PROTOCOL

IMAGINATOR: a pilot study of a brief functional imagery training intervention for self-harm in young people, supported by a smart-phone 'app'

Short title: IMAGINATOR: functional imagery training for self-harm in young people

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i) Amendment History

Amendment No.	Protocol Version No.	Date issued	Author(s) of changes	Details of Changes made

ii) Synopsis

Study Title	IMAGINATOR: a pilot study of a brief functional imagery training intervention for self-harm in young people, supported by a smart-phone 'app'
Short Title	IMAGINATOR: functional imagery training for self-harm in young people
Study Design	Proof of concept and feasibility study comparing individuals randomly assigned to Standard Care (SC)+Immediate Functional Imagery Training (FIT) vs SC plus 3-month Delayed FIT
Study Participants	Individuals with a current history of repeated self-harm behaviour, aged 16-25 years old
Number of Participants	Participants to complete study N=32; participants to be recruited N=40, based on 25% attrition rate.
Planned Study Period	August 2016 – March 2017
Primary Objective	To test whether Functional Imagery Training (FIT) supported by a smartphone 'app' (*Imaginator* app) (Immediate FIT+SC) reduces the presence and the frequency of self-harm episodes over 3 months after the intervention above standard care (Delayed FIT + SC).

Secondary Objectives	The secondary objectives of the research are to test whether compared to standard care FIT supported by the *Imaginator* app: a) reduces the severity of self-harm behaviour and the frequency of Emergency Department (ED) attendance for self-harm behaviour at 3 months after the intervention; b) improves participants' self-efficacy ratings that they will not self-harm when experiencing distress at 3 months after the intervention; c) modifies the characteristics of mental imagery associated with self-harm when this is present; d) improves: (i) clinical and functional outcomes (mood, affective lability, anxiety, wellbeing and quality of life), and (ii) processes associated with self-harm behaviour (emotion regulation and distress tolerance, impulsivity and compulsivity, craving, impact intrusive future imagery and self-harm imagery characteristics) at 3 months after the intervention; Further objectives are to test: e) that changes from pre to post-intervention in the above objectives are replicated in the Delayed FIT + SC at 3 months after delayed FIT; f) that in the immediate FIT group (Immediate FIT + SC), effects are maintained on all the objectives above at 6 months after the intervention; g) whether the above clinical and functional outcomes are correlated with frequency of functional imagery practice on the *Imaginator* app and of general use of the *Imaginator* app at 3 and at 6 months after the intervention. A final objective is to collect: h) feasibility data on recruitment rate, acceptability of intervention delivery and outcomes assessments, retention in treatment and follow-up;

Primary Endpoint	Change in the presence and number of self-reported self-harm episodes over 3 months prior to the FIT intervention to over 3 months after randomization to the FIT intervention in the Immediate FIT + Standard Care (SC) group compared to the Delayed FIT + SC group.
Secondary Endpoints	Change from pre-randomization to 3 months post-randomization to FIT intervention in the following measures compared between the Immediate FIT + SC group vs. the Delayed FIT + SC group: a) average scores on severity of self-harm ratings, number of self-harm modalities and number of Emergency Department (ED) attendance episodes for self-harm behaviour recorded in ED hospital records over 3 months; b) average scores on a VAS scale of self-efficacy referred to self-harm; c) average scores on characteristics of mental imagery associated with self-harm when present (e.g. vividness, compellingness); d) average scores on questionnaires of clinical, functional and process outcomes (see Assessments) at 3 months after intervention; e) change from pre-randomization to 3 months after intervention in the Delayed FIT + SC compared to change from pre-randomization to 3 months after intervention in Immediate FIT + SC group; In the Immediate FIT + SC group: f) change from pre-randomization to 6 months after intervention in average scores on self-efficacy ratings on VAS scale referred to distress associated with self-harm, on number of Emergency Department (ED) attendance episodes for self-harm behaviour recorded in ED hospital records, and on average scores on questionnaires of clinical, functional and process outcomes; a) correlations between endpoints scores and the following measures of *Imaginator* app use: number of app sessions/logins and total duration of app use, number activity cycles completed, number of personalised media uploaded, number of completed guided imagery sessions and total duration of guided imagery completed, at 3 and

	6 months after the intervention. Feasibility data: g) total number of participants referred to IMAGINATOR from different recruitment sources and monthly recruitment rate; compared between Immediate FIT + SC and Delayed FIT + SC, attrition rate (percentage of participants completing intervention) and completion rate of follow-up assessments.
Intervention (s)	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.

ii) Key Abbreviations

FIT	Functional Imagery Training
SC	Standard Care
ED	Emergency Department
CI	Chief Investigator
NICE	National Institute for Clinical Excellence
MRC CBSU	Medical Research Council Cognition and Brain Sciences Unit
CAMHS	Child and Adolescent Mental Health Services
CPFT	Cambridge and Peterborough Foundation Trust
LPS	Liaison Psychiatry Service
PIS	Participant Information Sheet
CRHTT	Crisis Resolution and Home Treatment Team

1. Background and Rationale

1.2 The Problem with Self Harm

Self-harm is defined by the National Institute for Clinical Excellence (NICE) guidelines as the "act of self-poisoning or self-injury, irrespective of the apparent purpose of the act"(NICE, 2012). In the context of offering support or intervention and in line with the NICE guidelines approach, the IMAGINATOR study focuses on those acts of self-harm that are an expression of personal distress and where the person directly intends to injure themselves. However, the study does not use the terms 'deliberate' or 'intentional' as these are often perceived as stigmatizing, and because the extent to which the behaviour is intentional is not always clear.

Methods of self-harm can be broadly divided into self-injury (e.g. cutting, bruising, burning, self-battery and a large variety of less common self-mutilation modalities) and self-poisoning (overdose of prescribed or over-the-counter medication, or less frequently other substances or illicit drugs). The method used often influences whether self-harm comes to the attention of other people and of health-care services. 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 also 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).
In preparation for the current study, we discussed motives for self-harm with an advisory group of young people with an experience of repetitive self-harm: interestingly, the group's responses exemplify well the findings from previous research. Drivers for self-harm included: feeling numb, feeling out of control, wanting "things to get out of my head", feeling they have done something bad/ are a bad person, feeling guilty, anxious or sad.

Self-harm behaviour is more common than usually believed, especially in adolescence, and tends to often resolve spontaneously over time. A recent meta-analysis of international data, reported a lifetime prevalence of self-harm around 17.2% in adolescents, 13.4% among young adults, and 5.5% among adults (Swannell et al., 2014). A UK survey in schools described a lifetime prevalence of 13% in 15-16 years old and 8% incidence in the last year (Hawton et al., 2002). Recent data from a local survey in Cambridgeshire reported that the number of hospital admissions for self-harm has been higher than UK average (Cambridgeshire County Council, May 2015). It's important to note that only about one in eight adolescents in the community who self-report engaging in SH ever presents to hospital (Hawton et al., 2002, McMahon et al., 2014, Ystgaard et al., 2009).

Traditionally females are reported to self-harm more frequently, especially in early adolescence, however in the older teenage years the behaviour becomes more frequent in boys and rates level off in girls (Hawton et al., 2015). It has also been argued that data on gender differences may be skewed by report-bias, by research in psychiatric populations and by a focus on the most stereotypical form of self-harm such as cutting. In fact, more recent research suggests a more equal distribution between genders (Swannell et al., 2014). Factors associated with self-harm include a disadvantaged socio-economic background, social isolation and lack of support, negative life events including childhood emotional, physical or sexual abuse (NICE, 2012, Andover et al., 2012). A multi-center study across Europe showed that risk-behaviors, family related neglect and peer-related rejection/victimization, including bullying, are also associated with self-harm in adolescence, with a strong influence by both gender and

country (Brunner et al., 2014). Relationship problems with family members or partners are common and often trigger self-harm episodes (Hawton et al., 2012).

While most self-harm cases particularly in adolescents represent a form of transient distress (Hawton et al., 2002), 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 (Moran et al., 2012). Traits similar to those present in personality disorders are also frequently reported, although a diagnosis of personality disorder at a young age is controversial (Haw et al., 2001, Crowell et al., 2012). More general psychological characteristics associated with self-harm include feelings of entrapment, lack of belonging, perceiving oneself as a burden, a tendency to show black and white (or all or none) thinking patterns, low self-esteem, impulsivity and hopelessness (O'Connor et al., 2012, Hawton and Van Heeringen, 2000, Hawton, 2005). Moreover, deficits in problem-solving and emotion regulation skills have been reported (Speckens and Hawton, 2005, Mikolajczak et al., 2009).

Repetition is common after self-harm; about one in six individuals presenting with self-harm repeats over the next year and one in four after 4 years, in those who persist, the self-harm tends to become more serious (Moran et al., 2012). The extent to which non-suicidal self-harm and attempted suicide are qualitatively different or not is widely debated. Regardless, even episodes of self-harm with no reported suicidal intent are related to an elevated risk of repeat self-harm and suicide compared with the general population (Kapur et al., 2006). People who self-harm carry a fourfold risk of suicidal thoughts and behaviours within one year, a risk over and above the risk conferred by comorbid psychopathology and psychosocial risk factors (Whitlock et al., 2013, Wilkinson et al., 2011). Although some of this data may be skewed by research being carried out on samples that present to hospital for self-harm (and who may represent those with more severe self-harm behaviour), the association between self-harm and suicide risk is unanimously recognised as strong in the literature, and explains the urgent call for addressing the problem of self-harm in young people.

Moreover, self-harm warrants intervention *per se*: in young people it has been recognised as an important index of distress and poor mental health. Self-harm also has substantial personal impacts (e.g. shame, guilt, and physical damage costs). Finally, self-harm also bears relevant costs for the NHS (www.nccmh.org.uk), and is one of the most common presentations to general hospitals. Beyond the healthcare system, the costs expand to society, including families and workers in educational settings and the voluntary sector, especially as data suggests that over half of self-harm episodes do not come to the attention of the NHS or the individuals family (Hawton et al., 2002).

In summary, self-harm in young people 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.

