research: strengthening its practice*. Annu Rev Public Health, 2008. **29**: p. 325-50.
264. Schneider, B., *Participatory Action Research, Mental Health Service User Research, and the Hearing (our) Voices Projects*. International Journal of Qualitative Methods, 2012. **11**(2): p. 152-165.

265. Orlowski, S.K., et al., *Participatory Research as One Piece of the Puzzle: A Systematic Review of Consumer Involvement in Design of Technology-Based Youth Mental Health and Well-Being Interventions*. JMIR Hum Factors, 2015. **2**(2): p. e12.
266. Staley, K., T. Kabir, and G. Szmukler, *Service users as collaborators in mental health research: less stick, more carrot*, in *Psychol Med*. 2013. p. 1121-5.
267. Staniszevska, S., et al., *GRIPP2 reporting checklists: tools to improve reporting of patient and public involvement in research*. Bmj, 2017. **358**: p. j3453.
268. Poole, E. and T. Peyton, *Interaction design research with adolescents: Methodological challenges and best practices*. 2013. 211-217.
269. Ottman, K., et al., *Defining culturally compelling mental health interventions: A qualitative study of perspectives on adolescent depression in Lagos, Nigeria*. SSM - Mental Health, 2022. **2**: p. 100093.
270. Hawke, L.D., et al., *Don't Forget the Caregivers! A Discrete Choice Experiment Examining Caregiver Views of Integrated Youth Services*. The Patient - Patient-Centered Outcomes Research, 2021. **14**(6): p. 791-802.
271. Han, J., et al., *Use of Web Conferencing Technology for Conducting Online Focus Groups Among Young People With Lived Experience of Suicidal Thoughts: Mixed Methods Research*. JMIR Ment Health, 2019. **6**(10): p. e14191.
272. Monshat, K., et al., *Mental health promotion in the Internet age: a consultation with Australian young people to inform the design of an online mindfulness training programme*. Health Promot Int, 2012. **27**(2): p. 177-86.
273. Radovic, A., et al., *Supporting Our Valued Adolescents (SOVA), a Social Media Website for Adolescents with Depression and/or Anxiety: Technological Feasibility, Usability, and Acceptability Study*. JMIR Ment Health, 2018. **5**(1): p. e17.
274. Werner-Seidler, A., et al., *Pilot evaluation of the Sleep Ninja: a smartphone application for adolescent insomnia symptoms*. BMJ Open, 2019. **9**(5): p. e026502.
275. Munsch, A., *Millennial and generation Z digital marketing communication and advertising effectiveness: A qualitative exploration*. Journal of Global Scholars of Marketing Science, 2021. **31**(1): p. 10-29.
276. Turner, A., *Generation Z: Technology and Social Interest*. The Journal of Individual Psychology, 2015. **71**: p. 103-113.
277. Gan, D.Z.Q., et al., *Effect of Engagement With Digital Interventions on Mental Health Outcomes: A Systematic Review and Meta-Analysis*. Front Digit Health, 2021. **3**: p. 764079.
278. Spanhel, K., et al., *Cultural adaptation of internet- and mobile-based interventions for mental disorders: a systematic review*. npj Digital Medicine, 2021. **4**(1): p. 128.
279. Hall, J., et al., *Sustainable Technology for Adolescents and youth to Reduce Stress (STARS): a WHO transdiagnostic chatbot for distressed youth*, in *World Psychiatry*. 2022. p. 156-157.
280. Aboujaoude, E., et al., *Editorial: Digital Interventions in Mental Health: Current Status and Future Directions*. Front Psychiatry, 2020. **11**: p. 111.