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# Exploring intrusive experiences in older people across the spectrum of worry

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## Abstract

**Background**: Worry is theorised to function as a form of cognitive or experiential avoidance wherein an individual uses repetitive thinking in an attempt to avoid a future event or an aversive internal experience. There is evidence of a closer link between non-verbal thought (e.g. mental images) and emotion, physiology and behaviour than with verbal thought. Based on findings that worry is predominantly a verbal-linguistic activity, with less imagery occurring during worry episodes than during relaxation; it is theorised that worriers may move from non-verbal to verbal thought in order to avoid the greater arousal associated with non-verbal thought intrusions. This carries with it the unintended consequence of reducing emotional processing, leading to a subsequent increase in intrusive thoughts. Whilst cognitive science has emphasised the content of cognition and how this links to emotion, the psychological flexibility model suggests that content is less important than how we relate to our cognitive events. The degree to which we get entangled in our thinking, lack perspective on our thoughts and the degree to which cognition comes to regulate our behaviour over other sources is known as cognitive fusion. It is postulated that some individuals may be more prone to avoiding internal experiences due to the stance they take toward these experiences. In the long-term, worry should lead to a reduction in the experience of intrusive images and memories and an increase in intrusive thoughts; and this relationship should vary depending on an individual's stance in relation to their internal experiences. The purpose of the current study is to explore the experience of intrusive memories, images and thoughts in an older adult sample, and the relationship of these experiences to level of worry, cognitive fusion and psychological inflexibility.

**Method**: Sixty-two community dwelling older adults were involved in the study. Each completed questionnaire measures to assess level of trait worry, depression, cognitive fusion and psychological inflexibility, as well as an interview to determine whether diagnostic criteria were met for any mood or anxiety disorder and to complete an interview exploring the experience of intrusive memories, thoughts and images.

**Findings**: Higher levels of trait worry were strongly associated with higher levels of cognitive fusion and psychological inflexibility. Intrusive memories, images and thoughts were all reported in low levels across the sample. Level of worry was positively associated with the severity but not the occurrence of intrusive memories and thoughts. Higher levels of psychological inflexibility were associated with less occurrence of intrusive memories and images; whereas higher levels of cognitive fusion were associated with the increased occurrence of intrusive images. Higher levels of worry, cognitive fusion and psychological inflexibility were all associated with increased severity of intrusive thoughts. The findings are discussed in relation to previous research and to the Avoidance Theory and Acceptance Model of GAD. Implications are considered for further research and clinical applications.

# Contents

# 1. Introduction

## 1.1 Overview

Psychological enquiry has progressed through different stages of what is seen as the main focus of inquiry: through behaviourism, where behaviour was emphasised over thoughts; to the rise of cognitive behavioural traditions, where the content of thought became all important; now moving into so called third wave approaches where there is increasing recognition of the importance of the process of thinking and the way we relate to our thoughts, or the stance we take to them. It is no longer just what we think that is important, but how we think it.

According to the Dual Coding Theory (Paivio, 1971) we are capable of thinking in two distinct forms, verbally and non-verbally. These forms of thought are related to different functions (Paivio, 1991), have different associations with emotional responding (Holmes & Mathews, 2010) and are subject to individual differences in preference for processing style (form of thinking) (Richardson, 1977). Thoughts originating from either system can be initiated under voluntary control or arise outside of this control, intruding into awareness. The extent to which these intrusive thoughts are problematic may relate to an individual's beliefs about their thoughts and the ways in which they respond to them.

Worry is defined as 'a predominantly verbal-linguistic attempt to avoid future aversive events' (Borkovec, 1994, p28). It is known that worry activity, involves predominantly verbal thinking (Borkovec & Inz, 1990) and that intrusive thoughts are a common feature (Borkovec *et al.*, 1983). It has been proposed that worry may serve as a form of cognitive avoidance of negative emotional experience triggered by external or internal stimuli (such as intrusive images) by switching from non-verbal to verbal processing (Borkovec, 1994). It has been further suggested that this represents a form of experiential avoidance that may be linked to the way in which individuals relate to their internal experiences (Hayes *et al.,* 1996).

Across the lifespan it is argued that the repeated practice of processing habits can lead the experience of worry to 'grow' (Hirsch & Mathews, 2012). Older adults have been found to use fewer different strategies for coping with worry than have younger adults (Hunt *et al.*, 2003). This is consistent with

a consolidation of ways of processing information and coping with stressors over a lifetime. It is predicted that links between intrusions, worry and the relationship with, or stance taken to, internal experiences will be most clearly seen in this age group.

This study seeks to explore the experience of intrusive cognitions in the forms of thoughts, images and memories in older adults across the spectrum of worry. Additionally, it is intended to explore how intrusions are impacted by an individual's relationship with their internal experiences and how much they worry.

This thesis will begin by discussing mental representation and the basic forms thought can take. It will then turn to look at individual differences in mental representation and how mode of processing impacts emotion. This will be followed by consideration of another dimension of the thinking process, the extent to which thoughts are intentional (under our voluntary control) or intrusive (outside of voluntary control). There will then follow an overview of the concept of worry before description and critical analysis of two complementary theories of worry and generalised anxiety disorder that have direct bearing on this study. The nature and frequency of worry will then be considered across the lifespan, and the introduction will conclude with an outline of the aims and hypotheses of the present study.

## 1.2 Mental Representation

In order to begin to understand how the thinking process itself may impact our psychological well-being, it is necessary first to consider the different forms that thinking may take. This section will summarise the Dual Coding Theory (Paivio, 1971) and the supporting evidence as well as briefly considering major alternatives.

The basis of Dual Coding Theory (DCT) is that 'cognition is served by two modality-specific systems that are experientially derived and differentially specialized' (Paivio, 1991). The two systems: verbal and non-verbal, deal with linguistic and non-linguistic material, respectively. Paivio (1991) stressed that DCT may more properly be referred to as a multiple coding theory as the non-verbal system encompasses the different modalities of all sensorimotor systems (including, visual, auditory, and haptic or motor). It is visual imagery that has however, received the most attention empirically, which has led some to misunderstand the theory as dealing with visual and verbal systems only (Paivio, 1991).

The verbal and non-verbal systems are proposed to be functionally independent, yet interconnected and able to operate alone or in parallel. The systems can be activated in three ways: directly by external stimuli; through referential interconnections, such that a name evokes the image of the object it refers to and vice versa; and through associative interconnections, the spread of association within a system. An example might be seeing the word dog, this may trigger associated words through a spread of association in the verbal system, and, through referential interconnections, trigger images associated with dogs, which may trigger further non-linguistic or further linguistic associated material. It has been demonstrated that the non-verbal system produces superior recall in memory experiments, and that the two systems operating in parallel produce additive effects, over and above the results of one system operating alone (Paivio, 1991).

Individuals differ in the extent to which they habitually employ one system or the other (Paivio & Harshman, 1983). The predominant use of one system or the other is also determined, among other variables, by the level of abstractness (referring to ideas or qualities rather than material objects; Crozier *et al.,* 2008) or concreteness (relating to things that can be perceived by the senses; Crozier e*t al.,* 2008) of the subject matter. Imagery strategies are found to lend themselves better to consideration of concrete items whereas verbal strategies predominate for abstract items (Paivio, 1991).

A large base of empirical support has accrued over the years since the theory was first put forward (Paivio, 1971). The theory originally arose from empirical findings of the superiority of recall of concrete versus abstract words (e.g. Paivio, 1965), and that this held true when controlling for the meaningfulness of words (Paivio *et al.*, 1968). A factor analytical study including multiple variables thought to influence recall, found that imageability was the best predictor of recall by far, even surpassing concreteness (Paivio, 1968). Further work testing the hypothesis including: the use of pictures versus words (Dilley & Paivio, 1968); experimental manipulation of learning strategy together with strategy reports (Paivio & Yuille, 1969); and repetition trials, demonstrating the additive effect of parallel processing (Paivio, 1975), has further contributed to the evidence base for the theory.

A major criticism of DCT was that the findings could also be explained by depth or elaboration of processing as in the Levels of Processing Model (Craik & Lockhart, 1972) which holds that recall of an item is dependent upon the depth of processing it has been subjected to. This therefore eliminates

the need for a separate non-verbal system. Indeed, deep imagery coding of words is able to eliminate the superiority of picture stimuli in recall tests, however, when opportunities for elaboration are minimised, or when non-imagery elaboration is used, the picture superiority re-emerges (Paivio, 1975). A direct test of predictions arising from both models revealed that both phonemic and semantic processing, which represent different 'depths' of processing, produced equivalent levels of recall as predicted by DCT as both conditions required naming, and this recall was superior to a visual condition that did not require naming (D'Agostino *et al.*, 1977). The authors conclude that depth of processing alone is not sufficient to explain these findings without also considering the dual coding perspective.

Context Availability Theory (Schwanenflugel & Shoben, 1983) has likewise been put forward as an alternative explanation for faster recall of concrete versus abstract items. The theory asserts that concrete nouns are recognised faster than abstract nouns due to greater availaibility of contextual information for concrete words, rather than the non-verbal system proposed by DCT. Abstract nouns are therefore capable of equivalent recognition times when presented in meaningful context, with sufficient verbal information. Numerous studies using different manipulations of abstractness and contextual variables have failed to support predictions made by the model. An example comes from Sadoski *et al.* (2000) who presented sentences and paragraphs varying in abstractness but matched for verbal contextual factors, a large effect of concreteness was found as would be expected according to DCT. Similarly, concrete and abstract words that were presented, either within meaningful sentences or anomalous ones intended to inhibit relational processing, again led to superior recall for concrete words, whereas those presented within the meaningful context would be expected, according to the Context Availability Theory, to produce superior recall (Richardson, 2003). Taken together these findings indicate that contextual availability, whilst it may contribute to understanding of recall, is not, on its own a sufficient explanation.

In summary, dual coding theory asserts that human beings are capable of thinking in both verbal and non-verbal forms. These systems may operate independently but are also interconnected and can operate in parallel. The theory is both grounded in empirical findings and has a large and robust evidence base. The extent to which one processing strategy is employed over the other will vary as a function of task and individual preference. The next section will focus on individual differences in habitual mode of processing.

### 1.2.1 Habitual mode of processing

Put forward by Paivio (1971) and expanded on by others (e.g. Richardson, 1977), is the idea that individuals differ in their habitual mode of processing, generally referred to as the verbaliser – visualiser dimension. Interest in individual differences in processing modes is not new. As long ago as 1932, Bartlett described that those classified as visualisers tended to utilise a more subjective, self-orientation in problem solving, whereas verbalisers showed a tendency to use a more objective task orientation (Bartlett, 1932).

Differences in habitual mode of processing are supported by physiological studies, using breathing patterns, whereby visual imagery is associated with more regular breathing than is verbal thought (Richardson, 1977). The distinction is also supported by neuroscience findings with the authors concluding that 'modality-specific cortical activity underlies processing in visual and verbal cognitive styles' (Kraemer *et al.*, 2009). A correlation was found between self-reported preference for verbal processing and activity in the supramarginal gyrus, whereas a self-reported preference for visual processing was associated with activity in the fusiform gyrus. This is of particular interest given the extensive interconnectedness of the fusiform gyrus with the amygdala, part of the limbic system, important in emotion (Freese & Amaral, 2006).

In summary, individual differences in habitual mode of processing are supported by research findings and relate to different patterns of activation in brain areas. Visual processing, as opposed to verbal, shows activation in brain regions known to be highly interconnected with areas associated with emotion processing. The focus will now turn to the implications of the use of one or other form of processing, in particular the links between type of processing and emotion.

### 1.2.2 Sequelae of mode of processing

It is common for research to focus on visual imagery as, arguably the most accessible form of non-verbal cognition. Mental images, however, can occur in all sensory modalities and are primarily sensory-perceptual representations (Holmes & Mathews, 2010), a "seeing with the mind's eye or hearing with the mind's ear" (Kosslyn *et al.*, 2001, p 635). In contrast, verbal thought relies on human language and may be described as more closely resembling talking to oneself.

There are a number of important differences in how the two systems process information. Whilst images are constrained by their nature as concrete representations (i.e. things that can be perceived

by the senses), verbal thought has the freedom to be more abstract (i.e. existing in thought without a physical existence), therein lying its great adaptive value in being able to go beyond the constraints of the imageable. Verbal thought is however, confined by the structure of language to sequential processing, as opposed to the synchronous processing of non-verbal material (Paivio, 1991).

A key difference, in consideration of the possible relation of modes of thinking to mental distress, is how the two systems relate to emotion. The Dual Coding Theory suggests that emotional reactions are learned experientially and as such are linked to nonverbal objects and events. Through further conditioning, words may come to acquire affective qualities as part of their referential meaning (Paivio, 2013).

It has long been held that imagery is closely linked to emotion. Holmes and Mathews (2010) have gone beyond this general assertion to suggest that at least three possible ways exist in which imagery can evoke emotion. The first of these is by influencing emotional systems within the brain that respond to specific sensory signals (sight, sound, smell etc.) which may be externally generated or, internally generated (i.e. imagery) (Holmes & Mathews, 2010). It is proposed that basic emotional brain systems, such as fear, may respond directly to information in sensory form. This would provide an advantage in allowing an immediate response to threat without accessing slower, deliberate thought processes. Consistent with this, it has been reported that basic emotional responses can be triggered by stimuli outside of conscious awareness (Ohman & Mineka, 2001). Research findings suggest that both cortical and sub-cortical pathways are involved in responding to fear stimuli. This is supported by the finding that the way in which a fear stimulus is processed (attention focused on emotional or non-emotional aspects) modulates activation of brain regions associated with fear and defensive reactions (Mathews *et al.*, 2004), with the extent of modulation depending on how perceptually demanding the task is (Pessoa *et al*, 2002). In addition, anxiety sensitive individuals showed greater activation of associated brain regions indicating greater fear response to stimuli (Mathews *et al.*, 2004).

Emotional systems within the brain (particularly for fear) can respond directly to sensory information from either external stimuli, or internally generated images; and this response can be modulated by thinking processes. Thus, it is plausible that individuals experiencing distress due to internally generated imagery may use conscious thinking processes to shift attention in order to avoid the associated emotion. That the response of brain regions was greater in anxiety sensitive individuals

may suggest that these individuals may be more motivated to shift their attention in order to reduce distress in response to stimuli to which fight and flight responses are not available.

The second proposed mechanism by which imagery is proposed to evoke emotion is, by virtue of similar brain activation patterns, imagery evokes a broad range of emotions as would currently occurring emotional events. The overlap between processing of sensory perceptions and mental images is demonstrated by mutual interference in tasks involving both processes (Baddley & Andrade, 2000; Segal & Fusella, 1969) as well as neuro-imaging studies (e.g. Kosslyn & Thompson, 2003; Kosslyn *et al.*, 2001). Furthermore, it is suggested that mental imagery and direct sensory perceptions may more directly activate brain systems underlying emotions than later evolving symbolic representations (i.e. verbally based representational systems). Studies have demonstrated the activation of brain areas involved with emotion in response to imaged as well as actual stimuli such as facial expressions (Kim *et al.,* 2007) and the imagination of past (Cabeza & St. Jaques, 2007) and future events (Sharot *et al.*, 2007).

The potential of being able to create an image rich in sensory and emotional detail to project ourselves into the past or the future in terms of planning, decision making or reflecting on past experiences is vast. However, individuals who have a tendency to take their thoughts literally or as if they were, in fact the external events they represent, may experience considerable distress associated with such mental events, particularly if they are experienced as difficult to control.

The generation of emotions linked to past events leads to the third proposed way in which imagery elicits emotion: through reactivation of memories containing emotional material. It is suggested that, in the reactivation of autobiographical memories of specific past events, there may be generation of new emotions as well as reactivation of emotions experienced at the time of the remembered event (Holmes & Mathews, 2010). Holmes *et al.,* (2008) asked participants to integrate pictures with captions by producing either an image or a verbal sentence. It was found that images tended to contain personal events and associated sensory information, whereas verbal sentences were based on generic semantic knowledge, consistent with Baddley's (1932) findings with visualisers and verbalisers. It was also found that the emotional effect of imagery was partially mediated by the occurence of autobiographical memories (Holmes *et al.*, 2008).

In a series of experiments aimed at exploring the relationship between mode of processing and emotion, an 'emotional amplifier' effect of imagery was found, compared to a focus on verbal

meaning of the same information (Holmes & Mathews, 2005). Furthermore, the effect was found to hold true for positive as well as negative emotions (Holmes *et al.*, 2006). Interestingly the authors found an actual decrease in positive affect for the positive verbal condition, and this effect has since been replicated (Holmes *et al.*, 2009). The authors suggest that in some conditions verbal processing may actually undermine affective experience due to accessing conflicting information from semantic memory (Holmes *et al.*, 2009; Holmes & Mathews, 2010). A difficulty with this type of research arises from the possibility of parallel processing. It cannot be ruled out that the effects of imagery are the additive result of verbal and imagery processing. In further experiments designed specifically to test this, the results clearly showed that higher ratings of emotions were associated with the extent of imagery use but not the extent of verbal representation (Holmes & Mathews, 2010).

Further support for the differential abilities of imagery and verbal representations to evoke an emotional response comes from measuring individuals' physiological response. This also overcomes some of the difficulties of reliance on self-report for both mode of processing and emotional response which may be open to individuals' expectancy that they 'should' experience a greater emotional response to imagery versus verbal processing. An oft cited study is that of Vrana *et al.* (1986), in which a greater physiological response (heart rate) was found for fear imagery as opposed to neutral imagery or verbal processing (through silent repetition). A difficulty found with use of a repeated measures design was that when the imagery condition was presented first, increases in heart rate elicited continued during the verbal condition, which the authors speculate was due to continued imagery through parallel processing. A replication of the study using independent samples would seem to be warranted to disentangle the findings.

The link between imagery and emotion has implications for emotional distress and, potentially, the development or maintenance of psychological problems. Given that non-verbal thought and emotion are closely linked, it seems plausible that the form of thinking (i.e. verbal or non-verbal), may influence the level of distress associated with unpleasant thoughts and therefore an individuals response to their thoughts and the production of future imagery. In line with this hypothesis are findings that a tendency to avoid emotional expression was associated with lower levels of details in memories and images which may be suggestive of avoidance of emotions associated with the imagined content (D'Argembeau & Van Der Linden, 2006).

The way in which an individual responds to their thoughts, may influence the form and frequency of subsequent thoughts (e.g. the paradoxical rebound effect resulting from suppression; Wegner *et al.*, 1987). The form and frequency of subsequent thoughts and the extent to which they are under voluntary control or are intrusive may influence the level of control one perceives themselves to have over thinking and in turn, their level of psychological distress.

In summary, the degree to which individuals engage in verbal or non-verbal processing styles, as well as the degree to which these thoughts are under voluntary control may be important dimensions in understanding psychological distress. The next section explores the second of these dimensions in thinking; the extent to which thoughts occur outside of our voluntary control.

## 1.3 Intrusive versus intentional thought

Thinking is a powerful tool. Our ability to consider, ponder, plan, weigh up alternatives and revisit experiences through memory, is perhaps what has led human beings to be so evolutionarily successful. Not all thought, however, is intentional, by contrast thoughts described as intrusive or those that 'spring to mind unbidden', occur outside of voluntary control (Holmes & Mathews, 2010).

This form of unwanted thought features in a range of clinical conditions such as post traumatic stress disorder, obsessive compulsive disorder, depression, anxiety (Reynolds & Brewin, 1998) and insomnia and worry (Borkovec, 1985). Intrusive thoughts are normal and almost universal, with up to 99% of participants reporting experiencing them (Freeston *et al.*, 1991) and 13% experiencing them frequently (Belloch *et al.*, 2004). Furthermore, intrusive thoughts in the general population and clinical obsessions are not distinguishable in terms of content (e.g. Reynolds & Salkovskis, 1991; Belloch *et al.* 2004). Rather, differences are thought to lie in the processing of intrusions, response styles (Freeston & Ladouceur, 1993) and appraisals of the significance of the intrusion (Salkovskis *et al.*, 1995).

An investigation of responses to intrusive thoughts in a non-clinical sample revealed three main response styles: no effortful response; attentive thinking; and escape/avoidance. The two groups who employed effortful strategies (attentive thinking and escape/avoidance) were found to be more anxious and have more difficulty removing intrusions (Freeston *et al.,* 1991). In a follow up study linking response style with appraisals it was found that intrusions appraised as low probability and high disapproval tended to trigger escape/ avoidance and those appraised as high probability, low

disapproval tended to trigger attentive thinking. The authors suggest that these patterns may link to obsessive-compulsive problems and worry respectively (Freeston & Ladouceur, 1993).

The appraisal of intrusive thoughts is one aspect of meta-cognition. Meta-cognition may be defined as: "stable knowledge or beliefs about one's cognitive system and knowledge about factors that affect the functioning of the system; the regulation and awareness of the current state of cognition, and appraisal of the significance of thoughts and memories" (Wells, 1995, p. 302). The concept of meta-cognition is being applied to a growing number of conditions, most notably, worry in the form of meta-worry, or worry about worrying. In an exploration of meta-cognition, intrusive thoughts and worry and obsessional thinking (both of which conditions feature negative thought intrusions); meta-worry and thought suppression were found to significantly predict worry, whereas meta-worry and cognitive self-consciousness (awareness of thinking) were found to predict obsessional thoughts in a non-clinical sample (de Bruin, Muris, & Rassin, 2007).

Another form of meta-cognition, the degree to which an individual perceives their thoughts as having special significance has been termed thought-action fusion (TAF)(Shafran *et al.,* 1996). TAF is thought to have two components, firstly the belief that having a thought makes an event more likely to occur and secondly, that having a thought is morally equivalent to committing a forbidden action (Shafran *et al.,* 1996). Studies have found that TAF is higher in obsessional samples (Shafran *et al.*, 1996; Smari & Holmsteinsson, 2001) and that experimentally induced TAF is related to an increase in frequency of intrusive thoughts as well as associated distress (Rassin *et al.*, 1999). Related to TAF, it is suggested that an individual may feel compelled to act on a thought owing to to the belief that one is responsible for harm unless steps have been taken to prevent it (Salkovskis, 1985).

The beliefs an individual holds about thought intrusions they experience and how they respond to these experiences based on their appraisals, influence both the occurrence and severity of further intrusive thoughts. Whilst intrusive thoughts are normal and almost universal, they can become a distressing part of psychopathology due to the stance an individual takes to these experiences.

Intrusive thoughts have been little studied across the lifespan, although what there is suggests that intrusive thoughts remain a common, albeit less frequent phenomenon into later life (Magee & Teachman, 2012; Brose *et al.*, 2011). The use of suppression in response to these thoughts has been found to remain common with increasing age. Older adults, however, report greater suppression effort (Magee & Teachman, 2012). It is thought that this explains reports of less perceived control

over thoughts despite no difference in recurrence of thoughts between younger and older adults. Older adults also report higher levels of postive (Magee & Teachman, 2012) and lower levels of negative affect (Brose *et al.*, 2011) associated with intrusive thoughts which is thought to reflect improved emotion regulation with age (Magee & Teachman, 2012). With regard to the appraisal of thoughts, the same study found that older adults tended to interpret the recurrence of thoughts as a sign of cognitive failure but not of moral failure, in contrast with younger adults (Magee & Teachman, 2012).

Research indicating that older adults tend to use a smaller number of coping strategies compared to younger adults (Wisocki, 1994), may suggest that responses to both external and internal phenomena (such as thoughts and emotions) becomes less flexible with age through repeated use over a number of years. This may suggest that although intrusions are less frequently reported in this age group, patterns of appraisals and response may be more clear in older, rather than younger age groups.

Whilst the majority of research examining intrusive thoughts does not make any distinction between the form the thought is experienced in, recent research by Haganaars *et al.* (2010) suggests that all thoughts may not be created equal. The research points to the idea that intrusive images and intrusive verbal-based thoughts may actually be considered as different phenomena that are developed under different circumstances and may arise from independent memory systems. They found that a traumatic stimulus (as opposed to a neutral one) provoked intrusive images, but not thoughts, as did conditions interferring with processing of the trauma (by preventing participants from moving around). Further more, peri-traumatic anxiety and horror were associated with a higher frequency of subsequent intrusive images, but not thoughts. The authors suggest that this may reflect a two way relationship between imagery and emotion, in that not only does mental imagery elicit emotion (Holmes & Mathews, 2010), but that emotions accompanying an experience have an impact on the subsequent development of intrusive images. Further research is needed to clarify whether there is a special relationship between the emotions of horror and anxiety/fear, as flight emotions and the development of intrusive images or whether this may apply to all negative emotions (Hagenaars *et al.*, 2010).

Intrusive mental imagery has been reported to accompany a number of anxiety conditions. Images tend to be specific to the individual's concerns such as: health related in health anxiety (Wells & Hackman, 1993); involving social situations in social phobia (Hackmann, & McManus, 2000); and

agoraphobic situations in agoraphobia (Day, Holmes, & Hackmann, 2004). A common theme across the disorders is that many images involve memories of things experienced earlier in life. This raises questions as to the role images may play in clinical conditions where, rather than being situation specific, symptoms are present the majority of the time.

Parallels have been drawn between thought processes in depression and generalised anxiety. Both involve repetitive negative thought; depressive rumination tends to be focused on the past, whereas worry tends to be foused on the future (Papageorgiou, 2006). Research on intrusive images in depression has revealed that some depressed individuals do experience intrusive images (just under half of those interviewed), with intrusive memories being most common (Patel *et al.*, 2007). It has also been demonstrated through small case series that working therapeutically with these images can produce significant improvements in mood, without verbal challenging of negative beliefs (Wheatly *et al.*, 2007; Brewin *et al.*, 2009). It is known that intrusive thoughts are a prominent feature in excessive worry in general and generalised anxiety disorder in particular (e.g. Borkovec *et al.*, 1983). Less is known , however of the occurrence and possible role of intrusive images and memories in this condition.