1.3 Psychological treatments of self-harm in young people

Nice guidelines for long term management of self-harm recommend: *"[…] offering 3 to 12 sessions of a psychological intervention that is specifically structured for people who self-harm, with the aim of reducing self-harm. In addition: (i) the intervention should be tailored to individual need, and could include cognitive-behavioural, psychodynamic or problem-solving elements; (ii) therapists should be trained and supervised in the therapy they are offering to people who self-harm; (iii) therapists should also be able to work collaboratively with*

the person to identify the problems causing distress or leading to self-harm." (NICE, 2012)These recommendations are based on a variety of studies conducted so far on both adult and adolescent populations, which have been also more recently analysed in two Cochrane reviews (Hawton et al., 2016, Hawton et al., 2015).

As referred to by NICE, cognitive-behavioural, psychodynamic or problem-solving elements of current therapies for self-harm are based on targeting some of the factors identified as potential contributors or mechanisms underpinning self-harm behaviour (see 1.2). For example, the aim of therapies can be helping people improve their coping skills and self-esteem, tackling specific problems, overcoming psychiatric disorders, increasing their sense of social connectedness, and reducing impulsivity, aggression and unhelpful reactions to distressing situations.
One key focus of many therapeutic approaches (dialectic-behavioural therapy - DBT, mentalisation, some cognitive-behavioural therapy - CBT) stems from the evidence that individuals who self-harm have a poor ability to regulate emotions (Gratz, 2003) and tolerate distress (Nock and Mendes, 2008). Self-harm is believed to represent a strategy to escape from unwanted intense emotions perceived as uncontrollable, by directing attention away from the emotion; the resultant relief and reduction in emotional arousal confers a sense of regained control and reinforces the self-harm behaviour (Welch et al., 2008). To address this vicious cycle, DBT (and other therapies) protocols aim to develop skills for managing distress, regulating emotions, and have shown some success at reducing the frequency of self-harm in adults, in particular in people with multiple episodes/probable personality disorder (Linehan, 1993). Interventions based on similar principles (DBT adapted for adolescents, mentalisation) have also shown some promise in young age groups (Mehlum et al., 2014). However, despite the scale of the problem in adolescents there is a paucity of evidence for effective interventions focusing on emotion regulation skills for this age group.

The other more widely tested therapeutic approach is based on evidence of specific deficits in problem-solving ability in individuals who self-harm (McLeavey et al., 1987, Schotte and Clum, 1987, Williams and Pollock, 2008). CBT interventions for self-harm have particularly focused on problem-solving training (as this is a structural element of CBT), and have shown some evidence of fewer individuals repeating self-harm (Hawton et al., 2016) and of positive outcomes on hopelessness, depression and actual problem solving (Townsend et al., 2001).

Various studies have recognised the importance of developing short and pragmatic interventions. This is understandable as, given the associated risk of suicide and the psychological burden of engaging in repetitive self-harm, it make sense to offer some pragmatic support with short-term goals, while the different underpinning factors of self-harm are targeted with a long-term perspective (e.g. socio-economic factors or concurrent mental disorders). Addressing associated psychiatric disorders has shown good results on self-harm reduction, but exclusive focus on this may result in individuals being left with little help around the self-harm behaviour for long periods. Moreover, it leaves out all those individuals who do not present a clear psychiatric disorder diagnosis. Similarly, structural environmental factors that underpin self-harm behaviour (e.g. employment / housing / family factors) may present numerous barriers before they can be eradicated.
The intervention trials included in the Cochrane review for adults mainly targeted individuals following a suicide attempt, with a limited number of short interventions (up to 5 sessions) tested. The earliest was Hawton et al. (1987), which compared brief problem oriented counselling and treatment as usual in 80 patients following self-poisoning with no significant differences between the groups. Salkovskis et al. (1990) reported an intervention of cognitive behavioural problem solving compared to treatment as usual in 20 individuals who had attempted suicide. They found that the problem solving intervention improved depression, hopelessness, target problems, and reduced suicidal ideation up to one year post intervention. Guthrie et al. (2001) trialed psychodynamic

interpersonal therapy compared to treatment as usual in 119 adults who presented with self-poisoning. They found that psychodynamic interpersonal therapy led to a reduction in suicidal ideation and that participants were less likely to report self-harm. Tyrer et al. (2003) conducted a large randomized trial of a brief form of manualised cognitive therapy, and found no improvement in the proportion of individuals repeating self-harm in the 12 months of the study, compared to treatment as usual, although there were significant improvement in hopelessness and other symptomatology. Brown et al. (2005) used cognitive therapy in adults who had attempted suicide. Those who received cognitive therapy had lower suicide attempts, hopelessness and emotional dysregulation at 6, 12 and 18 months compared to the control groups. Finally, Tapolaa et al. (2010) report that their intervention which combined acceptance and commitment therapy and a solution focused brief therapy in 16 adult males led to a reduced incidence of deliberate self-harm as well as reduced levels of depression and emotional dysregulation. Overall, there is an indication that psychological interventions of 4-5 sessions using psychodynamic / cognitive or problem-solving approaches can be beneficial for adults following a self-harm episode / suicide attempt. However, there is no clear evidence of which approach best targets frequency / repetition of self-harm, and whether the same interventions could be extended to adolescents too.

In summary, a variety of interventions have been developed that either focus on associated psychiatric disorders or have a duration of above 4 weekly sessions; however, none of the approaches tested have reached so-called high quality evidence of efficacy at reducing self-harm repetition or frequency when evaluated by systematic reviews. Further treatment innovation is needed to develop short-term interventions able to reduce self-harm frequency and repetition. Accordingly, NICE guidelines highlight that an urgent area of research is to investigate *"the clinical effectiveness of brief psychosocial / low intensity intervention"* at improving outcomes of self-harm (including considering the use of electronic media in community mental health settings) (NICE, 2012). NICE also recommends that outcomes to be measured should include service users' engagement and experience, and both hospital-reported and self-reported repetitions of self-harm.

Importantly, no study offering a short intervention for self-harm specifically targeted at young people has been conducted so far to the standards to be included in the above reviews and guidelines. The IMAGINATOR study seeks to address this dramatic lack of effective short-term therapy for self-harm with a specific focus on young people and will be delivered in the community.

1.4 Treatment innovation: using imagery-focused interventions

Mental images are multi-sensory representations in the absence of an actual external percept leading to the subjective experience commonly described as 'seeing through the mind's eye, hearing through the mind's ear etc.' (Pearson et al., 2015). Mental images have a strong association with emotions and have been shown to elicit stronger emotional responses compared to verbal thoughts (Mathews et al., 2013). Unwanted mental images carrying intense negative emotions are central to several mental disorders (Holmes and Mathews, 2010). For example, individuals with social anxiety will experience intrusive images of them sweating and blushing intensely while they try to speak to someone, these images will fuel their anxiety about being judged by others and possibly stop them from attending further social situations. Depressed individuals on the other hand struggle to generate images of rewarding scenarios and this contributes to their lack of motivation and enjoyment (Holmes et al., 2016b). Mental imagery associated with self-harm also appears to be a common phenomenon and individuals describe that images associated with self-harm can carry many different emotional meanings (e.g. evoking a sense of relief, or increasing arousal and the urge to self-harm) in keeping with the individual and episode-specific motives of self-harm (Dargan et al., 2016, Weßlau et al., 2015). Compelling intrusive imagery of suicide has also

been implicated in maintaining suicidal ideation and risk (Crane et al., 2012). Moreover, imagery characteristics appear related to the intensity of emotional experiences: for example, more vivid or more real-like imagery of the future has been associated with higher levels of anxiety or affect instability (Di Simplicio et al., Under Review) The same applies for positive images, whereby greater vividness of positive imagery has been related to greater excitement during positive mood (Ivins et al., 2014), and repeatedly imagining positive scenarios in an experimental paradigm increases positive affect in healthy volunteers (O'Donnell et al., In Prep).

Overall, this evidence suggests that mental imagery is a common phenomenon, which many individuals are likely to experience in the context of high emotions, and that mental images could be used as a vehicle to change or generate emotions. Accordingly, imagery-based techniques have always been part of cognitive-behavioral therapy approaches (Hackmann et al., 2011). Targeting distressing mental images and promoting positive imagery has been used for trauma (http://www.nice.org.uk/CG26), depression (Brewin et al., 2009, Blackwell et al., 2015) and self-harm in personality disorders (Bamelis et al., 2014), and we have successfully treated cases with self-harm behaviour within a short course of imagery-focused therapy for bipolar disorder (Holmes et al., 2016a).

Mental imagery has also been shown to promote behaviour in various domains, from neutral / adaptive activities such as voting (Libby et al., 2007), physical exercise (Chan and Cameron, 2012) and sleep (Loft and Cameron, 2013), to maladaptive activities such as gambling (Whiting and Dixon, 2013). For example, in an experimental study on food consumption, university students who imagined situations where they could eat fruit and then imagined eating the fruit actually consumed more fruit relative to those allocated to control conditions (Knäuper et al., 2011). In another study on a sample of individuals with low mood, repeated training of positive imagery scenarios made participants able to engage in a challenging game for a longer duration (Pictet et al., 2011).

When trying to explain why imagining something makes it more likely to act one has to consider imagery of future events ("prospective imagery") involves simulating the actual event and allows individuals to ''pre-experience'' all aspects the event (Moulton and Kosslyn, 2009, Suddendorf and Corballis, 2007). Hence, via imagining future scenarios individuals may feel more ready for implementing their desired action with success; in fact, evidence in sports research shows that adding mental imagery training to physical practice of an exercise improves performance (Schuster et al., 2011). Moreover, prospective imagery also simulates the emotional consequences of a scenario: imagining an action may enhance motivation to perform it by anticipating how emotionally rewarding the action (or its outcome) is likely to be. Given that the vividness of imagery increases its emotional power, a vivid real-like mental image of completing a desired action can evoke a strong positive emotion; vividly imagining the reward of achieving a goal can in turn strengthen the motivation to engage in the action. For example, a study reported that the strength of hockey players' cravings to play hockey was also determined by the vividness of their imagery of playing (May et al., 2008). Based on this, recent research has developed a specific imagery intervention, called functional imagery training (FIT) as a technique to sustain motivation for achieving healthy goals (Andrade et al., 2012). FIT encourages individuals to imagine the benefits of working towards their goals, focusing particularly on benefits that are expected to happen right away (e.g. feeling good about oneself) (Kavanagh et al., 2014). By practising imagery about healthy goals, the benefits of these goals become more salient, and more likely to come to mind in relevant situations. So far, FIT has been shown to be a successful approach for interventions to reduce snacking (Andrade et al., 2012) and in addictive behaviours (Kavanagh, unpublished).

