1. TITLE PAGE

Title

Full title	Wait Less: Co-designing and Evaluating An Online Self-Help Brief Psychosocial Intervention (eBPI) For Young People With Mood Related Mental Health Problems To Reduce Waiting Lists in Specialist CYPMHS.
Short title	Wait Less

Research Reference Numbers

NIHR Portfolio number	NIHR158583
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CPMS ID	

Key Contacts

Principal Investigator	Professor Tamsin Ford	Professor of Child and Adolescent Psychiatry, University of Cambridge	tjf52@medschl.cam.ac.uk
Co-sponsors	Stephen Kelleher	R&D Manager, Cambridge and Peterborough NHS Foundation Trust	R&D@cpft.nhs.uk
	Lyndon Bridgewater	Assistant Director, Research Operations Office, University of Cambridge	lyndon.bridgewater@admin.cam.ac.uk
Funder	NIHR Health and Social Care Delivery Research Programme		

Collaborating Institutions

1	University of Cambridge	Tamsin Ford tjf52@medschl.cam.ac.uk
2	Cambridge BPI Ltd	www.cambridgebpi.com
3	Central and North West London NHS Foundation Trust	Julia Gledhill julia.gledhill2@nhs.net
4	Berkshire Healthcare NHS Foundation Trust	Nima Leffler Nima.Leffler@berkshire.nhs.uk
5	William Templeton Foundation for Young People's Mental Health	Peter Templeton pwt23@cam.ac.uk
6	University of East Anglia	Polly-Anna Ashford P.Ashford@uea.ac.uk Matthew Hammond M.Hammond@uea.ac.uk

Programme Co-ordination

The WAIT LESS study is being coordinated by Tamsin Ford as Chief Investigator. This protocol has been developed by the WAIT LESS Programme Management Group (PMG). For all queries, please contact Anne-Marie Burn (amb278@medschl.cam.ac.uk) and Rasanat Fatima Nawaz (rfn22@cam.ac.uk).

2. SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the trial publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the trial will be given; and that any discrepancies from the trial as planned in this protocol will be explained.

	Name	Position	Signature	Date
Trial Sponsor				
Chief Investigator	Tamsin Ford	Professor of Child and Adolescent Psychiatry		

General Information This protocol describes the WAIT LESS programme and provides information about the procedures for entering participants into the trial. Every care has been taken in drafting this protocol; however, corrections or amendments may be necessary. These will be circulated to the known Investigators in the trial.

3. CONTENTS PAGE

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4. LIST OF ABBREVIATIONS + DEFINITIONS

BPI	Brief Psychosocial Intervention
CYPMHS	Children and Young People's Mental Health Services (NHS)
CBT	Cognitive Behavioural Therapy
CNWL	Central and North West London NHS Foundation Trust
	Berkshire Healthcare NHS Foundation Trust
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
P/C	Parent/Carers
PPIE	Patient and Public Involvement and Engagement
WP	Work Package
YP	Young People

5. STUDY SUMMARY

Table 1: Study Summary

Programme title	Wait Less: Co-designing and Evaluating An Online Self-Help Brief Psychosocial Intervention (eBPI) For Young People With Mood Related Mental Health Problems To Reduce Waiting Lists in Specialist Children and Young People's Mental Health Services.
Work Packages full title	Is eBPI (Electronic Brief Psychosocial Intervention) a feasible, acceptable, and beneficial addition to traditional care for adolescents awaiting specialist CYPMHS services?
Funder and ref.	NIHR Health and Social Care Delivery Research (HSDR) Programme (NIHR158583)
Programme co-sponsor	University of Cambridge
Programme rationale	Increasing waiting lists for Children and Young People's Mental Health Services (CYPMHS) are a major barrier for young people trying to access mental health care. Latest figures for 2021-2 show a 47% increase in referrals to 6% of children and young people nationwide. Total numbers exceed 730,000, but rates vary widely by locality (1). Young people on the waiting list will include those with self-harm, suicidality, severe social impairment as well as many co-occurring anxious and behavioural symptoms. Average waiting time to initial assessment is 9 weeks, followed by a further 20 weeks wait for treatment, but this varies a great deal between clinics. Approximately 30% of young people on wating list attend fewer than two appointments (1) which suggests that earlier intervention might reduce their distress, and for some young people, allow them to leave the waiting list. This would free up CYPMHS capacity for those with more complex needs.

	Our proposal describes the development and early evaluation of an online intervention aimed at reducing the waitlists for specialist CYPMHS through the provision of a low intensity digital psychosocial intervention. We will coproduce an online adaptation of an existing NICE approved evidence-based face-to-face intervention, Brief Psychosocial Intervention (BPI) (2). Our team includes the inventors of BPI, which is the first psychotherapy developed for young people with input from young people rather than being a derivative of an adult mental health treatment protocol. Previous research showed that face-to-face BPI is both clinically and cost-effective. Further, BPI is now approved by NICE for the treatment of depression in teenagers.
Programme aims	We aim to test the feasibility, acceptability, and potential utility of eBPI, as well as to explore its potential to reduce suffering among adolescents on the specialist CYPMHS waitlists. If eBPI can offer rapid relief with depression, anxiety, and mood related presentations some patients may not need further face-to-face treatment. Our specific objectives are to: i) understand the experience of young people, parents /carers and clinicians in managing waitlists and how eBPI could be safely offered to those waiting ii) Codesign eBPI as an intervention, as well as establish the safety and standardised operational procedures to support its evaluation in NHS CYPMHS iii) determine if eBPI warrants a fully powered RCT to robustly establish clinical and cost effectiveness.
Pilot Trial	
Number of sites	Five services are part of the Berkshire NHS Foundation Trust (Newbury, Wokingham, Reading, Slough, and Bracknell), while the other five services are from Central and Northwest London NHS Foundation Trust (CNWL; Westminster, Kensington and Chelsea, Harrow, Hillingdon and Brent).
Sample size	Work package 1; 12 young people, 12 parents, 6 clinical managers and 12 clinicians Work package 2: No participants – advisory group will be consulted Work package 3; 10 young people Work package 4: 80 young people. 40 per arm: eBPI + WAU vs WAU
Participant inclusion criteria	**Young People Inclusion** • young people aged 12 to 17 years recruited from the CYPMHS waitlist for treatment because of low mood or depression. **Parent/Carer Inclusion** • A carer of a young person who has consented to take part in the study.
Participant exclusion criteria	• We have no initial exclusion criteria but anticipate that some may emerge during WP1 and 3.

Summary of trial intervention	We will coproduce an online adaptation of an existing NICE approved evidence-based face-to-face intervention, Brief Psychosocial Intervention (BPI) (2). BPI is now approved by NICE for the treatment of depression in teenagers. BPI is based on the three principles of psychoeducation, personal and social prescribing, plus habilitation/rehabilitation, and so is ideal to translate to a DHI for CYPMHS. We hypothesize that this will benefit young people and their families through the provision of an active low intensity intervention. Some may not require additional treatment so the numbers of young people waiting for treatment may reduce. Equally, those who require additional treatment may be encouraged to engage and traditional BPI would offer continuity of approach for face-to-face treatment. A successful DHI for CYPMHS waiting lists would help to manage the rising referral rate while increasing clinical through-put and filling a therapeutic gap in the clinical care pathway. eBPI, if effective and successfully implemented, would provide part of a seamless, staged program of treatment and care, for young people with moderate to severe mood disorders referred to specialist CYPMHS. If the clinical effectiveness of eBPI were established, we propose to research further translation into other contexts such as primary care, school-based mental health teams, acute paediatric services supporting children with long term physical health conditions such as cancer, and young people in local authority care.
Intervention duration	The eBPI intervention will last for eight weeks; starting month 24 and completing by the end of month 29 depending on recruitment date
Follow-up duration	Young people will also be invited to complete the Moods and Feelings Questionnaire (MFQ) at baseline and 10 and 18 weeks and half will be randomised to complete the Short Moods and Feelings Questionnaire (sMFQ) at 2,4,6,8 weeks in addition to these three main datapoints.
RCT duration	15 months
Outcome Measure	Our proposed primary outcome for the definitive trial is a reduction in depression symptoms by end of trial (eBPI> no eBPI) according to the short Moods and Feelings Questionnaire (sMFQ (45)), which is recommend to assess treatment response in the NICE guidance for treating depression in young people (46). The sMFQ was sensitive to improvement in previous UK-based RCTs of interventions for depression in young people (2,47,48). Goodyer's studies (2,47) suggest a five-point reduction on the MFQ represents the minimally clinically important difference for the assessment of superiority. ADAPT found a MFQ standard deviation of 14.6, so this size of a reduction would equate to an effect size of 0.34. These studies were of young people who had passed through the waiting list and we can find no reference waitlist studies, so current study will add value by gathering essential data to inform the estimation of the minimum clinically important difference in this novel research population. Our secondary outcomes include the proportion of cases choosing to leave the waitlist at three months (eBPI> no eBPI); young people will choose whether they want: a) remain on the waitlist to be seen face-to-face, b) return to the care of their primary services or c) withdraw from services entirely. We will also assess impairment using the Strengths and Difficulties Questionnaire Impact Supplement (49), Quality of Life with the EQ-5D young person's version (50), and access to services for economic evaluation, which include support from education, third sector and informal sources as well as CYPMHS and other health services with the Client Services Receipt Inventory (CSRI; (51). We will assess acceptability measured by engagement in eBPI (time spent on the system, sessions

logged into etc), retention and additional support required from CYPMHS and other services, as well as adverse effects using strategies developed in WP3.The schedule for measurement is illustrated in Table 1 and Figure 3. The low intensity data collection arm will collect baseline measures prior to randomisation, and at 10 weeks (which will be post-intervention for the eBPI arm) as well as at 18 weeks (months 28 to 31). The higher intensity data collection will add fortnightly completion of sMFQ from baseline until 10 weeks.