In summary, intrusive thoughts, images and memories are normal experiences that also play a role in clinical disorders including those associated with repetitive negative thoughts, either in the form of worry or rumination. It is thought that an individual's relationship with their thoughts may impact the degree to which they are experienced as problematic. Whilst intrusive images are implicated in a number of anxiety disorders and depression, less is known about how they may manifest in severe generalised worry as seen in generalised anxiety disorder (GAD).

The next section turns to look at worry, beginning by looking at worry as a general concept before considering the relationship of worry to anxiety and normal and pathological forms of worry before turning to theoretical understandings of worry and GAD.

## 1.4 Worry

It is, perhaps, due to the fact that worry is a part of everyday human experience that it did not receive much attention, as a psychological phenomenon, in its own right until the 1980's. It was a team at Penn State University who first turned their attention to worry, and contributed a huge amount to our current understanding (e.g. Borkovec *et al.*, 1983).

This chapter will attempt firstly, to define worry, then describe what we know of this phenomenon in relation to anxiety and its normal and pathological forms. Attention will then turn to theories contributing to our understanding of why and how we worry, finally considering how worry manifests across the lifespan.

Defined simply, worry is 'a predominantly verbal-linguistic attempt to avoid future aversive events' (Borkovec , 1994, p.28). The content typically concerns future events whose outcomes are uncertain, but contain the possiblity of one or more negative outcomes (Sibrava & Borkovec, 2006). It is a unique and, at the same time, universal (or very nearly so) human experience. A form of repetitive negative thinking, it plays a central role in anxiety disorders as well as varying continuously across the normal population (Ruscio *et al.*, 2001).

### 1.4.1 Worry and anxiety

Worry, as would be expected, is closely linked to anxiety and for a long time was considered as the cognitive manifestation of anxiety (e.g. Mathews, 1990). However, there is evidence that the two can be considered as separate constructs. The original validation study for the Penn State Worry Questionnaire reported correlations with a measure of trait anxiety of 0.69 and state anxiety of 0.49 (Meyer *et al.*, 1990), thus immediately allying worry more closely with trait anxiety than current emotional state, and suggesting that, whilst related, trait anxiety and worry are not one and the same.

Davey *et al.* (1992) described the unique sources of variance contributing to both trait anxiety and worry. Worry was found to be characterised by: problem-focussed coping strategies; and information seeking and monitoring coping strategies. Trait anxiety however, was characterised by: poor problem-solving confidence; poor perceived personal control; responsibility for negative outcomes; and avoidance or emotion-focused coping strategies. Both were associated with a tendency to define events as threats.

The above findings suggest that worry may occur in the absence of anxiety and, when it does, may take the form of an adaptive problem-solving process (Davey *et al.*, 1992). Normal worry has been defined as 'mild, transient, generally limited in scope, and experienced by the majority of individuals' (Ruscio , 2002).

### 1.4.2 Pathological worry

Normal and pathological worry exist, not as discrete constructs, but as different points on a continuum (Ruscio *et al.*, 2001). Whilst a great deal of worry research has focused on GAD, pathological worry is not confined to this disorder. In fact, in one study, only 20% of those experiencing pathological levels of worry met diagnostic criteria for GAD (Ruscio, 2002). It is suggested therefore, that there may be additional factors operating on worry in the context of GAD (Holaway *et al.*, 2006) and therefore caution should be used in intepreting the results of studies that have employed different criteria for defining pathological worry.

Whilst worry is central to the current Diagnostic and Statistical Manual (DSM-IV) (1994) diagnosis of GAD, it is thought to play a role more widely, across the anxiety disorders and depression. Whilst GAD is associated with high levels of non-specific worry, in other anxiety disorders worries may take on a specific focus such as social worry in social anxiety disorder or health worry in panic disorder (Wells & Carter, 2001). Elevated levels of worry are also found in Major Depressive Disorder (MDD) (Yook *et al.*, 2010) which is unsurprising given the frequent co-morbidity of GAD and MDD, the close association with rumination (Papageorgiou, 2006) and that worry induction is found to elicit almost equal levels of both anxious and depressed affect (Borkovec, 1994).

In summary, worry is a near universal phenomenon which consists of repetitive negative thought in which verbal-linguistic activity predominates. Whilst closely linked to anxiety, worry may be considered a separate construct with its own unique sources of variance and may be adaptive under certain circumstances. Normal and pathological worry, exist on a continuum throughout the general population, with pathological worry contributing to a wide range of clinical anxiety and mood disorders. The next section will outline and critically examine the evidence for two major theories of worry and GAD as they apply to this study.

## 1.5 Theoretical Understanding of Worry and Generalised Anxiety Disorder

There are many different theoretical accounts explaining all or part of the worry process. It is beyond the scope of this chapter to review them all. This section will outline the Avoidance Theory of Worry (Borkvec, 1994; Sibrava & Borkovec, 2006), and the Acceptance Model of GAD (Roemer *et al.*, 2005) which builds on and extends the understanding of worry as a form of avoidance.

### 1.5.1 The Avoidance Theory of Worry

The avoidance theory asserts that 'worry functions as a cognitive avoidance response, both to perceived threats in the future and to aversive images or other internal experiences, like emotions' (Sibrava & Borkovec, 2006, p 251).

Worry concerns itself with the future, with possible, but currently non-existent negative events, many of which the individual has little or no control over. Because there is no possible behavioural response to avoid the threat, the only recourse is mental attempts to solve or avoid the problem.

Sibrava and Borkovec (2006) make an important disctinction between thought and imagery. As discussed in a previous section (1.2.2) , imagery is closely connected with emotion, physiology and behaviour whereas verbal-linguistic thought is less so (Vrana *et al.*, 1986). As worry consists of primarilly verbal-linguistic thought, it is theorised that, in response to perceived threat, in the external or internal environment (e.g. distressing images), by shifting to abstract verbal-linguistic thinking, somatic activation associated with anxious experiencing can be reduced. This avoidance, thus serves to negatively reinforce the worry process. This however, also serves to preclude emotional processing which leads to increased subsequent intrusions which then serve as a stimulus for further worry.

Another important factor maintaining the worry process is hypothesised to be the presence of positive beliefs about worry. As worried about events rarely come to pass, these beliefs (i.e. that worry will prevent harm) reflect negatively reinforced avoidant behaviour (Sibrava & Borkovec, 2006).

### 1.5.2. An acceptance based model of GAD

The Acceptance Model is based on the principles and theory underlying Acceptance and Commitment Therapy (ACT) (Hayes *et al.*, 1999). The model builds on the concept of worry as a form of avoidance (Borkovec, 1994) but places it within the broader context of experiential avoidance, with worry as one form of such avoidance (Roemer *et al.*, 2005).

ACT, a contextual cognitive behaviour therapy, holds that, how people relate to their internal experiences (thoughts and feelings) better determines their psychological health than the form or content of these experiences (Bond *et al*., 2011).

Psychological inflexibility and in its converse, flexibility, are central to the Acceptance and Commitment Therapy (ACT) model of psychological ill health. Psychological inflexibility refers to the extent to which psychological reactions (or private events) dominate in guiding behaviour over chosen values and the contingencies of the present situation. This often leads to attempts to avoid experiencing unwanted internal events (i.e. experiential avoidance). In contrast, psychological flexibility refers to the degree to which an individual is able to fully contact the present moment and the accompanying thoughts and feelings without unecessary defense, thus enabling them to adapt their behaviour in pursuit of chosen goals and values depending on what the current situation affords. The converse of experiential avoidance is therefore acceptance (Bond *et al*., 2011).

Cognitive fusion is a component of psychological inflexibility and refers to the relationship an individual has with their thoughts (and other internal events). Specifically, it refers to the extent to which an individual is 'fused' to their thoughts or responds to them 'as if' they were an external event or literally true. Phrased another way, cognitive fusion is the dominance of cognitive events as a source of behavioural regulation, relative to other sources of behavioural regulation such as the immediately available contingencies between behaviour and reward (Gillanders *et al*., under review).

In this model, GAD is conceptualised as a disorder characterised by experiential avoidance, explicitly linking the ideas of Borkovec (1994) that worry is a cognitive activity that serves an avoidant function, to the suggestion by Hayes *et al.* (1996) that many clinical disorders may have an experientially avoidant function.

Experiential avoidance refers to attempts to change or avoid difficult internal experiences (thoughts, feelings and physiological sensations), even though this leads to actions that are not consistent with an individual's goals and values (Bond *et al*., 2011). Attempts at experiential control are considered ultimately futile as internal experiences are not under intentional control, likewise, attempts at avoidance are likely to lead to paradoxical increases. Such avoidance is also likely to interfere with the adaptive value of emotions and lead to maladaptive behaviours (e.g. substance abuse, disengagement with valued experiences) (Roemer *et al.*, 2005).

Worry, according to the model, may be viewed as an experiential avoidance strategy reinforced by short term reduction in arousal but carrying with it the long term consequence of maintaining further experiential avoidance due to maintenance of threatening associations. It is further proposed that worry itself may come to be an aversive internal experience in GAD.

The theory builds on the work of Borkovec by placing worry as an avoidance strategy within the larger context of experiential avoidance. The concept of cognitive fusion provides an explanation of why some individuals may come to be distressed by internal experiences or become motivated to avoid them even though the content or occurrence does not differ from individuals who are not motivated to respond in this way. Furthermore the concept of psychological flexibility, along with acceptance as the oppostive of experiential avoidance, opens up new possibilities for therapeutic intervention for problematic worry.

## 1.5.3 Research Findings

### *1.5.3.1 Worry as avoidance*

Central to the argument that worry acts as a form of cognitive avoidance is evidence that anticipatory worry prevents an increase in arousal in response to a stressor; and that worry leads to a decrease in arousal immediately following exposure to a stressor.

A number of studies support the assertion that a period of anticipatory worry is associated with a smaller increase in arousal on exposure to a stressor, than is relaxation (Borkovec & Hu, 1990; Llera & Newman, 2010; Peasley-Miklus & Vrana, 2000). This effect is only found, however, when using the worry/relaxation period as a baseline, and not when using a pre-manipulation baseline (Llera & Newman, 2010; Peasley-Miklus & Vrana, 2000).

Newman and Llera (2011) offer an alternative explanation for findings of reduced response to a stressor. They report that a period of worry (compared to relaxation or neutral condition) resulted in higher physiological activation and negative affect. Subsequent exposure to a fear stimulus, using worry as the baseline, led to less physiological and subjective responding in worry than other conditions. However, there were no differences between conditions in absolute levels of negative emotionality during the stimulus film. This is taken to suggest that rather than allowing avoidance of fearful emotions, the already heightened negative emotionality caused by the worry period prevented further increases in response to fear exposure. They propose therefore, that rather than an avoidance of negative emotion altogether, it is the avoidance of a negative contrast, with the experience of a decrease in negative emotions (e.g. relief when a feared outcome doesn't occur) that serves to negatively reinforce worry. This interpretation is supported by other similar findings

(Peasley-Miklus & Vrana, 2000; Hofmann *et al.*, 2005) along with reports of GAD worriers and controls that worry 'helps' to prepare for bad events (Borkovec & Roemer, 1995).

Findings on the effect of worry following exposure to a stressor are limited. Butler *et al.* (1995) in a general population sample, found that following exposure to a stressor, worry (compared to imagery) was associated with a decrease in anxiety but led to more subsequent intrusive images. Replication of the Butler *et al.,* (1995) study is needed to replicate this finding and to extend the methodology to include measurement of physiological markers, to overcome the limitations involved with reliance solely on self-report.

Stapinksi *et al.* (2010) in a sample of GAD participants, used a study design that combined response to a stressor and anticipation of re-exposure. Both worry and imagery were associated with higher anxiety ratings than relaxation following exposure to a stressor. Worry was also associated with increased skin conductance (indicating sympathetic arousal) following exposure and this was maintained at re-exposure. Consistent with Llera and Newman's (2010) contrast avoidance theory, the authors concluded that worry may produce a state of preparation for threat thus lessening aversiveness when negative outcomes occur.

In the Stapinksi *et al.* (2010) study, there are a number of methodological differences which may make replication of the Butler *et al.* (1995) finding difficult. Firstly, the manipulation period in the Butler *et al.* (1995) study immediately followed exposure to the stressor whereas in the Stapinksi *et al.* (2010) study, a practice manipulation period using a different worry topic preceeded the main manipulation period which may have masked any anxiety reducing effect of the worry condition. Secondly, anticipation of re-exposure to the stressor may have prevented any decrease in anxiety due to the competing demands of recovering from exposure and anticipating further exposure. Thirdly, the stressor was rated as only moderately anxiety provoking in the Stapinksi *et al.* (2010) study which is supported by a lack of significant change in skin conductance or heart rate from baseline to exposure. There was no change in reported anxiety level from baseline to trigger for the worry group and small changes for imagery and relaxation. It is therefore questionnable as to whether the experiment is in fact measuring the response to a stressor in all groups. The lower anxiety ratings for relaxation therefore would appear to result from a reduction from baseline anxiety level for the relaxation condition. These findings are consistent with those of other studies that have

found that a period of repetitive thought is associated with increased anxious and depressed affect (e.g. McLaughlin *et al.*, 2007) without exposure to a stressor.

McLaughlin *et al.*, (2007) found that worry and rumination were both associated with increased anxious and depressed affect and decreased positive affect from baseline both in an unselected sample and those high in trait worry or rumination. Furthermore, they reported that repetitive negative thought was capable of generating negative mood in participants not already experiencing chronic negative affect.

Similarly, Stokes and Hirsch (2010), in a sample of high worriers using self-referent worry topics, found that anxious and depressed affect increased from baseline for both worry and imagery groups. Following a post-manipulation breathing phase, anxious and depressed affect decreased significantly in both conditions, however they decreased further following imagery, than following worry, which may indicate increased emotional processing in the imagery condition.

Over an extended period of worry versus positive or neutral repetitive thought Behar *et al.*, (2012) found that anxious affect decreased from the first to the third of five worry periods (22.5 minutes total worry period) and then increased. By contrast, repetitive thinking on a neutral topic produced increasing levels of anxiety over the course of the manipulation with end levels of anxiety higher in the neutral, than in the negative worry condition (Behar *et al.,* 2012). This study did not include a baseline measure of anxious affect, however, the first period levels of anxious affect reported in the worry condition were higher than in the neutral condition, it can therefore be inferred that anxious affect increased from baseline to the first worry period before decreasing. The increase in anxious affect over the manipulation period for the neutral conditions was interpreted as consistent with findings that reptitive thought can increase anxious and depressed affect (e.g. McLaughlin *et al.*, 2007). There is however another possible interpretation. The neutral condition was different from both positive and negative conditions in that it involved world events rather than a personally relevant event, which may explain why thoughts samples for the neutral condition were rated as more abstract than other conditions. It is possible that this level of abstraction of thinking may itself have led to an increase in anxious affect or that abstract thinking on the designated topic became increasingly negative and anxiety provoking over the manipulation period. Given that participants were asked to consider economic consequences and cultural ramifications of a world event, it seems plausible that this may have led to a series of 'what if..?' type questions akin to a worry process.

Initially it seems that studies using self-referent topics and without exposure to a stressor may be closer to the naturalistic worry experience in day to day life. However, this does not take account of the occurrence of events (external and internal) that lead to an increase in anxiety and so serve as triggers for worry. Exposure to an experimental stressor, either following a period of anticipation, or followed by a period of recovery may therefore more closely approximate the triggering of naturalistic worry. In studies that do not include an experimental stressor, the conjuring up of a worry topic in order to initiate a worry period may function as the trigger and explain the initial increase in anxious and depressed affect from baseline to worry. An extended period of worry following this initiation may therefore approximate the recovery after a stressor as seen in the Butler *et al.* (1995) study. The subsequent increase in anxious affect over an extended period of worry supports the findings of studies of intrusions following worry periods (e.g. Butler e*t al.,* 1995; Stokes & Hirsch, 2010) that worry may maintain anxious meanings and interfere with emotional processing. Based on the findings of York *et al.*, (1987) it may be predicted that over a longer still worry period (e.g. 30 minutes) emotional processing may have been facilitated leading to a further decrease in anxiety.

Another key aspect of the avoidance function of worry is the hypothesis that imagery (with its close links to emotion) will produce a greater increase in anxiety than will worry. Findings are inconsistent on this topic. Studies that have involved exposure to a stressor prior to a worry period have found, in line with the theory, that worry has led to lower anxiety levels than imagery (Butler *et al.* 1995; Nelson & Harvey, 2002). When asked to worry about a self-chosen worrisome topic, the expected difference has not emerged (Stokes & Hirsch, 2012). One possible reason for this is that mood ratings taken at the end of a period of imagery may actually reflect habituation to an initial increase in anxiety. Another explanation, as described above is that in the absence of a specific stressor or trigger for worry, in order to initiate a worry episode it is necessary to conjure up a worry topic (possibly by creating an image or verbal description of the topic), over a short manipulation period a difference in anxiety between conditions may therefore not be expected. A study by Behar (2005) compared anticipatory worry in verbal and imagery form and found that verbal worry was associated with higher anxiety than was imaginal worry. This is consistent with the interpretation of the findings of anticipatory anxiety tasks above, that anticipatory anxiety may serve to prepare an individual for a stressor by preventing a negative contrast, rather than by avoiding negative affect.

Further research is needed to bring clarity to this area using frequent ratings of affect and with longer manipulation periods. It is also possible that intentional imagery does not provoke the same

emotional response as the intrusive imagery that may be involved in naturally occuring worry episodes, which may approximate more closely to exposure to a stressful visual stimulus such as a film clip or aversive imagery.

***Summary***

Apparently contradictory research evidence concerning the avoidant function of worry may, firstly, reflect different functions of worry in anticipation of and recovery from a stressor. Findings are consistent with worry serving to prepare for the occurrence of a threat and to avoid a negative contrast as suggested by Llera and Newman (2010). Secondly, the temporal effect of worry on negative affect, anxious affect in particular, may be reflected in studies finding an initial increase in anxious affect from baseline (e.g. Stokes & Hirsch, 2010) which may approximate exposure to a stressor or naturalistic worry trigger, followed by a decrease in anxious affect which may reflect recovery from a stressor (Butler *et al.* 1995; Behar *et al.* 2012) through avoidance of negative affect, followed then by an increase in anxious affect (Behar *et al.,* 2012) which may reflect increased emotional processing over longer periods of worry as reported by York *et al.* (1987).

This interpretation is supportive of the avoidant function of worry, with the acknowledgement that anticipatory worry may function as avoidance of a negative contrast rather than absolute avoidance of negative affect. Further research is needed to explicitly test these hypotheses and disentangle the findings of different research methodologies.

There is some evidence that imagery does produce a greater anxiety response in some circumstances than does worry, as would be predicted by the theory. Further research is required to replicate these findings and clarify under what circumstances this does in fact occur.

#### *1.5.3.2 Worry as experiential avoidance*

Above are summarised findings that worry serves to prevent negative contrast and avoid negative arousal following exposure to a stressor. There is also evidence that imagery may lead to greater anxiety than does worry, so supporting the theoretical assertion that worriers switch to verbal-linguistic activity to avoid affectively laden imagery.

This section examines evidence that worriers are more inclined to use experiential avoidance more generally, as described in the Acceptance Model. Initial support for a model incorporating experiential avoidance and fear of emotion, comes from several studies finding fear of anxiety and

experiential avoidance to be associated with both worry and GAD severity (Roemer *et al.*, 2005; Roemer *et al,.* 2009). Moreover, experiential avoidance was found to have a small unique relationship with GAD symptomatology when controlling for worry, and a separate significant relationship with worry (Roemer *et al.*, 2005).

Greater distress about emotions and greater experiential avoidance was reported for a clinical sample compared to a non-clinical sample, with distress about anxiety and experiential avoidance accouting for unique variance in intolerance of uncertainty, which has previously been found to be related to GAD (Gentes & Ruscio, 2011), and worry severity (Lee *et al.*, 2010).

These preliminary findings are supportive of the model, however, they must be interpreted with some caution owing both to the reliance on self-report methodologies and the lack of control for comorbid disorders. Further studies exploring the relationships between worry and experiential avoidance and psychological flexibility would appear to be warranted to replicate and extend existing findings to other age and demographic groups as well as comparing clinical and non-clinical worriers. Studies incorporating measures of related ACT variables such as cognitive fusion may also help to delineate the processes involved in experiential avoidance in worriers.

#### *1.5.3.3 Worry and thought*

Worry is predominantly verbal as opposed to non-verbal activity, both for clinical populations of worriers and 'normal' worriers (Borkovec & Inz, 1990). This predominance of verbal thought is more pronounced for those diagnosed with GAD, and is apparent even during periods of relaxation (Borkovec & Inz, 1990). Images that do occur during GAD worry periods are briefer (Hirsch *et al.*, 2011).

Related to the verbal-linguistic content of worry, the worry process has been found to be more abstract than other types of thinking and, in an experimental situation, this has been found to be a function of the degree to which the topic is of concern to the individual (Stober & Borkovec, 2002). Behar *et al.* (2012) found that the thinking process becomes increasingly abstract over a period of repetitive thinking regardless of the valence. Counter-intuitively, neutral repetitive thought was found to be more abstract than either positive or negative conditions; negative thought was more abstract than positive thought with a medium effect size (*d*=.58), however this result did not reach significance. Examination of the prompts for each condition suggests that the topic intended to be

neutral, which related to world events, may itself have been more abstract than either positive or negative conditions which both related to the self (see discussion in section 1.5.3.1).

There are a number of consequences hypothesised to arise from the verbal nature of worry including a reduction in emotional processing (Wells & Papageorgiou, 1995) and a reduction in attentional capacity available for other tasks which may serve to maintain the worry process (Leigh & Hirsch, 2011). The following section will consider implications for emotional processing.

#### *1.5.3.4 Worry and emotional processing*

Support for the hypothesis that worry interferes with emotional processing comes from several strands of research. This section will consider habituation to phobic stimuli and the occurrence of intrusive thoughts in the context of worry.

A presentation of a phobic stimulus usually results in a strong emotional reaction both subjectively and physiologically. Repeat presentations over a period of time lead to a reduction in this response, with degree of reduction postulated to relate to degree of emotional processing (Foa & Kozak, 1986). A period of worry, prior to exposure has been found to suppress the cardiovascular response to the phobic stimulus (Borkovec & Hu, 1990; Borkovec *et al.*, 1993) without suppressing the subjective fear experience, thus preventing successful habituation of the response over repeat presentations.

Intrusive thoughts have long been argued to result from a failure of emotional processing (Rachman, 1980). It is suggested that individuals engage in repetitive verbal thought as a method of cognitive avoidance of affect laden imagery, so reducing arousal in the short term; with the consequence of inhibiting emotional processing, thus leading to frequent negative thought intrusions (Borkovec *et al.*, 1983). The long-term failure to emotionally process material may lead to ongoing emotional and physiological arousal, which may in turn lead to more worry, and consequently more intrusions (Sibrava & Borkovec, 2006).

Consistent with the arguement that worry blocks emotional processing are the results of several studies in which processing strategy was manipulated following exposure to a distressing film. Worry compared to imagery, resulted in more subsequent intrusive thoughts (Butler *et al.,* 1995; Stokes & Hirsch, 2010). Wells and Papageorgiou (1995) went beyond these findings and, following exposure to a distressing film clip, compared: worry about the stressor; unrelated worry; imagery about the stressor; a distractor task; and settling down as usual. It was found that the number of intrusions over

the following three days was highest for worry about the film, followed by unrelated worry, distraction, imagery and lowest for settling down as usual. The authors concluded that worry can both inhibit emotional processing and additionally, that the difference between number of intrusions following worry about the stressor and unrelated worry resulted from 'tagging' of threat-related material in memory such that the period of worry serves to increase the availability of related material in memory.

A post manipulation check in the Butler *et al.* (1995) study, revealed that the instruction to worry (compared to an instruction to use imagery) led to the expected results without a difference between groups in the actual amount of time engaged in worry or imagery (according to self-report). This poses an intriguing question regarding the mechanism for the observed effects. The authors speculate that the manipulation served to modify attentional strategies to focus on either worry or imagery although both strategies were already engaged (Butler *et al.*, 1995). Stokes and Hirsch (2010) excluded data from participants who did not report spending the majority of the manipulation period engaged in their designated form of mentation. It would be interesting therefore to compare the findings from the study with and without the excluded data.

Given that different conditions in the Butler *et al.* (1995) study led to the expected results this may indicate that intentional strategies were engaged as instructed, with intrusive thoughts or images accounting for the time spent in the non-instructed mode. There is some support for this interpretation from post-manipulation data. Participants in the worry condition reported that images occurring during worry were spontaneous intrusions that they paid little attention to (Butler *et al.*, 1995). This may suggest that whilst habitual processing mode may be overcome for intentional thought, it may continue to dominate in the case of thought intrusions. Further research making a distinction in post-manipulation checks between intentional and intrusive strategies may reveal important information on the mechanism of such effects. Gaining information on participants habitual processing style may also help to disentangle the findings.