Based on the evidence of the strong links between imagery, emotion and motivation towards behaviour, and of self-harm being associated with intense distressing emotional state (as well as sometimes mental images that

encapsulate those emotions), we propose that an imagery-based intervention such as FIT could represent a short innovative intervention for self-harm. In particular, the IMAGINATOR study proposed that FIT can promote alternative helpful behaviours to be implemented when individuals feel the urge to self-harm, instead of self-harming.

As described above, individuals experience a variety of emotions (e.g. "out of control", "numb") and motives (e.g. "get back in control", "feel something") that drive self-harm. Most individuals who self-harm are sometimes able to engage in alternative responses to those emotions and motives (e.g. they can find an alternative action to "get back in control" or "feel something", such as going for a run, listening to music etc.). However, when distress is high, remembering the alternative action, getting the motivation to engage in it, and sustaining the effort of trying, becomes problematic; even more problematic, when repetition of self-harm has induced the habit of using it as quick and effective tool (e.g. to release tension or increase arousal). Practising an alternative action via mental imagery can help overcome this challenge, and thus help reduce self-harming repetition. By imagining a functional alternative behaviour to self-harm, individuals can simulate and anticipate the positive feeling of e.g. "getting back in control" without having self-harmed. Imagining how they will achieve their goal (e.g. "going for a run") and the sense of reward and accomplishment they will get from it could sustain their motivation to actually do it. Repeated practise individually cued at times when one is usually more vulnerable (e.g. at night, before an exam etc.) can facilitate overcoming the shortcut to self-harming when distress becomes intense. Interestingly, the importance of supporting motivation towards implementation of adaptive goals has been recently addressed in another exploratory trial of a brief intervention for patients admitted to hospital for self-harm, showing that implementing intention-based interventions holds promise in reducing future suicidal ideation and behaviour (Armitage et al., 2016). This supports the idea of a short intervention exclusively focused on promoting alternative behaviours to self-harm and supporting motivation and engagement in achieving them.

In summary, we propose that Functional Imagery Training (FIT) can help individuals who self-harm identify adaptive behaviours as an alternative goal when they feel like self-harming. By practising the adaptive mental imagery, they will boost their desire for those goals and rehearse the pathways towards them as an alternative to self-harm. Practicing vivid and real-like imagery of alternative behaviours and goals is likely to produce rewarding and positive emotions and support individuals to implement the new behaviours instead of self-harming. Importantly, FIT can be adapted to any individual driver and trigger of self-harm and therefore lends itself to being a brief management intervention regardless of what the principal contributing factor is. As such, FIT has the potential of being an extremely helpful intervention for all those young people who are either excluded from or waiting for more complex interventions.

1.5 Engaging young people

As previously highlighted, self-harm behaviour needs urgent attention in young people. Short efficacious interventions targeted at this group are still lacking (Hawton et al., 2015, NICE, 2012). Young people struggle to engage with traditional mental health services (Plaistow et al., 2014), and of those who self-harm the majority don't present to healthcare services and don't disclose their behaviour to family nor to any support service (Hawton et al., 2002). Of particular concern regarding after-care of adolescents who engage in self-harm and who present to hospital is the fact that adherence to recommended treatment tends to be relatively poor; between 25% and 50% of adolescents will not attend any follow-up sessions (Granboulan et al., 2001, Taylor and Stansfeld, 1984).

A key challenge is then to develop an intervention that will be short, well-received and engaging for young people experiencing self-harm, including elements that allow self-management and a sense of self-empowerment.

Smartphone usage by young people is high (Pew Research Center, April 2015) as is their preference for smartphone apps (Lenhart, 2015). Therefore, enhancing a psychological intervention via a smartphone app could be a successful strategy to ensure that young people keep practicing the therapy techniques and engaging with what was learned in therapy once the sessions are over and without the need of face to face follow-up. Smartphone app-based support also allows patients to individualise the tools that enhance therapy practice (e.g. individualised settings for reminders to practice exercises), and that sustain motivation to keep practicing and working for therapy goals (e.g. gamification via a rewards system). Personalizing app and gamification are extremely common in current apps used by young people and therefore can embed practicing therapy techniques into a familiar app-user environment and into familiar habits. Imagery-based interventions focus on visual techniques and are therefore easily amenable to be supported by a smartphone app. For example, FIT highlights the role of mental imagery (including pictures and sounds in the mind) in supporting positive emotions and motivation, which makes the use of personal photographs, videos and music uploaded on a smartphone an intuitive way to cue and reinforce imagery practice and goal achievement. Examples of guided imagery can also be included in an app in the form of short audios, to support the continuous FIT after the sessions.

Therefore, we propose to tailor FIT to young people by adding a smartphone app support, which can make the intervention more interesting and approachable to this age group and can overcome the barriers to access treatment which are reported in young people. We have developed a bespoke app called *Imaginator*. *Imaginator* was created collectively via six meetings of a Young People Advisory Group (YPAG: 4 members, 1 male, aged 19 to 22 years old, with a lived experience of self-harm, recruited via Iliana Rokkou User and Carer R&D Manager of the Cambridge and Peterborough NHS Foundation Trust, CPFT, or because they had expressed and interest from participating in previous research at the MRC Cognition and Brain Sciences Unit, MRC CBSU). The YPAG started by discussing what kind of support would be helpful to enhance FIT and help young people get the most from the intervention with the IMAGINATOR study Chief Investigator (CI) Dr Di Simplicio. This led to devising the main app functionalities step by step together with the CEO of the app development company App Shine Development; John Harper who then built the app prototypes. Prototypes were tested by YPAG members and feedback was used to build the final app version, released to researchers at the MRC CBSU.

This collaborative non-hierarchical process and the characteristics of the *Imaginator* app are in line with recommendations from the YoungMinds charity (Royal College of Psychiatrists, 2014): *Imaginator* highlights that therapy functions as a collaborative process with balanced power with therapeutic sharing of responsibility (i.e. the app replicates what done in sessions but is fully managed and personalized by the young person); the app highlights emotional aspects of self-harm management with no reference to medical and physical aspects of treatment.

2 Methodology: proof of concept study

Traditionally, proof of concept clinical trials are used at an early stage of clinical drug development when a compound has shown potential in animal models and early safety testing. These small-scale studies are designed to detect a signal that the drug is active on a pathophysiologically relevant mechanism, as well as preliminary evidence of efficacy in a clinically relevant endpoint (Schmidt, 2006). A similar approach has been translated to

trials of psychological interventions, which aim to demonstrate in principle that a certain method or idea has the potential of being used for a specific condition, for example in PTSD (Litz et al., 2007) gambling (Christensen et al., 2013) for internet-based CBT (Månsson et al., 2013).

As Functional Imagery Training (FIT) has never been tested before as an intervention to reduce self-harm in young people, a proof of concept trial is the optimal design for this early stage of treatment innovation. The intervention is based on adapting a FIT protocol for reduction of alcohol abuse developed by Kavanagh (Co-Investigator on the IMAGINATOR study), which enhances traditional motivational interviewing for behavioral change via the use of mental imagery. Adaptation of the protocol to reduction of self-harm is based on similarities between the two processes of a dysfunctional behavior (drinking, self-harming) associated with distress.

As proof of concept trial, the IMAGINATOR study aims to detect an indication that the new intervention FIT can be efficacious at reducing a significant endpoint for self-harm, such as self-harm frequency, and that it can be delivered to and well received by the target population of young people aged 16-25. Moreover, the trial will allow the collection of feasibility data on the acceptability of FIT and of recruitment and retention in treatment, which can be used to design the next steps of intervention testing (e.g. a pilot/full randomized controlled trial). Following NICE recommendations the IMAGINATOR study will measure outcomes that include service users' engagement and experience, and both hospital-reported and self-reported repetitions of self-harm (NICE, 2012).

IMAGINATOR is a proof of concept rater-blind randomized-controlled trial of FIT + standard care (SC) as delivered by the local primary and secondary care NHS trusts for young people (16-25 years old) with an experience of repeated self-harm over the previous three months. Participants are randomly allocated to receive FIT + SC within two weeks from assessment (Immediate FIT+SC) or after a delayed period of 3 months (Delayed FIT+SC). The study design and time line is summarised in Appendix 3.

2.1 Population under Investigation

This study focuses on individuals who are experiencing current repeated self-harming behaviour (at least two episodes over the last 3 months), aged 16-25 years old, and who are seeking support to reduce / stop self-harming. The age group has been chosen based on evidence that self-harm is most prevalent in adolescents, but repetitive self-harm behaviour with worse implications for mental health tends to be present or persist in late adolescence and young adulthood. Thus this age group is the one with the most urgent need for new effective interventions.

2.2 Summary

IMAGINATOR is a proof of concept study that investigates the delivery of Functional Imagery Training (FIT) for self-harm to young people aged 16-25 who experience current repeated self-harming behaviour. 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". FIT is intended as a brief and focused transdiagnostic intervention that can be added to any other pharmacological or psychological therapy. To improve access to and engagement with the intervention by young people, we will deliver FIT and encourage participants to support their therapy by using the *Imaginator smartphone app.*

The IMAGINATOR study provides two sessions of FIT + Standard Care (SC), followed by phone support sessions and smartphone app-based support, based on cognitive behavioural and motivational interview principles and in line with NICE guidelines for long-term management of self-harm behaviour.

The study is based in Cambridgeshire (Cambridge and Huntingdon localities) and run at multiple sites both in and out of NHS premises, namely: the Medical Research Council Cognition and Brain Sciences Unit (MRC CBSU) in Cambridge; the Children and Adolescents Mental Health Services (CAMHS) clinic in Douglas House, part of Cambridge and Peterborough NHS Foundation Trust (CPFT), Cambridge; and the Hinchingbrooke General Hospital, Hinchingbrooke NHS Trust, Huntingdon.