The process evaluation would determine if eBPI and our trial methods are feasible and acceptable for young people, parents, and clinicians. After the final follow up, young people and their parents from each study arm (n=10 eBPI vs. n=10 no eBPI; months 31 to 33) will be interviewed about their experiences of the intervention and other support received, as well as participation. The health economic evaluation will consist of a detailed calculation of the costs of the eBPI intervention, and analysis of resource use data collected during the study using the CSRI. As part of the process evaluation interviews, we will ask questions about service use and out of pocket costs to inform the data to be collected in a future health economic evaluation, as well as asking if "spill over effects" are incurred by parents or other family members. We will also ask about the best way to collect these health economic data, including mode and frequency of data collection.

A purposive sampling strategy would ensure a diversity of backgrounds and views are represented. Interviews will also be conducted with clinicians (n=10) at the end of the intervention delivery period to explore perceptions of the interventions' value, including anticipated benefits and harms. Interviews will be conducted face-to-face or via an online platform according to participant choice. Qualitative process interviews will commence with parents and young people as they complete the four month follow up and incorporate clinic staff once the services all patients from their CYPMHS have completed follow up.

Construct	**Measures for Young People**	**Baseline**	10 weeks	18 weeks	>18 weeks
Depression	Moods and Feelings Questionnaire (Primary Outcome)	X	X	X	
Impairment	Strengths and Difficulties Questionnaire Impact scale	X	X	X	
Waiting list choice	Wait; return to referrer; withdraw		X		
Quality of Life	EQ-5D-5L	X	X	X	
Services and personal costs	Client Service Receipt			X	

		Inventory – Child Version				
	Experience research processes	Process evaluation interview			X	X
	Experience of eBPI / waitlist	Process evaluation interview				X
	Experience of harms of psychological therapy questionnaire	Intervention arm only			X	

Plain English Summary

Children and Young People's Mental Health Services (CYPMHS) provide treatment for young people with poor mental health. CYPMHS are receiving more referrals, leading to very long waiting times. The increasing waiting lists for CYPMHS are a major barrier for young people trying to access mental health care. Young people on the waiting list will include some who self-harm, feel suicidal, and struggle with several types of difficulties. Whilst some receive a first assessment in 9 weeks, many others will wait over 20 weeks for their first assessment, often followed by a further 20 weeks wait for treatment. There are also big differences in the length of wait between clinics. Interestingly, 1 in 3 young people are seen only once or twice in CYPMHS despite waiting for so long. Access to support earlier might reduce their distress and free up CYPMHS capacity for those who need more treatment.

Brief Psychosocial Intervention (BPI) is an evidence-based face-to-face intervention which is recommended for the treatment of adolescent depression by NICE (National Institute for Health and Care Excellence). It is the first psychotherapy developed specifically for young people with input from young people and parents. Others are all based on treatments that were first designed for adults. Previous research has shown that face-to-face BPI works well and is value for money.

In this study, we will co-produce a digital self-service version of BPI with young people, parents and health professionals (called eBPI). We want to find out if eBPI offers rapid relief from suffering for young people with depression and mood related problems on the CYPMHS waiting list. This may mean some need less or even no further treatment.

Our research has four parts:

- Working out how to safely provide eBPI to young people on CYPMHS waiting lists
- Co-design eBPI with young people, parents with input from service providers
- Using eBPI with a small number of young people to spot snags and finalise how best to use it (user testing)
- Test if eBPI is effective enough to run a full trial and determine value for money

Based on our earlier work, we think that 15 to 30 out of each 100 teenagers on the waiting list for low mood or depression would recover and not need further treatment. This research will tell us how well eBPI works, whether it is value for money and if it is worth testing in a larger study.

We will invite young people and parents/carers to join two advisory groups to support the researchers in this work. The advisory panels will help to design and deliver the study, including co-developing study materials, reviewing results, and working with the research team to communicate our findings in an engaging way.

SUMMARY OF RESEARCH

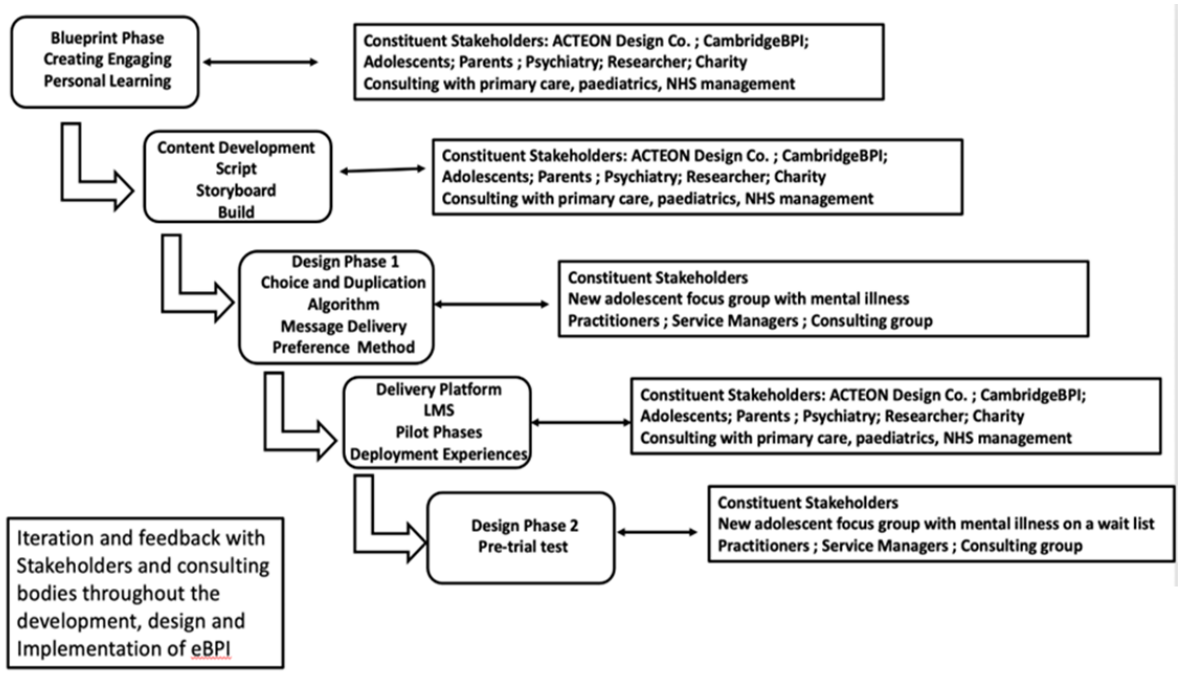
Increasing waiting lists for Children and Young People's Mental Health Services (CYPMHS) are a major barrier for young people trying to access mental health care. Latest figures for 2021-2 show a 47% increase in referrals to 6% of children and young people nationwide. Total numbers exceed 730,000, but rates vary widely by locality (1). Young people on the waiting list will include those with self-harm, suicidality, severe social impairment as well as many co-occurring anxious and behavioural symptoms. Average waiting time to initial assessment is 9 weeks, followed by a further 20 weeks wait for treatment, but this varies a great deal between clinics. Approximately 30% of young people on wating list attend fewer than two appointments (1) which suggests that earlier intervention might reduce their distress, and for some young people, allow them to leave the waiting list. This would free up CYPMHS capacity for those with more complex needs.