The studies cited above have all employed short worry periods (4 minutes, 4 minutes, and 5 minutes respectively) (Butler *et al.*, 1995, Stokes & Hirsch, 2010, Hirsch & Mathews, 2012). This is of interest as worry has been shown to have a curious ability to incubate or habituate negative intrusions depending on the amount of time spent worrying. Whilst brief periods of worry will lead to an increase in subsequent negative intrusive thoughts, long exposures will produce a reduction (York *et*

*al.*, 1987). Borkovec (1994) suggests that this incubation effect indicates that worrying can be 'self-perpetuating under certain temporal conditions and suggests that whilst short periods of worry delay emotional processing, this may not be true for extended periods of worry. This is consistent also with findings of Behar *et al.* (2012) (described in section 1.5.3.1) that worry led to a decrease in anxiety followed by a subsequent increase. Given that excessive worriers report worrying for long periods of time, this finding is counter-intuitive. Borkovec *et al.* (1983) suggest that the feeling of pervasive worry actually reflects the frequent triggering of brief worry periods rather than continuous worry. This is consistent with an avoidant function of worry, with individuals using brief periods of worry to reduce arousal and, either switching topic, or distracting themselves with external stimuli before their arousal level increases.

In summary, worry appears to reduce anxious responding to a stressor (distressing film or phobic stimulus) in the short-term but with the paradoxical effect of increasing intrusive thoughts in the longer term. This is generally accepted to result from a blocking of emotional processing due to the verbal nature of worry. The blocking of emotional processing may occur for short worry periods, with longer periods of worry leading to an increase in arousal facilitating emotional processing and a decrease in subsequent intrusions.

#### *1.5.3.5 Disengagement with values and goals*

Related to experiential avoidance is the concept of valued action and the idea that experiential avoidance comes at the cost of cutting an individual off from activities and actions that are valued by them. Michelson *et al.* (2011) found that treatment seeking GAD individuals reported significantly less valued action than controls and that this was not fully accounted for by depression comorbidity. Valued action was also found to contribute a unique variance to quality of life in GAD.

These preliminary findings are supportive of the Acceptance Model of GAD, further studies may show whether this is specific to GAD, related to worry more generally, or a feature of psychopathology more generally.

#### *1.5.3.6 Worry and meta-cognitions*

Both positive beliefs about worry (Avoidance Theory), and worry as an aversive experience (Acceptance Model) are combined in the meta-cognitive model of GAD (Wells, 2006).

The Meta-cognitive Model proposes that individuals with GAD hold both positive and negative meta-beliefs about worry. When faced with a problem, owing to their positive beliefs, worry is selected as a coping strategy. Positive beliefs therefore serve to motivate the use of worry initially, and whilst they are not in themselves seen as a marker of pathology, they can lead to an over-reliance on worry as a coping strategy (Wells, 2006). Both individuals with GAD and non-anxious controls have been found to hold positive beliefs about worry in relation to determining ways of avoiding or preparing for negative events, to superstitiously reduce their likelihood, to problem solve or motivate action. Only the belief that worrying helped to distract from more emotional topics that they did not want to think about characterised GAD participants and not controls (Borkovec & Roemer, 1995) which suggests an avoidant function of worry for these individuals.

The Acceptance Model proposes that worry itself becomes an aversive experience over time. In Meta-Cognitive Theory it is described that over time individuals develop negative meta-cognitive appraisals of worry, its controllability and consequences. When these beliefs are triggered during a worry episode, they lead to meta-worry, or worrying about worry (also known as Type 2 worry), with emotional and physical symptoms increasing anxiety and the sense of threat.

Meta-worry (the tendency to view worry itself as aversive or harmful) has indeed been found to be more strongly associated with pathological worry than has ordinary, worry (Wells & Carter, 1999, 2001). Individuals with GAD have been found to endorse both positive and negative beliefs about worry (Davis & Valentiner, 2000). Ruscio and Borkovec (2004) in a comparison of GAD and non-GAD high worriers found that positive beliefs about worry are universal, awareness of thoughts was found to vary with worry severity. Negative beliefs about worry were however, reported to be distinctive of GAD.

In summary, positive beliefs about worry as described in the Avoidance Theory have been found to be universal. The belief that worrying helps to distract from more emotional topics has been reported to distinguish between GAD and non-GAD worriers (Borkovec & Roemer, 1995). That worry itself becomes an aversive experience over time is supported by research on meta-worry (or worrying about worry). Meta-worry has been found to be more strongly associated with pathological worry than worry about everyday topics (Wells & Carter, 1999, 2001).

#### *1.5.3.7 Therapeutic applications*

A therapy based on the Acceptance Model, Acceptance Based Behaviour Therapy (ABBT), has received preliminary support in an open trial (Roemer & Orsillo, 2007), a small wait list control trial (Treanor *et al.*, 2011) and a small RCT (Roemer *et al.*, 2008) comparing ABBT to wait list control group. Impressive results of 78% of patients no longer meeting GAD criteria and 77% meeting criteria for high end-state functioning have been reported with 9 month follow up showing maintenance of gains or further improvement (Roemer *et al.*, 2008).

Treatment was found to impact GAD symptomatology and experiential avoidance as well as impacting on valued action (Michelson *et al.*, 2011), fear of emotions, emotion regulation, intolerance of uncertainty and perceived control over anxious emotions (Treanor *et al.*, 2011) when elements designed specifically to address these concepts were incorporated into treatment. These studies are particularly interesting because, unlike most mainstream therapies for GAD, ABBT does not specifically target worry and indeed post-treatment Penn State Worry Questionnaire (PSWQ) levels are still above the cut off used by many studies to classify problematic worry. It will be interesting to see from further studies therefore whether the mechanisms of change are the crucial distinguishing factors between high worry and GAD.

In one study focusing on mechanism of change in ABBT, Hayes et al. (2010) found that both acceptance of internal experiences and engagement in meaningful activities were related to responder status and that change in these factors predicted outcome above and beyond change in worry. Change in acceptance was also related to reported quality of life at post treatment.

### *Summary*

Worry functions as a form of avoidance of aversive internal or external stimuli in some circumstances and of negative contrast in emotional responding in others. Preliminary findings suggest that GAD is characterised by experiential avoidance and are in line with the hypothesis that worry may act as a form of experiential avoidance. Worry in general is associated with positive beliefs about worry, whereas GAD is associated with both positive and negative beliefs about worry, supporting the assertion that worry itself becomes an aversive experience. GAD is associated with disengagement from values and goals and has been found to respond well to an acceptance based treatment.

## 1.6 Worry across the lifespan

There is a paucity of research into worry during childhood but from the little that has been done it is clear that worry is common in children and adolescents with a large percentage of children sampled reporting some worrying (Orton, 1982) and 15 per cent in one study reporting excessive levels of worry (Bell-Dolan *et al.*, 1990). Gender differences in worry also begin in childhood with girls being found to worry significantly more than boys (Bell-Dolan *et al.*, 1990). With increasing age, the variety of worries increases and the content of worries is found to become more abstract, increasingly involving psychological and social issues rather than the concrete physical concerns of younger children (Muris *et al*, 2002; Weems *et al.,* 2000).

This social basis of worry continues into adulthood (Lindesay *et al.*, 2006) with social-based worries being the best predictor of the global tendency to worry (Ladouceur *et al.*, 2002). Other major worry topics such as finances and housing, work and health vary over the lifespan (Lindesay *et al.*, 2006), depending on the most salient issues for each life stage (e.g. Borkovec *et al.*, 1983). Gender differences persist, with women showing a tendency to worry more than men and with women outnumbering men in diagnoses for GAD by approximately two to one (Wittchen *et al.*, 1994). One study has suggested that this may be accounted for by the greater tendency of women to report the use of thought suppression and negative problem orientation (Robichaud *et al.*, 2003).

Gender differences are found, not only for GAD, but also depression. Unlike worry, differences in depression emerge only in adolescence (Nolen-Hoeksema, 2001). The gender difference is partly accounted for by the tendency to ruminate which has been found to prolong and intensify dysphoric mood episodes and increase the risk of developing depression (Nolen-Hoeksema, 1999). This may be taken to suggest that the processes underlying depression and GAD, rumination and worry, may be used as coping methods from childhood or early adolescence for girls moreso than boys and reflect a tendency toward inward-focused rather than action-based coping (Nolen-Hoeksema, 2001).

There is broad agreement that older adults, in general, report fewer worries overall, with around 15 per cent describing themselves as worriers (Powers *et al.*, 1992; Wisocki, 1994). It has been found that those who are ill or housebound worry more than their healthy and active counterparts (Wisocki, 1994) and there is some evidence that worry may increase among the oldest old (Neikrug, 2003). However, the overall prevalence rate for GAD is lower in those over 65 than for younger age groups (Blazer *et al*, 1991).

It has been reasoned that differences in worry rates among older adults may be due to a number of factors including: survival biases; cohort differences; the development of wisdom; and changes in coping strategies (Wetherell, 2006). Whilst we know that levels of worry are lower among older adults in general, it is not clear how this translates to an individual basis, whether individuals are worrying less as they age (due to factors such as change in coping strategies) or whether those who worry excessively are less likely to reach old age (survival biases). In one focus group study, the majority of older adult worriers felt that worry had intensified over their lifespan rather than decreasing (Wisocki *et al.*, 1998). This finding would tend to support the latter hypothesis, that those who worry excessively are less likely to reach old age. In reality there is likely to be multiple reasons for the reduction of worry in older age and indeed there is also some evidence that the use of coping strategies does change with age. One study reported that younger adults use a greater number of different coping strategies than do older adults, with older adults most commonly endorsing keeping busy and maintaining a positive attitude. This suggests, either that older adults have less need to employ coping strategies, or that, over time, they have tended to select the coping strategies that are perceived to work for them (Hunt *et al.*, 2003).

Whilst some studies report that health is the most prominent worry topic among older people (e.g. Wisocki *et al.*, 1986) other studies have highlighted issues related to aging as the main area of concern (Ladouceur *et al.* 2002). Whilst there is general agreement that social concerns are lower than for other age groups, a strong correlation between social concerns and tendency to worry remains (Ladouceur *et al.* 2002). Differences in findings between studies may reflect methodological differences or cohort differences, due to the differing age ranges used by different studies, spanning several different cohorts. As in other age groups, differences in worry content have not been found to distinguish between GAD and non-GAD groups (Diefenbach *et al.*, 2001).

In summary, worry is a common phemomenon across the lifespan, and is problematic for some individuals from childhood, through adulthood and old age. Pathological worry, in the context of anxiety disorders is a long term problem with only 3 per cent reporting onset of anxiety symptoms in old age and with average duration of anxiety disorders increasing with age (Blazer *et al.*, 1991). There is also anecdotal evidence to suggest that for individuals who experience high worry, worry intensifies with age (Wisocki *et al.*, 1998). Within the general population however, less worry is reported by older adults (Wisocki, 1994).

In the context of the present study, it is relevant that anecdotally, at least, worriers report that worry intensifies over their life span which is consistent with the assertion that, due to repeated use of processing habits worry can 'grow' over time (Hirsch & Mathews, 2012). The finding that older adults tend to use a smaller number of coping strategies than younger adults (Hunt *et al.*, 2003) is also consistent with a picture of a consolidation of ways of processing information and coping with stressors over the course of a lifetime.

## 1.7 The present study

Thinking can occur in both verbal and non-verbal modes and the extent to which an individual uses one or the other depends partly on the task at hand and partly on preference for processing style (Paivio, 1991). Little is known about what influences preference for processing style or how this may relate to psychopathology. Worry is accepted to be a predominantly verbal-linguistic process and it is theorised that it may function as a form of cognitive or experiential avoidance of internal experiences including intrusive images and the associated emotions (Borkovec, 1994; Roemer *et al.,* 2005). It is not currently known whether this may be influenced by, or influence an individual's preferred processing style.

Intrusive thoughts are a normal experience, the impact of which depends on the way an individual appraises and responds to these experiences (e.g. Rassin *et al.*, 1999; Salkovskis *et al.*, 1995). Little is currently known about the experience of intrusive thoughts, memories and images across the spectrum of worry, across the lifespan, or other factors that may influence whether worry is used in an attempt to avoid intrusions. Intrusive thoughts are known to occur in excessive worry which is hypothesised to occur due to the effect of worry on emotional processing (e.g. Butler *et al.*, 1995). Little is known however about the way in which intrusive thoughts and images differ in respect to their relationship with the tendency to worry.

Both worry and intrusions are known to occur from childhood onwards. It is argued that through repeated use of processing habits and coping styles, these tendencies and styles of thinking will be consolidated over time. It is therefore expected that an older adult population would provide an opportunity to study 'well rehearsed' individual styles of processing information and responding to internal experiences.

In order to better understand processes that contribute to an individual's tendency to worry, the current project will explore how the presence and nature of intrusive experiences (memories, images and thoughts) may relate to individuals tendency to worry across the spectrum of worry severity.

Psychological inflexibility and cognitive fusion will be measured to determine the contribution of these factors to worry tendency and the experience of intrusions.

Given the chronicity of the tendency to worry, it is likely that an older adults sample will have a long duration of their level of worry. It has been shown that people use fewer coping strategies in old age (Hunt *et al.*, 2003); and has been proposed that processing habits, and so the tendency to worry, can 'grow' over time (Hirsch & Mathews, 2012). It is therefore predicted that links between these factors will be shown most clearly in this age group.

## 1.8 Hypotheses

1) The presence and severity of intrusive memories and images will decrease as worry scores increase.
2) The presence and severity of intrusive thoughts will increase as worry scores increase
3) Cognitive fusion, psychological inflexibility and worry together will better predict the likelihood of reporting intrusions than worry alone.
4) The relationship between level of worry and intrusion severity will be accounted for by level of cognitive fusion and psychological inflexibility.

# 2. Method

## 2.1 Design

The study adopted a cross sectional design, with levels of trait worry, cognitive fusion and psychological inflexibility as predictor variables and the experience of intrusions (presence and severity) as outcome variables.

## 2.2 Power calculation and sample size

The study will explore the relationship between level of trait worry, cognitive fusion and psychological inflexibility and the experience of intrusions. As this is exploratory in nature, there are no studies available for direct comparison.

There are established links between some of the study variables. Previous research links worry with experiential avoidance (a component of psychological inflexibility) for which large effect sizes have been reported (r=.57) (Roemer et al., 2005). Worry has been demonstrated to result in increased intrusive thoughts following exposure to a stressor (F=.4, large effect size) (Stokes & Hirsch, 2010). Experimental induction of thought action fusion, related to beliefs about intrusion, has also been shown to result in an increase in subsequent intrusive thoughts (t-2.8, r=.6, large effect size). By contrast, a period of worry is linked to reduced imagery compared to a period of positive thinking, and is reduced still further in GAD patients compared to controls ($F^{2=}$.59, large effect size) (Hirsch *et al.,* 2011).

To summarise, previous research demonstrates large effect sizes for relationships between: worry and experiential avoidance; worry and intrusive thoughts; thought-action fusion and intrusive thoughts; and worry and reduced imagery. In light of these established links, it seems reasonable to predict medium to large effect sizes in the current study.

According to Cohen (1992) for an alpha level of .05 and power of .8, a sample size of 26 is needed to detect a large effect size, whilst a sample of 85 is needed to detect a medium effect size, in a regression based analysis with three independent variables.

## 2.3 Participants

A total of 62 participants were recruited. Participants were recruited through both community groups and organisations and clinical settings (mental health services). This was intended to provide greater representation of the full spectrum of worry rather than focusing solely on high or low worrying groups.

The term older adults covers a broad range of ages and several generations, in order to increase the representativeness of the sample, a wide variety of community groups and organisations were contacted, catering for different adult age groups.

Inclusion and exclusion criteria were developed in order to maximise the representativeness of the sample whilst safeguarding patients who may become distressed by the study process, not be able to provide full informed consent, of whose needs could not adequately be met by the restrictions on the study process (e.g. the need for translators).

***Inclusion criteria***

- The participant must be residing in a community setting either in their own private home or warden controlled accommodation.
- The participant must be aged 60 or older to be classified for study purposes as an older adult.
- The participant must be fluent in spoken and written English in order to cope with the demands of the study.

***Exclusion criteria***

- The participant self-reports cognitive impairment, to the extent that day to day functioning is impaired.
- The participant currently misuses drugs or alcohol.
- The participant has experienced a recent bereavement or trauma (past year).
- The participant reports current suicidal ideation.
- The participant meets criteria for a diagnosis of post-traumatic stress disorder.

Difficulties with memory or thinking were discussed during the informed consent process to determine their extent and impact on functioning. The other exclusion criteria were determined as part of the Structured Clinical Interview.

Individual's participation in the study was entirely on a voluntary basis, no fee or reward was offered for taking part.

## 2.4 Recruitment strategy

Participants were recruited through opportunity and snowballing sampling, as outlined below. As the intention was to recruit participants across the spectrum of worry recruitment was carried out across both community and clinical settings.

### *Community settings*

Participants were recruited predominantly through community centres, groups and organisations, although friends and family were also asked to pass details of the study to anyone over 60 they may know who may be interested in taking part.

Area managers of community services for older people within the target area were contacted and they agreed to pass on information about the study to individual centres. This was followed up by contacting individual centres, and, where appropriate dropping into groups and activities for the target age group. This ensured that information was communicated directly to service users.

When visiting community groups the chief investigator spoke to the group as a whole to briefly introduce the study and was then available, along with an assistant to answer individuals' questions or provide more detailed information for those interested in taking part.

Recruitment was widened to include two further geographical areas and contact was made with community and resource centres for older people as well as organisations likely to include members of the target age range such as adult learning centres, Rotary Club and Women's Institute. The researcher met with groups in person, though for some groups, introduction to the study was via electronic communications.

### *Clinical settings*

The chief investigator met with the Care of the Elderly multidisciplinary team and it was agreed that professionals within services in two local hospitals would identify patients on their caseload who may

meet diagnostic criteria for Generalised Anxiety Disorder (GAD). Clinicians were asked to provide the participant information sheet and to invite appropriate patients to contact the chief investigator if they were interested in taking part or wished to find out more about the study.

More detailed information and reminders were then sent via email to representatives of the different professional groups in attendance at the meeting, including Psychiatry, Occupational Therapy and Nursing. In addition a separate email was sent to colleagues working within the Older People's Psychology Services, with regular reminders and updates.

Due to low numbers of patients identified as meeting the study criteria the decision was taken to expand recruitment in the following ways: it was decided to provide more regular updates and reminders to staff, in person where possible, with details of numbers recruited to date and numbers still to recruit; a leaflet was developed to provide a more accessible initial introduction to the study; the inclusion criteria was expanded, with clinicians asked to provide information on the study to all patients presenting with clinical levels of anxiety rather than solely those likely to meet criteria for GAD. This decision was taken, as diagnostic uncertainty seemed to be leading to reluctance amongst clinicians to pass on details of the study for fear of being over-inclusive. The decision was also taken to expand recruitment to other areas in Scotland. Psychology departments in a further three health boards were contacted to assess their willingness to become involved in recruitment.

Due to service demands and populations served it was possible to expand recruitment to only one further health board. Contact was made with the Clinical Psychology service for older people within the new health board. It was agreed that recruitment would initially involve only one area team. As this strategy did not result in sufficient numbers of patients meeting the study criteria receiving the study leaflet, recruitment was expanded to include all area teams as well as colleagues in nursing and psychiatry.

## 2.5 Measures

### 2.5.1 Structured Clinical Interview for DSM-IV: Screening questionnaire, Anxiety Module, Depression Module

The Structured Clinical Interview (SCID-I) for DSM-IV is a semi-structured interview for determining whether an individual meets criteria for the major Axis 1 disorders according to the Diagnostic and

Statistical Manual-version four (DSM-IV). It is designed to be administered by a trained researcher or mental health professional (First *et al.*, 2002)

The SCID is comprised of separate modules for each class of diagnosis and it is recommended that interviewers should not administer a SCID which contains diagnoses they will not be assessing (www.scid.org/info/guideline.html, n.d.; retrieved Oct, 2012). This allows for the elimination of whole modules that are not relevant to the study being conducted, or the elimination of questions pertaining to subtypes if these are not needed. This results in a briefer version specific to the study being undertaken, thus minimising researcher and participant time.

For the current study, the decision was taken to include the screening questions along with the anxiety and depression modules.

### *Reliability and Validity*

There is a difficulty in determining the validity of the SCID which lies in the lack of an alternative 'gold standard' interview or instrument for comparison. Thus the SCID is currently compared to 'best estimate diagnosis' using the 'LEAD' standard, that is made based on a longitudinal assessment (L), done by expert diagnosticians (E), using all data (AD). The time and labour intensive nature of completing this type of assessment means its practical use is limited. However approximations of the procedure have been used in several studies and have demonstrated superior validity of the SCID over the standard clinical interviews at intake episode (e.g. Basco *et al.*, 2000, Fenning *et al.*, 1994, Kranzler *et al.*, 1996).

Studies of the reliability of SCID diagnoses have reported wide ranging results due to the many factors that influence the reliability of this type of instrument, including the design (joint interview or test/retest), the population sampled, and the training of the interviewer. Of relevance to this study are the values reported for major depressive disorder (MDD) kappa=.66, **(**Lobbestael *et al.*, 2010) kappa =.61, .81 (Zanarini *et al.*, 2000)) and generalised anxiety disorder (GAD) kappa=.75 (Lobbestael *et al.*, 2010), kappa =.44, .63 (Zanarini *et al.*, 2000)). Kappa is a statistic that corrects for chance agreement with values above .75 considered good, from .41 to .75 fair to good, and below .41 poor (Fleiss *et al.*, 2003). Agreement on diagnoses for MDD and GAD in the reported studies is therefore considered either fair to good or good.

The SCID for DSM-IV is currently used as the gold standard for research (e.g., Sheer *et al.*, 2000, Steiner *et al.*, 1995) in determining whether participants meet diagnostic criteria for the disorder/s in question. Self-report measures such as the Penn State Worry Questionnaire and the Geriatric Depression Questionnaire have been shown to discriminate well between clinical and non-clinical populations (see later descriptions), though were not developed as diagnostic measures. The decision was therefore made to use the SCID-I to explore the presence of anxiety and mood diagnoses in this sample.

### 2.5.2 Intrusions interview

The intrusions interview is a structured interview developed by Trishna Patel and colleagues for a study of imagery in major depression (Patel *et al.*, 2007). The interview consists of three sub-sections relating to memories, images and thoughts. In the first section (pertaining to memories) participants were asked to report 'any spontaneous autobiographical memories that kept coming to mind over the past week from a past event' (Patel *et al.*, 2007). If the last week was not typical they were asked about a typical week. If participants did not report intrusive memories they were asked to think back to a time when they had felt most depressed, and to report on their recollection of intrusive memories during that week. In a variation from the original methodology of Patel *et al.* (2007), if participants in the current study did not report any memories they were asked to think back to when they felt most worried or anxious (rather than depressed) and whether they experienced any intrusive memories at that time.

The total number of intrusive memories was recorded for each participant with the two most frequent and distressing being explored further in the interview. Participants are asked when the episode in the memory occurred and their age at the time as well as to briefly describe the content.

Participants were asked to rate on visual analogue scales from 0 to 100 the vividness of each memory; the extent to which different emotions accompanied the memory (such as anger, guilt, anxiety, helplessness); the 'sense of 'nowness' and re-experiencing of emotions and physical sensations that were present in the original event; and the average amount of time the intrusion usually lasts (seconds, minutes, hours). In the event that participants reported more than two emotions, they were asked which they considered to be the two predominant emotions linked to the intrusion in cases where this was not clear from intensity ratings.

Participants were asked to rate each memory (also on a 0-100 scale) on a further four dimensions, frequency, distress, uncontrollability and interference with daily activities. In a later study, these four questions were found to have internal consistency alpha levels ranging from .90 to .95 (Brewin *et al.*, 2009). These ratings were summed to provide a composite severity score, as described by Brewin *et al.* (2009).

The same questions were repeated for intrusive images and intrusive thoughts (for thoughts participants were asked to rate the degree to which the thought was the same each time, in place of rating vividness, and the degree of reliving was not inquired about). If a participant reported that they did not experience the phenomena that was being asked about, after clarifying understanding of the definition of the phenomena, the remaining questions from the sub-section were discontinued and instead the interviewer moved on to the next sub-section.

These sections were administered in a fixed order, however, if a participant reported an experience relating to a different sub-section to the one that was being administered, their complete response was recorded in the appropriate section before returning to the previous point in the interview schedule.

Following initial interviews it was decided to make minor alterations to the wording of the first imagery question, to maximise reporting of intrusive images and to add in two further questions. As the interview did not provide any information on the participants' habitual mode of processing, and it was not considered justifiable to include an additional measure, it was decided to include one question from the Verbalizer-Visualizer Questionnaire (VVQ) (Richardson, 1977). Participants were therefore asked 'are you aware that your thinking often consisting of mental pictures or images?', if they responded in the negative then this was clarified by asking 'are you aware that your thinking ever consists of mental pictures or images?'. Changes were approved by LREC and local NHS R&D departments.

### *Use*

The original study for which the interview was developed involved a UK sample of 66 adults between the ages of 24 and 61 years who had been referred for a study of the cognitive treatment of depression (Patel *et al.*, 2007). A later treatment outcome study involving ten patients between 30 and 56 years old also used the intrusions interview as a baseline and follow up assessment tool (Brewin *et al.*, 2009).

To the author's knowledge, this interview has not before been used with older adults. There is however, no content or wording expected to be problematic for older adults.

### *Alternatives*

Due to the exploratory nature of this study and the need to compare participants' experience of intrusive memories and images, there was no known alternative to the intrusions interview.

The possibility of developing an interview schedule specifically for the current study was considered. However using an existing measure was deemed preferable as the intrusions interview was expected to provide sufficient data to investigate the study hypotheses and would also have the advantage of allowing comparison with existing published research on a different patient population.

## 2.5.3 Penn-state worry questionnaire

This is a 16 item self-report questionnaire measuring trait worry (Meyer *et al.*, 1990) developed in the US. Respondents are required to indicate on a five point scale how typical or characteristic statements are of them.