3. Objectives

3.1 Primary Objective

a) The primary objective of the research is to test whether Functional Imagery Training (FIT) supported by a smartphone 'app' (*Imaginator* app) (Immediate FIT+SC) reduces the presence and frequency of self-harm episodes over 3 months after the intervention above standard care (Delayed FIT + SC).

3.2 Secondary Objectives

The secondary objectives of the research are to test whether compared to standard care FIT supported by the *Imaginator* app:

i) Reduces the severity of self-harm behaviour and the frequency of Emergency Department (ED) attendance for self-harm behaviour at 3 months after the intervention;

j) Improves participants' self-efficacy ratings that they will not self-harm when experiencing distress at 3 months after the intervention;

k) Modifies the characteristics of mental imagery associated with self-harm when this is present;

Further objectives are to test:

l) whether compared to standard care FIT supported by the *Imaginator* app improves: (i) clinical and functional outcomes (mood, affective lability, anxiety, wellbeing and quality of life), and (ii) processes associated with self-harm behaviour (emotion regulation and distress tolerance, impulsivity and compulsivity, craving, impact intrusive future imagery and self-harm imagery characteristics) at 3 months after the intervention;

m) that changes from pre to post-intervention in the above objectives are replicated in the Delayed FIT + SC at 3 months after delayed FIT;

n) that in the immediate FIT group (Immediate FIT + SC), effects are maintained on all the objectives above at 6 months after the intervention;

o) whether the above clinical and functional outcomes are correlated with frequency of functional imagery practice on the *Imaginator* app and of general use of the *Imaginator* app at 3 and at 6 months after the intervention.

A final objective is to collect:

p) feasibility data on recruitment rate, acceptability of intervention delivery and outcomes assessments, retention in treatment and follow-up.

4. Endpoints

4.1 Primary Endpoint

h) Change in the presence of and number of self-reported self-harm episodes over 3 months prior to the FIT intervention to over 3 months after randomization to the FIT intervention in the Immediate FIT + Standard Care (SC) group compared to the Delayed FIT + SC group.

4.2 Secondary Endpoints

Change from pre-randomization to 3 months post-randomization to FIT intervention in the following measures compared between the Immediate FIT + SC group vs. the Delayed FIT + SC group:

i) average scores on severity of self-harm ratings, number of self-harm modalities and number of Emergency Department (ED) attendance episodes for self-harm behaviour recorded in ED hospital records over 3 months;

j) average scores on a VAS scale of self-efficacy ratings referred to self-harm;

k) average scores on characteristics of mental imagery associated with self-harm when present (e.g. vividness, compellingness);

l) average scores on questionnaires of clinical, functional and process outcomes (see Assessments) at 3 months after intervention;

m) change from pre-randomization to 3 months after intervention in the Delayed FIT + SC compared to change from pre-randomization to 3 months after intervention in Immediate FIT + SC group[1];

In the Immediate FIT + SC group:

n) change from pre-randomization to 6 months after intervention in average scores on self-efficacy ratings on VAS scale referred to distress associated with self-harm, on number of Emergency Department (ED) attendance episodes for self-harm behaviour recorded in ED hospital records, and on average scores on questionnaires of clinical, functional and process outcomes;

b) correlations between endpoints scores and the following measures of *Imaginator* app use: number of app sessions/logins and total duration of app use, number activity cycles completed, number of personalised media uploaded, number of completed guided imagery sessions and total duration of guided imagery completed, at 3 and 6 months after the intervention.

Feasibility data:

o) total number of participants referred to IMAGINATOR from different recruitment sources and monthly recruitment rate; compared between Immediate FIT + SC and Delayed FIT + SC, attrition rate (percentage of participants completing intervention) and completion rate of follow-up assessments;

[1] *Note that to measure if the outcomes at 3 months after intervention are replicated in the Delayed FIT + SC group, we compare outcomes at 3 months after intervention in the Delayed FIT + SC group (for whom 3 months after intervention = 6 months after randomization) to the Immediate FIT+SC group (for whom 3 months after intervention = 3 months after randomization).*

5. Study Design and Procedures

5.1 Study Design

IMAGINATOR is a rater-blind randomised study comparing Immediate FIT+SC to Delayed FIT+SC. Randomization is stratified by gender and conducted using a randomization code prepared by the study statistician.

The design includes the following elements and study phases:

- Baseline Screening Visit
- Intervention: 2 FIT sessions delivered face-to-face by therapist with a one week interval at one of the study sites
- Follow up: 5 fortnightly support sessions delivered over the phone
- Smartphone app-based reminders, exercises and support during whole study duration
- Online outcome assessments at 3 and 6 months after randomization
- User-led feedback interviews in 8 participants per group upon study completion (after final assessment)

5.2 Study Participants

Participants are young individuals aged 16 to 25 years old who experience current repeated self-harm behaviour and are seeking support to manage and reduce self-harming via NHS / non-NHS services, or directly via self-referral to the IMAGINATOR study. The aim is to reach an N=16 participants per group (total = 32) who will have completed treatment and 3 months follow-up. Based on an expected 25% attrition rate from previous studies (Brown et al., 2005), 40 participants will be enrolled in the study using a randomization procedure (see 4.6).

5.2.1 Inclusion Criteria

- ➢ Age 16 – 25 years old
- ➢ Have adequate English language ability to permit the assessment and experimental measures to be completed and use of the smartphone app
- ➢ Presented with at least 2 episodes of self-harm (defined in 2.2) over the last three months
- ➢ Willing to receive support to reduce / improve management of self-harm urges and behaviour in person, over the phone and via Android smartphone app (own or made available by researchers*)
- ➢ Willing to have letters sent/phone calls made to their GP and other relevant clinicians
- ➢ Can commit to attending 2 consecutive weekly sessions, and 5 fortnightly phone follow-up sessions, and assessments over follow up period as required by the study
- ➢ Resident within geographical areas covered by the Cambridgeshire and Peterborough NHS Foundation trust (CPFT)

- ➢ Able to give consent

** Participants who will be given an Android smartphone (property of MRC CBSU) for use of the Imaginator app during the study, will return this at the end of the last Outcome Assessment. Upon return of the mobile device, researchers will ensure with the participant that all their personal data is deleted from the device and this will be cross-checked and signed off by both researcher and participant.*

5.2.2 Exclusion Criteria

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

- ➢ Experiencing current severe psychopathology that is of impediment to completing the study requirements, e.g. active psychotic symptoms (clinicians assessment)
- ➢ Currently treated under the care of the CPFT Personality Disorders Pathway
- ➢ Currently under the care of the CPFT Crisis Resolution and Home Treatment Team or under inpatient care
- ➢ Learning difficulties, organic brain disease, severe neurological impairment
- ➢ Current severe substance or alcohol abuse (clinicians assessment)
- ➢ Presence of active suicidal risk on the MINI (Sheehan et al., 1998) confirmed by convergent clinical opinion (see risk assessment protocol, Appendix 1)
- ➢ Unwilling to engage actively in the FIT intervention or to use an imagery-focused approach for treatment
- ➢ Unwilling to use a smartphone app
- ➢ Taking part in concurrent treatment studies investigating pharmacological or psychological treatment for self-harm

5.3 Study Procedures

5.3.1 Recruitment

Participants are recruited via the following routes:

- Referral by clinicians responsible for their routine primary care (GPs) or secondary mental health care within the CPFT
- Referral by Emergency Department (ED) staff or Liaison Psychiatry Services (LPS) staff following presentation to Hinchingbrooke hospital or Addenbrooke's hospital with a self-harm episode
- Referral by educational services (e.g. University, college, school or sixth form counselling) and charities for young people (e.g. Centre 33 in Cambridge); this can be either directly by educational services/charity staff or as a self-referral facilitated by the above staff, based on each institutions/centre preferred procedures
- Self-referral following advertisement in the community and on social media

Participants are given a short version of the Participant Information Sheet (short-PIS) during a routine appointment with their GP, psychiatrist, clinical psychologist, care coordinator or other mental health professional involved in their care team; or following assessment in the ED; or by their school/college/university counsellor/ nurse; or by youth centre staff. After reading the short-PIS, participants are asked if they would like to sign a "Consent to contact" form where they consent to be contacted by the research team. Consent to contact forms are passed by clinicians / educational or charity organisation staff to the research team. If preferred, participants can also contact the research team members directly themselves via the email imaginator@mrc-cbu.cam.ac.uk or telephone number contained in the short-PIS. The same contact details are also contained on all advertisement material for self-referrals from the community / social media.

On first contact, the research team 1) provides a brief introduction to the study and 2) sends the full PIS via email or in the post. If participants confirm their interest in the study after having received the PIS, the research team asks pre-screening questions to check some eligibility criteria (see Inclusion / Exclusion criteria: 5.2.1, 5.2.2). These contacts can be either via email or over the phone, based on participants preferences. If eligible based on pre-screening questions, a convenient date is arranged to complete screening at the Baseline Screening Visit at the research site most convenient for the participant. If participants are eligible after the Baseline Screening Visit, the first intervention session is booked in to take place within two weeks time (for participants allocated to the Immediate FIT + SC group) or in 3 months' time (for participants allocated to the Delayed FIT + SC group).

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 CPFT, in line with best practice NHS standards. Risk management continues to be delivered as per routine CPFT procedures and guidelines, by the participant care team/GP.

5.3.2 Baseline Screening Visit

The screening visit includes the following procedures:

5.3.2.1 Informed Consent

Participants are sent the full PIS on first contact with the research team (see 4.3.1). On arriving at the research site for the Baseline Screening Visit, participants are provided with a further copy of the PIS 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 using a signed and dated consent form is then taken prior to commencing the eligibility assessment. Informed consent is taken by trained researchers and under the supervision of the study PI.

Informed consent also includes: consent to inform GP, care coordinator and/or other named clinicians about participation in the study; consent to risk management procedures (see IMAGINATOR STUDY RISK ASSESSMENT PROCEDURES, Appendix 1**)** and to anonymised data sharing policies (see 8.3 and 8.4).