As illustrated in Figure 1, our proposal describes the development and early evaluation of an online intervention aimed at reducing the waitlists for specialist CYPMHS through the provision of a low intensity digital psychosocial intervention. We will coproduce an online adaptation of an existing NICE approved evidence-based face-to-face intervention, Brief Psychosocial Intervention (BPI) (2). Our team includes the inventors of BPI, which is the first psychotherapy developed for young people with input from young people rather than being a derivative of an adult mental health treatment protocol. Previous research showed that face-to-face BPI is both clinically and cost-effective. Further, BPI is now approved by NICE for the treatment of depression in teenagers.

We plan further codesign with adolescents, parents, charities and NHS professionals, to develop a low intensity digital version of BPI (eBPI) that might offer rapid relief from suffering for young people with depression and mood related presentations currently on the CYPMHS waiting list. We will achieve this through four work packages as follows:

- WP1 will explore young people and parents/carers' experiences of waitlists and evolve the clinical governance for eBPI through interviews with NHS managers and clinicians working with young people who are waiting for treatment;
- WP2 will codesign a low intensity eBPI treatment basing the content and process on the existing evidence for face-to-face BPI, iteratively incorporating feedback from young people, parents, clinicians, working with software engineers:
- WP3 will evaluate the eBPI prototype for clinical usability, feasibility, safety and managerial acceptability with between 5 young people each in two NHS clinics;
- WP4 will undertake a pilot trial of eBPI versus waiting as usual in 10 NHS CYPMHS within two NHS Foundation Trusts to test recruitment, retention, and research processes. The trial will recruit 80 young people, aged between 12 and17 years (40 in each arm) randomised to eBPI or waiting as usual. Progression to full trial will depend on the success criteria defined below.

Figure 1 overview of proposed research



BACKGROUND AND RATIONALE

The Problem

Many moderately to severely mentally ill young people languish on waiting lists while enduring ongoing disruption to their development despite the existence of effective treatments. This includes young people struggling with self-harm, suicidality, and social withdrawal. The record number of referrals into NHS Child and Young People Mental Health Services (CYPMHS) in recent years currently stands at 6% of children nationwide and vary widely by locality (1,3). Recent increases in CYPMHS' staffing levels have been swamped by steeper increases in referral rates leading to ever longer waits for assessment and treatment (1,3). In England, the number of children and young people in contact with specialist CYPMHS rose by 47% between 2021 and 2022 (1). Whilst some 40% of waiting list cases receive a first assessment within nine weeks, others may wait over 20 weeks with further additional waiting time to access treatment which is often 20 weeks or more (4).

Increased referrals are to be expected given Official Government Statistics from the national survey series, which demonstrate a sustained increase in probable mental health disorder among school aged children and young people from 1 in 9 in 2017, to 1 in 6 in 2020 and 2021, increasing further to 1 in 4 among 17- to 19-year-olds in 2022 (4). Nationally NHS CYPMHS accept approximately 77% of young people referred to them, but interestingly, some 30% are seen only once despite waiting so long for this initial appointment (1). This suggests that some young people waiting for treatment require only limited support. Staffing levels in NHS CYPMHS seem unlikely to increase sufficiently to

reduce waiting lists working in traditional patterns, so we need radical innovation to care pathways (3).

The James Lind Alliance identified support for children and young people on CYPMHS waiting lists as one of its top 10 research priorities in relation to children's mental health in 2018, which was echoed by the recent report form the Children and Young People's Mental Health Coalition report and the NIHR Applied Research Centre from the South West's prioritisation process with young people with lived experience (1,5,6). These young people worried that long waiting times might increase unhealthy coping strategies, such as self-medication with drugs or alcohol. The very limited evidence-base about waiting list experience suggests varied practice and a widespread lack of support despite some research suggesting that young people's mental health deteriorates while waiting (7–9). A recent survey of 57 CYPMHS suggested that some (12/16 responding) are offering various waiting list interventions, but with little evaluation or underpinning evidence (10). This is despite evidence that people's mental health may deteriorate, worryingly with reduced response to treatment when offered, and loss of motivation to seek help and engage in treatment (8,9). A study of young adults reflecting on their experience on CYPMHS waiting lists indicates that they felt very unsupported, relied heavily on family and friends and nearly all sought alternative help (7). Interestingly, research on adults suggested that guided self- help whilst waiting for treatment in mental health services improved participants mental health and engagement in subsequent treatment (11,12).

In psychological interventions for young people's mental health, the search for new treatment options has encompassed three clear elements. Increasing evidence suggests that brief psychotherapies are effective; delivery of even a single session has effects that can last months (13,14). Whilst these observations mainly involve young people with mild to moderate anxiety and depressive disorders outside specialist CYPMHS, our previous work suggests that at least 20% of severe depression presentations with comorbidities will also respond to one or two sessions of BPI (2). These brief therapies focus on explanation and educating young people about their mind plus offering a personal and social set of psychosocial prescriptions to act as antagonists to psychopathologically driven behaviours that undermine mental health. Digital health interventions (DHI) offer the potential for increased access. Indeed, recent randomized controlled (RCT) trial evidence has shown that explanations and psychosocial prescriptions can be delivered via DHIs (14). This raises the possibility that a DHI approach utilising psychoeducation, with personal and social prescribing, can be leveraged to assist waiting list patients in CYPMHS.

While the use of digital methodologies to enhance traditional face-to-face methods of assessment and intervention is appealing, the availability of valid and reliable DHIs for primary and secondary adolescent mental health care are, however, few (15,16). Currently most attention has been given to prevention and early detection DHIs for use in community and schools settings (17,18) although DHIs are also being developed for the treatment of existing mental health difficulties in adolescents (19). To date however, the implementation of DHIs in pragmatic real-world settings has been less than favourable compared with the RCT efficacy data (20). Co-design with the target cohort is essential to maximize take up of DHIs by young people regardless of their theoretical framework (21,22) and

underpins successful adoption and implementation. Reporting the type and level of human support provided as part of the intervention is also important for clinical patients should there be reluctance to use the DHIs. Finally, we hypothesize that having a DHI based on an existing evidence-based approach may prove effective where novel DHIs have disappointed. There is qualitative evidence that young people prefer DHIs with features such as videos, limited text, ability to personalize, ability to connect with others, and options to receive text message reminders (18). It follows that DHIs for use in CYPMHS waiting list patients must be coproduced with young people, including those with lived experience of mood disorder. Design implications that need consideration include expectations of treatment, concerns, and worries about current distress and impairment, and take-up of the DHI in real world settings.

To date there is one Web-based DHI for adolescent depression (or those at high risk), the MOODHwB, which is being produced in line with key guidance on the development and evaluation of complex interventions (19,23). The prototype was designed to be person-centred, multiplatform, engaging, interactive, and bilingual (English, Welsh), included mood-monitoring and goal-setting components, and was made available as a Web-based program and an app (24). The developers initially describe MOODHwB as a psychoeducational intervention and noted that effectiveness of the program remained unclear although a subsequent feasibility study provided encouraging results as a prelude to a fully powered RCT (19). It is now being tested as an intervention to be accessed for young people attending CYPMHS (19). A similar trial has been reported for adolescents in the community with mild to moderate anxiety and depressive features using an online methodology, where both psychoeducation and behavioural support with problem solving were offered as two separate packages; each was significantly better that a neutral control encouraging further developments of DHI tools (13). A similar conclusion regarding the value of psychoeducation was reached by the MOODHwB developers although with more emphasis on ‘active’ rather than ‘passive’ information (21). Interestingly, there is modest evidence that solution finding, problem solving, healthy habits and positive reinforcement of prosocial activities are all effective in isolation (24,25). These elements are all offered in BPI (see below) and might amplify effectiveness in combination.

The solution: BPI and e-BPI

BPI emerged through 25 years of research on depressed adolescents led by Goodyer and is now recommended as a face-to-face treatment by the National Institute of Health and Care Excellence (NICE) for the treatment of depression in young people (https://www.nice.org.uk/guidance/ng134). Importantly, it is the only NICE recommended treatment that was developed for young people, and additionally, with their input; the other recommended therapies (Cognitive Behavioural Therapy (CBT) and Interpersonal Therapies) were adapted from manuals initially developed for adults (2,26).

BPI is based on the three principles of psychoeducation, personal and social prescribing, plus habilitation/rehabilitation, and so is ideal to translate to a DHI for CYPMHS. We hypothesize that this will benefit young people and their families through the provision of an active low intensity intervention. Some may not require additional treatment so the numbers of young people waiting for treatment may reduce. Equally, those who require additional treatment may be encouraged to engage and traditional BPI would offer continuity of approach for face-to-face treatment. A

successful DHI for CYPMHS waiting lists would help to manage the rising referral rate while increasing clinical through-put and filling a therapeutic gap in the clinical care pathway. eBPI, if effective and successfully implemented, would provide part of a seamless, staged program of treatment and care, for young people with moderate to severe mood disorders referred to specialist CYPMHS. If the clinical effectiveness of eBPI were established, we propose to research further translation into other contexts such as primary care, school-based mental health teams, acute paediatric services supporting children with long term physical health conditions such as cancer, and young people in local authority care.