### *Reliability and validity*

The measure was originally developed in 1990 due to the identified lack of an instrument to measure trait worry, and it is in wide use today. The original paper reporting the development and validation of the measure reported a series of studies using US samples of college students. The authors reported good internal consistency across three separate samples with over 750 participants (mean $\alpha$=0.94). Females scored significantly higher than males across the first two samples ($p<0.002$, $p<0.01$ respectively). The authors reported test-retest reliability over two weeks (n=56, *r*=0.75), four weeks (n=52, *r*=0.74) and eight to ten weeks (n=45, *r*=0.92). Cohen (1992) summarises effect sizes for *r* as: small for *r*=>10, mediums for *r*=>30 and large for *r*=>50. By these criteria, there is a large effect size for the test-retest reliability of this measure.

The measure was found to correlate more strongly with the trait section of the State Trait Anxiety Inventory (n=389, *r*=0.64, large effect size) than with the state section of the same measure (n=395, *r*=0.49, medium effect size) or the Beck Depression Inventory (n=154, *r*=0.36, medium effect size). The measure was found not to be significantly influenced by social desirability as measured by the Marlowe=Crown Social Desirability Scale (Crowne & Marlowe, 1964) (n= 163, *r*= -0.09).

The scale was found to be capable of discriminating between those meeting full, partial and no criteria for GAD (n=392) using Scheffe post hoc analysis. Those meeting criteria for GAD also scored significantly higher than participants meeting criteria for post-traumatic stress disorder ($p<0.02$), indicating that the measure is able to discriminate between healthy and anxious populations as well as between two different anxiety disorders (Meyer *et al.*, 1990).

The measure has also been used widely with older adult populations and the psychometric properties for this group have been investigated.

An initial investigation of the psychometric properties of the measure was carried out with a US sample of older adults 47 of whom met criteria for GAD and 94 controls, aged 55-82. The study revealed good internal consistency ($\alpha$ =.80 to .89) and significant correlations with other measures including the Worry Scale (r=.43) and the state (r=.40) and trait (r=.58) subscales of the State Trait Anxiety Inventory. The overall psychometric properties were concluded to be adequate for use in older adult populations (Beck *et al.*, 1996).

A later replication and expansion of the earlier study was conducted using a sample of 57 older adults between the ages of 60 and 80, who met criteria for GAD diagnosis according to DSM-IV criteria. The authors reported similar findings with respect to internal consistency ($\alpha$=.83) and interrelations with other worry and anxiety measures (r=.45-.55). In this study the measure was also found to have good divergent validity, with only weak correlations with the Beck Depression Inventory (r=.16) and the Geriatric Depression Scale(r=.24). It was also found to be unrelated to demographic variables, unlike content related measures (Stanley *et al*, 2001).

Older adults have been found to report significantly lower scores than their younger counterparts and this difference holds across both unselected community dwelling older adults and patients with GAD (Hopko *et al.*, 2003). A cut off has been suggested of 50 for the 16 item version and 22 for the abbreviated version for optimal prediction of GAD diagnosis (Stanley *et al.*, 2001).

### *Versions and use*

The PSWQ is one of the most widely used measures to assess level of worry for both clinical and research purposes. The ease of use of the PSWQ has been questioned, particularly for older adults. It has been suggested, based on indications in two treatment outcome studies, (Stanley *et al.*, 2001; Wetherell *et al.*, 2003) that older adults may have difficulty in interpreting the meaning of the

reversed items, thus leading to questionable reliability of responses to these items. In response to these concerns, a shortened eight item version has been developed which is reported to correlate strongly with the full-length version (r=.92) and to have similar psychometric properties (internal consistency.α=.87, test-retest reliability *r*=.63) (Hopko *et al.*, 2003). Whilst these results are promising, this preliminary study was carried out with a relatively homogeneous sample, the majority of whom were female, aged 65-70 years and high functioning. The authors therefore suggest that further validation of the eight item version is needed, particularly with respect to its generalisability to more diverse population. It was therefore decided to use the 16 item version for the purposes of this study.

#### *Alternatives*

A self-report scale capable of measuring trait worry in an older population was sought, and the following alternatives were considered along with the PSWQ:

The Worry Scale was developed specifically for older adult populations (Wisocki *et al.*, 1986). It is a 35 item self-report questionnaire and assesses worry over three different domains. As it is longer than the PSWQ and not specifically a measure of trait worry it was deemed unsuitable for inclusion in the study.

The State-Trait Anxiety Inventory can provide separate scores for state and trait anxiety, and has been found to correlate well with the PSWQ, particularly the trait score (Meyer *et al.*, 1990). The measure is however, subject to copy right restrictions and therefore not freely available for use.

The PSWQ is a measure of trait worry with adequate psychometrics for use in an older adult population. It is a relatively short measure which is similar in format to two other measures being included in the study. The PSWQ is also widely used in both research and clinical practice which allows for comparison of the study sample with samples used in other research. The scale is also not restricted by copyright, is freely available and simple to score.

### 2.5.4 Geriatric Depression Scale

This self-report questionnaire was developed specifically as a screening tool for depression in older adults (Yesavage *et al.*, 1983). Respondents mark either yes or no to indicate whether statements have applied to them in the past week. The original scale comprised of 30 items, however a shorter 15 item version is in wide use today and even shorter 10, 5 and 4 item versions have been developed.

The 30, 15 and 5 item versions will be discussed below. The scale was originally developed in the US but has since been translated into many different languages and is widely used around the world for clinical and research purposes.

### *Reliability and Validity*

For the original validation study, for the 30 item measure, the scale was completed by 60 older people under treatment for depression and 40 community dwelling controls. The GDS was found to have good internal consistency (α .94), and good test-retest reliability ($r$=.85, p<0.001). The scale was found to be significantly correlated with other validated measures of depression: the Hamilton Rating Scale for Depression (Hamilton, 1960) ($r$=.80, p<0.001); and the Zung Self-rating Depression Scale (Zung, 1965)($r$=.84, p<0.001). The scale was also found to be able to effectively discriminate between classifications of severity of depression determined by correlation with the Research Diagnostic Criteria (RDC) for major affective disorder (Spitzer *et al.*, 1978) ($r$=.82, p<0.001) (Yesavage *et al.*, 1983).

A briefer 15 item version was developed for situations where time was a consideration (Sheikh & Yesavage, 1986). In the original validation study for the GDS-15, the sensitivity to accurately detect cases of depression was reported at 92% and specificity, that is the ability to correctly classify non-depressed respondent's, at 89%. The shorter version is highly correlated ($r$=.84, p<0.001) with the original, longer form (Sheikh & Yesavage, 1986).

In a recent meta-analysis comparing the 30 and 15 item versions, Mitchell *et al.* (2010) analysed a total of 17 studies in primary care. The GDS-30 (7 studies) was found to have a sensitivity level of 77.4% and specificity of 65.4%. Whilst the GDS-15 had a sensitivity level of 81.3% and specificity of 78.4%. The fraction of cases of depression correctly identified by the GDS-15 was found to be significantly higher than the 30 item version (p<0.0001). Based on their analyses, the authors recommended the GDS-15 item, but not the 30 item for screening late-life depression in primary care (Mitchell *et al.*, 2010).

The GDS-15 has also found to be of use in many other settings including inpatient (Lester & Berryhill, 1994) and care homes (Marc *et al.*, 2008) where it was found that diagnostic accuracy was not influenced by the severity of clinical or functional factors or sociodemographics. It was therefore suggested that the GDS-15 is a useful measure for screening diverse older adult populations.

The five item version (GDS-5) was developed from the 15 item version by selecting the five items most highly correlated with a clinical diagnosis of depression. In a sample of 74 frail, community dwelling older people, the GDS-5 was found to have a sensitivity of 97% (compared to 94% for the GDS-15) and a specificity of 85% (compared to 82% for the GDS-15). There was significant agreement found between depression diagnosis and scores on the GDS-5 (kappa = 0.81) (Hoyl *et al.*, 1999).

In order to minimise the time burden, and potential fatigue of study participants, the 15 item version was considered to offer the best compromise of time efficiency whilst still providing a measure of the severity of the depression or sub-threshold symptoms, which shorter versions, whilst useful for screening purposes, are not able to do (Almeida & Almeida, 1999).

### *Alternatives*

Other self-report measures in popular use with older adults include the Hospital Anxiety and Depression Scale (Zigmond & Snaith, 1983) and the Beck Depression Inventory –II (Beck *et al.* 1996). These scales where therefore considered along with the Geriatric Depression Scale for inclusion in the study both to provide a screen of, and a measure of severity of, symptoms of depression.

The Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983) was developed specifically for use in populations with physical ill health. The likelihood of living with a long term condition increases with increasing age the inclusion of somatic symptoms of depression has been found to be problematic in older adult populations (Yesavage *et al.*, 1983). It was therefore considered preferable to use a measure that did not heavily rely on somatic symptoms, which indicated the HADS as worthy of further consideration particularly as the HADS is widely used as a screening measure. In a clinical population of older adults, although strong correlations were found with other measures at initial assessment (*r*=.51-.54) and again at final assessment (r=.73-.79), they were not as high as has been found with other measures, this was particularly the case with initial assessments. The authors concluded that while the HADS may be a useful adjunct to other scales, the correlations were not of a magnitude to justify using the HADS as an alternative to other measures (Flint & Rifat, 1996).

The Beck Depression Inventory, second edition (BDI-II) (Beck *et al.*, 1996), was developed for use with ages 13 years and up. Whilst there was concern about the use of the original BDI (BDI-I) with older people due to the number of somatic symptoms included (Segal *et al.*, 2008), the BDI-II was developed with older, as well as younger adults, in mind and older adults were included in the original

study of the psychometrics of the scale (Beck *et al.*, 1996). With a sample of 376 community dwelling adults (n=229 age 17-29, n=147, age 55-90) good internal consistency was found for both younger (α .92) and older adults (α .86). There was no significant difference in mean score between the younger and older age groups (M=9.21, M= 7.63 respectively, p>.05) (Segal *et al.*, 2008).

However, this author's experience of using this measure in clinical practice echoes the concerns of Yesavage *et al.*(1983) that a more complex response format (in this case a forced choice between different categories of severity) and the inclusion of somatic symptoms (such as energy level) may cause difficulties in some older adults. There was a concern this could potentially lead to missing data if participants left out items they considered as not relevant to themselves, such as items relating to a decline in sexual function, which is common in non-depressed older adults (Yesavage *et al.*, 1983), or were unable to choose between responses, as may be anticipated in highly anxious participants. Use of the BDI-II is also restricted under copyright which made this a less favourable measure for inclusion in the study.

The Geriatric Depression Scale – 15 item (GDS-15) was considered as most closely meeting the needs of the study for a self-report measure allowing both screening for, and providing an indication of symptom severity of, depression in a community dwelling older adult sample. As the scale was specifically designed for use with older adults, it does not rely on somatic symptoms and is therefore not confounded by respondent's physical ill health. The scale was also developed with a simple yes/no response format making it very easy to complete, it was hoped this would minimise missing data through difficulties in finding the 'right' response category.

### 2.5.5 Acceptance and Action Questionnaire version two (AAQ-II)

The Acceptance and Action Questionnaire version two (AAQ-II) was developed as a short, seven item, self-report measure of psychological inflexibility and experiential avoidance (from now on referred to only as psychological inflexibility) as central to the Acceptance and Commitment Therapy model (ACT model) (Hayes *et al.*, 2004).

The scale has seven items and respondents are asked to indicate on a seven point scale (from never true to always true) the degree to which statements are true for them. Higher total scores indicate greater psychological inflexibility.

The AAQ-II measures the same concept as the AAQ-I (*r*=.97) but has improved on the psychometric problems of the first version. The measure has good internal consistency (mean α .84), and good test-retest reliability has been reported at both 3 months and 12 months (*r*=.81 and .79 respectively) (Bond *et al.,* 2011).

The AAQ-II is significantly correlated with scales measuring related concepts such as The White Bear Suppression Inventory (WBSI) (Muris *et al.*, 1996) (*r*=.59-.63), the Beck Depression Inventory (BDI-II; Beck *et al.*, 1996) (*r* =.70, .71) and the Beck Anxiety Inventory (BAI; Beck *et al.*, 1988) (*r*= .61) but the strength of association is not so high as to suggest they are measuring the same constructs. Hayes *et al., (*2004) noted that these correlations were as would be expected given that the AAQ-II cuts across several specific strategies and response domains to measure a more broad-based psychological phenomenon (Hayes *et al.,* 2004). The measure was found not to be significantly influenced by social desirability as measured by the Marlowe-Crowne Social Desirability Scale (MCSD) (Crowne & Marlowe, 1964) (r=-.09). Of relevance to the current study is that, although no psychometric data has been reported for older adults, no effect of age on mean score has been found within samples including participants under 21(n=35) and 51 and over (n=21) (Bond *et al*., 2011).

### *Alternatives*

A measure was sought that looked at how participants related to their own internal experiences. Alternatives include the Thought Control Questionnaire (TCQ) (Wells & Davies, 1994) and the White Bear Suppression Inventory (WBSI) (Muris *et al.,* 1996). As these relate specifically to thought control strategies and the use of thought suppression, respectively, these, and similar measures were considered too specific for the present study. Instead, a measure was sought that provided information on how an individual relates to a broader category of internal experience, including, but not limited to, thoughts. For this reason the AAQ-II was identified as a short, easy to complete measure that could provide information about an individual's relationships to their own thoughts, emotions and other internal experiences in one measure. The authors of the AAQ-II have also given permission for the copying and use of the AAQ-II for research and clinical purposes.

## 2.5.6 Cognitive Fusion Questionnaire (CFQ)

The Cognitive Fusion Questionnaire is a recently developed short self-report measure. Cognitive fusion is defined as 'the tendency for behavior to be overly regulated or influenced by cognition, compared to other sources of behavioural regulation, such as contact with direct contingencies'

(Gillanders *et al*., under review). Cognitive fusion includes believability of thoughts, dominance of cognitive events within a person's awareness, taking thoughts and beliefs literally and responding to cognitive events as if they were an external reality.

The scale has seven items and asks the respondent to rate on a seven point scale (from never true to always true) the degree to which each statement is true for them. Both the layout of the scale and the response format is the same as the AAQ-II.

Psychometric data has been reported for a number of separate samples totaling over 1800 participants. The authors report good internal consistency (mean α=.89) and good test-retest reliability over a one month period (r=.81, p<0.001). One of the samples tested (Dementia care givers) included older adults with a mean sample age of 68.6 years (sd: 11.5) and a range of 31-95 years (Gillanders *et al*., under review).

The CFQ is reported to correlate highly, and the direction that would be predicted by ACT theory, with measures of related constructs including The Acceptance and Action Questionnaire-II (AAQ-II; Bond *et al.,* 2011) *(r* =.72-.87, *p*<0.001*),* The Automatic Thought Questionnaire (Hollon & Kendall, 1980) (r=.61, p<0.001) and Beck Depression Inventory (BDI-II; Beck *et al.*, 1996) *(r* = .69, p<0.001). The CFQ is not significantly associated with a measure of social desirability (BIDR-IM; Paulhus, 1991) (r=-.19) (Gillanders *et al.,* under review).

The CFQ was developed due to the lack of an available alternative, which also meant there were not alternative measures available for consideration for inclusion in this study. This use of the same layout and response format as another measure to be used in the study was considered an advantage.

## 2.6 Ethical Issues

### 2.6.1 Ethic Approval

Approval was granted by the University of Edinburgh. As the current study involves NHS patients and recruitment through NHS services, ethical approval was also required from the local research and ethics committee and research and development departments for each hospital site involved. In the initial recruitment phase, ethical approval was granted by the local research ethics committee as well as the research and development department for one hospital site. Due to expansion of the recruitment and minor changes to the materials used, approval was sought, and

granted, through the local research and ethics committee for an amendment to the study. Research and development approval was granted for the original hospital site and an additional site in another NHS trust (see appendix 3).

### 2.6.2 Informed consent

All participants had a minimum of 24 hours between learning of the study and providing informed consent. The chief investigator, where necessary, read through the participant information sheet with potential participants and provided an opportunity to ask questions. Potential participants were able to take as long as they wished to consider taking part, and were encouraged to discuss participation with others if they wished. Those who agreed to take part were then asked to read through and sign the consent form and were advised that they could withdraw their consent at any time, without giving a reason.

### 2.6.3 Potential risks to participants

It was recognised that some participants who experience distressing intrusive memories, thoughts or images may find the intrusions interview difficult or upsetting. It was therefore planned to make clear to participants at the start of the interview, and at any time they became distressed, that they could stop the interview at any point. In the event of a participant becoming distressed the interviewer could also ensure that additional time was available to discuss the source of distress or any concerns the participant may have. It was planned that any severe distress would be communicated to the participant's GP with their consent, as well as signposting on to other sources or support, or recommending referral to the local psychology service where appropriate. No interviews were terminated due to participant distress, nor were any participants suffering distress to the extent that it was felt necessary to inform their GP or seek further support on their behalf.

In addition it was acknowledged that there was a risk that intrusions may link to a previous unresolved traumatic experience. For this reason the Structured Clinical Interview was always carried out first with participants being asked sensitively and directly about previous traumatic experiences. In the event that previous traumas were disclosed the presence of symptoms of post-traumatic stress disorder (PTSD) were inquired about. Participants who disclosed traumatic experiences, but who did not meet criteria for PTSD were asked if they wished to continue to the next part of the interview, and advised to stop the interview if they felt it was too distressing. It was planned to discontinue the interview with any participants meeting criteria for current PTSD.

No participants were found to be suffering from PTSD, although many participants did report that they had experienced traumatic events, all decided that they wished to continue with the interview.

### 2.6.4 Issues arising during study

It was planned that should any participant, in either group, disclose current or recent suicidal ideation; or meet criteria for previously undiagnosed or untreated major depression or anxiety disorder, the presence of these symptoms would be discussed with them and their consent sought to inform their GP. The possibility for a recommendation also to be made for a referral to the psychology department would also be discussed at this time. Two participants met criteria for an undiagnosed mood or anxiety disorder and provided their consent for their GP to be informed of this.

In the event of any participant being considered, by the interviewer, as at risk of self-harm or harming someone else, consent would be sought, if appropriate, to involve their GP and any other necessary agencies. However, the participant would be advised that this information would still need to be shared if they refused consent. No participant provided any information during the study procedure that would indicate they were at risk of harming themself or others.

## 2.7. Procedure

### 2.7.1 Interview procedure

The first part of the interview consisted of the mood and anxiety disorders module from the Structured Clinical Interview for DSM-IV, along with the screening module.

The Intrusions Interview was conducted in the second part of the interview. Responses were recorded using audio-recording equipment, with the participants' consent. Four participants requested that their interviews not be recorded for personal reasons.

### 2.7.2 Self-report questionnaires

Wherever possible, participants completed the questionnaires without the involvement of the chief investigator. In cases where sensory or literacy difficulties made this impossible, it was intended that either the chief investigator or another suitable person, read out items and alternative responses, and recorded the participant's responses. No participant required items to be read out due to sensory or literacy difficulties, although several participants requested large print versions of materials.

It emerged early in the study that some items did pose difficulties for participants. For the most part this was confined to the reverse score items on the Penn State Worry Questionnaire. To ensure participants were able to provide answers most closely reflecting their opinions and experiences, questionnaires were briefly checked in participants' presence so that missing or inconsistent answers could be clarified.

## 2.8 Analysis

### 2.8.1 Planned analysis

#### *Qualitative data*

The planned analysis of qualitative data was to focus on transforming qualitative descriptions of images, memories and thoughts into categories that could be numerically coded. This was to be achieved using content analysis guided by categories derived from previous work by the authors of the Intrusions Interview (Brewin *et al*., 1996) and used in the analysis of data from the Intrusions Interview (Patel *et al*., 2007). If the categories were not found to be exhaustive of themes contained in the current data, it was planned for additional categories to be derived from themes emerging from the data. It was decided that two raters would independently code the data and the inter-rater reliablity would be calculated.

#### *Statistical analysis*

It was planned to carry out correlational analysis to test the hypotheses:

1. The presence and severity of intrusive memories and images will decrease as worry scores increase.
2. The presence and severity of intrusive thoughts will increase as worry scores increase.
3. Cognitive fusion, psychological inflexibility and worry together will better predict the likelihood of reporting intrusions than worry alone.
4. The relationship between level of worry and intrusion severity will be accounted for by level of cognitive fusion and psychological inflexibility.

The planned statistical analysis was to use correlational analysis to investigate the first two hypothesis; and to further explore data in relation to the final two hypotheses using partial correlations and path analysis.

It was also planned to carry out partial correlations to determine the effects of mood. In the event of sufficient participants meeting diagnostic criteria for mood or anxiety disorders, it was intended to split the sample into groups and perform t-tests comparing these groups.

### 2.8.2 Handling and coding of data

A database was constructed to hold the data from the questionnaires and interviews. Paper copies of all completed study materials and an encrypted memory stick holding audio files were kept in a locked filing cabinet.

On inputting questionnaire data into the database it emerged that some questionnaires were incomplete or had been completed incorrectly. The decisions made as to how to code ambiguous answers are outlined below:

1) Some questionnaires had items to which no response had been given, in all cases, there were only one or two items per questionnaire for which no response had been provided, they were therefore prorated based on that participant's other responses.
2) Reverse scored items on one questionnaire resulted in missing or inconsistent data. Where it was not possible to clarify the responses the following steps were taken: where there were less than three missing or inconsistent responses these were prorated based on that participant's other responses; there were no cases in which there were more than three missing responses. This applied to data for four participants for the Penn State Worry Questionnaire. As this issue was identified at the beginning of recruitment, all further questionnaires were briefly checked in the participants' presence in order that any ambiguous responses could be clarified at the time.
3) The Intrusions Interview included both qualitative and quantitative data. Data from quantitative items was entered into the database. Qualitative descriptions were recorded as close to verbatim as possible, with accuracy checked with an audio recording of the interview. For the few participants who did not consent to audio recording, extra care was taken to record answers verbatim during the interview. These descriptions were entered into a separate spreadsheet and themes were coded quantitatively using content analysis. All descriptions were coded by two independent raters. Codes for up to two themes for each description were then entered into the database for further analysis.

4) In the event that participants had reported multiple emotions in response to intrusions, the two with the highest intensity ratings were recorded for further analysis. In the event ratings were tied, the two emotions indicated by participants to be the predominant emotions linked with the experience, were recorded.
5) As participants reported a wide range of emotions and many of these had only been rated by one or two participants, it was decided to group emotions to simplify coding. The grouping are as follows:
    i. Sadness, disappointment and loss
    ii. Guilt and regret
    iii. Shame and embarrassment
    iv. Anger, distaste and irritation
    v. Anxiety, fear, horror/dread.
    vi. Helplessness and pity
    vii. Happiness, contentment, reassurance, satisfaction, safety, enjoyment, amusement, joy, calming, lovely and pleasure
    viii. Affection, appreciation, caring, love, interest, arousal and pride
6) Scores for frequency, distress, uncontrollability and interference with daily activities for intrusions were summed to provide a single severity score.
7) Interview sections that were not applicable to individual participants were coded as missing data for the purposes of data entry.

## 2.9 Dissemination

A summary of findings was sent to individual participants who completed a contact form requesting an individual summary. The author has provided feedback regarding the findings of the study to professionals and organisations involved in the recruitment process where they had indicated an interest in this.

It is hoped to present the findings at conferences and to submit for publication in a peer reviewed journal to disseminate the findings more widely.

# 3. Results

## 3.1 Chapter overview

This section will begin by describing the characteristics of the study sample, moving on to the distribution of the data and assumptions for parametric testing before detailing the revised plan for analysis based on the characteristics of the data collected. Data exploring the characteristics of intrusions will be presented followed by the main analysis. Analysis of data will be presented beginning with correlations between questionnaire measures, then for each hypothesis in turn. The section will end by exploring the tendency toward an imagery based processing style reported in this sample.

## 3.2 Sample characteristics

The sample consisted of 62 participants (40 female) aged between 60 and 86 years with a mean age of 70.3 years, all participants were white British. The mean level of worry within the sample was 37 (sd: 16.82) which is consistent with other findings in unselected community samples of older adults (M:39) and slightly lower than unselected samples of younger adults (M:43) (Startup & Erickson, 2006). There was an overall higher mean worry score for female participants (M:41, *SD*: 17.969) than for male participants (M:31, *SD*:12.393) this was significant at $p<.05$ ($t_{(60)}$ 2.379, $p$=.021, d=.65). There was a low level of depression within the sample, with an overall mean score of 2 on the Geriatric Depression Scale.

Occupational data was categorised according to the Standard Occupational Classification 2010 (Office for National Statistics, 2010). Data was missing for 8% of participants, of the remainder: 40% are currently in work, or had worked before retirement, in professional occupations; 18% in administrative or secretarial occupations; 12% in skilled trades and; 12% in personal service occupations; the remainder had worked as managers or senior officials (5.3%), in sales and customer services (1.8%) or elementary occupations (e.g. waitress, cleaner).

Of the whole sample three met DSM-IV criteria for major depressive disorder, and ten for past major depressive disorder, four met criteria for generalised anxiety disorder, two for a specific phobia and one for panic disorder, data was missing or incomplete for four participants. The majority of

participants (43, 73%) did not meet criteria for any mood or anxiety diagnosis. Twenty-one participants (37%) reported one or more traumatic experience, however none met criteria for current post-traumatic stress disorder.

