Imperial College London

PROTOCOL

IMAGINATOR 2.0: Co-design and early evaluation of a novel blended digital intervention targeting self-harm in young people

Short title: IMAGINATOR 2.0 - co-design and early evaluation

Chief Investigator: Dr Martina Di Simplicio

Mood Instability Research Group
Division of Psychiatry, Imperial College London
2nd Floor, Commonwealth Building
Du Cane Road
London W12 0NN
Email: m.di-simplicio@imperial.ac.uk

Investigators: Dr Ben Aveyard
Ms Nora de Bode
Dr Lindsay Dewa
Dr Nejra Van Zalk
Professor Adam Hampshire
Mr Aaron McDermott
Ms Nusaybah Choudhury
Ms Emily Morse
Ms Saida Mohamed
Dr Emily Gardner-Bougaard
Ms Rachel Rodrigues

Sponsor: Imperial College London

Funder: NIHR i4i

R&D Number:
IRAS Number: 310211
REC Number:

AMENDMENT HISTORY

Amendment No.	Protocol Version No.	Date issued	Author(s) of changes	Details of Changes made
SA1	2	11/11/22	Rachel Rodrigues	1. Included a flyer to be distributed in West London NHS Trust to recruit participants (attached flyer, Imaginator_flyer_v1_241022). 2. Research Assistants embedded in the clinical teams in West London NHS Trust can contact young people under adult services directly to arrange a baseline screening visit, once the clinician has confirmed the young person is eligible and would benefit from the intervention. 3. Included an additional measure, (State_motivation_for_reducing_self-harm_scale_v1_11122), to be administered at the baseline screening visit and during the outcome assessments. 4. Therapists (e.g. medical doctors trained to deliver the intervention) can deliver the IMAGINATOR intervention in addition to the CWPs/CAPTs based in CCAMHS and MINT teams. 5. End of recruitment date planned for 31.05.23, and end of study date changed from Jan 2023 to Dec 2023. 6. Participants will be recruited from across any WLT team, in addition to CCAMHS and MINT teams. Other services in WLT were interested in delivering the intervention and so we have expanded this. Amended PIS to reflect this. 7. Removed the inclusion criterion 'participants need to consent for their GP to be contacted' as this was included in error in the initial protocol.

SA2	3	04/04/23	Rachel Rodrigues	1. Two questionnaires measuring anhedonia have been added to the baseline screening and outcome assessments. 2. One questionnaire to obtain written feedback on the intervention has been added to the post intervention outcome assessment. 3. The inclusion criteria for participants has been updated based on feedback from clinicians involved in the study. 4. The feedback interview topic guide has been included for approval.

TABLE OF CONTENTS

SYNOPSIS

Study Title	IMAGINATOR 2.0: Co-design and early evaluation of a novel blended digital intervention targeting self-harm in young people
Short Title	Short title: IMAGINATOR 2.0 - co-design and early evaluation
Planned Study Period	Study period: June 2022 – December 2023 Recruitment end date: 31st May 2023
Study Design	Case series
Study Participants	Participants are young individuals aged 12 to 25 years old who experience current repeated self-harm behaviour and are seeking support to manage and reduce self-harming via local mental health services.
Number of Participants	N = 20
Intervention(s)	IMAGINATOR intervention: Functional Imagery Training (3 x face to face sessions, 5 x follow up telephone support sessions) + IMAGINATOR app

Primary Objectives	To assess the **feasibility**, **acceptability** and **safety** of the IMAGINATOR intervention consisting of Functional Imagery Training (FIT) supported by a smartphone app (IMAGINATOR app) in YP aged 12-25 years old who self-harm.
Secondary Objectives	To explore potential effects of the IMAGINATOR intervention on the following outcomes: a) Changes in self harm frequency and severity b) Changes in mental health symptoms and functioning: low mood and anxiety, psychological wellbeing, suicidal thoughts and behaviour, engagement in other risky self-destructive behaviours including binge/purge behaviour and drug and alcohol misuse c) Emergency department visits d) Further treatment needs e) Maintenance of changes (from pre- to post-intervention) in the above outcomes at 6 months follow-up (3 months post-intervention). To explore potential mechanisms involved in self-harm change: a) Change in the characteristics of mental imagery associated with self-harm when this is present b) Change in the urge to self-harm c) Change in emotion regulation ability. To explore potential effects of the IMAGINATOR app: a) The relationship between use of the IMAGINATOR app and change in the above outcomes from pre- to post-intervention and at 6 months follow-up.

Primary Endpoints	**Feasibility:** An indication of feasibility assessed by calculating treatment adherence indicators such as average number of therapy sessions completed by participants, the percentage of participants completing different components of the intervention (face-to-face sessions, phone calls), and attrition. **Acceptability:** An indication of acceptability assessed by calculating scores on Credibility/Expectancy Scales, the Client Satisfaction Questionnaire, User Experience Questionnaire, and by analysing qualitative data obtained through the Experience of Service questionnaire and semi-structured feedback interviews. **Safety:** Safety of the intervention determined by reviewing *adverse events* recorded at each assessment and therapy session/phone call contact.

Secondary Endpoints	**Potential effectiveness of the IMAGINATOR intervention:** Change assessed from pre-FIT intervention to post-FIT intervention, and at 6 months follow up in the following outcomes: a) Average frequency of self-harm, and average severity of self-harm scores b) Average scores on questionnaires of clinical, functional and process outcomes (see Assessments) c) Proportion of YP needing further treatment in CCAMHS or other WLT services vs can be closed to CCAMHS or other WLT services d) Emergency department visits. **Potential mechanisms:** Change assessed from pre-FIT intervention to post-FIT intervention, and at 6 months follow up in the following outcomes: a) Average scores on characteristics of mental imagery associated with self-harm when present (e.g. vividness, compellingness) b) Average scores of the urge to self-harm c) Average scores on emotion regulation ability measures. **Potential effectiveness of the IMAGINATOR app:** a) Correlations between endpoint scores (listed above) and the following measures of IMAGINATOR app use: number of app sessions/logins and total duration of app use, number of activity cycles completed, number of personalised77 media uploaded, number of completed guided imagery sessions, total duration of guided imagery completed and use of any other key functionalities at 6 months follow up.

KEY ABBREVIATIONS

YP	Young people
YPAG	Young Persons Advisory Group
WLT	West London NHS Trust
CCAMHS	Community Child and Adolescent Mental Health Services
MINT	Mental Health Integrated Network Teams
FIT	Functional Imagery Training
CWP	Child Wellbeing Practitioner
CAPT	Clinical Assistant Psychology Therapist
SC	Standard Care
GSH	Guided Self-Help

1. BACKGROUND AND RATIONALE

The Problem with Self Harm

Self-harm behaviour is an act of self-injury regardless of intent (NICE, CG133). Prevalence is high with an estimated 20% of young people (YP) under 25 self-harming (Gillies et al. 2018).

Methods of self-harm can be broadly divided into self-injury (e.g., cutting, bruising, burning, self-battery) and self-poisoning (most frequently overdose of prescribed or over-the-counter medication). Method switching is common (Lilley et al., 2008) and co-occurrence of multiple methods is used as an index of severity (DSM-5, 2013). Individuals vary in the motives that drive and trigger self-harm. A recent study reported that getting “relief from a terrible state of mind" was the most common reason for self-harm in both boys and girls aged 14-16 (Rasmussen et al., 2016). Motives also change from episode to episode: a study of over 30,000 adolescents in seven countries described that over 80% of those who had harmed themselves in the previous month reported more than one reason for self-harm, including wanting to get relief from a terrible state of mind, wanting to die and wanting to punish oneself (Scoliers et al., 2009).

While most self-harm cases particularly in adolescents represent a form of transient distress, self-harm is more prevalent in those who suffer from a mental disorder. Symptoms of depression, anxiety, as well substance abuse are risk factors for self-harm behaviour and in particular for its repetition. For example, those who start self-harming as young adults are more likely to have presented with symptoms of depression and anxiety since adolescence (Uh et al. 2021). Adolescents who self-harm also have poorer educational and social outcomes (Mars et al. 2014). Self-harm is the strongest risk factor for suicide (Wilkinson et al. 2011): with those who self-harm estimated to be 17 times more likely to die by suicide than those who do not (Morgan et al. 2017).

In summary, self-harm in YP is a major social and healthcare problem. It represents significant morbidity, is often repeated, and has links to suicide, with substantial healthcare costs for the community. Effective early intervention would therefore be of great benefit.

Current Interventions

Unfortunately, most YP who self-harm do not receive adequate support (Rowe et al. 2014; Cox & Hetrick, 2017). Supporting adolescents who self-harm is challenging. This is likely because self-harm is a secretive behaviour and associated stigma is a barrier to help-seeking (Rowe et al. 2014, Gulliver et al. 2010).

A number of psychological interventions, such as cognitive-behavioural therapy (CBT) and dialectical-behavioural therapy (DBT), have shown promise in the treatment of YP who self-harm (Iyengar et al., 2018) but most of the evidence has been based on single trials (Hawton et al., 2015).

Two recent Cochrane reviews following up on Hawton et al. (2015) reported that there is still surprisingly little research on interventions for YP who self-harm (Witt et al., 2021a, 2021b). For example, of the interventions that have been studied, only DBT-A (DBT for Adolescents) has been shown to have positive effects on repetition of self-harm in adolescents and results are not entirely replicated in older adult samples. Implementation of interventions such as DBT in routine clinical practice is limited and complex because these interventions have only been tested in selected populations (such as those with a specific diagnosis) and require long commitment to therapy: for example, DBT-A is a resource intensive intervention, typically taking 6 months (i.e., 24 x1 hour sessions) to complete and including individual and group formats. So, it is costly, not easily available in health services under financial pressure and may not suit all YP. Moreover, while data suggest that YP minoritised by ethnicity, sexual orientation and gender identity have additional risk factors and different patterns of presentation and help-seeking (Williams et al., 2021; Gulliver et al.,2010), current interventions are not tailored to these specificities and needs.

As a result, there is a gap in the provision of targeted support, especially for YP with mild to moderate self-harm severity who could benefit from an early intervention (McManus et al., 2019). It has been recommended that, in light of the extent of the problems associated with self-harm, there is a need to pay more attention to developing and evaluating specific therapies for this population (Witt et al., 2021a) and an important future direction is to develop brief efficacious interventions that may be scalable to reach large numbers of youth (Glenn et al. 2019).

Digital Health Interventions (DHIs): Technology based interventions offer the potential for improved availability of immediate 24/7 support that is accessible at distance and with reduced stigma and resource cost. Not surprisingly, the National Health Service (NHS) is encouraging the use of scalable low-cost technology to provide health support and interventions as a means of addressing increased service demand (NHS England, 2017).

DHIs could provide particularly effective ways to reach adolescents with 83% of 12- to 15-year-olds owning a smartphone and 81% using this to go online (Ofcom, 2021). A systematic review and meta-analysis investigating the effectiveness of standalone DHIs for the self-management of suicidal ideation or self-harm (Witt et al., 2017) found some support for reduction of suicidal ideation (but not self-harm or attempted suicide) and concluded that further evidence on the safety and potential mechanisms of action of these interventions was needed before they could be recommended.