5.3.2.2 Eligibility Assessment

The session then proceeds with a structured clinical interview: The Mini International Neuropsychiatric Interview (MINI)(Sheehan et al., 1998). This is used to collect baseline data on the presence of past or present psychiatric

disorders, and record severity of any current symptoms, which may impede participation in the study (see exclusion criteria), including assessment of current suicidal risk (see exclusion criteria). Finally baseline information is collected on the presence, characteristics and frequency of self-harming behaviour.

Participants are deemed eligible or ineligible for proceeding to the next part of the study, based on their responses to the assessments above. Participants found to fulfill the relevant inclusion criteria are invited to complete the study. Participants who do not fulfill the inclusion criteria or who meet exclusion criteria do not continue with the study. Participants are informed of their eligibility, sensitively, by the research team. Those not eligible are signposted to other services for support; they are thanked for their interest and reimbursed for their time and any travel expenses.

It is estimated that the process of consent and eligibility assessment takes up to 60 minutes.

5.3.2.3 Collection of Baseline Measures

Eligible participants are then asked to complete further questionnaires assessing 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, see Outcome measures). All questionnaires are standard tools, which are commonly used in psychological studies. Specially designed measures for this study are: the *Single item questionnaire on self-harm frequency,* the *Two items questionnaire on self-harm severity,* the *Visual Analogue Scale (VAS) of self-efficacy on resistance to self-harm when distressed* and the *Self-Harm Imagery Interview* (see Outcome measures). Participants spend approximately 45 minutes completing questionnaires and they have a chance to take breaks.

5.3.2.4 Randomisation to Intervention

Participants are then randomly allocated to Immediate FIT+SC or Delayed FIT+SC by the study therapist using an online randomisation tool (https://www.sealedenvelope.com/) that allows investigators to randomise patients from anywhere with access to a web browser. This method of randomisation is ideal for multi-site trials where investigators have access to the internet at the point of randomisation (such as in the IMAGINATOR study). The therapist/CI will randomise participants by simply completing an on-screen form with patient anonymized details, inclusion and exclusion criteria. This system conforms to the requirements of all major regulatory bodies, such as International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Good Clinical Practice guidelines.

The first FIT session is then booked in accordingly (within one week for participants randomised to Immediate FIT+ SC, and in 3 months' time for participants randomised to Delayed FIT+SC).

5.3.2.5 Informing Participants GPs and Care Coordinators

A standard letter informing of their taking part in the study is sent by the research team to the participant's GP and Care Coordinator (if applicable), and/or any other 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).

5.3.3 Intervention Phase

5.3.3.1 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 formulation of idiosyncratic drivers of self-harm behaviour and of personal motives for change takes place as part of the Baseline Screening Visit together with the assessment of self-harm behaviour characteristics. This includes identifying risky situations for self-harm, triggers, recurrent emotional responses and associated cognitions including cognitions in the form of images (see Self-Harm Imagery Interview). By discussing mental images that may accompany self-harm behaviour, participants are familiarized 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.

The first FIT session focuses on motivational interviewing with embedded mental imagery practice. 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 in taking a photo of something that represents their target or goal for change.

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 (or a smartphone provided by the researchers*) and are instructed on the app use to support practising the functional imagery developed in session (see below). Finally, the first support call is scheduled in one week time.

At the end of each session participants complete the State Motivation for reducing Self-Harm scale (SM-SH, see Appendix). This is a scale based on the State Motivation scales for Exercise (Kavanagh et al., Under Review) that

assesses current strengths of motivational cognitions about physical activity and is used to inform what level of motivation has been reached to engage in alternative behaviour to self-harm and goal achievement in face to face sessions. To assess risk and adverse events, at the beginning of each session the therapist conducts the Columbia-Suicide Severity Rating Scale (C-SSRS) interview.

** Participants who will be given an Android smartphone (property of MRC CBSU) for use of the Imaginator app during the study, will return this at the end of the last Outcome Assessment. Upon return of the mobile device, researchers will ensure with the participant that all their personal data is deleted from the device and this will be cross-checked and signed off by both researcher and participant.*

5.3.4 Follow-up Phase

5.3.4.1 Follow up and support sessions

The Follow Up phase of FIT lasts for 6 and 3 months for the Immediate FIT+SC and Delayed FIT+SC groups respectively. It involves five support phone calls by one of the research team members over the first 3 months. The first phone support takes place one week after the second FIT session and has approximate 30 min 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 this is felt as useful by the participant, for example discussing how can the different app functionalities be used, personalised and maximised to support the FIT.

Further four phone support sessions are then delivered fortnightly (see Figure 1, appendix). These last approximately 15 mins and focus on further problem-solving, motivational encouragement and discussion of how to maximise the *Imaginator* app use.

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

5.3.4.2 Imaginator app-based support

The *Imaginator* app was developed over six meetings with the Young People Advisory Group (YPAG): 4 young people, 3 females and 1 male, aged 17-21 with a lived experience of self-harm behaviour, together with researchers and app developers from App Shine Development. The Young People Advisory Group tested the app over three weeks and following final feedback and adjustments the final app version was released to the research team for use by downloading from a password protected link.

The *Imaginator* app (see Appendix for screenshots) contains four main functionalities: 'Guided Imagery', 'How am I feeling?', 'My App' and 'Achievements'. These also correspond to icons on the main *Imaginator* app screen.

'Guided Imagery' contains seven audio imagery scripts. These are examples of functional imagery recorded by one of the researchers, based on themes suggested by the YPAG. For example, the group agreed that an alternative behaviour to self-harming that can help manage a variety of distressing emotions is to go for a walk. The 'going for a walk' guided imagery audio guides a participant to close their eyes and imagine vividly a walk in a park. The imagery encourages imagining every step and positive emotions, as a way of planning and motivating the behaviour, as is practiced in the FIT sessions. All the scripts last between 2 and 5 mins and resemble that functional

imagery training practised in session 2 of the FIT intervention. A 'your imagery' audio script is included that guides practicing functional imagery of participants bespoke image/behaviour without a specific content. Therefore the 'Guided Imagery' can be used by participants as templates to keep practising and improving further their functional imagery training. There is also a Breathing Exercise which helps participants to calm themselves through breathing.

'How am I feeling?' supports individuals to engage in helpful responses and plans when they are distressed. By selecting the icon, participants are invited to select a feeling from a drop-down menu and then rate its intensity. Based on the selection the app suggests a range of activities to engage with. Once participants select an activity they are also asked whether they need help, for example by accessing one of their pictures or music, or by listening to some guided imagery.

'My App' allows and encourages participants to upload personal media material as a support for their FIT practice. For example, they can upload pictures, videos and music already present on their smartphone as cues that will help them achieve the target set in the FIT sessions (e.g. if the aim is to engage in a behaviour to regain control over anxiety, they can support this by uploading photographs and music that feel calming). 'My App' also encourages participants to rate the activities that are used by the 'How am I feeling' functionality; by doing this the app can suggest activities in the order based on the individual's ratings and preference.

'Achievements' is a section where participants can activate and personalise a reward system that motivates to use the app. This functionality was designed following feedback from YPAG members who reported that they find apps with some element of gamification (rewards, points etc.) more fun and engaging. By default, participants receive a series of achievement badges on their first use of the 'My App' and 'Guided Imagery' functionalities. The system of badges has been set based on the YPAG recommendations: e.g. a 'gold badge' for 20 Guided Imagery complete practices, but each participant will be able to add their own bespoke achievements, e.g. an additional reward badge after an 'x' number of imagery practices.

Finally, *Imaginator* app has a 'Settings' menu that allows participants to individualise the app, for example by setting reminders, choosing to activate or inactivate achievement badges, setting a 'night time' profile when only indoors activities are suggested etc. There is also an 'Info' section with brief information about the research study, the app, helplines and useful contact numbers.

In summary, the *Imaginator* app is used by participants as a support to keep practising 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'.

5.3.4.3 Outcome Assessments

All participants complete two outcome assessments at 3 and 6 months after randomization. Outcome assessments are completed online on the website www.imaginator.mrc-cbu.ac.uk and over the phone. The online assessment consists of filling in self-report questionnaires (see below). The following phone assessment aims to assess the outcomes related to self-harm, suicidality and health economics, as these are conducted via clinician-rated

measures, and allows checking and completing any self-report questionnaire that might have been missed out online.

Participants receive a text message or email reminder to complete the online assessment on the day before the assessment is due. The reminder includes their username (identification number) and password to log into the website. If participants fail to complete the assessment within 24hrs, they are reminded daily for one week. If participants fail to complete assessments within a week they are called by the researchers. Once online assessment is completed researchers receive a notification and then contact the participant via phone to complete the assessment as detailed above. If participants have difficulties completing the assessment questionnaires online, they can choose to be sent these in the post, with a prepaid reply envelope, or to complete the assessment in person at the MRC CBSU.

At 3 months and 6 months after randomisation for the Immediate FIT + SC group and the Delayed FIT + SC group respectively, 1/2 of participants per group are also asked to come back to the MRC CBSU for a Feedback Interview run by one of the YPAG members or other service user identified via the Patient and Public Involvement group at the CPFT.

5.3.5 Delayed Functional Imagery Training

Participants allocated to Delayed FIT + SC group are informed that they will have to wait 3 months to receive the FIT intervention. At the end of their Baseline Screening Visit, an appointment is arranged for the first FIT session in approximately 3 months' time. 3 months after randomisation and before the scheduled first FIT session participants are asked to complete the outcome assessments following the same procedure as for the Immediate FIT + SC group (see above). If participants fail to complete the outcome assessment on time, the start of the Delayed FIT+SC intervention sessions is postponed until assessment is completed. The FIT sessions, phone support sessions and *Imaginator* app-based support are the same as for the Immediate FIT+SC group.