Face-to-face BPI is manualized with a choice of tools and tactics to be selected through a collaborative relationship between the therapist and young person. The objective is to improve current understanding and characteristics of current mental state and associated behaviours, to provide the young person with the skills to understand, monitor and evaluate their mental states, as well as a set of mental and behavioural tools to improve wellbeing. Qualitative analysis of 276 therapy audio tapes has established that has rapid effects as expected from prior RCTs of depressed young people (3,24). These improvements are transdiagnostic with clinical effects approximately equivalent across the domains of depression, anxiety, obsessionally and irritable behaviour (2,27). What is required methodologically is testing with managers, practitioners, young people and parents whether the current content structure is acceptable within a DHI and how best to codesign the logic of delivery on an e-platform.

BPI is delivered through one or more of 10 behavioural channels, selected in collaboration between therapist and young person (28). Unlike many manualised therapies, BPI is not menu driven and does not have a rigid order of sessions, but is person-centred, flexible, and sensitive to individual differences between young people and their varying mental state presentations. The median number of treatment sessions is six with an interquartile range of 4 to 11. The evidence shows that active psychotherapies such as BPI and CBT act relatively quickly with a 20%-30% improvement in symptoms and impairments within 6 weeks and fewer than 3 sessions (26). Two of the components in BPI (psychoeducation and prosocial prescribing) resonate with the psychoeducative component termed ‘the growth mindset’ (29) focusing on understanding mental states and the problem solving focusing on active behaviours, in the online trial of single session video treatment of adolescents with post covid mild anxiety and depression (13).

The most recent manualised form of BPI used in CYPMHS was rigorously evaluated in the NIHR funded IMPACT trial (2,30). The treatment manuals, workbooks for therapists, plus information for young people and parents will be source materials for the current proposal if funded. The contribution of young people and parents to the existing face-to-face conversation-based form of BPI and the feedback from the young people in the IMPACT process evaluation (31) will provide the first iteration of content and implementation for eBPI. We will determine if eBPI can fill the gap between referral and face-to-face treatment in specialist CYPMHS. The content of BPI has already been subject to extensive inclusion analysis of process use to determine the components that were associated with effectiveness in face-to-face BPI therapy (2).

BPI as a face-to-face intervention has been taught to a wide range of mental health professionals over the last 13 years, across several services in the NHS, as well as clinical and research sites in North America, Canada, Europe, Africa and Asia. The intervention was the psychosocial reference treatment for the IMPACT study which resulted in NICE UK approving BPI as a treatment for depressed adolescents (26). BPI has been independently demonstrated clinical value: a worldwide RCT of antidepressants used BPI as the reference pre-randomisation treatment to medicine phase in which 103 (13%) of 777 severely depressed young people who qualified to receive antidepressants on trial criteria responded to BPI and so did not progress to medication (32). Feedback from patients and professionals using BPI is very positive and the 'keep it simple, do it well' motto of BPI is appreciated by training practitioners. Qualitative analysis of user experience of BPI is also very positive (31).

A further advantage of our proposal is the potential for continuity of treatment concept from the waiting list to the clinic for those need additional treatment, given that the content of eBPI will be connected to face-to-face BPI, and the study is based in two NHS Trusts that are already using BPI. This would be the first hybrid staged care method where a DHI precedes a face-to-face intervention, which we propose to explore in the pilot trial process evaluation.

Why WAIT LESS is needed now

We desperately need novel interventions that reduce the patient distress and the intensity of service burden linked to the rising levels of referrals to CYPMHS (3). Young people who are not able to function well during their crucial teenage years pay a heavy developmental price, which jeopardises their future health, educational, occupational and social trajectories (33). Prospective studies demonstrate that the divergence of transient, from persistent, forms of depression emerge in adolescence. Intervention can reduce current mental state difficulties in both types with the possibility of booster sessions over time potentially damping the liability for recurrence (34–36). The implications of waiting for intervention for young people is now being revealed through neuroscientific investigations that demonstrate a loss of decision-making acuity, associated with atypical patterns of neural connectivity, and loss of typical maturation in myelination, amongst adolescents with high depression scores (37,38). Furthermore, the presence of depression impacts other aspects of development, such as school attendance and academic attainment, with potentially life changing implications (39,40). Reducing the time to treatment may increase the chance of remission, reduce relapse risk and provide moderately to severely depressed young people with the self-care psychosocial skills to improve their resilience, mitigating their risks for further mental illness in addition to reducing current levels of distress.

Aims and Objectives

We aim to test the feasibility, acceptability, and potential utility of eBPI, as well as to explore its potential to reduce suffering among adolescents on the specialist CYPMHS waitlists. If eBPI can offer rapid relief with depression, anxiety, and mood related presentations some patients may not need further face-to-face treatment. Our specific objectives are to:

i) understand the experience of young people, parents /carers and clinicians in managing waitlists and how eBPI could be safely offered to those waiting

ii) Codesign eBPI as an intervention, as well as establish the safety and standardised operational procedures to support its evaluation in NHS CYPMHS

iii) determine if eBPI warrants a fully powered RCT to robustly establish clinical and cost effectiveness.

WP 1: Patient experiences of waitlists and clinical governance for eBPI; Lead Burn; months 1 to 11.

Recruiting from ten participating CYPMHS, we will explore young people and carers' experiences and perceptions of: i) their mental illness, ii) the waiting list and treatment expectations, and iii) the value and use of a DHI to inform the codesign of eBPI. Consent procedures for young people and parents will follow the procedure described in detail in WP4. We will aim to run two focus groups with young people and two focus groups with parents/carers. We will recruit 6-7 participants to each group, which will be held in-person or online (to be decided with the participating CYPMHS). However, if young people or parents/carers do not feel able or comfortable to participate in a group, we will make a 1:1 interview available (max 15 interviews). Participants will receive a £25 voucher as a thank you for taking part. In parallel, we will explore the clinical governance of how eBPI could be delivered to young people while on the waiting list in these services.

We will also explore current practice and perspectives from participating services and referrers. We will conduct interviews or focus groups if more convenient for participants, with 6 Managers and 12 CYPMHS practitioners about prospective acceptability of eBPI and implementation. In addition, we will work with up to 10 representatives from the range of referral agencies across sites, such as General Practitioners, school mental health leads, and mental health charities. Data will be thematically analysed (42) to generate themes related to content priorities, implementation strategies and delivery for WPs 2 and 3. WP1 will map pathways, focus the research processes and define criteria of most relevance to young people, parents and clinicians that will be used to evaluate the patient experience of eBPI and the waitlist in WPs 3 and 4.

In preparation for grant Year 1, we will complete an ethnicity framework activity with the research team and PPI group members. This will be used to inform version 1 of our EDI strategy document, which will be updated as the project evolves. This work will be led by Norwich CTU.

WP2 Co-design of eBPI; Leads Goodyer and Kelvin; months 9 to 19

The conversion of BPI to eBPI will be overseen by a stakeholder group comprising young people, parents, and clinicians, who will be consulted at every step of the design and build process, and then again as the eBPI is implemented in WP4. The stakeholder groups will include members drawn from different ethnicities and other key characteristics to help ensure that eBPI iterations are race, language and culturally sensitive. Successful delivery of e-BPI depends on a set of key principles:

- effective, accessible content, providing and engaging user experience,

- acceptability to young people, parents and services/practitioners,
- successful integration with NHS systems and processes.

BPI is a synergy of three principal components as illustrated by Figure 2A

1. Psychoeducation to improve understanding mental states.
2. Prosocial and personal prescribing to enable adaptive behaviour.
3. Habilitation-rehabilitation to embed psychological growth and adaptive behaviours.

The traditional face-to-face BPI is delivered through a set of psychotherapy tools or skills that the therapist learns during training and selectively uses depending on their clinical judgement in collaborative discussion with the young person and their parents. Tool selection occurs within the framework of a case formulation. The eBPI designer and pathway implementation success is dependent on an iterative learning and a delivery process that involves all stakeholders from the outset, which will be sustained through to the end of the project. The key features that will contribute to successful e-BPI development will include (see Figure 2B, C and D below)

- graphical richness, including video.
- young person 'voice'-led.
- delivered as short, easy to digest, bitesize elements
- built on the existing BPI content, structure and process for efficacy
- Intuitive usability.
- multiplatform and multi device including mobile-first delivery to support equitable access.
- robust software and rendering formats conforming accessibility to all widely used devices and systems, including NHS systems.