Interview data was available for 57 participants. Of these, 65% (37) reported experiencing one or more types of intrusions over the past week. More than one type of intrusion was reported by 19% (11) with memories and images (9%) or memories and thoughts (5%) being the most common combinations. 26% of participants reported experiencing intrusive memories (15), 28% intrusive images (16) and 32% intrusive thoughts (18).

## 3.3 Distribution of data

All continuous data was checked for skew, kurtosis and homogeneity of variance. Calculation of z scores was performed due to the large sample size, resulting scores indicated that data did not meet the normality criterion for parametric testing.

Data from all questionnaire measures was found to be significantly positively skewed and data from the Penn State Worry Questionnaire (PSWQ) was significantly kurtotic. Log10 transformations were performed on all continuous data with one point added to adjust for scores of zero. Z scores for skew and kurtosis were non-significant for all measures, except for Geriatric Depression Scale (GDS) ($k_s$ 2.6) which was marginally significant using the criterion suggested by Field (2009) for larger sample sizes ($k_s$ 2.58). Distribution checks for data split by groups also confirmed non-normality of the distribution of GDS scores with significant positive skew for two of the groups (those reporting an absence of intrusive memories and thoughts).

Due to the remaining deviations from normality further transformations were carried out. Square root and reciprocal transformations did not result in normal distribution for all data. The transformations that had been performed were therefore considered the best fit for the data and log 10 transformed data were used for all further analysis.

Homogeneity of variance between groups was assessed using the Levene test (*F*), and checked by calculating the variance ratio (Hartley's $F_{max}$) due to the known sensitivity to sample size of the Leven test. For transformed data all results were non-significant except for PSWQ scores and intrusive memories (*F* (1,55) 13.389, *p*=.001) ($F_{max}$ 4.875). PSWQ scores were split also by sex and by the

tendency to think in images, results were non-significant for sex but were significant for the tendency to think in images ($F$(1,55) 6.710, $p$=.01)

## 3.4 Revision of planned analysis

Due to the characteristics of the data collected, it was necessary to make a revised plan for analysis. As a relatively small number of participants had reported experiencing intrusions in the form of images, memories or thoughts, this meant that only a small subsample of data was available for analysis of the severity of intrusions. A further implication of this was that in order to analyse the whole sample data, it was necessary to use the presence of intrusions alone as an outcome variable which is problematic as it is dichotomous and therefore precludes the use of correlational analysis.

Due to non-normal distribution of GDS scores, non-parametric Spearman's Rank-Order correlations were planned to establish relationships between questionnaire measures before moving onto examination of the study hypotheses.

In order to examine hypotheses one and two concerning the relationship between levels of worry and the presence and severity of intrusions, it was decided to use independent t-tests to test the difference between mean worry levels for those reporting, versus not reporting, each type of intrusion.With the non-parametric Mann-Whitney U test to be used for intrusive memory groups, due to heterogeneity of variance of worry scores for these groups. In order to test the association between the level of worry and the severity of intrusion it was decided to use Pearson's product-moment correlation in the smaller sub-sample reporting intrusions, despite this being low in power due to a small sample size ($n$=15-18)

Regression analysis was deemed the most appropriate method to assess the extent to which the predictor variables (worry, cognitive fusion and psychological inflexibility) were able to predict the outcome variable (presence of intrusions) for the entire sample. The decision was taken to exclude the Geriatric Depression Scale (GDS) from this analysis due to the non-normal distribution of scores.

It was planned to assess the relationship between the severity of intrusions and all questionnaire measures using Pearson's product-moment correlation with partial correlation to be carried out to further explore significant results.

Finally, exploratory descriptive analysis will be presented for the characteristics of intrusions and a non-parametric Mann-Whitney U test to test for the difference between worry scores for those reporting that they do or do not ever think in images.

## 3.5 Characteristics of intrusions

Tables 1 and 2 display a summary of the main characteristics of intrusions reported in this sample. There are low levels of intrusions reported overall, with these quite evenly distributed across the different types of intrusions. Thematic content of intrusions is displayed in table 2 along with frequencies these were assigned to descriptions by each rater. As can be seen from the table inter-rater reliability is either good or very good for all types of intrusions.

A general trend to increasing severity of intrusive experience can be seen from memories to images to thoughts. For memories and images this is mirrored in the mean scores for the sense of 'nowness' or reliving associated with the intrusion. There is also a shift in the most frequently reported emotion from sadness, for memories, to sadness, guilt and regret, for images, to anxiety for intrusive thoughts. This may in part be explained by a change in the content of intrusion, with relationship and family forming the most common theme for memories and images, but giving way to illness, injury and death for intrusive thoughts.

Table 1. C*haracteristics of reported intrusions, by type of intrusion*

| **Intrusions** | **Number of participants reporting** | **Most frequently reported emotion for 1st intrusion** | **Mean severity score[1] (sd) (0-400)** | **Mean sense of reliving (0-100)** | **Range of severity scores** |
|---|---|---|---|---|---|
| **Memories** | 15 (10 female) | Sadness 29% | 39.2 (38.397) | 13.33 | 2-115 |
| **Images** | 16 (12 female) | Sadness 23% guilt/regret23% | 62.5 (65.676) | 30.63 | 5-220 |
| **Thoughts** | 18 (13 female) | Anxiety 30% | 128.89 (109.964) | na | 10-400 |

[1] Severity score is the sum of scores for frequency, distress, uncontrollability and interference in daily life.

Table 2. *Content themes for intrusive memories, images and thoughts*

| | **Themes From most to least common** | **frequency 1st rater** | **frequency 2nd rater** | **Interrater reliability** |
|---|---|---|---|---|
| **Memories** | Relationship and family | 8 | 7 | Kappa =.9, |
| | Illness, injury and death | 4 | 4 | SE=.096 |
| | Social perception | 2 | 2 | *p*=.000 |
| | Abuse, assault or safety | 1 | 1 | |
| **Images** | Relationship and family | 9 | 9 | Kappa =.77 |
| | Illness, injury and death | 4 | 6 | SE=.108 |
| | Memorable places | 1 | 2 | *p*=.000 |
| | Social perception | 1 | 1 | |
| | Work or financial problems | 1 | 1 | |
| **Thoughts** | Illness, injury and death | 8 | 10 | kappa = .68 |
| | Relationship and family | 8 | 8 | SE=.105 |
| | Work or financial problems | 3 | 2 | *p*=.000 |
| | Social perception | 1 | 3 | |
| | Abuse, assault or safety | 1 | 1 | |

## 3.6 Correlations between questionnaire measures

Non-parametric, Spearman's rank-order correlations were carried out to allow inclusion of GDS scores. Scores on the Penn State Worry Questionnaire (PSWQ) were strongly correlated with scores on the Cognitive Fusion Questionnaire (CFQ) and the Acceptance and Action Questionnaire -II (AAQ-II). The CFQ and AAQ-II were strongly correlated with each other and the GDS had medium strength correlations with all other questionnaire measures (table 3).

Table 3*. Correlations between questionnaire measures for the full sample (n=62).*

| | | $r_s$ | *p* |
|---|---|---|---|
| **PSWQ** | GDS | .395** | 0.001** |
| | CFQ | .845** | 0.000** |
| | AAQ-II | .722** | 0.000** |
| **GDS** | CFQ | .403** | 0.001** |
| | AAQ-II | .384** | 0.002** |
| **AAQ-II** | CFQ | .785** | 0.000** |

## 3.7 Hypothesis one: The presence and severity of intrusive memories and images will decrease as worry scores increase.

### 3.7.1 Intrusive memories

A total of 15 participants reported experiencing at least one intrusive memory within the last week. Scores on the Penn State Worry Questionnaire (PSWQ) were compared for the two groups (those who reported intrusive memories and those who did not) and these are displayed graphically below in figure 1. As can be seen from figure 1. the mean score for the group reporting intrusions and the group not reporting intrusions were similar, whereas there is a large difference between the range of scores (26 and 64 respectively). Analysis with Mann-Whitney U test confirmed there was no significant difference between group means (intrusions group mean: 33 (*SD*: 7.48), no intrusions group mean: 38 (*SD*: 18.35), $p$=.852).

The severity of intrusion score is a sum of scores for: frequency of intrusion; distress; uncontrollability; and interference with daily life. For the sub-sample reporting intrusive memories ($n$=15) there was a significant positive correlation between PSWQ and the severity score for the first reported memory of moderate strength ($r$ =.456, $p$=.044) (table 6), this is in the opposite direction to that expected based on hypothesis 1.

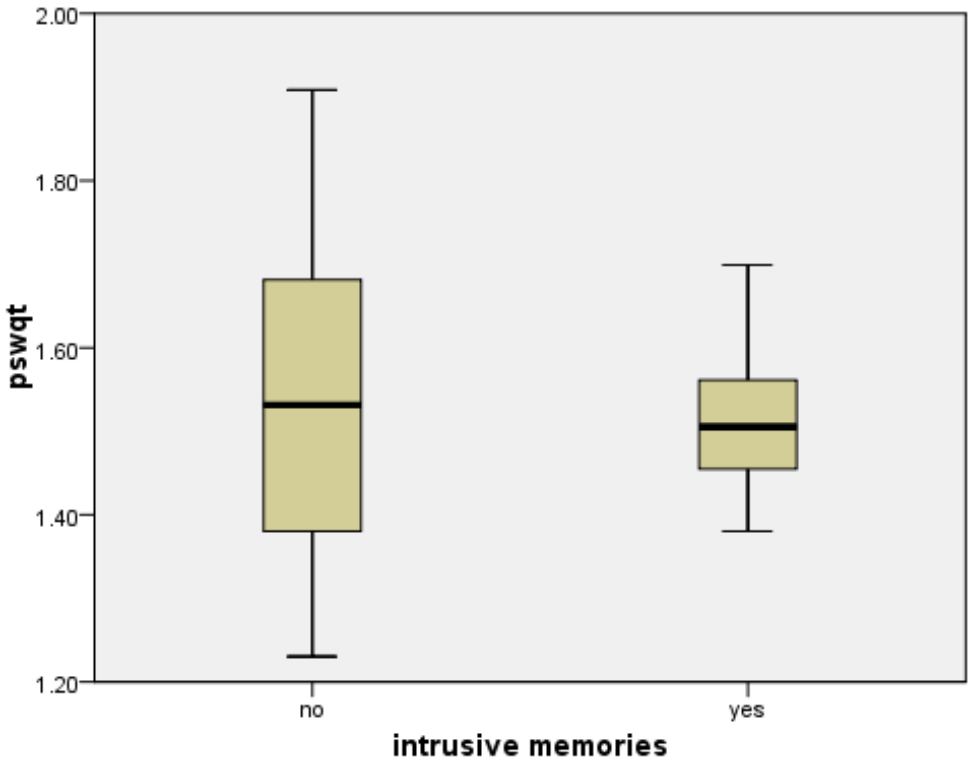


Figure 1. Box Plot of distribution of PSWQ scores for those reporting intrusive memories (Yes) and those not reporting intrusions (no)

### 3.7.2 Intrusive Images

A total of 16 participants reported experiencing at least one intrusive image within the last week. Comparison of PSWQ scores for the two groups (reporting images and not reporting images) revealed similar means, an independent t-test confirmed there was no significant difference between mean scores (Intrusions groups mean: 34 (*SD*: 10.24), no intrusions group mean: 37 (*SD*: 17.99), $t_{(55)}$ .133, *p*=.895). A box plot of the data (figure 2.) shows, as with intrusive memories, there is a large difference between the range of scores (32 and 64 respectively) for the two groups, which may reflect the smaller sample size of the group reporting intrusions.

For the sub-sample reporting intrusive images (*n*=16) there was a negative correlation close to zero, between severity of intrusion for images and PSWQ scores (*r* = -.031, *p*=.45).

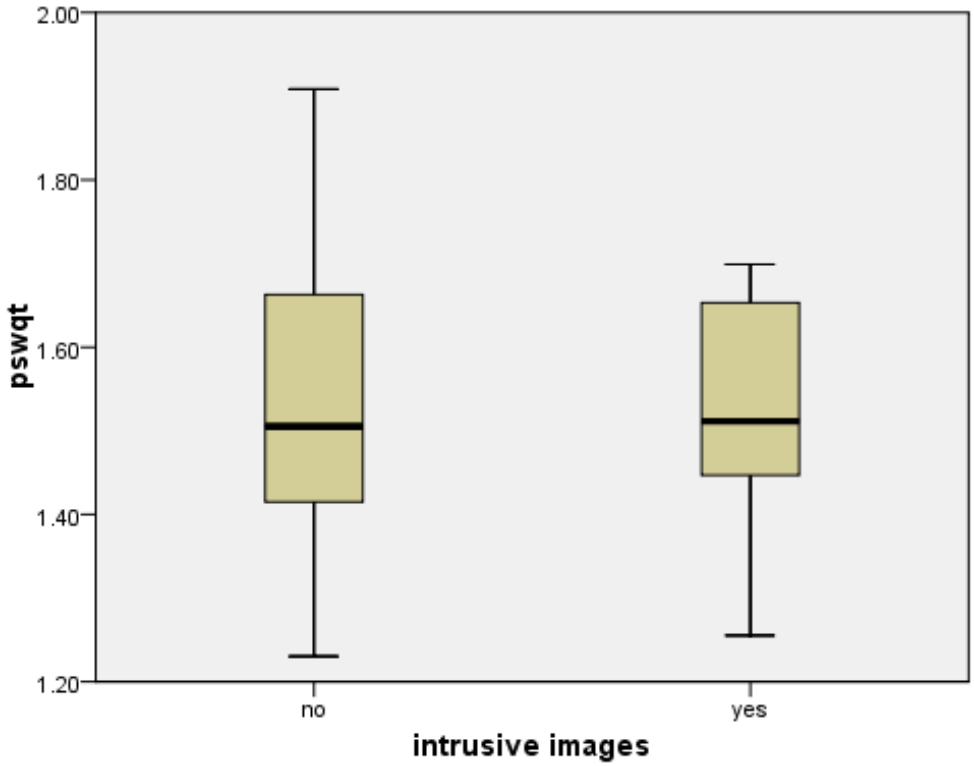


Figure 2. Box Plot of distribution of PSWQ scores for those reporting intrusive images (Yes) and those not reporting intrusive images (no).

***Summary***

Reports of intrusive images and memories occur over a reduced range of PSWQ scores, however, there is no significant difference between these groups' mean scores. The severity of intrusive memories was significantly positively correlated with PSWQ scores which is not in the expected direction based on hypothesis 1. None of the questionnaire measures correlated significantly with the severity of intrusive images.

## 3.8 Hypothesis 2: The presence and severity of intrusive thoughts will increase as worry scores increase.

### 3.8.1 Intrusive Thought

A total of 18 participants reported experiencing at least one intrusive thought within the last week. Comparison of PSWQ scores for the two groups (yes and no to presence of intrusive thoughts) showed similar means, this was confirmed by independent t test which showed no significant difference between group means (intrusions group mean: 41 (*SD*: 18.62), no

intrusions group mean: 35 (*SD*: 15.2), $t_{(58)}$ .-1.227, *p*=.225). A box plot of the data (figure 3.) shows, in contrast with intrusive memories and images, the range of scores for the two groups is similar (59 and 64 respectively).

For the sub-sample reporting intrusive thoughts (*n*=18) there was a strong significant positive correlation between severity of intrusion for thoughts and PSWQ score (*r*=.762, *p*=0.00).

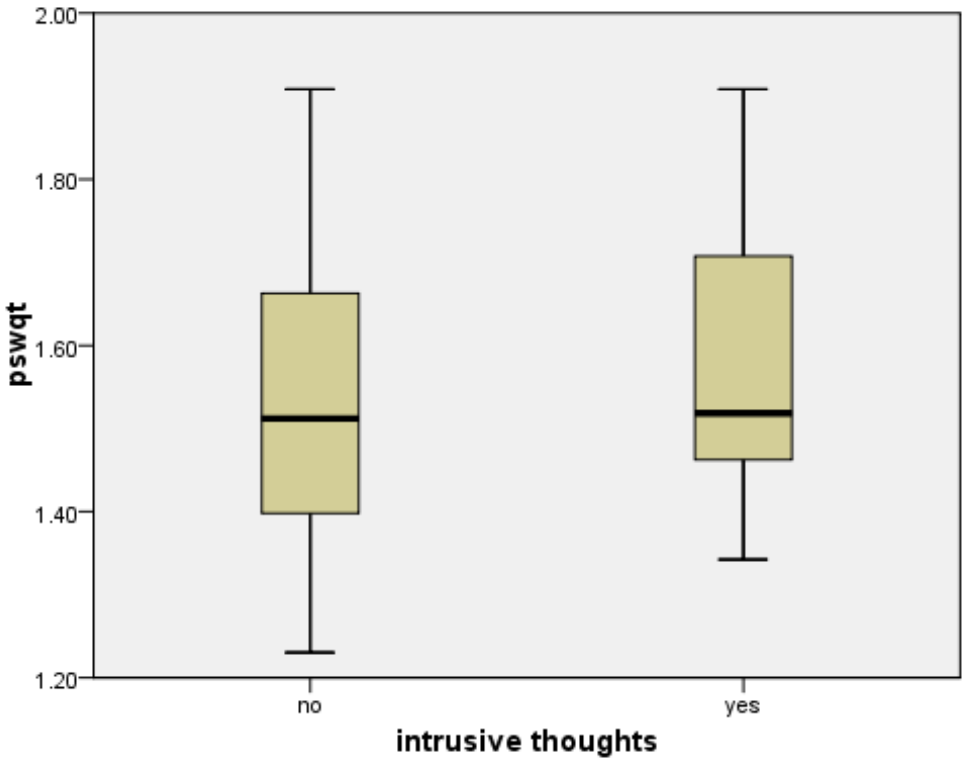


Figure 2. Box Plot of distribution of PSWQ scores for those reporting intrusive thoughts (Yes) and those not reporting intrusive thoughts (no).

### *Summary*

Figure 2 shows that, unlike images and memories, people who report intrusive thoughts score across a wider range on the PSWQ. There was no significant difference between these two groups in terms of mean levels of worry. For the sub-sample reporting intrusive thoughts there was a significant correlation between level of worry and the severity of intrusive thoughts, thus providing partial support for hypothesis 2.

## 3.9 Hypothesis 3: Cognitive fusion, psychological inflexibility and worry together will better predict the likelihood of reporting intrusions than worry alone.

Separate binary logistical regressions were carried out for each type of intrusion. Analyses were run initially with three variables (PSWQ, CFQ and AAQ-II) and then repeated with two variables (CFQ, AAQ-II). The variable that had the wald statistic closest to zero was excluded for the second analysis. The results are displayed in tables 4 (three variables) and table 5 (two variables).

In addition to the normality tests already performed on the data, checks were carried out for the linearity of the logit and multicollinearity. As cases were unrelated, the independence of errors assumption was automatically met (Field, 2009, p. 273).

### *Intrusive memories*

As table 4 shows, with three variables included in the model, none of the variables contributed significantly to prediction of the outcome (presence of intrusive memories). From the pattern of results it can be seen that, contrary to predictions, both PSWQ and CFQ scores had positive *b* values, in that an increase in score should lead to an increase in likelihood of intrusive memories being reported, neither result approached significance however. By contrast, AAQ score had a negative *b* value, indicating that an increase in score should lead to a decrease in the likelihood of intrusive memories being reported, this result approached significance ($p$=.057).

With only two predictors in the model it can be seen that the AAQ has a significant negative relationship with the presence of intrusive memories (p<.05), the confidence interval (CI 95% .000-.986) does not cross 1, therefore there is 95% confidence in the direction of the relationship (table 5).

### *Intrusive images*

In the three variable model, although the negative *b* values for both PSWQ and AAQ-II are in the expected direction, these variables are not significant predictors of imagery in this model. As can be seen from table 4., the *b* value for CFQ score is positive, indicating as scores increase so too does the likelihood of reports of intrusive images, the result is significant ($p$<.05). The 95% confidence intervals (CI 95% 2.86-2629514.83) do not cross one, therefore there is a 95% chance that this reflects the true direction of the relationship (Field, 2009, p. 289).

In the two variable model the negative relationship of the AAQ-II with intrusive imagery emerges as significant ($p$<.05, CI 95% .000-.841). The significant positive relationship between CFQ scores and the likelihood of reporting intrusive images remains ($p$<.05, CI 95% 1.423-176226.576).

### *Intrusive thoughts*

In the three variable model the *b* value for PSWQ score is negative, however the result is non-significant. For both CFQ and AAQ-II scores *b* values are positive and non-significant. There is no change in the predictive value of these variables in the two variable model.

Table 4. *Binary logistic regression analyses for intrusive memories, images and thoughts with three predictor variables PSWQ, CFQ and AAQ*

| *n=57* | B | SE | Wald | df | sig | Exp (B) | -2LL | Cox & Snell | Nagelkerke R square |
|---|---|---|---|---|---|---|---|---|---|
| **Intrusive memories** | | | | | | | | | |
| **PSWQ** | .023 | 3.305 | .000 | 1 | .994 | 1.024 | | | |
| **CFQ** | 4.183 | 3.191 | 1.718 | 1 | .190 | 65.566 | 63.245 | .075 | .108 |
| **AAQ** | -6.123 | 3.219 | 3.617 | 1 | .057 | .002 | | | |
| | | | | | | | | | |
| **Intrusive images** | | | | | | | | | |
| **PSWQ** | -3.504 | 3.654 | .919 | 1 | .338 | .030 | | | |
| **CFQ** | 7.916 | 3.503 | 5.107 | 1 | .024* | 2742.040 | 61.413 | .104 | .150 |
| **AAQ-II** | -5.391 | 3.207 | 2.826 | 1 | .093 | .005 | | | |
| | | | | | | | | | |
| **Intrusive thoughts** | | | | | | | | | |
| **PSWQ** | -.543 | 3.238 | .028 | 1 | .867 | .581 | | | |
| **CFQ** | 1.054 | 3.050 | .120 | 1 | .730 | 2.870 | 70.810 | .041 | .058 |
| **AAQ-II** | 1.657 | 2.714 | .373 | 1 | .542 | 5.245 | | | |

Table 5. *Binary regression analyses for intrusive memories, images and thoughts with two predictor variables: CFQ and AAQ*

| *n=57* | B | SE | Wald | df | sig | Exp(B) | -2LL | Cox & Snell | Nagelkerke R square |
|---|---|---|---|---|---|---|---|---|---|
| **Intrusive memories** | | | | | | | | | |
| **CFQ** | 4.194 | 2.771 | 2.290 | 1 | .130 | 66.301 | 63.245 | .075 | .108 |
| **AAQ-II** | -6.117 | 3.114 | 3.859 | 1 | .049* | .002 | | | |
| **Intrusive images** | | | | | | | | | |
| **CFQ** | 6.216 | 2.991 | 4.318 | 1 | .038* | 500.854 | 62.399 | .088 | .127 |
| **AAQ-II** | -6.271 | 3.111 | 4.063 | 1 | .044* | .002 | | | |
| **Intrusive thoughts** | | | | | | | | | |
| **CFQ** | .758 | 2.492 | .093 | 1 | .761 | 2.135 | 70.838 | .040 | .057 |
| **AAQ-II** | 1.540 | 2.627 | .344 | 1 | .558 | 4.664 | | | |

### *Summary*

Level of worry, as measured by the PSWQ, was not found to be a significant predictor for any type of intrusion. As psychological inflexibility increases, as measured by the AAQ-II, the likelihood of reporting intrusions decreases for both memories and images ($p<.05$). As cognitive fusion increases, as measured by the CFQ, the likelihood of reporting intrusive images increases ($p<.05$). None of the variables were found to be significantly related to the presence of intrusive thoughts.

## 3.10 The relationship between level of worry and intrusion severity will be accounted for by level of cognitive fusion and psychological inflexibility.

As can be seen from table 6, for the 32% of the sample that reported intrusion thoughts, scores on all questionnaire measures were significantly correlated with thought severity. Only the PSWQ was significantly correlated with the severity of intrusive memories and there were no significant correlations with the severity of images.

Table 6. *Pearson's Product-moment correlation between questionnaire measures and severity of intrusions for subsamples reporting intrusive images, memories and thoughts*

| | Memories (*n*=15) | | Images (*n*=16) | | Thoughts (*n*=18) | |
|---|---|---|---|---|---|---|
| | $r_{(13)}$ | *p* | $r_{(14)}$ | *p* | $r_{(16)}$ | *p* |
| **PSWQ** | .456* | .044* | -.031 | .454 | .762** | .000** |
| **CFQ** | .424 | .058 | .007 | .489 | .825** | .000** |
| **AAQ-II** | .369 | .088 | -.305 | .125 | .680** | .001** |

As significant correlations were found between worry, fusion, psychological inflexibility and the severity of intrusive memories and thoughts, partial correlations were carried out to examine the relative contribution of each of these constructs to the severity of intrusions, when other constructs were held constant.

The association between PSWQ scores and the severity of intrusive memories became non-significant when either the CFQ ($r$=.282, $p$=.328) or the AAQ-II ($r$=.449, $p$=.251) were held constant.

The association between PSWQ scores and the severity of intrusive thoughts became marginally non-significant when AAQ-II scores ($r$= .475, $p$=.054) were held constant and non-significant when CFQ scores ($r$= -.062, $p$=.813) were held constant. The association between CFQ scores and the severity of intrusive thoughts remained when scores were held constant for AAQ-II ($r$= .643, $p$=.005), and PSWQ ($r$=.491, $p$=.045). The association between AAQ-II scores and the severity of intrusive thoughts became non-significant when either the CFQ ($r$=-.107, $p$=.342) or PSWQ ($r$=.077, $p$=.384) were held constant.

Due to the small sample size for this section of the analysis and the number of statistical tests performed there is a greater chance of type 1 error. These findings must therefore be interpreted with caution and they are presented as further exploration of the main correlational findings, which may indicate interactions to be examined in further research.