5.4 Duration of Study

1. Baseline Screening Visit:
    - consent taking: 15 mins
    - eligibility assessment: 45 mins
    - collection of baseline measures: 45 mins
2. FIT intervention sessions (max 1.5 hours each)
3. Follow up support phone sessions:
    - first session: 30 mins
    - sessions two to five: 15 mins
4. Outcome Assessments: 2 x 30 mins online and 2 x 15 mins over the phone
5. Patient's feedback interview: 1 hour

Total duration of contact with research team and time involved in research activities: approximately 9 hours for all participants and 10 hours for participants also undertaking the feedback interview, over approximately six months.

Recruitment from the community will begin as soon as ethical approval is granted; recruitment and intervention within the NHS will begin as soon as NHS R&D approval is granted. Data analysis will take place at the end of data collection. It is hoped to finish collecting data by February 2017. The final report is planned to be prepared by April 2017.

All FIT sessions are audio recorded. At the end of each FIT session the therapist enters brief clinical notes describing the session content on the appropriate electronic notes system of CPFT for participants that are under CPFT care.

5.5 Participant Reimbursement

Participants are reimbursed for their time and travel expenses to and from the Baseline Screening Visit, and for time spent on the Outcome Assessments and Feedback Interview at the standard MRC Cognition and Brain Sciences hourly rate.

5.6 Definition of end of study

The end of study is the date when the last participant enrolled completes the last Outcome Assessment or Feedback Interview.

6. Assessments

This section provides a procedural overview and lists measures in order of administration.

6.1 Baseline Screening Visit

The *Mini International Neuropsychiatric Interview* (MINI)(Sheehan et al., 1998) is a short structured diagnostic interview which explores 17 disorders according to DSM diagnostic criteria. This interview will be carried out by trained researchers. Depending on the number of disorders experienced by participants the time taken for interview varies. In the current sample, it is estimated that the interview will take approximately 45-60 minutes.

The following <u>self-report and clinician rated measures</u> are also collected:

1) <u>Self-harm</u>:
    a) *Single item questionnaire on self-harm frequency*: ''In the last three months, have you tried to hurt yourself on purpose? If yes, how many times approximately?''

Participants are then supported to remember the last 3 episodes of self-harm, describing the method and characteristics of each one, and whether they resulted in intervention by a healthcare professional, using event-cued recall to identify their timing. These episodes are then used to estimate episode frequency. Participants are then asked whether the nature and frequency of these episodes was typical of the last 3 months. These data are then combined to provide an estimate of the total number of episodes over the previous 3 months.

This approach has been widely used to estimate the frequency of substance use (Baker et al., 2001); It is well suited to accurately recording the frequency of behaviours where that frequency may vary substantially across individuals.

b) *Two items questionnaire on self-harm severity*: ''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?''

Participants are first asked to nominate the episode that created the worst injury over the last 3 months, and describe the method and results of that episode of self-harm. This is rated by adapting the Clinician-rated Severity of Nonsuicidal Self-Injury Scale (DSM-5, 2013): non-severe = injuries not requiring surgical treatment (other than cosmetic) or medical intervention; severe = injuries requiring surgical treatment (e.g. sutures) or medical intervention (e.g. charcoal or pharmacological treatment); very severe = injuries requiring resuscitation / intensive care unit treatment. Second, participants are asked to list all methods used to self-harm and the total number is recorded by the researcher.

Clinician researchers will also record the number of admissions to Emergency Departments in Hinchingbrooke and Addenbrookes hospitals via checking the respective hospital electronic records systems.

c) *Visual Analogue Scale (VAS) of self-efficacy on resistance to self-harm when distressed*: 'If you felt each level of distress below, how confident are you that you would not self-harm? Rate your confidence next to each level of distress below, using any number between 0 and 100.'

Participants are asked to rate their self-efficacy (confidence they will not self-harm) on a 0 (= not at all confident / sure I wouldn't harm myself) to 100% (= absolutely confident I wouldn't self-harm) scale, for each level of an 11-items distress scale going from 0 (= not at all distressed or bored) to 10 (= extremely distressed—the worst I can imaging feeling).

d) *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.

2) Clinical and functional outcome measures:

a) *Depression Anxiety and Stress Scale Brief Version* (DASS) (Lovibond and Lovibond, 1995): This is a self-report measure of one week state negative affect and aims to assess symptoms of depression, anxiety and stress. A 4-point Likert scale ranging from did not apply to me at all – NEVER (0) to applied to me very much, or most of the time – ALMOST ALWAYS (3) is used to indicate the extent to which they have experienced each of the symptoms.

b) *Suicidality:* 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.

c) *Medication record*: Medication Summary Sheet listing name, dose and time period of any medication taken over the previous three months

d) *Affective Lability:* Affective Lability Scale (ALS), short version (Oliver and Simons, 2004): This is a self-report measure which assesses affect lability. Items are rated on a 4 point scale ranging between being very undescriptive (1) to very descriptive (4) of the participant.

e) The Warwick-Edinburgh Mental Well-being Scale (WEMWBS) (Tennant et al., 2007): This scale 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.

a) Young People Service Use Schedule (YP-SUS): This semi-structured interview gains information about participant's accommodation, education and employment situation and assesses how much contact with services individuals have had. It is a measure of resources use with a broad societal approach adapted from trials of psychological interventions for adolescents with unipolar depression (Goodyer et al., 2008).

2) Measures of processes related to self-harm

a) *Difficulties in Emotion Regulation Scale* (DERS) (Gratz and Roemer, 2004): This scale assesses clinically relevant difficulties in emotion regulation. Items assess difficulties in the following dimensions of emotion regulation: awareness and understanding of emotions, acceptance of emotions, the ability to engage in goal directed behavior and refrain from impulsive behaviours when experiencing negative emotions and access to emotion regulation strategies that are perceived as effective. It is rated on a five point likert scale ranging from almost never (1) to almost always (5).

b) *Obsessive Compulsive Inventory* (OCI) (Foa et al., 2002): The OCI is a self-report measure for assessing symptoms of obsessive compulsive disorder (OCD) It contains 18 item rated on a 5 point Likert scale assessing the extend to which the item has distressed the participant.

c) *Impulsive Behavior scale* (UPPS-P) (Whiteside and Lynam, 2001): This inventory measures four pathways to impulsive behaviours: premeditation, urgency, sensation seeking and perseverance. It is rated on a 5 point likert scale from agree strongly (1) to disagree strongly (4).

d) *Impact of Future Events Scale* (IFES) (Deeprose and Holmes, 2010): This is a scale assessing the presence of prospective mental imagery ("flashforwards"). The participants will be asked to report three personal future events they have been thinking and imagining during the last 7 days (positive or negative) and then to rate 24 sentences about them on a 5 point Likert scale. The sentences cover three themes: intrusive pre-experience, avoidance and hyper-arousal.

e) *Plymouth Sensory Imagery Questionnaire* (Psi-Q) (Andrade et al., 2014): This test assesses the imagery vividness through seven sets of items (one for each sensory modality plus two sets about general bodily sensation and imagery of feelings). For every set there are 5 items describing the subject to imagine and to be rated on vividness with a 11 point Likert scale (0 no image at all, 10 as vivid as real life).

f) *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).

6.2 Follow-up Outcome Assessments

Outcome assessments are conducted at 3 months and 6 months after randomization.

All outcome assessments (except for the self-harm ones and the YP-SUS, see above for detailed descriptions) are conducted online via the imaginator.mrc-cbu.cam.ac.uk website (the Imaginator website) a dedicated website developed using Wordpress form creator packages such as http://www.gravityforms.com and http://formidablepro.com. The Imaginator website is a custom secure Wordpress install based on an MRC server (with the same website hardening of the MRC CBSU Medical Research Council Cognition and Brain Sciences Unit, MRC CBSU server) with form creators installed as plugins working in conjunction with the main Wordpress install. This results in the Imaginator website being a separate standing website, but hosted on a MRC server, and is administered by named researchers Martina Di Simplicio and Elizabeth Appiah-Kusi and by the MRC CBSU IT and technical personnel. This ensures that no security is breached (access to MRC CBSU website and the Imaginator website is separate and no MRC CBSU information can be accessed via the Imaginator website) and that the Imaginator website and all the data collected on it are under the security protection guaranteed by MRC server standards.

Participants access the Imaginator website via a general https:// address and then are requested to login with their personal login number and password. This directs them to the questionnaires forms that they are due to fill in, which include clinical and functional outcomes measured at baseline (DASS, Medication record, ALS and WEMWBS, see above for detailed descriptions) and measures of processes related to self-harm (DERS, OCI, UPPS-P, IFES, CEQ-SH, see above for detailed descriptions).

Completed questionnaires are recorded under the participant's login number and no personal identifiable information is stored on the website and on the questionnaires. The questionnaire scores are then downloaded by the named researchers in the form of standard CSV files. Each score sheet contains participants' login number and date and time of completion, but no identifiable personal information. Each participant's webform, i.e. a page linked to their personal login number, will be activated upon study enrolment and maintained active until study completion. If participants drop out or stop participation prior to study completion, all mood monitoring data collected will be downloaded and the webform linked to their login number will be deleted. This system ensures data anonymity and confidentiality protection. Scored data are downloaded and kept on the MRC server, as all other study data, in line with data security protection policies.

Participants who chose so may opt to receive the questionnaires as pen and paper copies in the post with a prepaid envelop to send them back completed to the research team, or complete them in person at the MRC CBSU.

The self-harm outcome assessments (*Single item questionnaire on self-harm frequency,* the *Two items questionnaire on self-harm severity,* the *Visual Analogue Scale (VAS) of self-efficacy on resistance to self-harm when distressed* and the SHII), the C-SSRS (using a *Since Last Visit* version that asks about any suicidal thoughts or behaviours since the last time the C-SSRS was administered) and the YP-SUS are collected over the phone as described in 6.1.

The outcome measure of Emergency Department attendance following a self-harm episode will be collected via access to the Emergency Department records of Addenbrooke's and Hinchingbrooke hospitals by the research team (as consented by participants).