The design team will consist of:

- A young people's advisory group of four young people including at least one member with lived experience of depression.
- A parent of a depressed young person.
- A CEO of the Youth Mental Health Charity (Templeton; www.ypmh.org).
- Prof. Goodyer and Dr. Kelvin as Lead Teachers of BPI to the NHS and are Directors of CambridgeBPI (www.cambridgebpi.com).
- ACTEON Communications LLP as Designers of eBPI (www.acteoncommunication.com).
- Dr. Anne-Marie Burn as Lead qualitative research scientist.

In addition, the consulting expert advisory group will include:

- Dr. Isobel Heyman, Consultant liaison psychiatrist and a developer of a digital mental health tool for adolescents with epilepsy.
- Dr Julia Gledhill Consultant Child Psychiatrist, and lead for Child and Adolescent Mental Health Research within the CNWL NHS Foundation Trust.

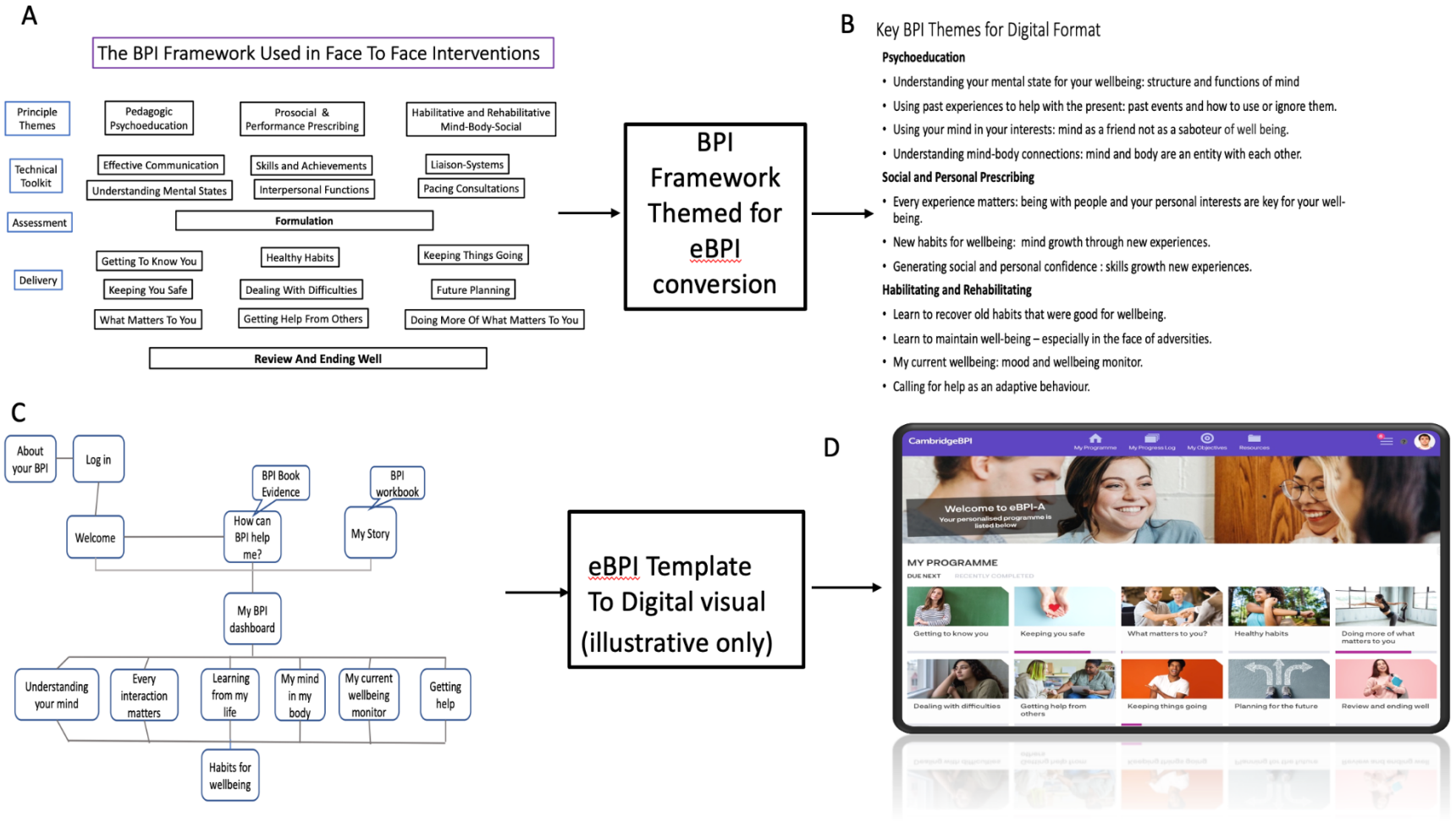
- Dr Nima Leffler Consultant Child and Adolescent Psychiatrist Wokingham CYPMHS

This team will condense the learning messages into concise bitesize elements, identify the most effective format for delivering each element (animation, interactivity, video, physical activity, conversation, reflection, etc.), and sequence the elements into a coherent programme (or programmes). Finally, they will identify and address any differentiation of needs and preferences within the target patient group. ACTEON LLP will be key partners responsible for developing the eBPI tool. Their learning management system, which is NHS standards compliant (AICC standards and SCORM) will host the eBPI user products; secure server and interfaces will be ensured and NHS data governance compliant. The design team will be embedded in a full complement of key stakeholders who will contribute throughout the design, development and implementation process.

Obviously, the final design will be altered during the iterative co-design process, but our initial vision is that young people will be guided through the three domains (psychoeducation, social/personal prescribing, habilitation/rehabilitation) and introduced to 10 self-delivery tools. We expect to have between four and six "episodes" of eBPI material, each lasting between five and ten-minutes. We anticipate that young people may want to repeat and return to one or more elements during their treatment episode, and we will explicitly monitor this in WPs 3 and 4 to develop guidance for future use. Throughout the study, technical support will be available to services, leads and or young people undertaking eBPI by text, email or telephone. We will also codesign methods for the eBPI tool to support the young person seeking additional support from the duty clinician at their CYPMHS, and to flag increasing distress or risk to waiting list managers. The development team plan to produce a multiplatform, responsive tool available on multiple devices. Young people will be allowed to choose which device they wish to use (mobile, tablet, personal computer) and which form or communication-media, for support they want to use, if needed (text, chat, etc). The program will be online from the ACTEON learning management system hosting services. We will scope the best fit interface between this and the participating NHS services and have costed for 10 tablets (one per CYPMHS) so as to avoid digital exclusion of potential participants who lack access to a personal device. We will monitor the latter in order to provide guidance for a definitive trial and subsequent NHS implementation.

The advisory board will have four young people *actively involved at any one time,* but they will be drawn from a much larger and less actively involved panel of young people. We tend not to set limits on these groups in terms of CYPMHS experience and numbers, but would aim for 25 as a minimum, with at least 15 with service / experience of depression. Teenagers have lots of demands on their time, and particularly those with poor mental health may struggle to commit to consistently high levels of engagement over long periods of time. In our experience having small groups who can actively engage for shorter periods permits greater overall involvement and broader representation. Our plans are similar for the parent advisers.

Figure 2 Using BPI as the foundation for eBPI



WP3: Initial acceptability, feasibility and safety; lead Burn; Months 14 to 20

WP3 will overlap with WP2 as the outputs from WP2 Iteratively feeds into initial user testing which in turn feed back into finalised design. We will apply User Acceptance Testing (UAT) to ensure that eBPI meets the requirements of end users, and ensures the quality, usability, accessibility and functionality of the software. This process will be able to identify and resolve any issues or bugs before the pilot study. The wider literature will inform the UAT plan early in the project to specify the objectives and testing criteria. Virzi (55) has shown that 5 users is sufficient to identify 80%-85% of usability problems, which means we can conduct multiple sessions and this will inform the iterative development of the intervention. We will apply Nielsen's heuristics (56) to measure the usability of the user interface, employing a usability survey and think aloud techniques (57).

We will recruit 5 young people from the participating NHS trusts (total 10) to user testing sessions to assess eBPI usability using a think-aloud-protocol (43), check implementation efficiency and finalise standard operating procedures around additional local service and duty clinician support. The eBPI intervention will last for 8 weeks. Following eBPI, young people and their parents will also provide feedback and information regarding their experiences of eBPI, as will service waitlist managers. The time allocated to WP3 will allow four young people to try eBPI (months 17 and 18) and tweaking of eBPI before six more young people try the refined version (months 19 and 20) with finalisation of eBPI in month 20.

Consent procedures for young people and parents will follow the procedure described in detail below (see WP4). The methodology will involve discovery of young people's and parent's experiences and refining eBPI through codesign procedures. We will collect quantitative data on acceptability (young person access and engagement with each section of eBPI), feasibility (engagement, support required, adverse effects) and research processes (data completeness, potential effect sizes). We will conduct semi-structured interviews of young person, parent/ carer and clinician experience so that we can refine the evaluation protocol and eBPI for WP4.