A systematic review of mobile health technology interventions (Melia et al., 2020) reported a proliferation of mobile health apps in recent years with around 10,000 health apps for mental health support alone at that time. Few of these apps had been developed specifically for YP and the rate at which new apps were being developed far exceeded the rate at which they were being scientifically evaluated (Melia et al., 2020).

Mobile apps are considered acceptable by YP who self-harm as potential self-help or guided-help tools (Arshad et al., 2020). Specifically recent qualitative findings (Čuš et al., 2021) indicate that

what YP want from mobile apps for self-harm is the ability to respond to a variety of needs and contexts (e.g., before and during an acute distress state, as well as after self-harming) and for apps to be easy to use in the aforementioned contexts (e.g., having immediate visual elements rather than long text to read). Initial evidence on digital tools suggest that approaches that include human connection are preferred by YP and also improve outcomes (Hollis et al., 2017; Dewa et al., in press; Kavanagh et al., 2014). Despite the unmet clinical need, to date only a handful of digital interventions for self-harm have undergone initial evaluation.

A recent scoping review (Cliffe et al., 2021) of mobile health interventions specifically supporting individuals who self-harm concluded that these are promising tools. However, most interventions to date have been developed and tested almost exclusively with White adult female populations and are not currently publicly available. Among the interventions reviewed, i.e. those that have undergone some form of scientific evaluation, most apps have been developed targeting self-harm in selected clinical populations (e.g., depression, borderline personality disorder), or settings, (e.g. suicidal adolescents discharged from acute inpatient stay, US army veterans), or without user-involvement (Cliffe et al., 2021). There are only 2 smartphone apps specifically developed for and generalisable to support all YP with self-harm: *BlueIce and ERITA*.

BlueIce (Stallard et al., 2018) has been co-developed with adolescents with lived experience and clinicians in the UK and is undergoing a feasibility RCT. It utilises techniques from DBT and CBT (the forms of traditional therapy that have some evidence of reducing self-harm so far) and includes monitoring symptoms. *BlueIce* is on the NHS app register and is available to CAMHS services on subscription. Limitations include that *BlueIce* has minimal personalisation and no user segmentation, is limited to adolescents and does not have a protocol for clear integration with clinician contact.

ERITA (Bjureberg et al., 2018) is an app that accompanies an internet-based emotion regulation treatment for adolescents (called ERITA) developed in Sweden and undergoing an efficacy RCT (NCT03353961). The treatment involves completing 12 weekly online modules (and offers parallel modules for parents). The app is integrated in the treatment and includes monitoring symptoms and suggestions for coping strategies related to what is learned in the module. However, *ERITA* also has minimal personalisation and no user segmentation and still requires a relatively long commitment to 12 structured sessions. Also, it does not include any direct clinician contact.

In summary, current interventions targeting self-harm in adolescents are time-consuming and costly, and do not reach the majority of those who self-harm. DHIs offer a potential avenue for delivering quick scalable support, promoting self-management and overcoming current barriers to treatment. To date, studies on app-based DHIs are few, and the DHIs / apps developed so far are limited to some groups and do not respond to all YP's preferences.

Increasing access to evidence based psychological interventions for YP: Whilst the number of children referred to CAMHS in England rose by 35% from 2018/19 to 2019/20, the number of children receiving treatment only rose by 4% in the same period (Lennon, 2021), highlighting a large unmet need.

Traditional service delivery models (where therapy is provided only by highly trained mental health professionals) limit access to evidence-based treatments (Kazdin & Rabbitt, 2013). In their paper examining novel models for delivering accessible, scalable, affordable and feasible mental health services, Kazdin and Rabbit (2013) discuss task-shifting and disruptive innovation, among other models. Task-shifting aims to strengthen and expand the healthcare workforce by redistributing service delivery tasks to individuals with less training than traditional healthcare workers and examples of disruptive innovation mostly involve the use of new technologies (e.g., increasing accessibility by delivering services online).

The Five Year Forward View of Mental Health (NHS England, 2017) led to funding being made available to train a new workforce of low-intensity Children and Young People IAPT therapists with a one year post graduate training. These 'Children's Wellbeing Practitioners' would increase access to evidence-based interventions for mild to moderate common mental health problems in line with a task transfer rationale (Ludlow et al. 2020), and with adult mental health service provision already offering a range of low-to-moderate intensity interventions across primary and secondary care.

Finally, another limitation in current mental health services is the artificial barrier at age 18, which is not designed to support the transition from adolescence to adulthood when self-harm, and other mental health problems, occur most. Accordingly, the NHS' long-term plan also aims to transform services towards providing a continuous comprehensive offer of care to 16-25 years old YP (NHS, 2019). Therefore, it is important to develop interventions designed and tested to span across this transition period to overcome a situation where an intervention may be available for someone at age 17 years and 9 months, but not 4 months later (or vice versa) due to differences in access thresholds between adolescent and adult services.

The Role of Mental Imagery in Self-harming Behaviour

YP who self-harm report vivid mental imagery of hurting themselves, such as details of tools and the action sequence to be performed, or the consequence (blood gushing) and the sensation of intense relief often generated by the actual act (Di Simplicio et al. 2020).

Playing out mental imagery of future scenarios in the "mind's eye" can have a powerful impact on behaviour (Renner et al., 2019). Following evidence of strong suicidal imagery in affective disorders that can predict change in suicidality (Ng et al., 2016), self-harm imagery has been added to the risk factors for the transition from contemplating self-harm to acting on the idea, as formulated in the Integrated Motivational Volitional model of self-harm (O'Connor & Kirtley, 2018; Wetherall et al., 2018).This model is one of the most prominent explanatory frameworks of suicidal behaviour and is applicable to understanding self-harm irrespective of intent

(O'Connor & Kirtley, 2018). It proposes that self-harm behaviour develops via a motivational and a volitional phase, i.e. from a phase when self-harm ideation starts to a phase when ideation turns into action with numerous contributing elements including cognitive factors with strong motivational properties such as mental imagery. The role of mental imagery in driving behaviour may be explained by its ability to emulate real-life experiences, and so its effect on emotion and motivation is much stronger than that of verbal-based cognitions (i.e. thoughts) (Holmes & Matthews, 2010; Ji et al., 2019).

Targeting Mental Imagery in Self-harm

Following on from the above evidence of the role of imagery in amplifying emotion and motivation, recent studies show that mental imagery interventions such as Functional Imagery Training (FIT) can be more effective than Motivational Interviewing at promoting change of problematic behaviours (Solbrig et al., 2018). Therapeutically targeting mental imagery in conjunction with Motivational Interviewing may therefore have a more profound effect on reducing self-harm behaviour and promoting more adaptive behaviour in line with YP's goals.

IMAGINATOR is a novel imagery-based intervention targeting self-harm (Di Simplicio et al. 2020). It is a blended digital intervention (i.e. combining direct clinical contact with a digital component) delivering Functional Imagery Training (FIT) (May et al., 2015) via therapist sessions, follow-up telephone sessions and a smartphone app (the "IMAGINATOR" app). FIT teaches individuals to use positive goal imagery that helps them resist the urge to self-harm in moments of distress and engage in an alternative behaviour. Vivid imagery of positive rewarding goal behaviours makes these feel close, desirable and easy to plan. For example, compelling imagery of running freely in nature or of a soothing warm drink with a friend harnesses motivation to put this into practice instead of self-harming. FIT broadly falls under CBT approaches and is derived from the Elaborated Intrusion Theory, a cognitive theory of desire and motivation backed by decades of research (May et al., 2015, Solbrig et al., 2019), which has been applied to other fields of behaviour change (dieting, exercise, addiction) (Di Simplicio et al., 2020). The IMAGINATOR app was previously developed together with YP with lived experience of self-harm as an Android-only app with the scope to support training the new imagery-based strategies developed in the FIT therapy sessions.

Our first proof-of-concept study compared IMAGINATOR (for brevity, we will refer to FIT plus the IMAGINATOR app as "IMAGINATOR") with treatment as usual in 38 YP aged 16-25 years old, and showed a medium-to-large effect size (d = 0.65-0.75 [CI: 0.3–16.1]) reduction of self-harm over 6 months following IMAGINATOR (Di Simplicio et al., 2020). Eighty-two % of participants said they would recommend the intervention to a friend. No adverse events were reported. Qualitative feedback highlighted that YP valued the focus on developing goals, positive emotions and motivational tools rather than unpacking negative cognitions (Maschauer et al., in prep). Mental imagery was also valued as a coping strategy that was easy to apply whilst maintaining privacy ("I can do it anywhere and nobody knows I am doing it") (Maschauer et al., in prep).

This work suggests that IMAGINATOR could be feasible, acceptable and helpful at reducing self-harm in YP with a potential for reaching those who often fall in the gap of current provision.

Need for Improvement, Re-design and Adaptation of IMAGINATOR

Evidence from the literature, our proof-of-concept study, working with NHS clinicians and with our Young Person's Advisory Group (YPAG) has since highlighted several limitations of the current IMAGINATOR intervention and the need for improvement.

Clinicians from NHS Children and Adolescent Mental Health Services (CAMHS) via workshops and presentations suggested that IMAGINATOR should be extended and made available to younger teenagers too (e.g. from age 12), as self-harm tends to start earlier than 16 years old and IMAGINATOR could hold promise in particular as an early intervention. Our YPAG agreed with this need and indicated that IMAGINATOR can be suitable for YP across the teenage-young adult age range, but provided that users can choose between a few different options of the app's look and modules to use. This reflects previous literature (Hetrick et al., 2020) suggesting the need for user segmentation around how an app feels, and modality of usage such as data tracking or gamification. YP also report that triggers and self-help strategies are often idiosyncratic (Gillies et al., 2018) further highlighting the importance of personalisation and the need to increase this drastically in the IMAGINATOR app.

Building on our proof-of-concept study, there is therefore a need for a further adaptation and development stage of the IMAGINATOR intervention before its efficacy can be tested in a randomised controlled trial. In particular, there is a need for:

- An iOS version of the app
- A new app design and functionalities to include a degree of personalisation, segmentation, inclusivity and modularity
- Tailoring the intervention to better serve the needs of minoritised YP
- Adapting the intervention to younger teenagers.

2. CASE SERIES EVALUATION

2.1 OVERVIEW OF METHODOLGY

We will run a case series study that investigates the IMAGINATOR intervention comprising of delivery of Functional Imagery Training (FIT) for self-harm supported by a new co-designed smartphone app to YP aged 12-25 who experience current repeated self-harming behaviour and have been referred to WLT teams, which includes the adult community mental health services (Mental Health Integrated Network Teams; MINT) and the Community Child and Adolescent Mental Health Services (CCAMHS). For the purpose of this study, self-harm is defined as per NICE

guidelines (NICE, 2012): "an act of self-poisoning or self-injury, irrespective of the apparent purpose of the act".