6.3 Participant Feedback Interview

1/2 of participants (purposely selected to represent a full variety of demographic characteristics, such as age, gender, education) per each intervention group are invited to come back to the MRC CBSU and undergo a participant feedback interview at 3 months and 6 months after randomization for the Immediate FIT + SC group and the Delayed FIT + SC group respectively. The interviews are led by a member of the YPAG group or other young service user from the CPFT PPI group previously adequately trained by the research team in interviewing skills. User-led interviews hold the advantage of minimising bias as participants feel that they can express their opinion on the intervention and the overall research study more independently and free of any expectation compared to interviews led by a member of the research team. In particular, being interviewed by a peer will ensure a more informal setting and horizontal approach for young people. This should make participants feel at ease to express criticisms and suggestions, and should facilitate the process of eliciting a truthful account of their experience in the study, including comments and ideas for future developments, in the form of an open and constructive dialogue. Interviews take place at the MRC CBSU under the supervision of a research team member that remains available should any queries arise. Interviews are recorded and stored on a secure server as the rest of the outcome measures data and FIT session recordings.

The areas covered by the interview are:

- Subjective experience of a short face to face intervention exclusively focused on management and reduction of self-harm via a cognitive and behavioural approach, including emotional aspects (such enjoyment and frustration) and practical aspects (such as ease of attendance)
- Perceived benefits relative to target of intervention (reducing self-harm) and to general wellbeing
- Difficulties and obstacles in sessions with motivational interviewing and with functional imagery
- Follow up support via phone sessions
- Support via the *Imaginator* app, in particular specific areas of perceived benefits and advantages, difficulties, additional value to phone follow up, disadvantages (practical and emotional)
- Suggestions for improvement on any other aspects of IMAGINATOR procotol

7. Statistics and Analysis

7.1 Sample Size

The sample size has been selected based on sample sizes in similar pilot proof of concept studies developing novel psychological interventions (Litz et al., 2007, Christensen et al., 2013, Månsson et al., 2013). Although previous studies show very good retention in treatment for young people samples, we have adopted a conservative estimate 25% drop-out rate. The aimed sample size is of 40 recruited participants to allow for 32 completed interventions and primary outcome completion (16 per group).

7.2 Statistical Analysis

We will use generalized linear mixed model with a Poisson distribution (which is indicated for count data, such as number of self-harm episodes) with the number of self-harm episodes as the dependent variable, subjects as a random effect with time (baseline vs. 3 months vs. 6 months) and treatment allocation (Immediate FIT+SC vs. Delayed FIT+SC) as fixed effects, and interaction effects of time x treatment allocation, to test that:

(i) there will be a greater reduction in the number of self-harm episodes over 3 months after intervention compared to pre-intervention in the Immediate compared to the Delayed FIT+SC group (primary outcome)

and

(ii) there will be a reduction in the number of self-harm episodes over 3 months also following delayed FIT compared to pre-intervention

(iii) the reduction in the number of self-harm episodes will be maintained at 6 months after intervention in the Immediate FIT+SC group

(secondary outcomes).

A general linear model analysis with the same independent factors will be conducted for the other secondary outcome measures (continuous data for which a linear distribution is assumed) of mood, affective lability, anxiety, wellbeing and quality of life, self-efficacy related to self-harm behaviour, emotion regulation and distress tolerance, impulsivity and compulsivity, craving, impact intrusive future imagery and self-harm imagery characteristics.

To test whether support via the *Imaginator* app is associated with greater reduction in self-harm behaviour, a set of Poisson regression analyses will be conducted with change in number of self-harm episodes and self-efficacy related to self-harm behaviour as dependent variables, and measures of *Imaginator* app use as predictors.

To explore whether measures of processes such as imagery characteristics, impulsivity and compulsivity, state motivation after FIT sessions are associated with treatment outcomes, non-parametric correlation analysis (e.g. Spearman Rank Correlation) will be conducted between the above measures and the primary outcome.

8. Ethics

8.1 Risks and Benefits

8.1.1 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. The study therapist (who is a consultant psychiatrist and CI on the study) has a wide experience in using these techniques in the context of treatment of mental disorders and including for self-harm symptomatology e.g. within bipolar disorder in the research study "MAPP: imagery-focused therapy for Bipolar Disorder" (NRES ref: 13/EE/0174) during which no incidents were reported attributable to the imagery-based therapy intervention for self-harm.

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 *(i) causing increased levels of distress* or *(ii) revealing risk of suicide or other acute psychiatric condition* that may need intervention. 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 the MINI clinical interview at the Baseline Screening Visit (see 4.6);
- being allocated to the delayed intervention condition following randomization (see 5.3.2.3);
- responding to questionnaires during the Baseline Screening Visit and the Outcome Assessments (see 4.6 and 4.8);
- 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 4.7 and 4.8).

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 MINI and other outcome assessments (such as questionnaires including questions about current and past psychological problems, details of self-harm behaviour, alcohol and drugs abuse) 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 engaging in these behaviors or exacerbate distress (Crawford et al., 2011, Deeley and Love, 2010, Muehlenkamp et al., 2010); instead asking about these issues may in fact reduce risky behaviors among high-risk participants (Smith et al., 2010, Gould et al., 2005, Muehlenkamp et al., 2010) and give them an opportunity to contribute to research and to "tell their story" (Biddle et al., 2013).

Secondly, a trained and experienced clinical researcher will conduct eligibility assessment at the baseline screening visit.

Thirdly, the study therapist has wide specific expertise in the use of imagery techniques and in working with young people and will conduct all FIT sessions. The therapist is well trained in delivering treatment, which includes detailed investigation and discussion of upsetting experiences in a way that puts the patient at ease, which is collaborative and perceived as useful and necessary for aiding symptoms resolution by both therapist and patient. Moreover, the therapist is well equipped to make sure that any distressful session ends by the participant feeling supported and endowed with the necessary coping strategies in place to go safely back to their home environment.

The therapist will also supervise the phone support sessions when run by another clinical researcher, and ensure that phone support sessions will end by the participant feeling supported and endowed with the necessary coping strategies in place to go safely back to their daily activities.

Finally, participants will be informed of the randomization procedure and the possibility of being allocated to Delayed FIT+SC prior to consenting to the study, so that they are fully aware they may have to wait for three months to receive any support. All participants allocated to Delayed FIT+SC will be signposted to the standard care support services and reminded of ways to access these and any emergency service.

All researchers will remain sensitive to signs of participant distress at all time and will terminate the MINI clinical interview, the specific intervention and procedure, 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 Visit.

For questionnaires completed online as part of the Outcome Assessments the following procedure is put in place to address any risk of distress following questionnaires completion:

- online questionnaires on the Imaginator website will be only accessible for participants from Sunday to Thursday (in order to allow contact within 24 hrs, i.e. on a working day, if needed);
- completion of questionnaires will generate an automatic email to the research team;
- the online questionnaire session starts and ends with a VAS measuring current affect before and after questionnaires completion on a 0-10 scale; this will allow researchers to check if completing the assessment was associated with a deterioration in the participant's affect;
- at the end of the questionnaires session, participants will be asked on the closing screen whether based on their replies they would like to be contacted by research team within 24 hrs; clicking on the button 'YES' on the screen will generate an automatic email to the clinical researchers, who will then contact the participant and ensure the adequate support measure are put in place.

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 acute intervention (e.g. mania, psychosis), 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:

- adequately assess mental state and risk of the participant once information is disclosed suggesting these may be problematic;
- 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;

- inform the participant's GP and/or other health (consultant psychiatrist, care coordinator etc.) named by the participant at the time of enrolment in the study via phone, email or letter;
- if necessary, liaise directly with local Crisis Resolution and Home Treatment Teams (CRHTT) or the Child and Adolescent Mental Health on-call system following the procedures of CPFT.

For participants referred to the study by a clinician in the CPFT, the clinician referring the patient will inform the team of the current risk levels of the participant before the research assessment, in particular current suicide risk. This will help the research team to ascertain whether any information given during the baseline screening assessment or during a FIT therapy session is not new (and hence already known about and managed by the clinical team) or new, and hence in need of being passed to the clinical team. Specifically, the clinical team already knows of non-suicidal self-injury (which is the reason for referral to the trial). The clinical team may or may not know of suicidal intent or psychotic symptoms, and the participant may reveal that during a study procedure.

If risk is disclosed during a FIT therapy session, the therapist (also CI on the study) will directly proceed as per points above.

If risk is disclosed during the Baseline Screening Visit, during and Outcome Assessment over the phone or during a phone support session run by another clinical researcher than the CI, they will follow the IMAGINATOR study Risk Assessment Procedures (see Appendix): this details when and how they will immediately alert the CI who will ensure the participant is safe and their mental state is taken care of as per points above. If the participant is under CPFT care, this procedure will include that the CI checks the participant's most recent mental health assessment on the CPFT electronic notes system and assess if the identified level of risk is not new (and hence already known about and managed by the clinical team) or new, and hence in need of being passed to the clinical team.

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

In addition to the regular professional skills development and supervision attended by the therapist and clinical researcher in the research team, quality of FIT intervention delivery is also provided by routine specific clinical supervision during the course of the study by Prof Kavanagh and Prof Holmes. This allows individual case discussion, ensures therapist's adherence to the intervention protocol and maintains high quality levels in treatment delivery throughout the study. The CI is a Consultant Psychiatrist in CPFT and is up to date with mandatory training and procedures of the CPFT for risk assessment and management.

8.1.2 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 CPFT mental health services. Participants will receive a support tool, such as the *Imaginator app*, to be used also after study completion.

8.2 Informed Consent

Participants are provided with information about the broad aims of the study, what participation entails, rights to withdraw and terms of confidentiality. It is clearly stated that the participant is free to withdraw from the study at any time for any reason with no obligation to give the reason for withdrawal. The participant is allowed as much time as wished to consider the information, and the opportunity to question the researchers, their GP or other clinicians involved in their care, or other independent parties to decide whether they will participate in the study. Written Informed Consent is then obtained by means of participant's dated signature, and signature of the person who presented informed consent. Consent includes specific consent for anonymised quotes to be reported in publications, for access to participant's Emergency Department records to assess the intervention outcome, and for anonymised data to be shared with other researchers as part of Open Science Frameworks. A copy of the signed Informed Consent form is given to the participant. The original signed form is retained at the study site.

8.3 Participant Confidentiality

Results and data collected during the study are used for the purpose of measuring the efficacy of the new intervention and what factors may influence its success. Data is recorded on research databases for the purpose of statistical analysis of the research outcomes. These databases are anonymised and participants are identified only by a participant ID number on any electronic database.