All participating clinics have standardised procedure for supporting young people who are on the waiting list, which will be available to all participants. Young people are provided with contact information for a duty clinician who they can contact should they experience worsening mental health or a crisis. We will explore if and how the eBPI tool may send relevant information to duty clinicians in this phase and develop a standardised operating procedure for flagging concerns and supporting young people that can be carried into WP4.

WP4 Pilot trial of eBPI versus waiting list as usual with embedded process and economic evaluation; lead Ford: months 21 to 32

The WP4 pilot trial aims to evaluate research measures, processes, and engagement with eBPI to provide essential information to support the design of an adequately powered definitive RCT, as well as data completeness of outcome measures. Our specific objectives are:-

- To estimate recruitment, retention and engagement with eBPI

- To explore whether higher intensity data collection, which would allow us to date response and explore mechanisms of change in a larger study, influence the completeness of data.

- To collect data on variance of depressive symptoms in the waiting list population (we can find no existing examples in the literature) to support the power calculation for the definitive trial.

The trial will **include** young people aged 12 to 17 years recruited from the CYPMHS waitlist for treatment because of low mood or depression. Eligibility commences from the moment of allocation to the waiting list and persists until a young person chooses to leave the waiting list or is offered a treatment by CYPMHS. From prior RCT research we can infer that the median age of wait list participants in scope for eBPI will be 15yrs and 3 months and 70% will be female sex as assigned at birth (2). We have no initial **exclusion criteria** but anticipate that some may emerge during WP1 and 3. Young people in crisis are likely to come off the waiting list so by definition will no longer be eligible. Some young people may deteriorate whilst part of the study and require active treatment from CYPMHS, which we will monitor in terms of safety and numbers to inform sample size calculation for a definitive trial. We would not withdraw access to eBPI should this occur, unless advised to do so by the treating CYPMHS practitioner. Such discussions will be carefully recorded and monitored.

We have consent to participate from two NHS CYPMHS trusts that include 10 separate CYPMHS. These clinics serve diverse communities with significant variations in ethnicity, employment and educational characteristics, and their waitlist practice varies, providing a rich context for our study. Five services are part of the Berkshire NHS Foundation Trust (Newbury, Wokingham, Reading, Slough, and Bracknell), while the other five services are from Central and Northwest London NHS Foundation Trust (CNWL; Westminster, Kensington and Chelsea, Harrow, Hillingdon and Brent). Both the Trusts have a defined clinical pathway for young people with anxiety/depression who have been referred for specialist assessment / treatment. For Berkshire, anxious/depressed young people are placed on the waitlist for the severe emotional team (SET); CNWL place their anxiety/depressed adolescent cases on the mood disorder waitlist. In both trusts these waitlists include neurodiverse young people who additionally have depressed mood. Project leads in each NHS Trust (Dr. Leffler in Berkshire and Dr. Gledhill in CNWL) will be responsible for supporting recruitment and the eBPI user's needs. They are also constituent members of the development and research team. From our collective experience, **successful recruitment of patients attending CYPMHS** depends on active involvement of the senior research staff with lead research clinicians in generating interest and involvement across the two NHS trusts, supplemented by energetic follow up by the research team. A clinical monitoring committee will monitor recruitment, engagement and retention from each clinic to share best practice and successful strategies.

We have scoped these waitlists; there are approximately 40 young people waiting for a face-to-face assessment and treatment per service (400 in total) with an estimated wait time of 36 to 52 weeks. We want to ensure the intervention cohort is representative of ethnic and cultural diversity in the catchment area, although we will be constrained by the population who seek help and are accepted

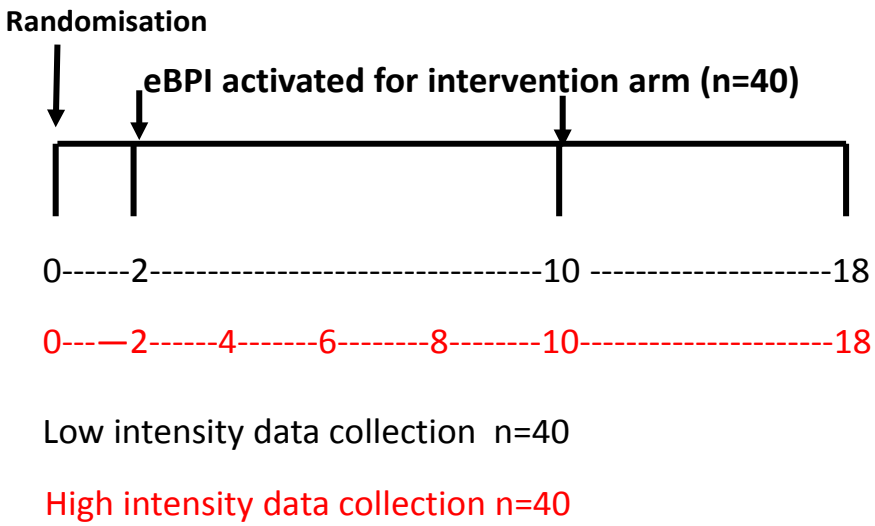
onto the waiting list. Working with the CYPMHS, our parent and young people advisory groups and our clinical trial experts (Hammond and Ashford), we will explore **strategies for recruitment** to select the most successful for a definitive trial. Young people and parents will be invited to hear more about the trial by the CYPMHS wait list manager or clinicians. How we provide information will be guided by input from our young persons and parent / caregiver advisory panels, but we know from previous studies that young people find traditional information sheets confusing and unhelpful. In previous studies, at young people's request, we have developed flyers that cover the salient points according to our young advisers but would equally consider videos or podcasts. These will be supplemented by more traditional information, as required by Research Ethics Committees, and a discussion with researchers to address any questions.

Across **all WPs**, **parents of those under 16 years** will **consent** for their child's involvement while **those aged 16 plus will consent for themselves**, although we will encourage their parents/ carers to be involved in WPs 3 and 4 provided the young person agrees. Likewise, we will seek **assent from young people aged under 16.** Young people will not be excluded if they lack digital access. The project team in partnership with the local service will provide access to an appropriate tablet if needed.

In preparation or the pilot study, we will use the NIHR EDI toolkit, in collaboration with the PPI advisory group and local advice from site clinicians and the Clinical Research Network to design the participant recruitment and retention processes needed for the study protocol. Given that we are recruiting from CYPMHS, recruitment to the study will depend on selection factors in the local community not under our control. We will however regularly review our recruitment selection against available wait list patient population though the clinical research subcommittee. This will be a standing item on the monthly agenda to ensure we detect bias in recruiting as early as possible and determine methods to rectify any such procedure.

Norwich CTU will randomly allocate young people to eBPI (n=40) or waiting as usual (n=40) at the individual level. Clinician support as provided by local CYPMHS policy will be available to both groups throughout. Because of the sex difference in the prevalence of depression in young people and our relatively small sample, we propose to stratify randomisation by sex assigned at birth so that we ensure some boys are recruited to each arm. We will stress to participants and participating clinics that **eBPI will be provided as part of, rather than instead of, being on the waiting list** because fear of losing their place is a common reason reported for not engaging in such interventions (44). Within each treatment group, we will additionally randomise to low intensity (baseline, post intervention and follow up; n=40) and higher intensity data collection (basic schedule plus fortnightly short version of the Moods and Feelings Questionnaire (MFQ; 45) until week 10; n=40; see Figure 3). The follow up schedule will remain unchanged for those who choose to come off the waiting list or are offered and accept treatment, unless they withdraw themselves from the study.

Figure 3 Data Collection Schedules



We propose to recruit between 8 and 10 young people per clinic to generate a total of 80 and anticipate that recruitment will be completed within three months (months 21 to 24; 3 to 4 young people per clinic per month). The eBPI intervention will last for eight weeks (starting month 22 and completing by the end of month 27 depending on recruitment date and allowing two weeks after baseline to randomise and set up eBPI for the intervention arm. Data from our own trials and examination of current wait lists in two collaborating CYPMHS suggests that 95% of those waiting accept treatment when initially offered. Given 30% only attend one session (4) while 1 in 5 CYPMHS patients who entered the IMPACT trial only had a therapy 'dose' of 2 sessions, we estimate that between 15 to 30% will respond to eBPI and choose to leave the waiting list compared to those waiting as normal. This sample size is sufficient to provide data to test these assumptions.