Cognitive fusion and psychological inflexibility are not independently correlated with the severity of intrusive thoughts. Partial correlations however suggest that the relationship between worry and memory severity is partially accounted for by cognitive fusion.

Worry, cognitive fusion and psychological inflexibility all correlate separately with the severity of intrusive thoughts. Partial correlations indicate that these relationships are not independent of one another, and instead indicate that the relationship between worry and the severity of intrusions may be accounted for by levels of cognitive fusion and, in part, by psychological inflexibility.

## 3.11 Tendency to think in images

A single question, with a further clarifier if needed, was included to give an indication of the participants' self-reported preferred processing style. Whilst firm conclusions cannot be drawn from a single unvalidated question, the findings are reported here as another avenue that may shed some light on the findings and provide directions for future investigations.

Participants were asked ‘are you aware that your thinking ever consists of mental images or pictures?’, fifty-one participants answered this question, 11 (9 female) saying no, they did not ever think in images, and 40 (24 female) saying yes, they did at times think in images. The mean PSWQ score for those saying no, that they never thought in images was 52 (*SD*: 22.75) and for those saying yes, they did at times think in images was 32 (*SD*: 11.58). The difference between means is significant ($t_{(49)}$ 3.269, *p*=.002).

Participants who reported that they did not think in imagery had a higher mean worry score than those who do, at least occasionally think in worry.

# 4 Discussion

## 4.1 Summary of results

The purpose of this research was: firstly to explore the presence and nature of intrusive cognitions in an older adults sample; secondly to determine whether an individual's level of worry was related to their experience of intrusive cognitions; and thirdly whether an individual's level of cognitive fusion (henceforth referred to as fusion) or psychological inflexibility (henceforth referred to as inflexibility) explains, or adds to the explanation of this relationship. A brief summary of results follows.

### *Characteristics of Intrusions*

Intrusions were reported by 65% of the present sample, with 19% reporting that they experienced more than one type of intrusion. Memories were reported by 26%, images by 28% and thoughts by 32%.

From an exploration of the characteristics of the intrusive experiences reported, it is clear that the most frequent themes are associated with relationships and family; and illness, injury and death. Relationships and family was the most common theme for both intrusive memories and images, with illness, injury and death the second most common theme. The most commonly associated emotions were sadness, for memories and sadness, along with guilt and regret for images.

The characteristics of intrusive thoughts were somewhat different with the most common theme being illness, injury and death, with relationships and family the second most common. The most common associated emotion was anxiety. The severity of intrusions was lowest for intrusive memories (M: 39) and highest for intrusive thoughts (M: 129) with intrusive images lying in between (M: 63). The sense of reliving accompanying intrusions was lowest for memories (M: 13.33) and higher for images (M: 30.63), this was not applicable for intrusive thoughts.

### *Correlations between questionnaire measures*

Strong correlations were found between worry, fusion and inflexibility and between fusion and inflexibility. Medium strength correlations were found between depression scores and worry, fusion and inflexibility.

### *Hypothesis one: The presence and severity of intrusive memories and images will decrease as worry scores increase*

Hypothesis one was not substantiated by the findings of this study. There was a small number of intrusions reported overall. Reports of intrusive images and memories occurred over a reduced range of worry scores, however, there was no significant difference between the groups' mean worry scores.

For the severity of intrusions, worry scores were significantly correlated with intrusive memories but not intrusive images. The direction of the relationship indicates that as worry scores increase, so too does the severity of intrusive memories, which is contrary to hypothesis one.

### *Hypothesis two: The presence and severity of intrusive thoughts will increase as worry scores increase*

Hypothesis two was partially substantiated. In contrast to images and memories, reports of intrusive thoughts occurred across a wide range of worry scores. There was no significant difference between those who reported experiencing intrusive thoughts and those who did not in terms of mean levels of worry. For the sub-sample reporting intrusive thoughts there was a significant correlation between level of worry and the severity of intrusive thoughts.

Hypothesis 3: Cognitive fusion, psychological inflexibility and worry together will better predict the likelihood of reporting intrusions than worry aloneThe findings of this study partially support hypothesis three, however, the pattern of findings are more complex than predicted by this hypothesis.

As inflexibility increased, so the likelihood of reporting intrusions decreased for both memories and images. As fusion increased, the likelihood of reporting intrusive images increased.

Neither inflexibility nor fusion significantly related to the presence of intrusive thoughts (as opposed to memories or images) in this sample. Level of worry did not significantly predict the presence of intrusive memories, images or thoughts in this sample.

The findings indicate that level of inflexibility and fusion impacts the presence (or reporting) of imagery-based intrusions (memories and images), whereas worry does not. The pattern of findings suggest that fusion and flexibility are better predictors of the reporting of intrusions than is worry.

***Hypothesis 4: The relationship between level of worry and intrusion severity will be accounted for by level of cognitive fusion and psychological inflexibility.***

Level of worry was significantly associated with the severity of both intrusive memories and thoughts. Whilst this is as predicted for intrusive thoughts, it is contrary to predictions for intrusive memories. Both fusion and inflexibility are positively correlated with severity of intrusive thoughts but not memories or images.

Worry, fusion and inflexibility were all found to be separately associated with the severity of intrusive thoughts. Partial correlations indicated that these relationships were not independent of one another. Instead, the results indicate that the relationship between worry and the severity of intrusions may be explained by level of fusion and influenced by level of inflexibility. The relationship between level of worry and intrusive memory was also partly accounted for by level of cognitive fusion and to a lesser degree by inflexibility.

***Tendency to think in images***

The group of participants reporting that they do not ever think in images had a significantly higher mean worry score that those reporting that they do, at least occasionally, think in images. When considered together with the observed pattern of reported intrusive memories, images and thoughts an interesting parallel emerges.

Although there was no significant difference in mean worry score for groups experiencing and not experiencing intrusions, less intrusive memories and images were reported at higher levels of worry. This mirrors the tendency for those who report that they do not ever think in imagery to have higher levels of worry. As intrusive thoughts would be unaffected by this tendency they would be expected to be reported across the spectrum of worry, as is observed in this sample.

## 4.2 Detailed discussion of results

### 4.2.1 Intrusive Experiences

Intrusive experiences were reported by 65% of the sample. Each type of intrusion however, was reported at relatively low levels, by between a quarter and a third of participants.

In previous research, intrusive memories have been reported to be a common phenomena, albeit not as common as intrusive thoughts (Brewin *et al.*, 1996). The content of intrusive memories has been found to relate most commonly to themes of illness, injury and death (Brewin *et al.* 1996; Brewin *et al.* 1998; Patel e*t al.,* 2007), which in the current study was found to be the second most common theme. The emotions most commonly associated with memories is also relatively consistent between studies, with sadness frequently reported as the most, or one of the most commonly associated emotions (Brewin *et al.*, 1996; Patel e*t al.,* 2007). The finding that relationship and family in this study was the most common theme for intrusive memories, may reflect the low level of depression in this sample whilst other studies have used depressed samples or mixed samples with both depressed and non-depressed individuals.

The proportion of participants reporting intrusive memories is consistent with findings by Brewin *et al.* (1998) in a sample of cancer patients aged 24-81yrs (mean 54yrs). Using an interview measure, 23 per cent of the sample reported intrusive memories. There was significant variation within the sample however. Those who were severely depressed were 4 times more likely to report intrusive memories (43%) than were non-depressed patients (11%). Patel *et al*. (2007) used the Intrusions Interview to explore intrusive memories and images in depressed patients. Intrusive memories were reported by 44 per cent of the sample. A still higher level of intrusive memories was found by Reynolds and Brewin (1999) with 73 per cent of the sample reporting that they had recently experienced an intrusive memory. In the same study, 98 per cent of participants diagnosed with PTSD reported experiencing one or more intrusive memories in the past week. The higher levels reported by depressed participants in this sample may relate to the methodology; participants were first asked about negative life events and traumatic experiences which may have primed them to recollect more intrusive memories associated with these events.

In the current study intrusive images were reported at a simiar rate to intrusive memories, however comparison with the literature in this area is complicated by the fact that many studies have not drawn a distinction between the two. In a study of intrusive experiences in a non-clinical population, Parkinson and Rachman (1981a) found that 40 out of 60 participants reported that they experience intrusive imagery (including memories) whereas 58 out of 60 reported that they experience intrusive thoughts. Findings from another study suggest that the occurrence of intrusive images (not including memories) may be linked to stress. Parkinson and Rachman (1981b), found

that 16 out of 25 mothers under stress (with a child in hospital) reported experiencing intrusive images whereas, four out of 25 mothers not under stress reported such images.

The occurrence of intrusive images under conditions of stress or anxiety is consistent with findings from participants with anxiety disorders who report experiencing intrusive images in anxiety provoking situations. One such study found that 100 per cent of agoraphobic patients reported images in agoraphobic type situations (Day *et al.*, 2004); in another, 77 per cent of social phobia patients reported intrusive imagery in social situations (Hackmann *et al.*, 1998). In contrast, only five per cent of depressed patients reported intrusive imagery (as opposed to memories) (Patel *et al.,* 2007).

Of direct relevance to the current findings, is a study comparing patients with panic disorder and GAD (Breitholtz *et al.*, 1998). The authors reported that 32 per cent of panic patients and 27 per cent of GAD patients reported experiencing intrusive images (including memories). These findings are surprising given the findings in the current study that those reporting that they did not ever think in imagery had a higher mean worry score and that few images were reported by high worriers. There are considerable differences however in the mean level of depression reported in the current sample, which was very low, to that of Breitholtz *et al.* (1998) which indicated mild to moderate depression. In light of previous findings in relation to depression and intrusive memories (Patel e*t al.*, 2007), direct comparison between these samples is difficult.

Levels of intrusive imagery in control groups have been reported to vary between zero per cent for agoraphobic situations (Day *et al.*, 2004) to 47 per cent for social situations (Hackmann *et al.*, 1998). Levels of intrusive imagery in an unselected community sample are not available for direct comparison; however it appears that intrusive imagery is a highly variable phenomenon, depending at least in part on state anxiety (Hackmann *et al.*, 1998) and stress level (Parkinson & Rachman, 1981b), the measurement of which were beyond the scope of the present study. In addition Brewin *et al.* (2010) have highlighted the issue of methodological differences between studies and the lack of validated tools for capturing the experience of intrusive images. In a review of studies in this area, Brewin *et al.* (2010) reported that rates of imagery reported tend to be lower when participants are asked about experiences over a restricted time period. This is consistent with the idea that intrusive imagery varies depending on the current situation and state of the individual rather than remaining stable over time. This is particularly important when considered in context of

the findings of the current study and suggest that the low levels of imagery reported may be owing, at least in part, to the restricted time frame of one week inquired about in the Intrusions Interview.

The time frame of inquiry may also be an important factor in the reporting of intrusive thoughts. Intrusive thoughts have been found to be a common experience (Rachman & de Silva, 1978) and are the most commonly reported type of intrusion (Brewin *et al.,* 1996). They are, however, reported to be less frequent in older adults (Magee & Teachman, 2012). The relatively low levels reported in this sample may be owing to the reduced frequency of these experiences in older age. Magee and Teachman (2012) found that older adults reported experiencing intrusive thoughts on average between once per week and once per month, compared to between once per day and once per several days for younger adults. In the current study, participants were asked about their experiences over the past week. Magee and Teachman's (2012) findings suggest that although a participant may experience intrusive thoughts in general, they may not experience them with sufficient frequency for this to be picked up on the Intrusions Interview.

The emotion most commonly associated with intrusive thoughts reported in this sample differed from imagery based intrusions (images and memories). Whilst sadness was most commonly associated with imagery based intrusions, anxiety was most commonly associated with intrusive thoughts. A similar finding was reported by Brewin *et al.* (1996); whilst sadness and happiness were most commonly associated with intrusive memories, fear was most commonly associated with intrusive thoughts. This findings adds further weight to the argument that different forms of intrusions represent different phenomena which are likely to relate differently to other constructs.

### 4.2.2 Hypothesis one: the presence and severity of intrusive memories and images will decrease as the severity of worry increases

Previous research has found that autobiographical memories most commonly consist of detailed visual scenes linked to an original experience (Patel *et al.,* 2007). It has also been argued that projecting oneself into the past or future relies on very similar mechanisms (D'Argembeau & Van Der Linden, 2006). It was therefore expected that intrusive memories may have similar characteristics to intrusive images and relate to other study variables in similar ways.

Characteristics of these two types of intrusions are similar with respect to the proportion of the sample reporting them, content themes, and associated emotions. Mean scores for severity and reliving were however lower for memories than for images.

Hypothesis one was based firstly, on research that shows that imagery is capable of eliciting emotion, more so than verbally based cognitions (Holmes & Mathews, 2010) and secondly, theories and research suggesting that worry may serve as a means to avoid distressing emotional experiences (experiential avoidance) (Borkovec, 1994; Hayes *et al.*, 1996). It was therefore expected that as levels of worry increased across the sample, less intrusive images and memories would be reported due to this avoidant function. Furthermore it was expected that the severity of intrusions would be linked with the motivation to avoid and so would decrease as worry increased.

The hypothesised relationship between the presence of non-verbal intrusions and worry was not substantiated by the findings. In the present sample, no significant difference was found between mean worry scores between those reporting, or not reporting, memories or images, nor did worry significantly predict the presence or absence of non-verbal intrusions in a logistic regression analysis. The observed pattern of results shows that reports of non-verbal intrusions occurred over a reduced range of worry scores with no reports of intrusions by the highest worriers in the sample (those with PSWQ score above 50). Participants reporting that they did *not* experience intrusions were, however, distributed throughout the sample, which may account for the similar mean scores between groups.

Related to the tendency to experience intrusive memories and images is the tendency to experience, or be aware of, cognitions consisting of images or mental pictures. Exploratory analysis of a single question relating to individuals' tendency to think in images revealed that those who reported that they do not ever think in imagery have a significantly higher mean worry score than those that do. While conclusions that can be drawn from a single question are limited, there are some interesting questions and implications arising from this finding. Firstly, it seems reasonable to suggest that the experiencing of intrusive images is reliant on, at least occasional, thinking in images, this finding is therefore consistent with hypothesis one. Secondly, it raises the question as to why the tendency to think in images should be linked to level of worry.

One possible explanation for this finding lies in the age range of the current sample. As this study looked at older adults, it may be presumed that their level of tendency to worry may be longstanding. Chronic avoidance of images by high worriers, as suggested in Borkovec's avoidance theory of worry (Borkovec, 1994) may conceivably lead to a preference for a verbal processing style. Hirsch and Mathews (2012) suggest that processing habits may become more automated over time leading to a tendency for worry to 'grow'. It would be interesting therefore to see this finding extended and

investigated across age ranges, based on these arguments it would be expected that in younger age groups this difference would be seen to a lesser degree, or not at all.

An alternative explanation may lie in the different effects of thinking about a worrisome topic in verbal or imagery form. Separate studies have shown that engaging in imagery on a worrisome topic (Stokes & Hirsch, 2010) or following exposure to a stressor (Butler, Wells, & Dewick, 1995) results in a reduction of intrusive thoughts. Conversely, engaging in verbal processing (worry) was associated with an increase in intrusive thoughts which is thought to result from inhibition of emotional processing. One possible explanation for the finding that those who do not ever think in imagery have a higher mean worry score, is that a verbal processing style leads to a vulnerability for excessive worry. As this vulnerability should be present across age groups, a replication with a younger age group may help to clarify the mechanism involved.

These two explanations are not, of course, mutually exclusive, a coping style characterised by experiential avoidance, particularly of emotionally laden imagery, may lead to an individual preference for a verbal processing style. In turn this may maintain the worry process through inhibition of emotional processing resulting in maintenance of intrusive thoughts that in turn act as triggers for further worry. This is speculative at this stage and requires testing through further research.

### *Summary*

It was not possible to demonstrate conclusively in this sample that higher levels of worry are associated with lower levels of reported intrusive memories and images. A related finding that participants who reported they did not ever think in images tended to report a higher level of worry, suggests this warrants further study. Alternative possible explanations were put forward for the relationship between processing style and level of worry, suggesting that the long-term avoidance of worry may lead to a preference for a verbal processing style, or that verbal processing style may constitute a risk factor for the development of excessive worry.

The findings related to the severity of intrusive memories and images will be considered along with hypothesis four to avoid duplication.

### 4.2.3 Hypothesis two: the presence and severity of intrusive thoughts will increase as worry scores increase.

Evidence from multiple research studies shows that intrusive thoughts increase following verbal processing of a worry topic (Stokes & Hirsch, 2010) and are increased by a period of worry after exposure to a stressor (Butler, Wells, & Dewick, 1995). It has also been reported that worriers will report more frequent distractions by negative thoughts than non-worriers during a monotonous task (Borkovec *et al*., 1983). Based on these, and similar, findings it was hypothesised that the more an individual tends to worry, the more they will tend to experience intrusive thoughts.

The results of the current study did not support the hypothesis that the likelihood of reporting intrusive thoughts would increase as worry scores increase, which may be owing to the relatively small number of high worriers within the sample. A slightly higher proportion of the sample reported experiencing recent intrusive thoughts compared to memories or images (18 compared to 15 and 16 respectively).

The results did show that the severity of intrusive thoughts increased as worry scores increased. The severity score is made up of individual scores for frequency, distress, uncontrollability and interference with daily life. Although individuals with higher levels of worry may not have an increased likelihood of experiencing, versus not experiencing, intrusive thoughts, they may experience a higher frequency of thoughts, or experience their thoughts as more distressing, uncontrollable or perceive them to interfere to a greater degree with their daily lives.

The finding that the severity of intrusive thoughts increases as worry scores increase is consistent with research finding increased frequency of intrusive thoughts after a worry period as well as reports that high worriers diagnosed with generalised anxiety disorder (GAD) experience their worries as more uncontrollable and pervasive than those without GAD (Craske *et al.,* 1989).

### 4.2.4 Hypotheses three and four: Cognitive fusion, psychological inflexibility and worry together will better predict the likelihood of reporting intrusions than worry alone. The relationship between level of worry and intrusion severity will be accounted for by level of cognitive fusion and psychological inflexibility.

Or : Cognitive fusion, psychological inflexibility and worry together will better predict and explain the presence and severity of intrusive experiences than will worry alone. Psychological inflexibility and in its converse, flexibility, are central to the Acceptance and Commitment Therapy (ACT) model of psychological ill

health. Psychological inflexibility refers to the extent to which psychological reactions dominate in guiding behaviour over chosen values and the contingencies of the present situation. This often leads to attempts to avoid experiencing unwanted internal events (i.e. experiential avoidance) (Bond *et al*., 2011). Cognitive fusion is a component of psychological inflexibility and refers the extent to which an individual is 'fused' to their thoughts or responds to them 'as if' they were an external event or literally true (Gillanders *et al*., under review).

In the context of intrusions, it may be expected that the higher the level of fusion, the more an individual would tend to respond to an intrusion 'as if' it were an actual event. It would follow that those high in fusion may experience intrusions as more distressing than those low in fusion. In individuals high in inflexibility, an event, such as an intrusion, leading to distressing emotions would be more likely to trigger experiential avoidance. Given the theorised avoidance function of worry, it seems likely that there would be a link between level of inflexibility and the tendency to use worry as a form of avoidance. It was therefore hypothesised that fusion, inflexibility and worry together would better predict the presence of intrusions than worry alone and that the relationship between worry and severity of intrusions would be explained by levels of fusion and inflexibility.

#### *4.2.4.1 Intrusive Memories and images*

Increasing levels of inflexibility predicted a decrease in the reporting of intrusive memories and images. Increasing levels of fusion predicted an increase in the reporting of intrusive images but not memories. Increasing levels of worry predicted an increase in memory severity but not image severity.

The findings for decreased reporting of intrusions as inflexibility increased may be interpreted as evidence that these phenomena are being actively avoided. This is consistent with a study that demonstrated that participants' high experiential avoidance (based on scores on the AAQ-I) showed increased avoidance (as indicated by reaction time delay) to aversive images, compared to a low experiential avoidance group (Cochrane *et al*., 2007). Furthermore, the same study study found an increase in left-hemisphere activity (as indicated by event-related potentials) in response to aversive imagery for participants high in experiential avoidance. One explanation for this, is that individuals high in experiential avoidance use verbal processing strategies (e.g. worry) to cope with aversive images and the associated distress (Cochrane *et al*., 2007). In the current study, no relationship was found between the presence of intrusive memories or images and the level of worry. It may be that

the number of participants with high levels of worry was insufficient to detect an effect, or that worry is only one avoidance strategy used by individuals with high inflexibility and high experiential avoidance.

Memories and images, as image-based intrusions were expected to share similar characteristics and relate to study variables in similar ways. As described above, both types of intrusions share similar characteristics, however there are important differences in how they relate to fusion and worry.

Fusion was found to be a significant predictor of the occurrence of intrusive images. This is consistent with higher levels of fusion leading to increased awareness of intrusions and an increase in the perceived distress associated with them. The mean severity rating was higher for images than for memories, thus when combined with high fusion, distressing images would be likely to trigger avoidance. As it was found, both that increased levels of fusion led to increased occurrence of images, and increased inflexibility led to decreased occurrence of images, it may be that there is a threshold of experience below which increased fusion leads to increased awareness of intrusions and above which avoidance leads to intrusions no longer entering awareness.

Given that the mean severity ratings for images were higher than for memories, it may, at first, seem counter-intuitive that there was not a link between image severity and level of worry. The explanation of this may lie in the association (or lack thereof) between image severity and fusion. Thus an individual may experience severe intrusive imagery but if they do not respond to these experiences as if they were literally true, but instead as transient thoughts, they would not be motivated to avoid. Thus, when an individual experiences severe intrusive images and has high fusion, attempts to avoid the experience will be initiated. Over time, repeated practice at avoiding distressing intrusions may result in these intrusions no longer reaching conscious awareness. That level of fusion is predictive of the reporting of intrusive images and inflexibility/experiential avoidance is negatively predictive of intrusive images is consistent with this explanation, however this requires testing through further research.

Fusion was not found to be a significant predictor of the occurrence of intrusive memories. Given that an individual who is high in fusion is more likely to respond to an intrusion as if it were a current event, it may be that the contextual information present in a memory in some way guarded against this effect. Ehlers and Clark (2000) suggest that, as experiences are incorporated into autobiographical memory, the information they contain is both organised and elaborated. This is

thought to enhance intentional retrieval and reduce involuntary (intrusive) triggering. Memories reported in this study had been involuntarily triggered, but the sense of reliving (nowness) was relatively low, which may indicate that these memories had undergone a higher degree of organisation and elaboration, than had the images reported, which were accompanied by a greater sense of reliving. That this offers a full interpretation is cast into doubt however by the pattern of findings for memory severity.

Within the small subsample of those reporting memories, increasing severity of intrusions was associated with increasing worry scores. This became non-significant when either fusion or inflexibility scores were held constant, although a moderate strength correlation remained between worry and memory severity when holding inflexibility constant. Neither fusion nor inflexibility were independently significantly associated with the severity of intrusive memories, although, that, for fusion approached significance (p=.058).

The fact that intrusive memories were reported by these participants indicates that they were either not motivated to, or not successful at, avoiding these intrusions despite the fact that levels of worry were associated with higher levels of severity. It seems plausible that the more severe an intrusion is perceived to be, the more likely it is that worry will be triggered as a coping strategy. That this relationship is partly explained by the level of fusion may suggest that worry is only triggered when an individual has a higher level of fusion.

Given that memories of increasing severity are associated with increasing levels of worry and that this relationship is partly accounted for by level of cognitive fusion, it may be expected that the occurrence of memories would also be associated with these variables. One explanation why this may not be the case, is that memories for past events can be associated with both worry and rumination. This is consistent with findings from a study using the Intrusions Interview to investigate intrusive memories and images in depression. The authors reported that intrusive memories were more common than images (Patel *et al.,* 2007), and in a separate study, clinical improvement of depression was reported through imagery re-scripting as a stand-alone treatment (Brewin *et al.,* 2009). Whilst some memories may trigger concerns for the future, and so experiential avoidance (e.g. through worry), others may trigger rumination on past events, mood states or failures (McLaughlin *et al.*, 2007). It is possible therefore that cognitive fusion may be related either to an increase, or a decrease in the occurrence of intrusions depending on the implications of the intrusion for the

individual. As this study was not designed to detect such a relationship, further research is needed to confirm or modify this hypothesis.

A question remains as to why memories and images related differently to worry and cognitive fusion in this study. One interpretation of the observed pattern relies on memories as accounts of past events. Memories for past events that have been successfully incorporated into autobiographical memory as evidenced by lower levels of reliving or 'nowness' would not be expected to be associated with high distress, frequency, uncontrollability and interference in daily life (Ehlers & Clark, 2000). It may be reasoned therefore, that intrusive memories are only experienced as severe when an individual has higher levels of fusion. An individual may then respond to a distressing memory either with experiential avoidance or rumination, as discussed above. Images, on the contrary may relate to any period of time and may occur out of context, their severity therefore may be related to the triggering of here and now emotions and relatively unrelated to levels of fusion. Individuals who have high levels of cognitive fusion may however, be more likely to be aware of, and so report intrusive images.

#### *Summary*

The higher the level of fusion the more distressing an intrusion would be perceived to be. In individuals high in inflexibility, intrusions leading to distressing emotions may be more likely to trigger experiential avoidance. Given the theorised avoidance function of worry, worry may function as one form of experiential avoidance.