A case series is a descriptive study that follows a group of patients who have a similar diagnosis or who are undergoing the same procedure over a certain period of time and is the most appropriate design for reporting on a novel therapeutic intervention with a new population. The IMAGINATOR intervention has been tested with 16-25 year olds using a proof of concept trial (Di Simplicio et al., 2020) but as the current study proposes to also include younger participants (12-17 year olds) and a newly developed version of the IMAGINATOR app, a case series is the optimal design to assess the feasibility and acceptability of the new IMAGINATOR intervention following further protocol/materials development and with a different population.

The IMAGINATOR intervention provides three sessions of FIT + Standard Care (SC), followed by phone support sessions and smartphone app-based support, based on cognitive behavioural and motivational interviewing principles and in line with NICE guidelines for long-term management of self-harm behaviour. FIT is intended as a brief and focused transdiagnostic intervention that can be added to any other pharmacological or non-concurrent psychological therapy. To improve YP's access to and engagement with the intervention, we will deliver FIT face-to-face and encourage participants to support their therapy by using the new IMAGINATOR smartphone app.

The study will be based in the West London NHS Trust.

2.2 CO-PRODUCTION

All stages of the study (design, recruitment, testing, analysis and interpretation of results) will be co-produced with our Young Person's Advisory Group (YPAG), four YP with lived experience of self-harm and other mental health difficulties. Details of co-production are outlined below.

IMAGINATOR app co-design: We followed a participatory design approach to co-develop the new IMAGINATOR app around the core functionality of supporting and training adaptive mental imagery. The YPAG worked with the research team to find and select a group of 14 YP with lived experience of self-harm to co-design the app, ensuring the group covered a wide age range (12-25 years old), gender and those minoritised by ethnicity, gender identity and sexual orientation. The clinicians' contribution enabled us to maximise opportunities and identify obstacles to integrating app use, sustainability and clinical input.

The app was designed based on the Design Council's Double Diamond Process (Figure 1), via a series of structured half day co-design workshops with key stakeholders (YP, clinicians), research team members, app designers and software developer. The YPAG co-facilitated all workshops with the research team.

Once the app prototype was produced, we conducted structured **usability testing** to refine the app design, and in-house **alpha testing** to exclude any potential issues with the prototype,

ensuring the final app design followed the 15 standards outlined by the Information Commissioner's Office in their 'Age-Appropriate Design Code' so as to comply with the obligations under data protection law to protect YP's data online (ICO, accessed 2021).

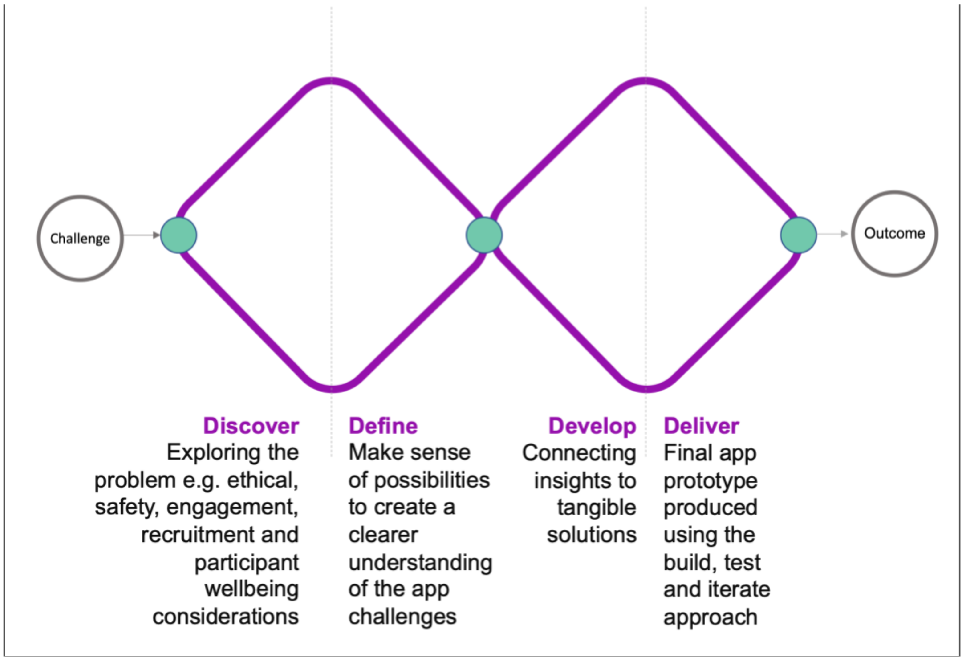

Figure 1: Co-design process using the Design Council Double Diamond Process

Case Series Design: The YPAG has contributed to designing the study procedures, including advising on the most important and relevant outcome measures.

Management of and undertaking research: The YPAG is informing and monitoring all aspects of the study, from planning to data collection and will be trained to conduct user-led feedback interviews with participants at the end of the intervention.

Analysis of results: The YPAG will work with the research team to analyse the data and interpret results.

Dissemination: Our dissemination strategy will be co-produced with the YPAG. We will co-present and co-author peer reviewed papers with young people with lived experience of self-harm at conferences and in journals, and use innovative ways to ensure our research engages and reaches diverse audiences. Our main dissemination tool will be a video co-produced using the SciAni video animation with our YPAG, including co-design, voiceover and scene sign-off with young people (see our work (https://youtu.be/_OnZEJSc4jA).

Building on previous work with young people, findings will be communicated also through:

- User-friendly digital magazine
- Blogs and reflection papers
- Workshops for academics, clinicians and other stakeholders
- Research updates via relevant websites and social media platforms.

2.3 OBJECTIVES

Primary Objective

The primary objective of this research is to assess the feasibility, safety and acceptability of the IMAGINATOR intervention consisting of Functional Imagery Training (FIT) supported by a smartphone app (IMAGINATOR app) in YP aged 12-25 years old who self-harm.

Secondary Objectives

The secondary objectives of the research are to explore:

1) Potential effects of the IMAGINATOR intervention on the following outcomes:
   a) Changes in self harm frequency and severity
   b) Changes in mental health symptoms and functioning: low mood and anxiety, psychological wellbeing, suicidal thoughts and behaviour, engagement in other risky self-destructive behaviours
   c) Emergency department visits
   d) Further treatment needs
   e) Maintenance of changes (from pre- to post-intervention) in the above outcomes at 6 months follow-up (3 months post-intervention).

2) Potential mechanisms involved in self-harm change:
   a) Change in the characteristics of mental imagery associated with self-harm when this is present
   b) Change in the urge to self-harm
   c) Change in emotion regulation ability.

3) Potential effects of the IMAGINATOR app:
   a) The relationship between use of the IMAGINATOR app and change in the above outcomes from pre- to post-intervention and at 6 months follow-up.

2.4 ENDPOINTS

Primary Endpoints

Feasibility: An indication of feasibility assessed by calculating treatment adherence indicators such as the average number of therapy sessions completed by participants, the percentage of participants completing different components of the intervention (face-to-face sessions, phone calls), and attrition (the percentage who complete post-intervention assessment).

Acceptability: An indication of acceptability assessed by calculating scores on Credibility/Expectancy Scales, the Client Satisfaction Questionnaire, User Experience Questionnaire and other bespoke acceptability measures identified by the YPAG, and by analysing qualitative data obtained through the Experience of Service questionnaire and semi-structured feedback interviews.

Safety: Safety of the intervention determined by reviewing *adverse events* recorded at each assessment and therapy session/phone call contact.

Secondary Endpoints

Potential effectiveness of the *IMAGINATOR* intervention:
Change assessed from pre-FIT intervention to post-FIT intervention, and at 6 months follow up in the following outcomes:

a) Average frequency of self-harm, and average severity of self-harm scores over the past 3 months
b) Average scores on questionnaires of clinical, functional and process outcomes (see Assessments)
c) Proportion of YP needing further treatment in CCAMHS/MINT/other WLT services vs can be closed to CCAMHS/MINT/other WLT services
d) Emergency department visits.

Potential mechanisms:
Change assessed from pre-FIT intervention to post-FIT intervention, and at 6 months follow up in the following outcomes:

a) Average scores on characteristics of mental imagery associated with self-harm when present (e.g. vividness, compellingness)
b) Average scores of the urge to self-harm
c) Average scores on emotion regulation ability measures.

Potential effectiveness of the *IMAGINATOR* app:

a) Correlations between endpoint scores (listed above) and the following measures of *IMAGINATOR* app use: number of app sessions/logins and total duration of app use, number of activity cycles completed, number of personalised media uploaded, number of completed guided imagery sessions, total duration of guided imagery completed and use of any other key functionalities at 6 months follow up.

2.5 STUDY DESIGN

IMAGINATOR is a case series study describing FIT as a low intensity intervention alongside standard care (SC) in a sequential sample of YP referred to any WLT team, in addition to CCAMHS or MINT.

The design includes the following elements and study phases:

1. Baseline Screening Visit
2. Intervention: 3 x 1 hour FIT sessions delivered face-to-face by a Child Wellbeing Practitioner (CWP), Clinical Assistant Psychology Therapists (CAPT) or therapist
3. Follow up: 5 x support sessions delivered over the phone (the first one in week 4, then fortnightly)
4. Smartphone app-based reminders, exercises and support from the second FIT session
5. Outcome assessments within a week of final session (at the end of intervention), and at 3 months post intervention
6. User-led feedback interviews with participants upon study completion (after final assessment).

2.6 PARTICIPANTS

Participants are young individuals aged 12 to 25 years old who experience current repeated self-harm behaviour and are seeking support to manage and reduce self-harming via local mental health services.

Inclusion Criteria

1. Aged 12 - 25 years old
2. Presented with at least 2 episodes of self-harm lifetime, with at least 1 of these in the past month OR 5 episodes of self-harm in the past year (based on NSSI Disorder criteria in the DSM-5) and currently reporting self-harm urges or difficulties stopping
3. Have a smartphone
4. Can commit to attending 3 consecutive weekly FIT sessions, and 5 follow-up telephone sessions, and assessments over follow up period as required by the study
5. Have adequate English language ability to permit the assessment and experimental measures to be completed, and use the smartphone app
6. Willing to consent to receive support to reduce / improve management of self-harm urges and behaviour; in person or by video, and over the phone and via smartphone app
7. If 12 – 15 years old, willing for parent/guardian to provide consent to study participation
8. Willing to have letters sent/phone calls made to relevant clinicians
9. Resident within geographical areas covered by West London NHS Trust.

Exclusion Criteria

The participant may not enter the study if any of the following apply:

1. Severe learning disability or pervasive developmental disorder
2. Current acute psychotic episode
3. Current substance dependence

4. Imminent risk of suicide or harm to others (based on clinicians' risk assessment, see Section 4.1)
5. Insufficient English language fluency to complete study outcome measures
6. Taking part in concurrent treatment studies investigating pharmacological or psychological treatment for self-harm
7. Unwilling to engage actively in the FIT intervention or to use an imagery-focused approach for treatment
8. Unwilling to use a smartphone app.