Measures (see Table 1)

Our proposed primary outcome for the definitive trial is a reduction in depression symptoms by end of trial (eBPI> no eBPI) according to the Moods and Feelings Questionnaire (sMFQ (45)), which is recommend to assess treatment response in the NICE guidance for treating depression in young people (46). The sMFQ was sensitive to improvement in previous UK-based RCTs of interventions for depression in young people (2,47,48).. Goodyer's studies (2,47) suggest a five-point reduction on the MFQ represents the minimally clinically important difference for the assessment of superiority. ADAPT found a MFQ standard deviation of 14.6, so this size of a reduction would equate to an effect size of 0.34. These studies were of young people who had passed through the waiting list and we can find no reference waitlist studies, so current study will add value by gathering essential data to

inform the estimation of the minimum clinically important difference in this novel research population.

Table 1 Basic low intensity schedule for data collection

Construct	Measures for Young People	Baseline	10 weeks	18 weeks	>18 weeks
Depression	Moods and Feelings Questionnaire (Primary Outcome)	X	X	X	
Impairment	Strengths and Difficulties Questionnaire Impact scale	X	X	X	
Waiting list choice	Wait; return to referrer; withdraw		X		
Quality of Life	EQ-5D-5L	X	X	X	
Services and personal costs	Client Service Receipt Inventory – Child Version			X	
Experience research processes	Process evaluation interview			X	X
Experience of eBPI / waitlist					X
Experience of harms of psychological therapy questionnaire	Experience of harms of psychological therapy questionnaire			x	

Our secondary outcomes include the proportion of cases choosing to leave the waitlist at three months (eBPI> no eBPI); young people will choose whether they want: a) remain on the waitlist to be seen face-to-face, b) return to the care of their primary services or c) withdraw from services entirely. We will also assess impairment using the Strengths and Difficulties Questionnaire Impact Supplement (49), Quality of Life with the EQ-5D young person's version (50), and access to services for economic evaluation, which include support from education, third sector and informal sources as well as CYPMHS and other health services with the Client Services Receipt Inventory (CSRI; (51). We will assess acceptability measured by engagement in eBPI (time spent on the system, sessions logged into etc), retention and additional support required from CYPMHS and other services, as well as adverse effects using strategies developed in WP3.The schedule for measurement is illustrated in Table 1 and Figure 3. The low intensity data collection arm will collect baseline measures prior to randomisation, and at 10 weeks (which will be post-intervention for the eBPI arm) as well as at 18

weeks (months 28 to 31). The higher intensity data collection will add fortnightly completion of sMFQ from baseline until 10 weeks.

The **process evaluation** would determine if eBPI and our trial methods are feasible and acceptable for young people, parents, and clinicians. After the final follow up, young people and their parents from each study arm (n=10 eBPI vs. n=10 no eBPI; months 31 to 33) will be interviewed about their experiences of the intervention and other support received, as well as participation. The **health economic evaluation** will consist of a detailed calculation of the costs of the eBPI intervention, and analysis of resource use data collected during the study using the CSRI. As part of the process evaluation interviews, we will ask questions about service use and out of pocket costs to inform the data to be collected in a future **health economic evaluation**, as well as asking if "spill over effects" are incurred by parents or other family members. We will also ask about the best way to collect these health economic data, including mode and frequency of data collection.

A purposive sampling strategy would ensure a diversity of backgrounds and views are represented. Interviews will also be conducted with clinicians (n=10) at the end of the intervention delivery period to explore perceptions of the interventions' value, including anticipated benefits and harms. Interviews will be conducted face-to-face or via an online platform according to participant choice. Qualitative process interviews will commence with parents and young people as they complete the four month follow up and incorporate clinic staff once the services all patients from their CYPMHS have completed follow up.

Study participant support

The research team will support participants in all WPs with matters related to the research. Technical support for eBPI will be codeveloped in WP2, refined in WP3 and evaluated as part of WP4. We currently envisage a range of different modes that young people could use to access this support in real time, for example by chat function, direct message, or video / audio call. The policies and practices of each NHS Trust regarding the safety and well-being of waitlist cases will be adhered to during WP3 and 4, and WP1 and 3 will develop and refine standard operating procedures to facilitate this. The nature of any support given during intervention period will be recorded and discussed by the clinical monitoring committee during WP3 and 4.

DISSEMINATION

We will work with PPIE members to develop a dissemination and impact plan. Young people and parents / carers will be actively involved in dissemination and engagement activities e.g. producing videos about the project using TikTok and creating a newsletter. This will include informing stakeholders of progress and results via social media, a study newsletter, and blogs such as Mental Elf. In line with INVOLVE recommendations, we will close the feedback loop on decision-making to ensure PPIE members know how their insights are being used.

Outputs and anticipated impact will include:

- A novel eBPI platform that could support treatment for young people on waitlists.
- Standardised operating procedures for the safe delivery of eBPI within specialist CYPMHS that could provide a template for other studies.
- Knowledge about waitlist trajectories and reasons for leaving or staying on the waitlist and the impact of being on a waitlist on young people and their families that could inform service provision, commissioning, and policy; we will support this by producing policy briefings for commissioners and service providers, supplemented by blogs and podcasts for young people and families.
- Protocol of a definitive RCT to support application for subsequent study.
- Enhanced knowledge of recruitment and retention to improve the efficiency of mental health intervention trials in clinical populations of young people.
- Each WP will lead to at least one conference presentation, such as the British Association of Behaviour Cognitive Therapists and the European Society for Child and Adolescent Psychiatry.
- At least two academic papers for peer reviewed publication; the first from WPs 1,2 and 3 on the coproduction of eBPI will be submitted to *Journal of Medical Internet Research; Formative Research* and the second from WP4 will be submitted to *Lancet Psychiatry*. A further paper about strategies to maximise recruitment and retention and the impact (if any) of data collection intensity will be written if data permit.

PROJECT TIMETABLE

The project will run from March 2024 until end of February 2027, but we will start preparing protocols for WPs 1 and 2 as soon as funding is secured as well as working towards the relevant ethical and trust approvals to minimise the chance of delay. Preparatory work with Acteon Communications LLP, the proposed technical partner, is already underway. Year 1 mainly comprise WP1, with WP2 starting in month 9. WP1 will explore the experience and expectations of waitlists from the perspective of young people, parents and clinicians. This will provide a map of current pathways and define the processes and criteria for the evaluation of patient experience and develop standardised operating procedures for WP3 and 4. WP2 comprising the coproduction of eBPI informed by the early findings from WP1. The timing of WP2 will overlap with both WP1 and WP3 (early testing of eBPI) to allow iterative feedback between codesign and early experience with the platform in CYPMHS. Norwich Clinical Trials Unit (NCTU) will carry out preparatory work from the beginning of year 2 to ensure a smooth operational implementation of the feasibility trial (WP4) in terms of trial and data management. During set-up, the CTU Research Lead will work with the

research team and Young People's Advisory Group to identify ways to maximise recruitment and retention, including acting on knowledge gained during earlier work packages, and reviewing previously published work (e.g. from the ORRCA recruitment and retention methodology database https://www.orrca.org.uk/). The initial approach, consent process, follow-up and other contact during the study will be carefully considered, and we anticipate building flexibility and choice into the study protocol to recruit young people to facilitate equality, diversity and inclusion. Identifying research processes that are feasible with this study population will be valuable for a subsequent definitive RCT but will also inform other researchers working with young people with depression. The pilot RCT will commence in month 21; quantitative data collection will complete in month 29 and the process evaluation in month 31, allowing five months for analysis, writing up and dissemination.

SUCCESS CRITERIA AND BARRIERS

Ford, in collaboration with each WP lead, will be responsible for identifying and managing risks and potential barriers. They will undertake a formal risk assessment and maintain a risk register. Risk or barriers to delivery will be a standing item for all team meetings to ensure the early identification of any issues arising, and to enable us to take timely remedial or mitigating action. If difficulties were not rapidly resolvable, we would inform the Project Steering Committee and our grant manager at NIHR as appropriate. The following are the key areas of risk identified to date:

1. **Challenging timescale;** this programme has four interrelated WPs, which creates a time-pressure from the outset; the development of eBPI (WP2) is particularly crucial to later work, but mitigated by the fact that Goodyer and Kelvin are already engaged with Acteon Communications LLP and preliminary work has already begun. Reviewing our progress against key goals at team meetings will quickly detect unexpected delays. We are an experienced team and with strong project management anticipate being able to stick to our proposed timeline which is realistic and adequately resourced.

2. **Failure to recruit and retain participants** across all WPs; all co-applicants have experience and professional networks that can be brought to bear to support recruitment. Our scoping work suggests enthusiasm to access eBPI in both NHS trusts, and the team has considerable expertise in clinical trials among young people with poor mental health so have many effective strategies to boost recruitment and prevent attrition.