For data collected online via the IMAGINATOR website identification occurs only via the participant's individual login number, this is the same as their ID number on all research databases. Data will also be collected on participants' attendance to the Emergency Departments (ED) at Addenbrooke's and Hinchingbrooke Hospitals over the duration of the study. This will be done by Dr Caroline Meiser-Stedmann and Dr Martina Di Simplicio who have regular access to the ED databases in their clinical capacity. This data will also be recorded using the anonymized ID number on research databases. A document matching identity and login number is centrally managed by the research team and only accessed by named research team members.

All documents are stored securely and only accessible by study staff and authorised personnel. The study will comply with the Data Protection Act which requires data to be anonymised as soon as it is practical to do so. Participants' confidentiality is only breached in case of the Baseline Screening Visit or other study sessions disclosing information relevant to their health and safety, by communicating this to the participant's GP or other indicated health professional (as detailed above).

As the study entails a treatment procedure, it is important that participation in the study is integrated in the routine mental health clinical care of each patient. For this purpose, records of FIT sessions are written and recorded using the specific clinical data electronic systems present in primary care and in CPFT for those participants who are under CPFT care. This equates to the therapist involved in the study having access to the related patient clinical records in CPFT over the study duration.

8.4 Data Handling and Record Keeping

Paper-based consent forms and participant questionnaires will be stored at the two following study sites: the Medical Research Council, Cognition and Brain Sciences Unit, Cambridge and Liaison Psychiatry Services, Hinchingbrooke Hospital, Huntingdon, in secure storage. All other data will be anonymised. A study specific participant ID number will identify the participant. 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 two study sites. Data completed via the website IMAGINATOR will be downloaded and also stored on network drives at the Medical Research Council, Cognition and Brain Sciences Unit, Cambridge.

The named researchers on the study will have access to participants' contact details while they are taking part in the study.

Analysis of the data from the study will be undertaken by the Chief Investigator, the study statistician Dr Peter Watson and other named researchers. This analysis will take place at the Medical Research Council, Cognition and Brain Sciences Unit, Cambridge.

At the end of the study all the data will be transferred to the Medical Research Council, Cognition and Brain Sciences Unit, Cambridge and stored for a period of ten 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 this time Prof. Emily Holmes will be custodian for the data archived following the Medical Research Council, Cognition and Brain Sciences Unit, Cambridge archiving procedures. Named researchers will have sole access to the data over this time period.

Anonymised data may be made available to other researchers after the end of the study via data repositories such as Open Science Framework. This will be explained to participants in the PIS and Informed Consent form.

9. Finance and Insurance

Financing will be provided by CLAHRC EoE and MRC CBSU.
MRC, in its role of sponsor, will provide indemnity for the research conducted in accordance with MRC Indemnity Statement and Clause 4 of the contract governing such research.

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APPENDIX

Contents

Appendix 1. Imaginator study risk assessment procedures

The study procedures listed below may reveal risk of suicide needing timely intervention:

- responding to the MINI clinical interview at the Baseline Screening Visit (in person), conducted by a research assistant; the MINI interview has a suicidality module, with scores above 8 indicating moderate risk of suicide.
- responding to questionnaires on self-harm during the Outcome Assessments over the phone, and to the Columbia-Suicide Severity Rating Scale (C-SSRS) conducted by either the study therapist (also CI on the study) or research assistant;
- answering questions that investigate details of self-harm behaviour and associated emotions during the FIT sessions (conducted by study therapist) and during the follow up phone support sessions (conducted by study therapist or research assistant).

If a participant discloses thoughts about death during one of the Outcome Assessments over the phone, during one of follow-up phone support calls or during a FIT session, the following set of questions will be asked:

- Have things felt so bad in the last month that you have thought of trying to take your own life?
- (if no, no more questions)
- Have you actually tried to kill yourself?
- Does anybody else know about this? Do your parents or friends / partner know?
- Do you think you might try to take your life in the next few days?

If yes to 'Do you think you might try to take your life in the next few days?' or a score above 8 on the MINI suicidality module, the research assistant speaks to Dr Di Simplicio (study therapist and CI, as well as consultant psychiatrist) before the participants go home/ whilst participant still on the phone.
If yes to 'Have things felt so bad in the last month that you have thought of trying to take your own life?' but no to 'Do you think you might try to take your life in the next few days?' the research assistant speaks to Dr Di Simplicio within 24 hours for advice on how to act. The research assistant also tells the participant that they are going to have to speak to a clinician and clinician may advise contacting the patient's parents/next of kin and GP.
If the patient says they have had thoughts of wanting to be dead but answer no to 'Have things felt so bad in the last month that you have thought of trying to take your own life?' then Dr Di Simplicio and the participant's clinician will be informed at the next available opportunity.

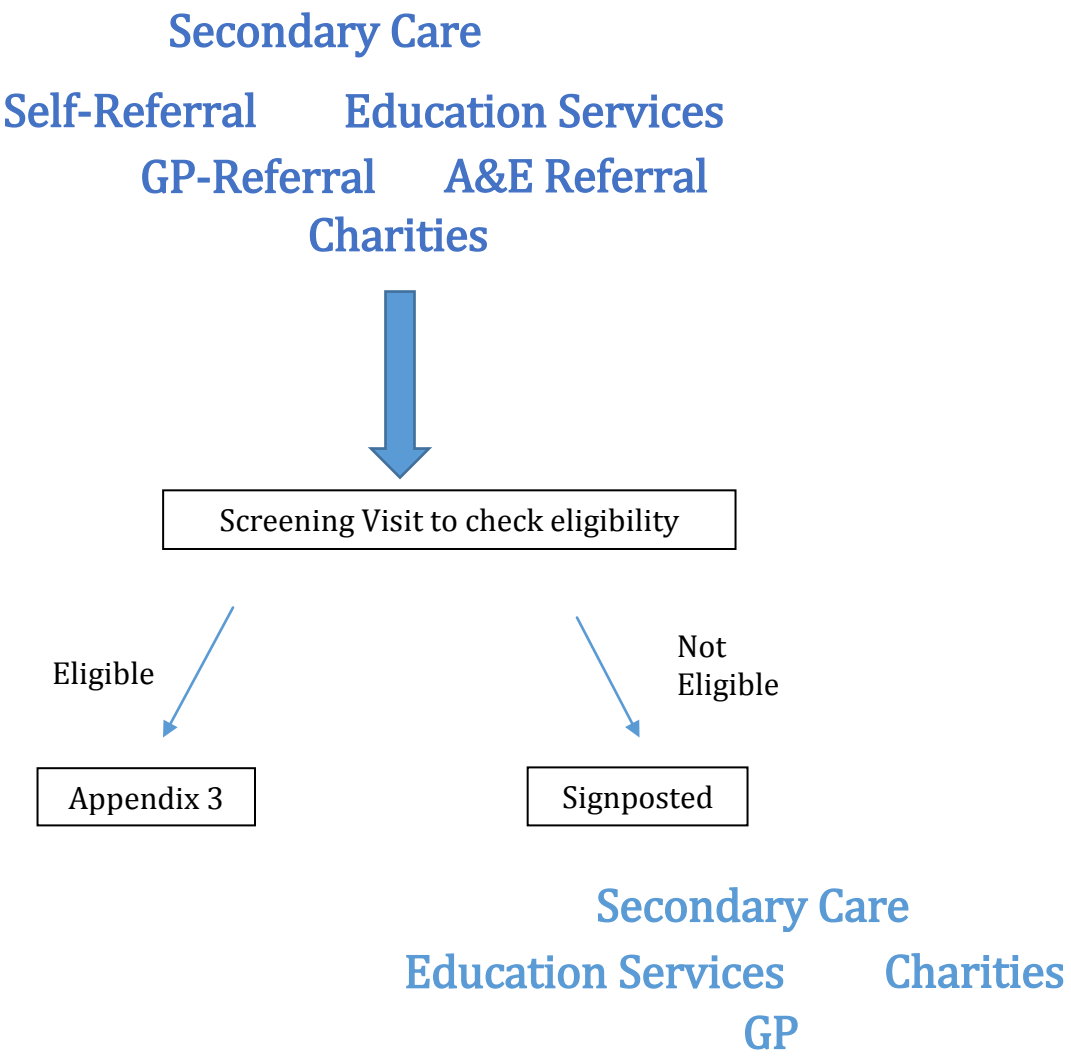
Dr Di Simplicio, once alerted by the research assistant or if detecting suicidal risk directly, will ensure the participant is safe and their mental state is taken care of by:

- adequately completing mental state and risk assessment as needed (including consideration of current risk levels of the participant before the research assessment as known via the participant's CPFT care team referral, when available);
- carrying out all possible interventions to reassure, support, reduce active distress to the minimum possible once this has become apparent;
- agreeing 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;

- informing via phone, email or letter the participant's GP and/or other health professional (consultant psychiatrist, care coordinator etc.) named by the participant at the time of enrolment in the study;
- if necessary, liaising directly with local Crisis Resolution and Home Treatment Teams (CRHTT), or the Child and Adolescent Mental Health on-call system following the procedures of CPFT.

If risk of another acute psychiatric condition that may warrant timely intervention is detected (e.g. mania or psychosis) during the completion of the MINI clinical interview, the research assistant speaks to Dr Di Simplicio who completes the same procedures listed above.

Appendix 2 Referral and eligibility process



Appendix 3 Participants journey through the study once deemed eligible

Randomisation

Month	Week		
	1	FIT Therapy Session 1	
	2	FIT Therapy Session 2	
	3	Phone Support	
1	4	Outcome Assessment	Outcome Assessment
	5	Phone Support	
	7	Phone Support	
	9	Phone Support	
	11	Phone Support	
3	12	Outcome Assessment	Outcome Assessment
	13		FIT Therapy Session 1
	14		FIT Therapy Session 2
	15		Phone Support
4	16		Outcome Assessment
	17		Phone Support
	19		Phone Support
	21		Phone Support
	23		Phone Support
6	24	Feedback Interview	Outcome Assessment, Feedback Interview