2.7 PROCEDURES

Overview of procedures

1. Baseline Screening Visit (1hr total):
- consent taking: 20 mins
- collection of baseline measures: 40 mins

2. FIT intervention sessions (3hrs total):
- 3 sessions: max 1 hour each

3. Follow up support phone sessions (1hr 30mins total):
- first session: 30 mins
- sessions two to five: 15 mins

4. Outcome Assessments (1hr 30mins total):

- Post intervention via video-call/in person (as preferred) with researcher: 45 mins
- 6 months follow-up (3 months after intervention) via video-call/in person (as preferred) with researcher: 45 mins

5. Patient's feedback interview: 1 hour total

The total duration of contact with the research team and time involved in research activities will be approximately 7 hours for all participants and 8 hours for participants also undertaking the feedback interview, over approximately six months.

Recruitment

Participants will be recruited into the study from any team across WLT, including CCAMHS and MINT teams.

Referrals into WLT CCAMHS and MINT mostly come from GPs, schools and the Single Point of Access line and are discussed in daily/weekly referrals meetings. Outcomes include: offering low-

intensity psychological interventions (for adolescents, CBT based Guided Self-help, GSH, for low mood or anxiety delivered by CWPs; for adults, group interventions such as Emotion Regulation Skills groups delivered by CAPTs); further consultation to assess need/suitability for a high intensity psychological intervention (e.g. for adolescents mainly CBT or family therapy, for adults DBT or trauma-focused therapy); in particular for adults, medication review etc. When referral information is insufficient, a further triage call is conducted by a clinician to get more information from the referrer, young person, parent/carer, or school. This often includes information about history of self-harm and other risks.

YP referred into WLT teams, including CCAMHS/MINT will be pre-screened for eligibility to participate in the IMAGINATOR study as part of this routine referrals discussion and triage process. YP presenting with current self-harm that is deemed suitable for a low-intensity intervention (based on the teams' clinical judgment) will be asked by a member of the clinical team if they would like to find out more about the IMAGINATOR study, alongside a plan part of routine care. This will include YP accepted on the wait list for another high intensity intervention (e.g. in CCAMHS wait list time approx. 1 year, in MINT wait list for DBT approx. 6 months) or YP offered a low-intensity intervention (e.g. in CCAMHS, wait list for GSH for low mood/anxiety delivered by CWPs approx. 4 weeks; in MINT wait list for low-intensity groups approx. 1 month). YP who are offered a low-intensity psychological intervention as well as invited to take part in the IMAGINATOR study will be able to choose whether to take part in IMAGINATOR before or after the other intervention.

Flyers will also be distributed in WLT waiting rooms and Drs' offices. Young people who would like to find out more, can then contact the research team directly or speak to their clinician who will then contact the research team. YP recruited in this way will receive the IMAGINATOR intervention from a therapist in WLT depending on their age and location.

Following the above, YP (or their parent/guardian if < 16 year old) who i) are interested in taking part in the study and ii) express verbal consent for the clinician to share their contact details with the research team, will be contacted by the research team (Imperial College researchers). Alternatively, YP aged >16 years old who are screened as suitable and potentially benefitted by the intervention by their clinical team are contacted directly by the WLT Research Assistants who are embedded in the clinical teams and regularly attend referrals and multidisciplinary team meetings. Potential participants (or their parent/guardian if < 16 year old) will be sent the Short Participant Information Sheet by email and provided a brief introduction to the study (via email or phone as preferred) and asked if they would like to arrange a Baseline Screening Visit. If they agree, a video/in person appointment will be arranged and the Full PIS will be emailed to the YP (and parent/carer where needed).

The above procedures ensure that participation in the study is additional to and does not replace the participants' routine primary and/or mental health care, i.e. the FIT intervention is to be considered as an additional intervention to standard care as provided in the WLT, in line with

best practice NHS standards. Risk management continues to be delivered as per routine WLT procedures and guidelines, by the participant's WLT team.

Baseline Screening Visit

The screening visit will be conducted in person or online via Imperial Zoom, as preferred by participants, lasts approximately 1 hour and includes the following procedures:

Informed Consent: Participants are provided with a further copy of the PIS if needed and asked if they have any outstanding questions. The researcher goes through the study information verbally with participants. If the participant remains interested in the study, informed consent is then taken prior to commencing the eligibility assessment by sending a link to an online consent form on Qualtrics. Informed consent is taken by trained researchers. Informed consent also includes: consent to risk management procedures (see IMAGINATOR Study Risk Assessment Procedures, Section 4.1**)** and to anonymised data sharing policies (see Section 4.4). The consent form is downloaded from Qualtrics as a pdf, signed by the researcher, and then a copy is emailed to the participant.

For participants aged <16 years old, parental consent is sought alongside participant's assent using the same procedures outline above. Once parental consent has been obtained, participants will decide if they prefer their parent to be present for the remaining of the assessment or not.

Collection of Baseline Measures: Eligible participants are then asked to complete further baseline questionnaires and interviews (see 3.7 Assessments and Questionnaires) assessing: the presence, characteristics and frequency of self-harming behaviour; demographic characteristics; measures of clinical and functional outcomes; and measures of characteristics and processes associated with self-harm and with FIT (e.g. mental imagery characteristics). All questionnaires are standard tools, which are commonly used in psychological studies. Specially designed measures for this study are: the *Timeline Follow Back Technique to assess self-harm frequency;* the *Two items questionnaire on self-harm severity;* and the *Self-Harm Imagery Interview* (see Section 3.7). All measures will be collected using Qualtrics, either on the researcher's laptop if in person, or by sending the participant links to the questionnaires via the Imperial Zoom chat.

At the end of the Baseline Screening Visit, the researcher will ask the participant if they have any further questions about the study or therapy sessions, and check that the participant feels ok before ending the visit. If the participant is upset for any reason, the researcher will follow risk assessment procedures outlined in section 4.1 Risks and Benefits, and contact the duty clinician when necessary. The researcher will inform the participant that the therapist will contact them within 2 weeks to book in the first therapy session.

Finally, the researcher shares the baseline RCADS/DASS-21 measure with the therapist, CWP or CAPT, who then administer the RCADS (most salient subscale/s) or DASS-21, as applicable, at each therapy session to track symptoms.

Informing Clinicians of Young Person's Participation

A standard email informing of their taking part in the study is sent by the research team to the lead clinician involved in their routine care named by the participant, and the participant's referrer into the study (if applicable and different from the above).

Intervention Phase

Functional Imagery Training (FIT): Functional Imagery Training comprises of three elements: a) formulation of idiosyncratic drivers of self-harming behaviour and reasons for change; b) motivational interviewing combined with mental imagery techniques that enhance motivation to change the self-harm dysfunctional habit; c) formulation of goals for change (i.e. the goal is a desired behaviour alternative to self-harm) and practice of functional imagery to support goal achievement.

The first FIT session focuses on formulating idiosyncratic drivers of self-harm behaviour and personal motives for change, and using motivational interviewing with embedded mental imagery practice. This includes identifying risky situations for self-harm, triggers, recurrent emotional responses and associated cognitions including cognitions in the form of images. By discussing mental images that may accompany self-harm behaviour, participants are familiarised with the concept of mental imagery and how mental images can drive emotions and behaviour. A first exploration of *pros* and *cons* of self-harm behaviour is carried out, and of the reasons supporting each participant's desire to change. An individualised formulation of the patient's current problem is discussed and drawn out as a diagram, which identifies a "target" for change that could be the focus of treatment. This formulation is then reviewed at the beginning of the first FIT sessions. For example, if a participant identifies that their most prevalent driver of self-harm is the need to gain control over anxiety, the target of the intervention will be to develop and plan an alternative response to gain control over anxiety and advantages of achieving this without self-harming.

After reviewing their formulation of drivers for self-harm and motives to change, participants are encouraged to identify in detail advantages of reducing self-harm. For example, they are asked to recall and visualise memories of occasions when they didn't self-harm and associated positive aspects, and to imagine future short-term and long-term scenarios of successful goal achievement (e.g. "how I would be in a year's time if I stopped self-harming"). Mental imagery is used to simulate positive aspects of behavioural change and thus support motivation for change. At the end of the session participants are asked to commit to the change by completing a homework task that consists of taking a photo of something that represents their target or goal for change.

In this session, the young person will also identify other key goals they want to work towards in the therapy and record these using a 'goals measure'. Progress in working towards these goals will then be reviewed and measured in the following sessions.

The second FIT session focuses on developing a plan of an alternative behaviour to self-harm and on functional imagery training to support this goal. In this session the goal is made concrete and translated into a short-term plan, i.e. something to be done in the next few days / week as an alternative to self-harming (e.g. "what I will do tomorrow to achieve my goal of managing anxiety without self-harming). Obstacles to change are discussed together with planning strategies to overcome them. Once a plan is outlined, participants are guided to practice it from beginning to end using mental imagery and are trained to harness mental imagery characteristics (e.g. vividness, realness) so that the imagery simulation amplifies motivation and drive to put in place the desired behaviour (e.g. "when I feel anxious, going for a short walk").

At the end of the second FIT session, participants download the *IMAGINATOR* app on their smartphone and are instructed on the app use to support practicing the functional imagery developed in session (see below). Finally, the first support call is scheduled in one week time.

The third FIT session focuses on discussing how practicing the functional imagery went, and problem-solving ways to improve the imagery plan. The therapist will work with the young person to fine tune the imagery, to help enhance any beneficial effects the imagery may have on emotion regulation.

To assess risk and adverse events, at the beginning of each session the therapist conducts the Columbia-Suicide Severity Rating Scale (C-SSRS) interview.

Follow-up Phase

Follow up and support sessions: The Follow Up phase involves five support phone calls by the therapist/CWP/CAPT who conducted the FIT. The first phone support takes place one week after the second FIT session (approx. 30 mins duration). This session focuses on refining the functional imagery practice and problem-solving obstacles to training the imagery techniques. Suggestions - aim to incorporate the *IMAGINATOR* app as much as possible if the participant feels this is useful, for example discussing how the different app functionalities can be used, personalised and maximised to support the FIT.

Four further phone support sessions (approx. 15 mins each) are then delivered fortnightly, which focus on further problem-solving, motivational encouragement and discussion of how to maximise the *IMAGINATOR* app use.

To assess risk and adverse events, the therapist will conduct a clinical risk assessment at the beginning of each phone session.

IMAGINATOR app-based support: The IMAGINATOR app was co-designed with YP with lived experience of self-harm (see 2.2. Co-production). It is used by participants as a support to keep practicing and training FIT to achieve their behavioural change goal during the study follow-up

phase. The IMAGINATOR app does not introduce any new element from what has been discussed and developed in the FIT face-to-face sessions and is neither intended to nor designed to be used as a self-standing tool. To ensure confidentiality, the IMAGINATOR app makes no reference to self-harm and all push-ups and notifications only refer to 'IMAGINATOR'.

Routine follow-up: The therapist/CWP/CAPT) will follow up routinely with the young person at 16 – 18 weeks.