Individuals with low levels of cognitive fusion may experience severe intrusions without the need to avoid them. That memory severity was more closely associated with worry, than was imagery severity, and the occurrence of images was associated with fusion whereas occurrence of memories was not suggests that intrusive memories and images may serve different functions or be triggered and maintained in different ways. The differences may be explained by the greater past orientation of memories as well as the increased availability of contextual information, and the link between memories and rumination.

### *4.2.4.3 Intrusive Thoughts*

In the current sample, the occurrence of intrusive thoughts was distributed across levels of worry and was not significantly predicted by levels of worry, cognitive fusion nor psychological inflexibility.

The severity of intrusive thoughts was positively associated with worry, cognitive fusion and psychological inflexibility.

A link between intrusive thoughts and worry has been repeatedly demonstrated (e.g. Borkovec *et al*., 1983; Butler *et al.* , 1995; Stokes & Hirsch, 2010). Whilst the presence of intrusive thoughts was not significantly predicted by worry in this sample, there was an association between worry and the severity of intrusive thought (which includes frequency) which is consistent with previous research (e.g. Butler e*t al.* 1995). Consistent with the link between worry and intrusion severity are the characteristics of intrusions in this sample, in contrast to memories and images, the most frequent theme was illness, injury and death and the most commonly associated emotion, anxiety. Unsurprisingly, given the characteristics of intrusive thoughts in this sample, intrusive thoughts were associated with the highest mean severity rating.

The severity of intrusive thoughts was associated with worry, cognitive fusion and psychological inflexibility. However, only the level of cognitive fusion remained significantly positively associated with thought severity when controlling for the other variables.

Individuals high in cognitive fusion are more likely to respond to their thought 'as if' they were literally true. Given that the most common theme for intrusive thoughts was illness, injury or death and the most commonly associated emotion, anxiety, it seems likely that these internal events could be experienced as very distressing. This is supported by the higher mean severity score for intrusive thoughts. For an individual who is also high in psychological inflexibility this would motivate attempts to avoid the internal experience (experiential avoidance) thus activating worry as a form of cognitive avoidance. Given the ability of short periods of worry to incubate intrusive thoughts (Wells & Papageorgious, 1995), this is likely to lead to further intrusions and a vicious cycle of worry leading to increased intrusions and increased intrusions leading to more worry.

### *Summary*

These findings are based on a small sub-sample of participants who reported experiencing intrusive thoughts and requires replication and extension in a larger sample in order to draw firm conclusions. Within the current sample, thoughts were the most commonly reported intrusive experience and occurred across the spectrum of worry. The relationship of the severity of intrusive thoughts to worry is consistent with previous research findings that worry leads to increased frequency of intrusions (e.g. Borkovec *et al.,* 1983). The finding that severity of intrusive thoughts is also associated with

fusion and inflexibility, and that only the relationship with fusion remains when controlling for other variables, indicates that the stance an individual takes in relation to intrusive thoughts is related to the severity of those intrusions.

## 4.3 Conclusions

The Avoidance Theory of worry asserts that 'worry functions as a cognitive avoidance response, both to perceived threats in the future and to aversive images or other internal experiences like emotions' (Sibrava & Borkovec, 2006, p. 251). Building on the work of Borkovec (1994), the Acceptance Based Model suggests that worry is an experiential avoidance strategy (Hayes *et al.*, 1996). Both models propose that worry is maintained by the negative reinforcement of a short term reduction in arousal but with the consequence of a reduction in emotional processing and so a maintenance of threatening associations (Roemer *et al.*, 2005).

The current study builds on these theories by exploring the relationships between two key concepts in the ACT literature, psychological inflexibility (together with experiential avoidance) and cognitive fusion, and how these and worry are related to different forms of intrusive experience in an older adult population.

Intrusive memories, images and thoughts were all present in relatively low levels across a sample of community dwelling older adults. Intrusive memories and images shared many similarities including content, associated emotions and how they related to inflexibility. Intrusive thoughts were characterised by different content, emotions, increased severity and different relationships with study variables. The finding of differences between intrusions based predominantly on imagery (memories and images) and those based on verbal thought is consistent with findings by Hagenaars *et al*., (2010) which suggests that intrusive images and thoughts are in fact different phenomena. The current study further adds to this literature by proposing that memories, images and thoughts all relate differently to other constructs and may serve different functions as well as relating in different ways to psychopathology.

Intrusive memories have been found to be common among depressed patients (Patel *et al*., 2007). This is consistent with the interpretation of the findings of the current study suggesting that individuals with high cognitive fusion may respond to intrusive memories either through experiential avoidance or rumination. As rumination was not measured in the current study, this hypothesis requires direct testing through further research.

Intrusive imagery has been found to characterise a number of anxiety disorders. This study finds little evidence for a role of intrusive images or memories in the development or maintenance of worry in this sample of older people. Instead the findings suggest that severe intrusive images are only related to the tendency for experiential avoidance when individuals also experience high fusion, and may therefore occur without avoidance in individuals with lower levels of fusion. This indicates that, it is the occurrence of intrusive images in the context of cognitive fusion that is linked to psychopathology rather than the experience of images alone. Other finding suggest that the experience of intrusive imagery may be extremely variable and related to current circumstances and an individual's level of anxiety and stress. These experiences may therefore not be best captured by inquiring about a restricted time period.

The current study found that inflexibility and experiential avoidance are associated with worry and negatively associated with the occurrence of intrusive memories and images. This is consistent with the theoretical view of worry as a form of avoidance (Borkovec, 1994; Roemer *et al.,* 2005). It was also found that worry, fusion and inflexibility were associated with increasing severity of intrusive thoughts. This lends further support to the argument that worry is associated both with avoidance and with the long-term maintenance of threatening associations leading to further intrusions. The findings of the current study further suggest a role for cognitive fusion in pathological conditions involving all forms of intrusive experiences.

A number of limitations of the current study preclude drawing firm conclusions from these findings and these will be discussed next.

## 4.4 Limitations

### *Generalisability*

Care must be taken with generalising the results of this study due to the homogenous nature of the sample. Participants were all from a white, British background and 40% had backgrounds in profession such as teaching and healthcare indicating a high general level of education within the sample. There were also more female participants than male (65% versus 35%) which is significant given that gender differences are consistently found on measures of worry, with women tending to have higher scores (Robichaud *et al.*, 2003), and this was confirmed by the results of this study. Worry

scores have also been found to be effected by age, with older adults in general tending to score lower than younger adults (Hunt *et al.*, 2003) or middle aged adults (Skarborn & Nicki, 2000) but with some evidence that worry may rise again amongst the oldest-old (Neikrug, 2003). Detailed analysis by age and gender was, unfortunately beyond the scope of this study, however, a tendency toward lower worry scores among older adults may have impacted on recruitment of individuals with higher worry scores.

Interpretation of the results is restricted by the relatively small number of high worriers in the sample. One possibility is that with larger number of participants intrusive thoughts and images would have been distributed more evenly across the spectrum of worry scores. It is, however, interesting to compare the pattern of memories and images with that of thoughts, although there were similarly small numbers of participants reporting intrusive thoughts, these were distributed across the spectrum of worry, whereas those for memories and images were not.

It was originally intended that recruitment across both clinical and non-clinical settings would allow recruitment of participants evenly distributed across the spectrum of worry. In reality, recruitment through mental health services for older adults encountered a number of related problems. Mental health and, in particular, psychology services are a scare resource for older adults. Where services are available therefore, they serve predominantly secondary and tertiary levels of care. This led to difficulty related to the severity and comorbidity of the patient population. The numbers of patients meeting the study criteria was small, a number of participants who met the inclusion criteria, also met exclusion criteria due to current severity of their mental ill health. A related difficulty is that it may be expected that patients with very high levels of worry and comorbidity may worry about taking part in research, or have difficulty in making a decision, and therefore be reluctant to contact the researcher. These complications indicate that a more representative sample may have been recruited through general primary care, rather than specialist services.

### *Reporting of intrusions*

As described above, whilst 65 per cent of the sample reported intrusions, there were relatively low numbers of participants reporting each type of intrusion. Comparison to previous research indicates that restricting inquiry to the past week may have led to under-reporting, particularly of images and thoughts in this sample. In addition, there are a number of other methodological considerations that may have impacted on the reporting of intrusions. It may be that for the majority of individuals,

intrusions may be relatively fleeting and untroublesome and therefore not be recalled in retrospect. It is also possible that highly avoidant individuals would avoid talking about distressing intrusions, this would be in line with a finding that participants high in experiential avoidance were less likely to agree to participate in a further study involving aversive images (Cochrane *et al.,*2007). It may also be that older people are less used to reporting on these experiences or that cohort beliefs about sharing of private experiences lead this group to respond differently to the intrusions interview. It may also be that intrusive experiences in general are less common, or less frequent in older age. Due to vast differences in methodologies employed as well as populations sampled in studies of intrusive experiences it is difficult to determine the precise impact of these factors on the current findings.

Due to the small number of participants reporting each type of intrusive experience this meant that parts of the analysis were completed on only a small sub-sample which dramatically reduces the power and increases the risk of type II errors. The number of correlations conducted on this data also increases the risk of type one error, it was not considered appropriate to conduct a Bonferroni correction due to the possibility of increasing type II errors. The adoption of a more conservative significance level was considered, however on closer examination of the data, it was adjudged that whilst this would reduce the likelihood of type I errors, it would also reduce the meaningfulness of the data. It was therefore decided to interpret the findings with caution and as an indication of relationships that warrant further investigation, rather than conclusive findings.

A difficulty of interpretation lies in the fact that although the presence of intrusions was restricted in range, the absence of intrusions was not. The reporting of the occurrence of intrusive memories and images was restricted to worry scores from 23 to 49 and 17 to 49 respectively. In contrast, the absence of intrusive images and memories was reported across the range of worry scores (16-80). This wider distribution of worry scores for those not reporting intrusions may have given rise to the similar mean scores between groups. This suggests that not reporting experiencing intrusive images or memories during a given week is influenced by multiple factors, and indicates that an improved tool for capturing the tendency to experience intrusions is required to more accurately assess the relationship with worry.

The low reporting of intrusions in this sample suggests that there are many possible factors influencing whether an individual experiences, or reports experiencing, intrusions during a given week, with worry being just one such. There are also indications that different factors may influence

the experience of, or reporting of, different types of intrusions. Taken together with the lack of consistently used and validated tools for capturing the experience of intrusions, in order for research in this area to progress, there is an urgent need for the development of validated tools.

A measure of the tendency to experience intrusions in different forms may provide less specific information about the characteristics of individual intrusions but may capture a better sense of an individual's overall experience of intrusion. Not being required to give a description of specific intrusions may enhance responding among highly avoidant individuals. Another option for more accurate recording of intrusive experiences would be prospective recording of intrusions over a longer period of time, through experience sampling, which would allow the detailed capture of characteristics of intrusions without the difficulties associated with retrospective recollection. The development of a new tool to capture the experience of intrusions in this population was beyond the scope of this study, consequently, study design was limited by currently available measures.

### *Confounding variables*

It was intended to include a measure of depression (GDS) in the analyses to rule out the effects being due to mood and to check for possible suppressor effects of mood on the relationships between study variables. Due to the non-normal distribution of the GDS data (which persisted following a number of transformations), the decision was taken to exclude data for this measure from the analysis. This limited the interpretation of the data and the inclusion of a measure of mood disturbance may have added much to the understanding of the relationships between variables.

Due to the small number of participants meeting diagnostic criteria for GAD within this study sample, it was not possible to analyse the data according to diagnostic groups, this is problematic as it is known that there are differences between high worriers with and without GAD. Previous research also suggests a link between depression and intrusive memories (Patel, et al., 2007), which suggests that depression was a potential confounding factor.

## 4.5 Research implications

The present study is the only study, known to the author, to have examined links between cognitive fusion, psychological flexibility, worry and the experience of intrusions in different forms. The current study is exploratory in nature, however the findings of relationships between study variables seem to warrant further investigation.

### *Intrusions*

Only very little is known about how different forms of intrusions may be developed and maintained and how these may interact with other variables in psychological distress. Research in this area is currently hampered by a lack of appropriate high quality tools to capture data about intrusions. As outlined above, further investigations in this area may benefit from the development of a measure of the tendency to experience intrusions in different forms or a prospective measure of the occurrence of intrusions such as through diaries or experience sampling.

The findings from the current study suggest that there may be a link between an individual's preference for processing style (verbal or non-verbal) and their level of worry. There is clearly a need for replication of this finding using a validated measure. The Verbalizer-Visualizer Questionnaire (VVQ; Richardson, 1977) is one such measure, however the authors themselves acknowledge that a major problem revealed by factor analysis is that whilst it sets out to measure the tendency to use either a verbal or non-verbal processing style, verbal items are actually measure verbal ability (as opposed to tendency to use a verbal processing style). There is therefore a need for revision of the existing measure or development of a new measure to facilitate further research on this variable. In particular, in light of the age range of the current study, it would be informative to compare groups of worriers and non worriers of different ages.

### *Worry, cognitive fusion and psychological inflexibility*

Strong correlations were found between worry, cognitive fusion and psychological inflexibility in this sample. Due to the difficulties generalising from a relatively homogenous older adults sample to the general population, replication of this finding in different populations is needed to confirm this finding. One interpretation of the link between these variables and their relationship to intrusions has been put forward, further studies are required to confirm and extend these findings in order to clearly establish the roles these variables play in the many different manifestations of worry. Given the known relationships between measures of worry, cognitive fusion and psychological flexibility with measures of depression symptomatology, it will be of paramount importance to include a measure of depression in future studies of these variables to fully understand the relationships between them.

## 4.6 Clinical implications

Until relatively recently, the most effective, and most widely available, treatments for GAD were applied relaxation and cognitive-behaviour therapy (CBT). A review of psychological treatments for GAD reported the lowest recovery rate at post-treatment for applied relaxation (34%) and cognitive therapy (36%), followed by CBT (46%), the most effective treatment was shown to be meta-cognitive treatment (MCT) with 80 per cent of patients meeting recovery criteria based on PSWQ scores, although promising, this was based on only ten patients (Fisher, 2006).

Treatment of psychological distress with worry as a prominent feature has in the past focused on modifying worry itself, or beliefs about worry. The findings of the current study give an indication that worry itself may be a symptom of overarching patterns of psychological inflexibility and cognitive fusion. Whilst these findings require replication and extension, this is consistent with preliminary findings for the effectiveness of Acceptance Based Behaviour Therapy (ABBT). Acceptance Based Behaviour Therapy (ABBT) is a recent development in the treatment of GAD and is based on Acceptance and Commitment Therapy (ACT) and specifically the Acceptance Model of GAD and worry (Roemer *et al.*, 2005). Preliminary results indicate 78 per cent of patients no longer meeting GAD criteria, with 77 per cent meeting criteria for high end-state functioning (Roemer *et al.*, 2008). Unlike the majority of existing treatments for GAD, ABBT does not specifically target worry. Suggested mechanisms of change are acceptance of internal experiences and engagement in meaningful activities (Hayes *et al.*, 2010).

The findings of the current study support the relevance of ACT constructs, including psychological inflexibility and cognitive fusion, to older adults; and indicate that these constructs relate in a meaningful way to the experience of worry. Whilst the application of ACT specifically to older adult groups has, so far, been little studied, a pilot study applying ACT to treatment of GAD in older adults concluded that it is feasible to use ACT with this age group. Treatment gains were substantially smaller than those found with younger adults and the authors suggest that adapting treatment to include fewer, but more relevant, elements may be more effective (Wetherell *et al*., 2011).

The finding that a proportion of older people do experience intrusive memories, images and thoughts, and that these may be distressing, particularly for those with higher levels of cognitive fusion, suggests that it may be worthwhile to routinely inquire about a patient's experience of intrusions during assessment. Findings from previous research about the therapeutic value of

working directly with intrusive memories (Brewin *et al.,* 2009) points towards these experiences as being potentially important targets for therapeutic intervention in cases where they are reported.

In summary, intrusive memories, images and thoughts should be inquired about in routine assessment and, when severe, may provide targets for therapeutic intervention in their own right. A greater understanding of the variables and processes involved in development and maintenance of worry may help to maximise the effectiveness of treatment for conditions involving the worry process which include GAD, specific anxiety disorders and depression. The present study provides some evidence that the use of cognitive defusion and acceptance techniques may be useful for individuals with severe intrusive thoughts and memories and for individuals with high worry. It also supports the validity of ACT constructs, psychological inflexibility and cognitive fusion, in older people.

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# Appendices

i. Participant Information

ii. Ethics Correspondence

iii. Research and Development Correspondence

iv. Intrusions Interview with Modifications in [ ]

## Participant Information

- Leaflet
- Participant Information Sheet
- Consent Form

Contact:

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Or

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## What thoughts and images pop into your mind?

If you are over 60 years old, read on for details about taking part in imagery research.

We are looking for people over the age of 60 to take part in a research project. The project explores the links between images and memories that pop into our minds unasked, the way we respond to them, and how much we worry. This is perhaps better to illustrate with an example: Imagine you are about to go to the supermarket. Suddenly an image flashes into your mind of standing at the checkout and forgetting the pin number for your card. One person might begin to worry about the possibility of this happening, and as a result, might make sure they have cash with them, or even avoid going altogether. Another person may just shrug off the image and not think of it again.

By finding out more about these differences in the ways people respond to thoughts and images, we hope to find more effective ways of helping people who are troubled by distressing thoughts and images, as well as worry.

Taking part in the study involves completing a consent form and four short questionnaires as well as an interview about symptoms of anxiety and depression, and experience of images and memories that pop into your mind unasked (intrusive images).

If you think you might like to take part, or just want to find out more, please contact Emma Miller on 01561 378536 or e.f.miller@sms.ed.ac.uk

Please pass on information about the project to any friends or family you think may be interested in taking part.

Many thanks.

# Participant Information Sheet

## An exploration of older people's experiences of intrusive thoughts, images and memories, across the spectrum of worry.

The aim of the study is to find out whether images and memories that are intrusive, or come to mind as if out of nowhere, are a problem for those over 60, with varying levels of worry. It will also look at how these images are linked to our experience of worry and emotions.

I would like to invite you to take part in my research study. Before you decide I would like you to understand why the research is being done and what it would involve for you. I will go through the information sheet with you and answer any questions you may have. This should take about 20 minutes.

Part 1 tells you the purpose of the study and what taking part would involve; Part 2 gives you more detailed information about how the study is being conducted.

Please ask if there is anything that is not clear

### What is the purpose of the study?

The reason for studying intrusive images and memories is to better understand the links between imagery, worry and other thinking processes and to develop more effective ways of helping those who are experiencing distress.

### Why have I been invited to take part?

I am looking for around 60 people over the age of 60 to take part in this study. Participants will fall into one of two groups, one group who have a diagnosis of Generalised Anxiety Disorder, and one group who do not.

### Do I have to take part?

It is up to you to decide whether to take part. I will describe the study and go through this information sheet with you. If you agree to take part, I will then

ask you to sign a consent form. You can change your mind at any time. You do not need to give a reason if you decide to withdraw. Taking part in the study will not affect your care or treatment now or in the future.

## What will happen to me if I take part?

It is always best to take some time to think over the information you have been given and to discuss it with family and friends.

If, after taking time to think about it, you decide you would like to take part in the study I will meet with you, in private to answer any questions you may have. If you are happy to proceed you will then be asked to complete a written consent form.

Next we will go through a series of interview questions expected to last for around one hour, although we can stop for a break half way through, or at any other time you need to. The interview will be in two parts; firstly, you will be asked some questions about your experience of symptoms related to mood and anxiety; in the second part of the interview you will be asked some questions about your recent experience of memories and images.

You will then be asked to fill out four short questionnaires which should take about half an hour. Each questionnaire asks about different symptoms or experiences, one asks about your mood, one about worry, one about your emotions and one about how you react to your thoughts.

This will complete your participation in the study and I will not contact you again, other than to send a summary of the findings from the research if you would like.

## What are the possible disadvantages and risks of taking part?

Taking part in any research involves a commitment of your time and some inconvenience. This will be kept to a minimum by arranging to meet you as close as possible to your home, and in a relaxed and friendly environment.

Whilst I do not expect anyone to be distressed by taking part in the study, it is possible that some people may find talking about their experience of

memories and images upsetting. In this event, the possibility of a referral to the Older Peoples' Psychology Service will be discussed with you.

## What are the possible benefits of taking part?

There are not expected to be any direct benefits of taking part in the study. It is however very important that Older Peoples' experiences and views are included in research. In taking part in research, you will be helping to add to our understanding of the links between worry, imagery and emotions.

## What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

## Will my taking part in the study be kept confidential?

Yes, we will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

If the information in Part 1 has interested you and you are considering taking part, please read the additional information in Part 2 before you decide.

# Part 2

## What will happen if I change my mind about taking part?

You have the right to ask any questions or to withdraw at any point in the study. If you decide to withdraw, any information you have provided will be deleted if you wish. You do not have to provide a reason for withdrawing from the study.

## What if there is a problem?

I do not expect anyone to be harmed by taking part in the study. If however anyone should feel upset or distressed they will be encouraged to seek support either from any mental health professional involved in their care, or to contact the Edinburgh Psychology Service for Older People.

If you have a concern about any aspect of this study, please speak to myself, or one of the supervisors overseeing the study. All contact details can be found at the end of this information sheet.

If you remain unhappy and wish to complain formally, the details of how to make a complaint to the NHS are also to be found at the end of this information sheet.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence, then you may have grounds for a legal action for compensation against NHS Lothian or the University of Edinburgh, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

## Will my taking part in the study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential. All results of the study will be anonymised so that you cannot be identified. Your contact details will be kept securely for the duration of the study, these will be kept separately from interview and questionnaire data.

If, during the course of the study you disclose information that either a crime has been committed or that you, or someone else, is at risk of harm, I would be obliged to contact the relevant agencies which may include the police or health or social services. If possible this would be discussed with you and an appropriate course of action agreed upon.

## Will my General Practitioner be informed?

Yes, a brief letter will be sent to your GP to inform them that you are taking part. If any concerns are raised during the study, regarding your wellbeing, I will request your permission to write to your GP again and also to the Older Peoples' Psychology Service, if appropriate.

As outlined in the section on confidentiality, your GP, as well as any other appropriate agencies would be contacted in the event of a disclosure of a crime or a risk to yourself or someone else.

## What will happen to the results of the research study?

The results will be written up and submitted to the University of Edinburgh as part of my doctoral thesis. They will also be submitted for publication in a peer reviewed journal and may be presented at conferences. All results will be anonymised so no-one will be able to identify you or the information you provided.

If you would like a copy of the findings from the research, I will be happy to send you a summary written in non-technical language. If you prefer, you can request a copy by contacting Emma Miller at the address at the end of this information sheet.

## Who is organising and funding the research?

The research is being sponsored jointly by the University of Edinburgh and NHS Lothian.

## Who has reviewed the study?

All research in the NHS is reviewed by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by Lothian Research Ethics Committee.

## Further information and contact details

## For further information about this study:

## Chief Investigator

Emma Miller

Clinical Psychology,
University of Edinburgh
School of Health in Social Science
Teviot Place
Edinburgh
EH8 9AG

e.f.miller@sms.ed.ac.uk
01561 378 536

## Academic Supervisor

David Gillanders
Academic Director
Doctoral Programme in Clinical Psychology
University of Edinburgh
School of Health in Social Science
Teviot Place
Edinburgh
EH8 9AG
0131 651 3946
david.gillanders@ed.ac.uk

## Should you wish to speak to someone not directly involved in the study, please contact:

Dr Ken Laidlaw

Professional Lead for Older Peoples' Psychology Services

Jardine Clinic

Royal Edinburgh Hospital

Edinburgh, EH10 5HF

Tel: 0131 537 6776

## For advice on whether to take part:

Please feel free to speak to family, friends or any health professional involved in your care. The chief investigator will be please to answer any further questions or concerns you may have.

## Who to approach if you are unhappy with the study:

In the first instance, please speak to the chief investigator or one of the supervisors overseeing the study.

If you are still unhappy and wish to make a complaint, please contact:

The Independent Advice and Support Service:

**0131 558 3681**

The NHS Lothian complaints department for Elderly Mental Health:

**0131 537 9522 or 0131 537 9523**

Or contact

NHS Lothian Complaints Team
2nd Floor
Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG

Tel: 0131 465 5708

# Consent Form

## An exploration of older people's experiences of intrusive thoughts, images and memories, across the spectrum of worry.

Chief Investigator, Emma Miller, Trainee Clinical Psychologist

Participant identification number:

| | *Please initial box* |
|---|---|
| *I confirm that I have read and understood the information sheet dated 01/04/2012 (version 4) and had the opportunity to ask questions and have had these answered satisfactorily.* | ☐ |
| *I understand that my participation is voluntary and that I may withdraw at any time, without giving a reason.* | ☐ |
| *I understand that if I withdraw this will not affect my care or treatment now or in the future* | ☐ |
| *I understand that should I share information which causes concern about my well-being or the well-being of others this information may be shared with my GP or other appropriate agencies.* | ☐ |
| *I understand that anonymised findings may be published and that information identifying me will remain confidential* | ☐ |
| *I consent to audio recording of my interview and for recordings to be retained until the end of the study* | ☐ |
| *I agree to take part in this study* | ☐ |

**Participant's signature**…… **Date**…….

**Print name**……

**Investigators signature**…… **Date**…….

**Print name**……

Appendix II.