3. **Managing the diffused team;** Ford will have oversight of all WPs as the Programme Lead, and our collaboration is built on a network of established and successful working relationships. We have clearly delineated roles and responsibilities and will use frequent clear communication in and between meetings to ensure the dispersed nature of our project team does not impede the smooth delivery of this research. Recording of remote meetings and meeting minutes will be circulated promptly to inform those who were unable to attend and to record key decisions and outputs.

4. **Illness or change of role of a senior team member:** We have engaged a broad base of experts in mental health with overlapping skills, which creates potential resilience in case of changes within the collaboration.

5. **Risk to self or others or child safe-guarding concerns:** These are likely to emerge during the delivery of eBPI but could emerge in any WPs during interviews or questionnaire completion. Research staff will all be trained to follow clear standing operating procedures agreed with the Project Management Group and Steering committee. These will be written guidelines that describe the procedures that should be taken when disclosures are made. If appropriate, relevant information will be fed into the CYPMHS processes and reported as a potential Serious Adverse Effect. They will be noted centrally to allow any patterns to be identified.

6. **Data security or ethics breach:** Our protocol and data management will be supported by explicit standard operating procedures and mandatory staff training on data governance and ethical research. There will be rapid reporting and review of any breaches involving the Project Steering Committee and NIHR as appropriate.

7. **Withdrawal of a clinical site from WP3:** We consider this unlikely as there are strong links between the co-applicants across sites leading to successful delivery of complex projects. Finally, Ford, Goodyer and Kelvin have extensive collaborative child mental health networks and we are confident that if required, we could encourage an additional site (s) to join the study.

Progression to definitive trial would require the following **success criteria** to be met:

- **Recruitment** (target 40 per trust, 8 per clinic, total 80) – progression recommended if a minimum of **60 were recruited.**
- **Engagement with eBPI** in the treatment arm (target 40); minimal clinically relevant engagement will be assumed to be 2 activitations of eBPI but this will be refined during WPs 1 to 3 and reviewed after WP4. Progression would be recommended if **65% of those randomised engaged** (this would be between 19 and 26 depending on recruitment figures).
- **Retention** (target 70 or 87%) – progression recommended if **75% or more (ie 60 if 80 recruited)** were retained at 18 weeks:

Progress to a definitive RCT would not be viable if our pilot study does not collect sufficient data to inform the full protocol. Specifically: if fewer than 50 participants were recruited; fewer than 30% of those recruited engaged; or fewer than 50% were retained. We plan an interim review once recruitment is completed (end of month 26), when approximately half of the sample will have progressed to the post treatment data collection at 10 weeks and a quarter to 18 weeks. This would provide time for us to consult stakeholders, the clinical trials unit and our trial steering committee to devise strategies that might improve recruitment, engagement, and retention by the end of the trial.

PROJECT MANAGEMENT

Ford as Chief Investigator will assume responsibility for the financial management and delivery of the project. The Core Research Team (all co-applicants and junior researchers) will meet monthly via teleconference with input from the wider team of collaborators and representatives from the Young People and Carers Advisory Groups at quarterly Project Management Group meetings. We will convene an independent Steering Committee who will meet annually with the option of convening more frequently if required to provide critical scrutiny of the work. Both Team and Project meetings will monitor progress against the

proposed timeline, discuss results and coordinate findings between the four WPs as they arise and to discuss and solve possible risks or barriers to the delivery of any individual programme of work. Each WP will proceed independently with weekly meetings of those directly involved to monitor progress; the minutes of these meetings will be circulated to the Core Research Team. During WP3, we will set up a clinical monitoring committee to monitor recruitment, retention, and safety in WPs 3 and 4; we anticipate meeting weekly but may need to convene additional meetings to review adverse effects during the delivery of eBPI in WPs 3 and 4. Our Young People's and Parents Advisory Groups will contribute across all WPs.

ETHICS

Applications for approval via an NHS Research Ethics Committee is being sought at the time of submission to the NIHR REALMS portfolio. Recruitment and consent processes for all primary data collection will ensure participation is informed and voluntary, and anonymity in reporting will be guaranteed.

We will work closely with our advisory groups to make sure information about the studies and consent is communicated in an accessible manner. All potential participants will receive information about the study (purpose, design, timescales, what involvement would entail, how data will be managed, etc.) before deciding whether to take part.

We will work within best practice guidance and statutory regulations for all data access, storage and processing. Each participant will be assigned a unique identifier, which will be stored separately to all research data. Data will be held on a secure database on password-protected computers on university networks, and access will be restricted to the research team.

Participant vulnerability

This study will inevitably involve participants who are vulnerable by virtue of their age and mental health. The latter may also apply to parents or carers. It is therefore essential that we have strong standardised operational procedures to ensure participant safety should risk of harm to self or others become evident, or if other safe-guarding concerns emerge. Although young people will be

referred to the study from CYPMHS and will remain linked to these services during the study, some young people may choose to leave the waitlist, and we will therefore need additional procedures agreed with their local services to ensure the safety of this latter group. Service organisation varies between our sites, so we will prepare site specific standardised operating procedures in partnership with the involved teams. Ford, Goodyer, Kelvin, Leffler and Gledhill are all highly experienced clinicians with strong track records of research with clinical populations of young people and parents. We will ensure that at least one senior person with Level 3 child protection training is always available during office hours to support junior researchers who are concerned about participants, as well as liaising closely with the participating CYPMHS and we will ensure that junior research staff have basic child protection and risk management training.

The risk protocol will involve the completion of a standardised proforma which will be signed the PI (Ford) and sent to the site lead (Neffler or Gledhill) within 48 hours. The PI will complete a serious adverse event form (SAE) sending a copy to the Trial Steering Committee and approving ethics board. The Participant Information Sheet will clearly inform young people and parents that if they disclose information that suggests potential harm to themselves or someone else, the study team would need to share this information, and potentially breach their confidentiality. The core research team will all complete Good Clinical Practice Training and we will ensure that any junior researchers supporting the programme grant are also trained.

DATA GOVERNANCE

All data will be held in accordance with GDPR. Each young person, carer and therapist will be assigned a unique identifier, which will be stored separately to all research data. All data will be held on a secure database on a password-protected computer at the University of Cambridge (all WPs). Access to data will be restricted to the research team. Other researchers will be able to access quantitative data for secondary analyses on application to the researchers once these datasets are locked. We envisage that all participants will complete measures using a web-based tool, however, paper copies will be made available should participants prefer this.

RESEARCH EXPERTISE

Our team has a strong track record and previous successful collaborations. The team reflects the needs of the programme in terms of lived experience (Templeton), and PPI with young people and parents (Burn), as well as the necessary academic expertise. Our skills cover young people's mental health research (Ford, Goodyer, Kelvin, Gledhill, Leffler), BPI (Goodyer, Kelvin, Gledhill, Leffler), clinical trials (Ashford, Hammond, Goodyer, Ford, Kelvin), statistics (White), economic evaluation (Morris), implementation (Templeton), digital coproduction (Burn) and qualitative research (Burn).

Between them, Ford and Goodyer have contributed to more than 20 RCTs as principal investigator, co-applicant or steering / data monitoring committee membership. BPI is cited in NICE guidance while of Ford's previous trials (STARS, NIHR Public Health Board) led to her contribution to the Educational Endowment Foundation Practitioner Guidance (45), which demonstrates the ability

leverage practical impact from research. Furthermore, Ford has an exemplary track record in the delivery of large multi-site complex studies. Hammond is the deputy director of Norwich CTU, while Ashford is an experienced senior CTU trial management lead and methodologist specialising in mental health studies. Morris is an experienced health economist with expertise in cost-effectiveness analysis of health interventions, while White is an experienced statistician with expertise and interest in missing data. Kelvin combines NHS RCT PI expertise with extensive digital learning expertise as well as involvement in national-level service change and implementation. Leffler and Gledhill are both experienced NHS consultant child and adolescent psychiatrists who are research active so can bridge the research-practice divide at their respective NHS trusts. Templeton brings his extensive knowledge of implementation in complex systems as well as lived experience and the expertise of the William Templeton Foundation for Young People's Mental Health. Burn has extensive experience of supporting PPI and will run the Young People's and Parents' Advisory Groups, supported by junior researchers.

Version	Date	Author	Changes
V1		Tamsin J Ford	First version
V1.2	16/04/2024	Tamsin J Ford	Updated title page. Added NIHR acknowledgment. Only included key contacts. Updated work package title under study summary. Updated sample size. Added version control table. Included all revision suggested by Andy Wood listed in the email sent 11/04/2024.
V1.3	29/04/2024	Tamsin J Ford	Added "Experience of harms of psychological therapy questionnaire" to the table on page 24. Removed reference to the Gantt Chart and Flow Diagram in the heading of the Project Timetable section and removed IP section.

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