Outcome Assessments (post intervention and 6 months follow-up)

All participants complete outcome assessments post intervention (the week after the final telephone session) and at 6 months follow-up from intervention start (3 months after the end of the intervention). Outcome assessments are completed via video-call or in person depending on the participant's preference. Measures are collected using Qualtrics (see 3.7 Assessments and Questionnaires for measures). The participant completes the questionnaires on the researcher's laptop if in person, or by a link to the questionnaires sent through the Imperial Zoom chat.

The outcome measure of Emergency Department attendance following a self-harm episode will be collected via access to routine clinical records of West London NHS Trust where entries by Liaison Psychiatry clinicians are reported following Emergency Department assessments on the North West London Whole Systems Integrated Care Dashboard (as consented by participants). This would include communication of assessments conducted out of area.

Participant Feedback Interview (6 months follow-up)

Researchers and trained YPAG members will conduct semi-structured interviews face-to-face or via video-call. Given our small sample-size we will seek to interview 2/3 of participants consented into the study until data saturation is achieved. Interview topic areas will include experience of the intervention and of the research procedures and motivations/barriers in accessing and using the IMAGINATOR intervention. We will seek to include a diverse sample in terms of socio-demographic characteristics. A qualitative process evaluation focusing on app-usability and design will be conducted using an established co-production methodology (Dewa et al., 2021a, 2021b).

For the app component, interviews will explore:

- barriers and facilitators to use;
- use of imagery audios and of tracking symptoms/experiences;
- expectations about future use, design and functionality suggestions; and,
- ideas for implementation into different settings.

Supervision Arrangements

IMAGINATOR cases will be discussed as part of therapist/CWP/CAPTs' routine weekly individual case management supervision. In addition, the PI (Di Simplicio) will provide group clinical skills supervision focusing on the delivery of IMAGINATOR. All FIT sessions are audio recorded, which is routine practice in WLT for training purposes.

End of Study Definition

The end of study is the date when the last participant enrolled completes the last Outcome Assessment or Feedback Interview. It is hoped to finish collecting data by December 2022. The final report is planned to be prepared by January 2023.

2.8 ASSESSMENTS AND QUESTIONNAIRES

1) The following measures are collected during the **Baseline Screening Visit** and again during the **Outcome Assessments (post intervention and at 6 months follow-up):**

Self-harm measures

Administered by researcher:

a) **Self-harm frequency over the past 3 months:** Using the timeline follow-back technique (TLFB, Sobell & Sobell, 2008). This is an interview method conducted by the researcher who reconstructs together with the participant the number of self-harm behaviours using calendar cues. It has been successfully used in previous self-harm research including our proof-of-concept study (Di Simplicio et al., 2020; Maschauer et al., in preparation).

b) **Self-harm severity over the past 3 months:** A combined measure of a Visual Analogue Scale, severity criteria used in the NSSI disorder in the Diagnostic and Statistical Manual of Mental Disorder Fifth Edition (DSM-V, 39) and the number of different self-harm methods used (also termed self-harm versatility), elicited via these open questions: ''In the last three months, how severe was the worst injury that you inflicted to yourself? Can you list all the ways that you have used to harm yourself in the last three months?'' This method was advised by the YPAG to avoid scales listing numerous self-harm methods which could be triggering/enabling.

c) **Mental imagery related to self-harm:** Using the *Self-Harm Imagery Interview* adapted from (Hales et al., 2011): This interview is about mental images that deal with self-harm or occur with self-harm. It asks participants to think about one of these and explores their thoughts and emotions in relation to the image.

d) Suicidal thoughts and behaviour: Using the *Columbia-Suicide Severity Rating Scale* (C-SSRS) (Posner et al., 2011) is widely used interview for suicide risk assessment and

measurement of suicidal ideation and behaviour. The *Lifetime/Recent* version will be used at screening to gather recent history of suicidality including suicidal ideation and/or behaviour. The scale measures four constructs: severity of ideation on a 5-point ordinal scale (from 1=wish to be dead, to 5=suicidal intent with plan); intensity of ideation via 5 items (e.g. frequency, duration etc.), each rated on a 5-point ordinal scale; behavior rated on a nominal scale (including actual, aborted, and interrupted attempts, preparatory behavior and non-suicidal self-injurious behavior); and lethality rated on a 6-point ordinal scale. **This measure will additionally be used at the start of each face-to-face FIT session.**

e) Motivation to reduce self-harm: Using the State Motivation for Reducing Self-harm (SM-SH) scale (Parham et al., 2017). This scale measures participants' motivation to control their self-harm using 12 items that measure the strength of their motivational cognitions in the present moment, rated on a 10-point likert scale, from 0 (never) to 10 (constantly).

Self-report:

f) **Urge to self-harm:** Using the *Craving Experience Questionnaire for Self-Harm* (CEQ-SH), adapted from CEQ (May et al., 2014) This questionnaire assesses the urge to self-harm and assesses frequency, intensity, salience or dismissability of intrusive thoughts surrounding self-harm. It is rated on a 10 point Likert type scale ranging from not at all (0) to constantly (10).

Clinical and functional measures

Self-report:

a) **Symptoms of low mood and anxiety:** using **1)** the *Revised Children's Anxiety and Depression Scale (RCADS)* for **12 – 17 year olds**, is a 47 item youth self report questionnaire with six subscales (separation anxiety disorder, social phobia, generalised anxiety disorder, panic disorder, obsessive compulsive disorder, and low mood (major depressive disorder)) and a total anxiety scale and total internalising scale. The RCADS has good internal consistency, test-retrest reliability and convergent validity. **2)** the *Depression, Anxiety and Stress Scale (DASS-21)* (Antony et al., 1998), for **18 – 25 year olds**, a 21-item scale measuring levels of depression, anxiety and stress over the past week. It has acceptable to excellent internal consistency validated in both clinical and non-clinical samples. The depression scale measures symptoms associated with dysphoric mood e.g. worthlessness; the anxiety scale measures symptoms associated with physiological arousal such as trembling, as opposed to symptoms of generalised anxiety; and the stress scale measures symptoms of tension and reactivity to stressful events;

b) **Psychological wellbeing:** using t*he Warwick-Edinburgh Mental Well-being Scale* (WEMWBS) (Tennant et al., 2007), which consists of 14 positively worded items. Items are rated on a 5 point likert scale ranging between none of the time (1) and all of the time (5) with five

response categories and assesses mental wellbeing covering both hedonic and eudemonic perspectives.

c) **Emotion regulation abilities:** using the *Difficulties in Emotion Regulation Scale-Short Form* (Kaufman et al., 2016), an 18-item scale adapted from the original long version that measures general emotion regulation ability as well as various aspects of emotion regulation (in six subscales), e.g. difficulties engaging in goal directed behaviour when upset, and limited access to emotion regulation strategies. The scale has high internal consistency.

d) **Engagement in other risky, self-destructive behaviours** (e.g., binge eating, substance misuse): using the *11-item behaviour supplement to the Borderline Symptom List* (Bohus et al., 2001). The scale has high internal validity and test-retest reliability.

e) **Alcohol misuse/dependence:** Alcohol Use Disorders Identification Test (AUDIT) (Saunders et al., 1993) This is a 10-item measure of alcohol misuse and possible dependence, in which participants are asked to rate items related to their drinking (e.g. 'How often do you have a drink containing alcohol') on a 5-point scale. The AUDIT is an effective means of identifying hazardous or harmful drinking behaviour.

f) **Cannabis misuse/dependence**: Cannabis Use Disorder Identification Test Revised (CUDIT-R) (Adamson et al., 2010) This measure is used to screen for problem cannabis use. Participants are asked to rate a series of eight items relating to their cannabis use (e.g. 'How often do you use cannabis') on a 5-point likert scale. The measure has excellent internal consistency.

g) **Anhedonia:** Anhedonia Scale for Adolescents (ASA) (Watson et al., 2021) is designed for use in 11-18 year olds and measures anhedonia on a 4 point likert scale using 15 questions. The ASA has high test-retest reliability. Temporal Experience of Pleasure Scale (TEPS) (Gard et al., 2006) captures a trait disposition to anticipation and consummation of pleasure using 18 items and a 6 point likert scale. The TEPS is internally consistent and temporally stable.

3) The following measures are collected **once the intervention has started:**

Acceptability measures

a) **Credibility/Expectancy Questionnaire** (Devilly & Borkovec, 2000), is a short questionnaire measuring cognitively based credibility and affectively based expectancy of the therapy. The questionnaire has high internal consistency and good test-retest reliability. This will be used after the first face-to-face session.

b) **Client Satisfaction Questionnaire** – 8 item version (Attkisson & Zwick, 1982), provides a sensitive and comprehensive measure of patient satisfaction with the therapy received. This will be used post-treatment.

c) **User Experience Questionnaire** (Laugwitz et al., 2008), assessed post-treatment (see Section 2.6 for details)

d) Imaginator Feedback Questionnaire, administered post-treatment to obtain written feedback on the Imaginator intervention.

e) **Adverse events** will be recorded at each assessment and therapy session/phone call contact.

Usability of the app

Engagement metrics will be collected directly from the app, including:

a) Time to first access the app
b) Total number of times accessed
c) Total number of days/weeks the app accessed on
d) Number of times used per week
e) Duration of use per functionality.

Factors associated with app engagement:

a) Questions relating to socioeconomic status, such as approximate yearly personal or parental income.
b) Questions relating to technology/digital skills.

Feasibility and adherence to therapy protocol

An indication of feasibility will be assessed by calculating treatment adherence indicators, such as:

a) Average number of therapy sessions completed by participants
b) Percentage of participants completing different components of the intervention (face-to-face sessions, phone calls)
c) Attrition (the percentage who complete post-intervention assessment).
d) Adherence to therapy protocol by therapists will be checked on a random sample of therapy session recordings against the therapy session checklist (part of the Imaginator manual).

Qualitative assessments

a) Semi-structured interview schedule developed using an established co-production methodology (Dewa et al., 2021a, 2021b), and used by the research team and YPAG during follow up interviews.

2.9 DATA ANALYSIS

Sample Size

We aim to reach N=15 participants who will complete treatment and 6 months follow-up assessments. Based on an expected 25% attrition rate from our previous study (Di Simplicio et al., 2020), N=20 participants will be enrolled in the study.

Statistical Analysis

Quantitative data will be summarised into descriptive statistics such as means, medians, inter quartile range, standard deviations for all measures and percentage change and Cohen's *d* for the clinical outcomes repeated at pre- and post-intervention. Qualitative data will be analysed using a co-produced thematic analysis approach based on Braun & Clarke (2006) and Dewa et al. (2021a, 2021b). Data and all appropriate documentation will be stored for a minimum of 10 years after the completion of the study, including the follow-up period.

3. ETHICS

3.1 ETHICS APPROVAL

The Study Coordination Centre has obtained approval from the West of Scotland Research Ethics Committee (REC) 5 and Health Research Authority (HRA). The study must also receive confirmation of capacity and capability from each participating NHS Trust before accepting participants into the study or any research activity is carried out. The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

3.2 RISKS AND BENEFITS

Risks: There are only low foreseeable serious risks associated with this project. The treatment protocol of FIT is in keeping with NICE guidelines and current psychological interventions for self-harming behaviour. Elements included in FIT such as motivational interviewing, formulation of drivers of self-harm and use of mental imagery techniques for targeting self-harm are part of established psychological therapies such as cognitive-behavioural therapy, dialectical-behavioural therapy and schema therapy commonly used for individuals who self-harm. Our previous study using this protocol reported no adverse events (Di Simplicio et al., 2020).

Participants' wellbeing and safety will be taken into account as a priority concern at all points in the study.

However, theoretically it is possible that a number of procedures (listed below) included in the study may result in *causing increased levels of distress*. If this would be the case the necessary steps to guarantee the participant's wellbeing and safety will be taken as described below.

Study procedures that ask to recall information about current and past psychological problems and/or current and past problematic experiences may result in *(i) i.e. increased perceived distress* and/or *(ii) i.e. disclosure of information relevant for the participants' mental health and safety*. These include:

- responding to questionnaires during the Baseline Screening Visit and the Outcome Assessments (see 3.6 and 3.7);
- answering questions that investigate details of self-harm behaviour and associated emotions during the FIT sessions and during the follow up phone support sessions (see 3.6).

The ***risk (i), i.e. of major distress*** being caused by the above study procedures will be minimised in three major ways:

Firstly, participants will be fully informed about the content of the outcome assessments (such as questionnaires including questions about mood, self-harm behaviour, alcohol and drug use) so that they can prepare themselves and give fully informed consent to participate. Equally, they will be fully informed and prepared with regards to the contents and procedures of the FIT intervention. Research has demonstrated that asking about self-harming behaviors does not increase risk of harmful outcomes (Polihronis et al., 2020) but instead may in fact give participants an opportunity to contribute to research and to "tell their story" (Biddle et al., 2013).

Secondly, all researchers conducting eligibility assessment at the baseline screening visit will be trained and supervised by expert clinicians who will also provide cover at the time of the assessments ('duty clinicians').

The study therapists are qualified CWP/CAPTs or other clinicians (e.g. medical doctor) who are trained to deliver GSH interventions to YP with low mood or anxiety. They are used to discussing upsetting experiences with YP in a way that is collaborative, puts the young person at ease and is perceived as useful and necessary for aiding symptoms resolution by both therapist and patient. Moreover, these clinicians are well equipped to make sure that any distressing session ends by the participant feeling supported and endowed with the necessary coping strategies in place to go safely back to their home environment.

Case management supervision for the therapists/CWPs/CAPTs will be provided through routine weekly individual sessions with their supervisors and group clinical skills supervision will be provided the study therapist.

Therapists/CWPs/CAPTs and researchers will always remain sensitive to signs of participant distress and will terminate the assessment or specific intervention, or the session itself, if the participant becomes distressed and wants to stop. In our experience, it is rarely, if ever necessary

that clinical interviews are interrupted, as participants are aware of what the interviews will entail and are readily able to answer the questions they contain. Researchers will also check the participant's mood state and safety upon completion of the self-report questionnaires during the Baseline Screening and Outcome Assessments Visits.

The ***risk (ii) i.e. of disclosing information that is relevant to the participant's safety and health***, such as a mood state that meets criteria for a tier 3 intervention (e.g., psychosis or eating disorder), or the presence of suicidal risk, will be addressed by putting in place the following series of procedures that will ensure the participant is safe and their mental state is taken into account:

- Review confidentiality with young person
- Supportively assess risk (in terms of safeguarding or clinical risk)
- Carry out all possible interventions to reassure, support, reduce active distress to the minimum possible once this has become apparent;
- Agree with the participant on a strategy to ensure their needs, in terms of mental state and safety, are met as soon as possible. This is likely to include informing other individuals such as family, friends, and other mental health workers or clinicians;
- Therapists/CWP/CAPT will inform senior colleagues (e.g., their supervisor, duty clinician) immediately and follow their advice. This may involve liaison with the local CAMHS or adult Crisis Team.

If risk is disclosed during a FIT therapy session or phone support session, the CWP/CAPT/therapist will directly proceed as per points above.

If risk is disclosed during the Baseline Screening Visit or during the Outcome Assessments, interview run by a researcher or YPAG member, they will follow the IMAGINATOR study Risk Assessment Procedures: this details when and how they will immediately alert the duty clinician who will ensure the participant is safe and their mental state is taken care of as per points above.

Participants will be informed and will have consented to this set of procedures prior to the beginning the Baseline Screening Visit.

In addition to the regular professional skills development and supervision attended by the therapists/CWPs/CAPTs, quality of FIT intervention delivery is also provided by routine specific clinical supervision during the course of the study by Dr Martina Di Simplicio (CI) and Dr Ben Aveyard. This allows individual case discussion, ensures therapist's adherence to the intervention protocol and maintains high quality levels in treatment delivery throughout the study. Dr Di Simplicio and Dr Aveyard are a Honorary Consultant Psychiatrist and a Highly Specialist Clinical Psychologist, respectively, in West London NHS Trust and are up to date with mandatory training and Trust procedures for risk assessment and management.

Benefits: Participants have the opportunity to participate in a clinical research study which can be interesting and which may enable them to feel that they are helping others and that some benefit may come from their difficult experiences. Participants also have the opportunity to experience a treatment intervention that may prove beneficial for the improvement or resolution of symptoms that they are experiencing. This is particularly relevant as immediate intervention for reduction of self-harming behaviour is currently lacking in the local West London NHS Trust services. Participants will receive a support tool, such as the *IMAGINATOR app*, to be used also after study completion.

3.3 ADVERSE EVENTS

Definitions

Adverse Event (AE): any untoward medical occurrence in a patient or clinical study subject.

Serious Adverse Event (SAE): any untoward medical occurrence or effect that:

- **Results in death**
- **Is life-threatening** – *refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe*
- **Requires hospitalisation, or prolongation of existing inpatients' hospitalisation**
- **Results in persistent or significant disability or incapacity**
- **Is a congenital anomaly or birth defect**

Medical judgement will be exercised in deciding whether an AE is serious in other situations. Important AEs that are not immediately life-threatening or do not result in death or hospitalisation but may jeopardise the subject or may require intervention to prevent one of the other outcomes listed in the definition above, will also be considered serious.

Reporting Procedures

All adverse events will be reported. Depending on the nature of the event the reporting procedures below will be followed. Any questions concerning adverse event reporting will be directed to the Chief Investigator in the first instance.

Non serious Aes: All such events, whether expected or not, will be recorded- it will be specified if only some non-serious Aes will be recorded, any reporting will be consistent with the purpose of the trial end points.

Serious Aes: An SAE form will be completed and emailed to the Chief Investigator within 24 hours. However, hospitalisations for elective treatment of a pre-existing condition will not need to be reported as SAEs.

All SAEs will be reported to the West of Scotland REC 5 where in the opinion of the Chief Investigator, the event was:

- 'related', ie resulted from the administration of any of the research procedures; and
- 'unexpected', ie an event that is not listed in the protocol as an expected occurrence

Reports of related and unexpected SAEs will be submitted within 15 days of the Chief Investigator becoming aware of the event, using the NRES SAE form for non-IMP studies. The Chief Investigator will also notify the Sponsor of all related and unexpected SAEs.

Local investigators will report any SAEs as required by their Local Research Ethics Committee, Sponsor and/or Research & Development Office.

Contact details for reporting SAEs
RGIT@imperial.ac.uk
CI email (and contact details below)
Email: m.di-simplicio@imperial.ac.uk
Please send SAE forms to: m.di-simplicio@imperial.ac.uk
Tel: 07512646698 (Mon to Fri 09.00 – 17.00)

3.4 INFORMED CONSENT

Consent to enter the study will be sought from each participant (and parents / legal guardians where appropriate) only after a full explanation has been given, an information leaflet offered and time allowed for consideration. Signed participant consent will be obtained. The right of the participant to refuse to participate without giving reasons will always be respected. After the participant has entered the study the clinician remains free to give alternative treatment to that specified in the protocol at any stage if he/she feels it is in the participant's best interest, but the reasons for doing so should be recorded. In these cases the participants remain within the study for the purposes of follow-up and data analysis. All participants will be free to withdraw at any time from the protocol treatment without giving reasons and without prejudicing further treatment.

Written Informed Consent is obtained in accordance with MHRA guidance (Joint Statement on Seeking Consent by Electronic Methods v1.2 September 2018), while the researcher is in person or on video-call with the participant, by means of a dated digital signature on an online consent form (see below for links to forms). After the participant has completed the consent form, the researcher taking consent will download a pdf copy of the consent form and add their digital signature. The consent form, signed by both participant and researcher, is then emailed to the participant. An encrypted copy will be stored on a secure computer drive at Imperial College London. For participants who are <16, participant assent is sought alongside parent/guardian consent, and the assent and consent forms are handled using the same procedures outlined above.

Consent and Assent Forms:

Consent Form (participants aged 16 – 25):
https://imperial.eu.qualtrics.com/jfe/form/SV_a5HceLkfT7hf68C

Assent Form (participants aged 12 – 15):
https://imperial.eu.qualtrics.com/jfe/form/SV_cO3z5scFZxHhdps

Parent/Guardian Consent Form (participants aged 12 – 15):
https://imperial.eu.qualtrics.com/jfe/form/SV_1X1bCl1PL9ugf9Y

3.5 DATA MANAGEMENT AND PARTICIPANT CONFIDENTIALITY

The Chief Investigator will preserve the confidentiality of participants taking part in the study and is registered under the Data Protection Act.

The following documents and data will be collected during the study:

- Digital consent/assent forms
- Participant questionnaires and structured interviews collected via Qualtrics
- Participants' attendance to the Emergency Departments (ED) over the duration of the study, collected by researchers on the team who have regular access to WLT clinical records in their clinical capacity (Di Simplicio, Aveyard, Gardner-Bougard).
- Digital recordings of co-design workshops and interviews, and transcripts of co-design workshops and interviews.

Data will be pseudonymised. A study specific participant ID number will identify the participant on questionnaires and structured interviews collected via Qualtrics, transcripts and ED attendance. The name and any other identifying detail will not be included in any study electronic database compiled for the purpose of statistical analysis of the research outcomes. Electronic data will be stored on network drives and encrypted discs held at the study site. A document matching identity and login number is centrally managed by the research team and only accessed by named research team members.

Digital recordings from co-design workshops and interviews will be stored in encrypted network drives at the study site. Transcripts from the recordings will be pseudonymised and data will be processed and stored in separate encrypted network drives.

Data from the app will be transferred to Amazon Web Services. We will apply established approaches for ensuring maximum data security on the IMAGINATOR app. The data protection procedures will be the same as those approved for a wide range of control and clinical studies in the UK and in countries around the globe (e.g., 17IC4009). In brief, app data (imagery, mood

ratings, app use) will be transferred directly from the app and collected on a remote web server, using Amazon Web Services (specifically, the London based eu-west-2 datacentre). Remote storage of these data will be in pseudonymised format and will be linked to the Qualtrics collected data using the same pseudonymised numerical user identifier codes. Email addresses to login in the app will be stored alongside user passwords and anonymous codes in a separate database 'key'. The database is encrypted and password protected. The servers are behind a firewall in the secure Amazon cloud computing facility described above. These measures represent a high-level of data security that are the standard for any app that requires users to login and enter potentially sensitive information. Study investigators will be the only users who can download datasets describing the entire sample via two-factor authentication. Only the database administrator (CoI Hampshire, Imperial College London) and PI will have access to database that holds the email address key. As part of the app design process, we will explore if direct data communication from the app to the therapist would be compliant with the above data security principles.

The study will comply with the Data Protection Act 2018, which requires data to be anonymised as soon as it is practical to do so. Participants' confidentiality is only breached in case of disclosure of information relevant to their health and safety, in which case this will be communicated to an indicated health professional (as detailed above).

All documents are stored securely and only accessible by study staff and authorised personnel. The data will be stored in compliance with GDPR guidelines. Data will be stored for a period of at least 10 years after the date of publication of results in accordance with the minimum standard for journal publications as outlined in the British Psychological Society Good Practice Guidelines for the Conduct of Psychological Research in the NHS, and the American Psychological Association Publication Manual (fifth edition). During the time of storage Dr Martina Di Simplicio will be custodian for the data, and it will be stored using appropriate data archive facilities provided by the Division of Psychiatry. Named researchers will have sole access to the data over this time period.

Dr Martina Di Simplicio, Ms Rachel Rodrigues and other named researchers, will undertake analysis of the data from the study. This analysis will take place at the Division of Psychiatry, Imperial College London and will be supported by the research centre experts in statistical and qualitative data analysis methods.

Anonymised data (quantitative and qualitative) may be made available to other researchers after the end of the study upon request.

4. FINANCE, INSURANCE AND AUDIT

4.1 INDEMNITY

Imperial College London holds negligent harm and non-negligent harm insurance policies which apply to this study.

4.2 SPONSOR

Imperial College London will act as the main Sponsor for this study. Delegated responsibilities will be assigned to the NHS trusts taking part in this study.

4.3 FUNDING

NIHI i4i are funding this study. Participants will be reimbursed for their time with £10 per hour for the outcome assessments and feedback interview, but will not receive any reimbursement for the therapy (face to face or phone calls).

4.4 AUDITS

The study may be subject to audit by Imperial College London under their remit as sponsor and other regulatory bodies to ensure adherence to GCP and the UK Policy Frame Work for Health and Social Care Research.

5. PUBLICATION POLICY

The study will follow NIHR's policy on publications (see general policy for publications link below), including their open access policy (link below). The open access policy states articles must be immediately, freely and openly accessible to all, freely discoverable, and that the NIHR will pay reasonable fees to enable immediate open access.

General policy for publications: https://www.nihr.ac.uk/documents/nihr-research-outputs-and-publications-guidance/12250

Open access policy: https://www.nihr.ac.uk/documents/nihr-open-access-policy/28999

6. REFERENCES

Angold, A., Costello, E. J., Messer, S. C., Pickles, A., Winder, F., & Silver, D. (1995). *Development of a short questionnaire for use in epidemiological studies of depression in children and adolescents* International Journal of Methods in Psychiatric Researc (Vol. 5, pp. 237–249).

Antony, M. M., Bieling, P. J., Cox, B. J., Enns, M. W., & Swinson, R. P. (1998). Psychometric properties of the 42-item and 21-item versions of the Depression Anxiety Stress Scales in clinical groups and a community sample. *Psychological assessment*, *10*(2), 176.

Arshad, U., Farhat-Ul-Ain, Gauntlett, J., Husain, N., Chaudhry, N., & Taylor, P. J. (2020). A Systematic Review of the Evidence Supporting Mobile- and Internet-Based Psychological Interventions For Self-Harm. Suicide & life-threatening behavior, 50(1), 151–179. https://doi.org/10.1111/sltb.12583

Attkisson, C. C., & Zwick, R. (1982). The Client Satisfaction Questionnaire: Psychometric properties and correlations with service utilization and psychotherapy outcome. *Evaluation and program planning*, *5*(3), 233-237.

Biddle, L., Cooper, J., Owen-Smith, A., Klineberg, E., Bennewith, O., Hawton, K., ... & Gunnell, D. (2013). Qualitative interviewing with vulnerable populations: Individuals' experiences of participating in suicide and self-harm based research. *Journal of affective disorders*, *145*(3), 356-362.

Bjureberg, J., Sahlin, H., Hedman-Lagerlöf, E., Gratz, K. L., Tull, M. T., Jokinen, J., ... & Ljótsson, B. (2018). Extending research on Emotion Regulation Individual Therapy for Adolescents (ERITA) with nonsuicidal self-injury disorder: open pilot trial and mediation analysis of a novel online version. *BMC psychiatry*, *18*(1), 1-13.

Bohus M, Limberger MF, Frank U, Sender I, Gratwohl T, Stieglitz RD. (2001). Development of the Borderline Symptom List. *Psychother Psychosom Med Psychol.* 51(5):201-11.

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative research in psychology*, *3*(2), 77-101.

Chorpita, B. F., Yim, L., Moffitt, C., Umemoto, L. A., & Francis, S. E. (2000). Assessment of symptoms of DSM-IV anxiety and depression in children: a revised child anxiety and depression scale. *Behaviour research and therapy*, *38*(8), 835–855. https://doi.org/10.1016/s0005-7967(99)00130-8

Cliffe, B., Tingley, J., Greenhalgh, I., & Stallard, P. (2021). mHealth interventions for self-harm: Scoping review. *Journal of medical internet research*, *23*(4), e25140.

Cox, G., & Hetrick, S. (2017). Psychosocial interventions for self-harm, suicidal ideation and suicide attempt in children and young people: What? How? Who? and Where? Evidence Based Mental Health, 20(2), 35–40. https://doi.org/10. 1136/eb-2017-102667

Čuš, A., Edbrooke-Childs, J., Ohmann, S., Plener, P. L., & Akkaya-Kalayci, T. (2021). "Smartphone Apps Are Cool, But Do They Help Me?": A Qualitative Interview Study of Adolescents' Perspectives on Using Smartphone Interventions to Manage Nonsuicidal Self-Injury. *International journal of environmental research and public health*, *18*(6), 3289.

De Beurs, D, Fried, EI, Wetherall, K et al. (2019). Exploring the psychology of suicidal ideation: A theory driven network analysis. *Behaviour Research and Therapy*, 120. 103419. ISSN 0005-7967

Devilly, G. J., & Borkovec, T. D. (2000). Psychometric properties of the credibility/expectancy questionnaire. *Journal of behavior therapy and experimental psychiatry*, *31*(2), 73-86.

Dewa et al. (in press). Quality social connection as an 'active ingredient' in digital interventions for young people with depression and anxiety: a systematic scoping review and meta-analysis. JMIR.

Dewa, L. H., Crandell, C., Choong, E., Jaques, J., Bottle, A., Kilkenny, C., ... & Aylin, P. (2021). CCopeY: a mixed-methods coproduced study on the mental health status and coping strategies of young people during COVID-19 UK lockdown. *Journal of Adolescent Health*, *68*(4), 666-675.

Dewa, L. H., Lawrence-Jones, A., Crandell, C., Jaques, J., Pickles, K., Lavelle, M., ... & Aylin, P. (2021). Reflections, impact and recommendations of a co-produced qualitative study with young people who have experience of mental health difficulties. *Health Expectations*, *24*, 134-146.

Dewa, L. H., Lavelle, M., Pickles, K., Kalorkoti, C., Jaques, J., Pappa, S., & Aylin, P. (2019). Young adults' perceptions of using wearables, social media and other technologies to detect worsening mental health: A qualitative study. *PLoS One*, *14*(9), e0222655.

Di Simplicio, M., Appiah-Kusi, E., Wilkinson, P., Watson, P., Meiser-Stedman, C., Kavanagh, D. J., & Holmes, E. A. (2020). Imaginator: A proof-of-concept feasibility trial of a brief imagery-based psychological intervention for young people who self-Harm. *Suicide and Life-Threatening Behavior*, *50*(3), 724-740.

Fleming, T., Merry, S., Stasiak, K., Hopkins, S., Patolo, T., Ruru, S., ... & Goodyear-Smith, F. (2019). The importance of user segmentation for designing digital therapy for adolescent mental health: findings from scoping processes. *JMIR mental health*, *6*(5), e12656.

Gard, D. E., Gard, M. G., Kring, A. M., & John, O. P. (2006). Anticipatory and consummatory components of the experience of pleasure: a scale development study. *Journal of research in personality*, *40*(6), 1086-1102.

Gillies, D., Christou, M. A., Dixon, A. C., Featherston, O. J., Rapti, I., Garcia-Anguita, A., ... & Christou, P. A. (2018). Prevalence and characteristics of self-harm in adolescents: meta-analyses of community-based studies 1990–2015. *Journal of the American Academy of Child & Adolescent Psychiatry*, *57*(10), 733-741.

Glenn CR, Esposito EC, Porter AC, Robinson DJ. Evidence Base Update of Psychosocial Treatments for Self-Injurious Thoughts and Behaviors in Youth. *J Clin Child Adolesc Psychol*. 2019;48(3):357-392. doi:10.1080/15374416.2019.1591281

Gulliver A, Griffiths KM, Christensen H. Perceived barriers and facilitators to mental health help-seeking in young people: a systematic review. BMC Psychiatry. 2010 Dec 30; 10():113

Hales, S. A., Deeprose, C., Goodwin, G. M., & Holmes, E. A. (2011). Cognitions in bipolar affective disorder and unipolar depression: imagining suicide. *Bipolar disorders*, *13*(7-8), 651-661.

Hawton K, Saunders KE, O'Connor RC. Self-harm and suicide in adolescents. Lancet. 2012 Jun 23;379(9834):2373-82. doi: 10.1016/S0140-6736(12)60322-5. PMID: 22726518.

Hawton, K., Witt, K. G., Salisbury, T. L. T., Arensman, E., Gunnell, D., Townsend, E., ... & Hazell, P. (2015). Interventions for self-harm in children and adolescents. *Cochrane database of systematic reviews*, (12).

Hetrick SE, Subasinghe A, Anglin K, Hart L, Morgan A and Robinson J (2020) Understanding the Needs of Young People Who Engage in Self-Harm: A Qualitative Investigation. Front. Psychol. 10:2916. doi: 10.3389/fpsyg.2019.0291

Hollis, C., Falconer, C. J., Martin, J. L., Whittington, C., Stockton, S., Glazebrook, C., & Davies, E. B. (2017). 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 and Allied Disciplines, 58(4), 474–503. https://doi.org/10.1111/jcpp.12663

Holmes, E. A., & Mathews, A. (2010). Mental imagery in emotion and emotional disorders. *Clinical psychology review*, *30*(3), 349-362.

ICO (accessed 2021). Introduction to the Age appropriate design code https://ico.org.uk/for-organisations/guide-to-data-protection/ico-codes-of-practice/age-appropriate-design-code/

Iyengar, U., Snowden, N., Asarnow, J. R., Moran, P., Tranah, T., & Ougrin, D. (2018). A further look at therapeutic interventions for suicide attempts and self-harm in adolescents: an updated systematic review of randomized controlled trials. *Frontiers in psychiatry*, 583.

Kavanagh, D. J., Andrade, J., May, J., & Connor, J. P. (2014). Motivational interventions may have greater sustained impact if they trained imagery-based self-management. *Addiction*, *109*(7), 1062–1063.

Kazdin, A.E. and Rabbitt, S.M. (2013) Novel Models for Delivering Mental Health Services and Reducing the Burdens of Mental Illness. Clinical Psychological Science, 1, 170-191.
http://dx.doi.org/10.1177/2167702612463566

Kaufman, E. A., Xia, M., Fosco, G., Yaptangco, M., Skidmore, C. R., & Crowell, S. E. (2016). The Difficulties in Emotion Regulation Scale Short Form (DERS-SF): validation and replication in adolescent and adult samples. *Journal of Psychopathology and Behavioral Assessment*, *38*(3), 443-455.

Laugwitz, B., Held, T., & Schrepp, M. (2008, November). Construction and evaluation of a user experience questionnaire. In *Symposium of the Austrian HCI and usability engineering group* (pp. 63-76). Springer, Berlin, Heidelberg.

Law, D., & Jacob, J. (2015). Goals and Goal Based Outcomes (GBOs): Some useful information. Third Edition. London, UK: CAMHS Press

Lennon (2021) https://www.childrenscommissioner.gov.uk/wp-content/uploads/2021/01/cco-the-state-of-childrens-mental-health-services-2020-21.pdf

Ludlow, C., Hurn, R., & Lansdell, S. (2020). A Current Review of the Children and YP's Improving Access to Psychological Therapies (CYP IAPT) Program: Perspectives on Developing an Accessible Workforce. Adolescent health, medicine and therapeutics, 11, 21–28. https://doi.org/10.2147/AHMT.S196492

Lilley, R., Owens, D., Horrocks, J., House, A., Noble, R., Bergen, H., ... & Kapur, N. (2008). Hospital care and repetition following self-harm: multicentre comparison of self-poisoning and self-injury. *The British Journal of Psychiatry*, *192*(6), 440-445.

Mars, B., Heron, J., Crane, C., Hawton, K., Lewis, G., Macleod, J., … Gunnell, D. (2014). Clinical and social outcomes of adolescent self harm: population based birth cohort study. BMJ (Clinical Research Ed.), 349, g5954. https://doi.org/10.1136/bmj.

May, J., Andrade, J., & Kavanagh, D. J. (2015). An Imagery-Based Road Map to Tackle Maladaptive Motivation in Clinical Disorders. *Frontiers in Psychiatry*, *6*, 14. https://doi.org/10.3389/fpsyt.2015.00014

Maschauer E, Aveyard B, Appiah-Kusi E et al. “Young People feedback on a novel blended digital intervention supporting Young People Who Self-Harm”, in preparation

McManus S, Gunnell D, Cooper C, Bebbington PE, Howard LM, Brugha T, Jenkins R, Hassiotis A, Weich S, Appleby L. Prevalence of non-suicidal self-harm and service contact in England, 2000-14: repeated cross-sectional surveys of the general population. Lancet Psychiatry. 2019 Jul;6(7):573-581.

Melia, R., Francis, K., Hickey, E., Bogue, J., Duggan, J., O'Sullivan, M., & Young, K. (2020). Mobile health technology interventions for suicide prevention: systematic review. *JMIR mHealth and uHealth*, *8*(1), e12516.

Morgan, C., Webb, R. T., Carr, M. J., Kontopantelis, E., Green, J., Chew-Graham, C. A., … Ashcroft, D. M. Incidence, clinical management, and mortality risk following self harm among children and adolescents: cohort study in primary care. BMJ 2017;359:j4351. https://doi.org/10.1136/bmj.j4351;

Ng, R. M., Di Simplicio, M., McManus, F., Kennerley, H., & Holmes, E. A. (2016). 'Flash-forwards' and suicidal ideation: A prospective investigation of mental imagery, entrapment and defeat in a cohort from the Hong Kong Mental Morbidity Survey. *Psychiatry research*, *246*, 453-460.

NHS England. Mental Health Workforce Plan for England. London, UK: Health Education England; 2017. [Google Scholar]

NHS, Mental Health Implementation Plan (2019) https://www.longtermplan.nhs.uk/wp-content/uploads/2019/07/nhs-mental-health-implementation-plan-2019-20-2023-24.pdf

O'Connor, R. C., & Kirtley, O. J. (2018). The integrated motivational–volitional model of suicidal behaviour. *Philosophical Transactions of the Royal Society B: Biological Sciences*, *373*(1754), 20170268.

Ofcom Children and parents: Media use and attitudes report 2018. Ofcom. 2018. [2020-01-27]. https://www.ofcom.org.uk/__data/assets/pdf_file/0024/134907/children-and-parents-media-use-and-attitudes-2018.pdf.

Ofcom Children and parents: Media use and attitudes report 2020/21. Ofcom. 2021 https://www.ofcom.org.uk/__data/assets/pdf_file/0025/217825/children-and-parents-media-use-and-attitudes-report-2020-21.pdf

Parham, S. C., Kavanagh, D. J., Gericke, C. A., King, N., May, J., & Andrade, J. (2017). Assessment of motivational cognitions in diabetes self-care: the motivation thought frequency scales for glucose testing, physical activity and healthy eating. *International Journal of Behavioral Medicine*, *24*(3), 447-456.

Polihronis, C., Cloutier, P., Kaur, J., Skinner, R., & Cappelli, M. (2020). What's the harm in asking? A systematic review and meta-analysis on the risks of asking about suicide-related behaviors and self-harm with quality appraisal. *Archives of Suicide Research*, 1-23.

Posner, K., Brown, G. K., Stanley, B., Brent, D. A., Yershova, K. V., Oquendo, M. A., … Mann, J. J. (2011). The Columbia–Suicide Severity Rating Scale: Initial Validity and Internal Consistency Findings From Three Multisite Studies With Adolescents and Adults. *American Journal of Psychiatry*, *168*(12), 1266–1277. https://doi.org/10.1176/appi.ajp.2011.10111704

Rasmussen, S., Hawton, K., Philpott-Morgan, S., & O'Connor, R. C. (2016). Why do adolescents self-harm?. *Crisis*.

Renner, F., Murphy, F. C., Ji, J. L., Manly, T., & Holmes, E. A. (2019). Mental imagery as a "motivational amplifier" to promote activities. *Behaviour Research and Therapy*, *114*, 51-59.

Rowe SL, French RS, Henderson C, Ougrin D, Slade M, Moran P. Help-seeking behaviour and adolescent self-harm: a systematic review. Aust N Z J Psychiatry. 2014 Dec; 48(12):1083-95.

Scoliers, G., Portzky, G., Madge, N., Hewitt, A., Hawton, K., De Wilde, E. J., ... & Van Heeringen, K. (2009). Reasons for adolescent deliberate self-harm: a cry of pain and/or a cry for help?. *Social psychiatry and psychiatric epidemiology*, *44*(8), 601-607.

Shaffer, D., Gould, M.S., Brasic, J., Ambrosini, P., Fisher, P., Bird, H., & Aluwahlia, S. (1983). A Children's Global Assessment Scale (CGAS). Archives of General Psychiatry, 40, 1228-1231.

Sobell, L., & Sobell, M. (2008). Alcohol Timeline Followback (TLFB). In American Psychiatric Association (Ed.), *Textbook of Psychiatric Measures.* (pp. 477–479). Washington, DC: American Psychiatric Association.

Solbrig, L., Whalley, B., Kavanagh, D. J., May, J., Parkin, T., Jones, R., & Andrade, J. (2019). Functional imagery training versus motivational interviewing for weight loss: a randomised controlled trial of brief individual interventions for overweight and obesity. *International Journal of Obesity*, *43*(4), 883-894.

Stallard P, Porter J, Grist R A Smartphone App (BlueIce) for Young People Who Self-Harm: Open Phase 1 Pre-Post Trial JMIR Mhealth Uhealth 2018;6(1):e32

Tennant, R., Hiller, L., Fishwick, R., Platt, S., Joseph, S., Weich, S., Parkinson, J., Secker, J., & Stewart-Brown, S. (2007). The Warwick-Edinburgh Mental Well-being Scale (WEMWBS): Development and UK validation. *Health and Quality of Life Outcomes, 5,* Article 63. https://doi.org/10.1186/1477-7525-5-63

Uh S, Dalmaijer E S, Siugzdaite R, Ford T J., Astle D E (2021). Two Pathways to Self-Harm in Adolescence, Journal of the American Academy of Child & Adolescent Psychiatry.

Watson R, McCabe C, Harvey K, Reynolds S. Development and validation of a new adolescent self-report scale to measure loss of interest and pleasure: The Anhedonia Scale for Adolescents. Psychol Assess. 2021 Mar;33(3):201-217. doi: 10.1037/pas0000977. PMID: 33779202.

Wetherall, K., Cleare, S., Eschle, S., Ferguson, E., O'Connor, D. B., O'Carroll, R. E., & O'Connor, R. C. (2018). From ideation to action: Differentiating between those who think about suicide and those who attempt suicide in a national study of young adults. Journal of affective disorders, 241, 475–483. https://doi.org/10.1016/j.jad.2018.07.074

Wilkinson, P., Kelvin, R., Roberts, C., Dubicka, B., & Goodyer, I. (2011). Clinical and Psychosocial Predictors of Suicide Attempts and Nonsuicidal Self-Injury in the Adolescent Depression Antidepressants and Psychotherapy Trial (ADAPT). American Journal of Psychiatry, 168(5), 495–501. https://doi.org/10.1176/appi.ajp.2010.10050718

Williams, A. J., Jones, C., Arcelus, J., Townsend, E., Lazaridou, A., & Michail, M. (2021). A systematic review and meta-analysis of victimisation and mental health prevalence among LGBTQ+ young people with experiences of self-harm and suicide. PloS one, 16(1), e0245268. https://doi.org/10.1371/journal.pone.0245268

Witt, K., Spittal, M. J., Carter, G., Pirkis, J., Hetrick, S., Currier, D., ... & Milner, A. (2017). Effectiveness of online and mobile telephone applications ('apps') for the self-management of suicidal ideation and self-harm: a systematic review and meta-analysis. *BMC psychiatry*, *17*(1), 1-18.

Witt, K. G. et al. Psychosocial interventions for self-harm in adults. Cochrane database Syst. Rev. 4, CD013668 (2021).

Witt, K. G. et al. Interventions for self-harm in children and adolescents. Cochrane database Syst. Rev. 3, CD013667 (2021).