## Ethics Correspondence

- Ethics Application
- Ethics provisional Approval
- Reply to Ethics
- Ethics Approval
- Amendment Application
- Amendment Approval

## Welcome to the Integrated Research Application System

## IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

**Please enter a short title for this project** (maximum 70 characters)
Exploring intrusive imagery in Generalised Anxiety Disorder -version 1

**1. Is your project an audit or service evaluation?**

○ Yes ◉ No

**2. Select one category from the list below:**

○ Clinical trial of an investigational medicinal product
○ Clinical investigation or other study of a medical device
○ Combined trial of an investigational medicinal product and an investigational medical device
○ Other clinical trial or clinical investigation
◉ Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
○ Study involving qualitative methods only
○ Study limited to working with human tissue samples, other human biological samples and/or data *(specific project only)*
○ Research tissue bank
○ Research database

**If your work does not fit any of these categories, select the option below:**

○ Other study

**2a. Please answer the following question(s):**

| | | |
|---|---|---|
| a) Does the study involve the use of any ionising radiation? | ○ Yes | ◉ No |
| b) Will you be taking new human tissue samples (or other human biological samples)? | ○ Yes | ◉ No |
| c) Will you be using existing human tissue samples (or other human biological samples)? | ○ Yes | ◉ No |

**3. In which countries of the UK will the research sites be located?***(Tick all that apply)*

☐ England
☑ Scotland
☐ Wales
☐ Northern Ireland

**4. Which review bodies are you applying to?**

☑ NHS/HSC Research and Development offices
☑ Research Ethics Committee

☐ Patient Information Advisory Group (PIAG)
☐ Ministry of Justice (MoJ)

**5. Will any research sites in this study be NHS organisations?**

◉ Yes ○ No

**6. Do you plan to include any participants who are children?**

○ Yes ◉ No

**7. Do you plan to include any participants who are adults unable to consent for themselves through physical or mental incapacity?** *The guidance notes explain how an adult is defined for this purpose.*

○ Yes ◉ No

**8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service in England or Wales?**

○ Yes ◉ No

**9. Is the study, or any part of the study, being undertaken as an educational project?**

◉ Yes ○ No

**9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?**

◉ Yes ○ No

**Integrated Research Application System**
**Application Form for Research administering questionnaires/interviews for quantitative analysis or mixed methodology study**

NHS
National Patient Safety Agency
National Research Ethics Service

## Application to NHS/HSC Research Ethics Committee

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

**Short title and version number:** (maximum 70 characters - this will be inserted as header on all forms)
Exploring intrusive imagery in Generalised Anxiety Disorder -version 1

*Please complete these details after you have booked the REC application for review.*

**REC Name:**
Lothian Research Ethics Committee 02

**REC Reference Number:**
10/S1102/9

**Submission date:**
11/02/2010

## PART A: Core study information

### 1. ADMINISTRATIVE DETAILS

**A1. Full title of the research:**

An exploration of the presence and nature of intrusive imagery in older people with Generalised Anxiety Disorder

**A2-1. Give details of the educational course or degree for which this research is being undertaken:**

Name and level of course/ degree:
Doctorate in Clinical Psychology

Name of educational establishment:
University of Edinburgh

Name and contact details of academic supervisor:

| | Title | Forename/Initials | Surname |
|---|---|---|---|
| | Mr | Michael | Hopley |
| Address | School of Health in Social Science | | |
| | The University of Edinburgh, | | |
| | Teviot Place, Edinburgh | | |
| Post Code | EH8 9AG | | |

| | |
|---|---|
| E-mail | mike.hopley@ed.ac.uk |
| Telephone | 01316513972 |
| Fax | 01316513971 |

Name and contact details of student:

| | Title | Forename/Initials | Surname |
|---|---|---|---|
| | Miss | Emma F | Harris |
| Address | 1/3 Albion Terrace | | |
| | Edinburgh | | |
| Post Code | EH7 5QX | | |
| E-mail | emma.harris5@nhs.net | | |
| Telephone | 01315385019 | | |
| Fax | | | |

*A copy of a current CV for the student (maximum 2 pages of A4) must be submitted with the application.*

**A2-2. Who will act as Chief Investigator for this study?**

- (●) Student
- ( ) Academic supervisor
- ( ) Other

**A3. Chief Investigator:**

| | Title | Forename/Initials | Surname |
|---|---|---|---|
| | Miss | Emma F | Harris |
| Post | Specialist Psychological Practitioner | | |
| Qualifications | Bsc(hons)Psychology and Neuroscience | | |
| Employer | NHS Lothian | | |
| Work Address | Older Adults Psychology Service | | |
| | Jardine Clinic | | |
| | Royal Edinburgh Hospital, Edinburgh | | |
| Post Code | EH10 5HF | | |
| Work E-mail | emma.harris5@nhs.net | | |
| * Personal E-mail | emmafharris@hotmail.com | | |
| Work Telephone | 01315376614 | | |
| * Personal Telephone/Mobile | 01315385019 | | |
| Fax | | | |

*A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.*

**A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?**
*This contact will receive copies of all correspondence from REC and R&D reviewers that is sent to the CI.*

| | Title | Forename/Initials | Surname |
|---|---|---|---|
| | Ms | Elspeth | Currie |
| Address | The Medical Research Institute | | |
| | 47 Little France Crescent | | |

| | |
|---|---|
| | Edinburgh |
| Post Code | EH16 4TJ |
| E-mail | e.currie@ed.ac.uk |
| Telephone | 0131 242 9461 |
| Fax | |


**A5-1. Research reference numbers.** *Please give any relevant references for your study:*

| | |
|---|---|
| Applicant's/organisation's own reference number, e.g. R & D (if available): | |
| Sponsor's/protocol number: | |
| Protocol Version: | 1 |
| Protocol Date: | 24/01/2010 |
| Funder's reference number: | |
| International Standard Randomised Controlled Trial Number (ISRCTN): | |
| ClinicalTrials.gov Identifier (NCT number): | |
| European Clinical Trials Database (EudraCT) number: | |
| Project website: | |

| Ref.Number Description | Reference Number |
|---|---|

**A5-2. Is this application linked to a previous study or another current application?**

○ Yes ◉ No

*Please give brief details and reference numbers.*

## 2. OVERVIEW OF THE RESEARCH

***To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.***

**A6-1. Summary of the study.** *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. This summary will be published on the website of the National Research Ethics Service following the ethical review.*

This research aims to explore the occurrence, nature, and possible role of intrusive imagery in Generalised Anxiety Disorder (GAD) in older adults. To meet this aim a group of older people with a diagnosis of GAD and a control group without a diagnosis of GAD will complete an interview about intrusive images as well as completing four brief questionnaires.

**A6-2. Summary of main issues.** *Please summarise the main ethical and design issues arising from the study and say how you have addressed them.*

Taking part in the study will involve a time commitment on the part of participants as well as travel involved for the interview. In order to minimise the burden on participants, the number of measures to be completed has been reduced from earlier in the design process and participants will have the option to complete the interview over two appointments where necessary. It is also intended to use community venues to reduce the need for participants to travel.

It is also acknowledged that participating in research, may, for some older people, be a daunting prospect. It is hoped that this may be reduced by the use of community venues as well as creating a welcoming atmosphere, by providing

relaxed opportunities to discuss questions or queries over a cup of tea.

It is possible that disclosure of intrusive images may be embarrassing or distressing for some individuals or that intrusions may stem from a past traumatic event. All interviews will be carried out by a clinician (the chief investigator) with the therapeutic skills required to deal with distressing disclosures and to source additional support for any participants who may need it.

In the event of a disclosure relating to a previously unreported crime or the suspicion that there may be an ongoing risk, either to the participant or someone else, this information will be passed on to the appropriate agencies. Potential participants will be made aware of the circumstances under which confidentiality would be broken as part of giving informed consent.

The study will involve a clinical sample of older adults with Generalised Anxiety Disorder. Whilst participation in the study is not expected to cause distress, it is possible that in a population already suffering psychological distress an exacerbation of this could occur. In the unlikely event that this should happen the individual would be encouraged to contact either a mental health professional already involved in their care or the older peoples' psychology service.

## 3. PURPOSE AND DESIGN OF THE RESEARCH

**A7. Select the appropriate methodology description for this research.** *Please tick all that apply*:

- ☐ Case series/ case note review
- ☐ Case control
- ☐ Cohort observation
- ☐ Controlled trial without randomisation
- ☐ Cross-sectional study
- ☐ Database analysis
- ☐ Epidemiology
- ☐ Feasibility/ pilot study
- ☐ Laboratory study
- ☐ Metanalysis
- ☐ Qualitative research
- ☐ Questionnaire, interview or observation study
- ☐ Randomised controlled trial
- ☐ Other (please specify)

**A10. What is the principal research question/objective?** *Please put this in language comprehensible to a lay person.*

Are older adults with Generalised Anxiety Disorder more likely than those without Generalised Anxiety Disorder to experience intrusive imagery?

**A11. What are the secondary research questions/objectives if applicable?** *Please put this in language comprehensible to a lay person.*

Are measures of imagery processes correlated with measures of worry in older people?

Is the relationship between intrusive imagery and worry mediated by cognitive fusion and emotional avoidance?

**A12. What is the scientific justification for the research?** *Please put this in language comprehensible to a lay person.*

According to the Diagnostic and Statistical Manual version IV, Generalised Anxiety Disorder (GAD) is ‘ an anxiety disorder that is characterized by excessive, uncontrollable and often irrational worry…….’(American Psychiatric Association, 1994).Since the adoption of worry as a central component of GAD there has been a burgeoning of

research in the area with a number of theories being put forward to explain the phenomenon.
Worry is described as involving 'recurrent negative thinking about past stressful events, current difficulties and anticipated future problems' (Papageorgiou, 2006 in Davey and Wells, 2006 pp. 2006) and is defined by Borkovec (In Davey and Tallis, 1994 pp.28) as a 'verbal-linguistic attempt to avoid future aversive events'. Borkovec (In Davey and Wells, 2006 pp. 239) suggests that worry serves the purpose of cognitive avoidance. That is, a mental process aimed at eliminating perceived threat either in the form of external events or internal events, such as aversive imagery or emotional states. Borkovec proposes that catastrophic images may motivate thought-based cognitive avoidance, so avoiding emotions linked to images.
Kosslyn asserts that 'imagery appears to play a special role in representing emotionally charged material' (Kosslyn, 1994 pp. 405). The occurrence of a catastrophic image of a possible future event would therefore be expected to trigger an emotional reaction and may, therefore, be expected to lead to the adoption of cognitive avoidance as a strategy. However, it may be hypothesised that this would only occur if an individual has a tendency to attempt to avoid negative emotion (emotional avoidance) or if the individual tends to interpret mental representations (thoughts/ images) of an event as if it actually was the event itself (cognitive fusion).

This study is concerned with exploring the nature and frequency of intrusive imagery experienced by those with a diagnosis of GAD compared to those without, as well as levels of emotional avoidance and cognitive fusion which are hypothesised to moderate the relationship of intrusive imagery to worry.

**A13. Please give a full summary of your design and methodology.** *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

The study has a between-subjects correlational design which compares a clinical sample meeting criteria for GAD with a control sample without a diagnosis of GAD of a similar age and cohort.

Participants for the clinical sample will be identified and approached by a clinician involved in their care or they may contact the chief investigator directly in response to study publicity.
Participants for the non-clinical sample may also contact the chief investigator directly in response to study publicity. The chief investigator will also contact community groups to pass on study information to their members.

Each participant will meet with the chief investigator to complete the following interviews:
Structured Clinical Interview for DSM-IV (GAD section) (15 minutes)
Intrusions interview (30-40 minutes)

They will then be asked to complete the following self-report measures (expected to take around 30 to 40 minutes):
Pennstate Worry questionnaire (16 items)
Geriatric Depression scale (15items)
Acceptance and action questionnaire version 2 (10 items)
Cognitive Fusion Questionnaire (13 items)

This will complete participants involvement in the study. All those taking part will receive a summary of the main findings at the end of the study.

**A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?**

- [x] Design of the research
- [ ] Management of the research
- [ ] Undertaking the research
- [ ] Analysis of results
- [ ] Dissemination of findings
- [ ] None of the above

*Give details of involvement, or if none please justify the absence of involvement.*
Earlier versions of the research questions and methodology were piloted with members of the public, the results and feedback from this led to changes in both the main research questions and the design.

## 4. RISKS AND ETHICAL ISSUES

### RESEARCH PARTICIPANTS

**A17. Please list the principal inclusion and exclusion criteria.**

Community dwelling adults aged over 60
Without a diagnosis of dementia or significant self-reported cognitive impairment to be determined by asking participants whether they have any problem with their memory and if so whether this causes them problems day to day.
No self-reported current suicidal ideation
No self-reported drug or alcohol misuse
Fluent in spoken and written English

For the clinical group participants will meet diagnostic criteria according to DSM-IV for Generalised Anxiety Disorder, for the comparison group participants will not meet criteria for the disorder.

### RESEARCH PROCEDURES, RISKS AND BENEFITS

**A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol.** *These include seeking consent, interviews, non-clinical observations and use of questionnaires.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

| Intervention or procedure | 1 | 2 | 3 | 4 |
|---|---|---|---|---|
| Informed consent | 1 | 0 | up to 10 minutes | The researcher, NHS or community setting. |
| SKID GAD | 1 | 0 | 15 mins | The researcher, NHS or community setting. |
| Intrusions Interview | 1 | 0 | 30-40 mins | The researcher, NHS or community setting. |
| Acceptance and Action Questionnaire | 1 | 0 | 5 minutes | self-report |
| Penn-state worry inventory | 1 | 0 | up to 10 minutes | self-report |
| Geriatric Depression Scale | 1 | 0 | up to 10 minutes | self-report |
| Cognitive Fusion Questionnaire | 1 | 0 | up to 10 minutes | self-report |

**A19. Give details of any clinical intervention(s) or procedure(s) to be received by participants as part of the research protocol.** *These include uses of medicinal products or devices, other medical treatments or assessments, mental health interventions, imaging investigations and taking samples of human biological material. Include procedures which might be received as routine clinical care outside of the research.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days).
4. Details of who will conduct the intervention/procedure, and where it will take place.

| Intervention or procedure | 1 | 2 | 3 | 4 |
|---|---|---|---|---|

**A21. How long do you expect each participant to be in the study in total?**

Based on completion times for individual measures, it is estimated that the total participation time will be around one and a half hours. Pilot interviews will be carried out to determine this more precisely.

**A22. What are the potential risks and burdens for research participants and how will you minimise them?**

*For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.*

The study will involve a time commitment on the part of the participant. Time taken will be kept to a minimum with every effort taken to make best use of the time available. Should participants not be able to commit to the total time necessary in one sitting, arrangements may be made for two shorter interviews.
The participant will be required to travel to a suitable setting for the interviews to be carried out. To minimise the burden on participants it is hoped to use local community and NHS facilities to avoid the need for unnecessary travel by participants.
It is possible that through discussing intrusions, some participants may experience distress or a temporary increase in the frequency or intensity of intrusions. This risk will be explained to participants along with the support available should they need it.

**A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?**

(●) Yes ( ) No

*If Yes, please give details of procedures in place to deal with these issues:*

It is possible that some participants may find the disclosure of intrusions distressing or embarrassing. It is also possible that intrusions may stem from a past traumatic experience, in the case of a crime that has been committed or risk of harm to the participant or other persons further action would be taken in line with NHS trust policy. Participants would be made aware of this before giving their consent to participate along with the opportunity to discuss the risks and benefits of participating with the researcher, other care professionals and family and friends. All interviews will be carried out by a Specialist Psychological Practitioner with experience in the area of older adults. Should any disclosure requiring action or causing distress be made during the study the researcher would arrange appropriate support for the individual during the process.

**A24. What is the potential for benefit to research participants?**

The opportunity to contribute to research intended to improve understanding of and therefore care provided for older adults.

**A26. What are the potential risks for the researchers themselves?** *(if any)*

## RECRUITMENT AND INFORMED CONSENT

***In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.***

**A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used?***For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).*

Clinical group

Clinicians will be asked to identify potential participants from their records. Minimal information including contact details and that the potential participant meets inclusion criteria would then be passed to the chief investigator with the individuals' consent.

Non-clinical group

Groups of potential participants will be identified based on attendance at or membership of community groups. Individual potential participants will then be self-selected with interested individuals asked to contact the chief investigator.

**A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?**

○ Yes ◉ No

*Please give details below:*

**A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?**

◉ Yes ○ No

*If Yes, please give details of how and where publicity will be conducted, and enclose copy of all advertising material (with version numbers and dates).*

The study will be advertised in community settings such as cafés community groups, churches, GPs surgeries, as well as hospital sites.

**A29. How and by whom will potential participants first be approached?**

Potential participants for the clinical sample will either be approached by their clinician or respond directly to study publicity.
Potential participants for the non-clinical sample may respond to advertisements or may be contacted by the chief investigator(on a group basis).

**A30-1. Will you obtain informed consent from or on behalf of research participants?**

◉ Yes ○ No

*If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.*

*If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.*

All potential participants will be provided with an information sheet about the study and given time to discuss this with friends, family or professionals involved in their care. They will also be given the opportunity to ask any questions they may have. On indicating verbally that they understand the study and what they would need to do and that they would like to participate, potential participants will be asked to complete and sign a consent form. Informed consent will be taken by the chief investigator and will be viewed as an ongoing process throughout the research with participants free to withdraw their consent at any time.

*If you are not obtaining consent, please explain why not.*

*Please enclose a copy of the information sheet(s) and consent form(s).*

**A30-2. Will you record informed consent (or advice from consultees) in writing?**

◉ Yes ○ No

**A31. How long will you allow potential participants to decide whether or not to take part?**

Potential participants may take as long as they wish to decide but will be encouraged to take at least 24 hours.

**A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs?***(e.g. translation, use of interpreters)*

Due to the constraints of the study it will not be possible to include potential participants who have special communication needs or are unable to fluently understand verbal and written information in English.

**A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study?** *Tick one option only.*

- (●) The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.
- ( ) The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.
- ( ) The participant would continue to be included in the study.
- ( ) Not applicable – informed consent will not be sought from any participants in this research.

*Further details:*

## CONFIDENTIALITY

**In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.**

### Storage and use of personal data during the study

**A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)?***(Tick as appropriate)*

- [ ] Access to medical records by those outside the direct healthcare team
- [ ] Electronic transfer by magnetic or optical media, email or computer networks
- [ ] Sharing of personal data with other organisations
- [ ] Export of personal data outside the EEA
- [x] Use of personal addresses, postcodes, faxes, emails or telephone numbers
- [x] Publication of direct quotations from respondents
- [ ] Publication of data that might allow identification of individuals
- [x] Use of audio/visual recording devices
- [ ] Storage of personal data on any of the following:
  - [ ] Manual files including X−rays
  - [ ] NHS computers
  - [ ] Home or other personal computers
  - [ ] University computers
  - [ ] Private company computers
  - [ ] Laptop computers

*Further details:*
Contact details may be used in the recruitment stage and to send out a summary of the findings of the study. They will not be stored beyond the end of the study.

It is possible that direct quotations may be used to illustrate the findings of the study. In this eventuality additional

consent would be sought from individual participants concerned.

Audio recording will be used to ensure accuracy of interview data collected.

**A38. How will you ensure the confidentiality of personal data?***Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*

All participants will be allocated a study number to link data gathered from different measures. One list will be held and securely stored by the chief investigator linking identifiable information with the allocated study number in case of a participant wishing to withdraw from the study, missing data or the need to seek further consent for verbatim reporting of data.

**A40. Who will have access to participants' personal data during the study?** *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*

Personal data will be accessed by the chief investigator only. Personal information will be disclosed to the chief investigator only with consent of the potential participant.

## Storage and use of data after the end of the study

**A43. How long will personal data be stored or accessed after the study has ended?**

- (●) Less than 3 months
- ( ) 3 – 6 months
- ( ) 6 – 12 months
- ( ) 12 months – 3 years
- ( ) Over 3 years

## INCENTIVES AND PAYMENTS

**A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?**

( ) Yes (●) No

**A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?**

( ) Yes (●) No

**A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?**

( ) Yes (●) No

## NOTIFICATION OF OTHER PROFESSIONALS

**A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?**

○ Yes ◉ No

*If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.*

## PUBLICATION AND DISSEMINATION

**A50. Will the research be registered on a public database?**

◉ Yes ○ No

*Please give details, or justify if not registering the research.*

**A51. How do you intend to report and disseminate the results of the study?** *Tick as appropriate:*

- ☑ Peer reviewed scientific journals
- ☐ Internal report
- ☑ Conference presentation
- ☐ Publication on website
- ☐ Other publication
- ☐ Submission to regulatory authorities
- ☐ Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
- ☐ No plans to report or disseminate the results
- ☑ Other (please specify)

The study will be written up and submitted as a thesis for part fulfilment for the Doctorate in Clinical Psychology

**A53. Will you inform participants of the results?**

◉ Yes ○ No

*Please give details of how you will inform participants or justify if not doing so.*
A brief report will be sent to participants summarising the main findings of the study. More detailed information will be available on request.

## 5. Scientific and Statistical Review

**A54. How has the scientific quality of the research been assessed?** *Tick as appropriate:*

- ☐ Independent external review
- ☐ Review within a company
- ☐ Review within a multi−centre research group
- ☑ Review within the Chief Investigator's institution or host organisation
- ☐ Review within the research team
- ☑ Review by educational supervisor
- ☐ Other

*Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:*
The protocol and proposal has been reviewed by two academic supervisors, clinical supervisors and by an independent panel of clinical psychology researchers within the university programme team.

*For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.*

*For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.*

**A56. How have the statistical aspects of the research been reviewed?** *Tick as appropriate:*

- ☐ Review by independent statistician commissioned by funder or sponsor
- ☐ Other review by independent statistician
- ☐ Review by company statistician
- ☐ Review by a statistician within the Chief Investigator's institution
- ☐ Review by a statistician within the research team or multi−centre group
- ☑ Review by educational supervisor
- ☐ Other review by individual with relevant statistical expertise
- ☐ No review necessary as only frequencies and associations will be assessed – details of statistical input not required

*In all cases please give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned.*

| | Title | Forename/Initials | Surname |
|---|---|---|---|
| | Mr | David | Gillanders |
| Department | Clinical Psychology | | |
| Institution | University Of Edinburgh | | |
| Work Address | School of Health in Social Science | | |
| | Teviot Place | | |
| | Edinburgh | | |
| Post Code | EH8 9AG | | |
| Telephone | 01316593972 | | |
| Fax | | | |
| Mobile | | | |
| E-mail | david.gillanders@ed.ac.uk | | |

*Please enclose a copy of any available comments or reports from a statistician.*

**A57. What is the primary outcome measure for the study?**

The Intrusions Interview

**A58. What are the secondary outcome measures?** *(if any)*

Penn State Worry Questionnaire
Cognitive Fusion Questionnaire
Acceptance and Action Questionnaire
Geriatric Depression Scale

**A59. What is the sample size for the research?** *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

| | |
|---|---|
| Total UK sample size: | 52 |
| Total international sample size (including UK): | 52 |
| Total in European Economic Area: | 52 |

*Further details:*
It is intended to recruit 26 individuals meeting criteria for GAD and 26 as a control sample.

**A60. How was the sample size decided upon?** *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

The analysis of this study will be in two parts. Firstly a between groups design comparing older people with and without GAD across the two primary variables: imagery & worry, Previous studies comparing clinical and non clinical samples on measures of worry have found differences between groups that equate to large effect sizes (Meyer et al., 1990). For a between groups test of the difference between two means, Cohen (1992) suggests a sample size of 26 participants per group will have 80% power to detect a large effect size difference at the alpha level of 0.05.

As the second part of the study is exploratory research there are no studies available for direct comparison. There is however an established link between two of the variables, emotional avoidance and worry, for which large effect sizes have been reported (Roemer et al., 2005).

It is intended at this stage to recruit 52 participants in total. According to Cohen (1992) for an alpha level of .05 and power of .8, a sample size of 26 is needed to detect a large effect size, whilst a sample of 85 is needed to detect a medium effect size. A sample of around 50 will therefore be sufficiently powered to detect large to moderate effects and is considered a reasonable basis upon which to plan a correlational analysis.

**A61. Will participants be allocated to groups at random?**

○ Yes ◉ No

**A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.**

Content analysis will be performed on data from the intrusions interview with partial correlations / path analysis carried out on the resulting data and data from other measures.

## 6. MANAGEMENT OF THE RESEARCH

**A63. Other key investigators/collaborators.** *Please include all grant co–applicants, protocol co–authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

| Title | Forename/Initials | Surname |
|---|---|---|

Post
Qualifications
Employer
Work Address

Post Code
Telephone
Fax
Mobile
Work Email

## A64. Details of research sponsor(s)

**A64-1. Lead sponsor** *(must be completed in all cases)*

Name of organisation which will act as the lead sponsor for the research:

The University of Edinburgh

Status:

○ NHS or HSC care organisation ◉ Academic ○ Pharmaceutical industry ○ Medical device industry ○ Other

| | |
|---|---|
| Address | The Medical Research Institute<br>47 Little France Crescent<br>Edinburgh |
| Post Code | EH16 4TJ |
| Country | |
| Telephone | 0131 242 9461 |
| Fax | |
| Mobile | |
| E-mail | e.currie@ed.ac.uk |

**A64-2. Sponsor's UK contact point for correspondence** *(must be completed in all cases)*

| Title | Forename/Initials | Surname |
|---|---|---|
| Ms | Elspeth | Currie |

| | |
|---|---|
| Post | |
| Work Address | The Medical Research Institute<br>47 Little France Crescent<br>Edinburgh |
| Post Code | EH16 4TJ |
| Telephone | 0131 242 9461 |
| Fax | |
| Mobile | |
| E-mail | e.currie@ed.ac.uk |

**A64-3. Are there any co–sponsors for this research?**

◉ Yes ○ No

*Give details of all co-sponsors:*

Name of organisation:
NHS Lothian

Status:

◉ NHS or HSC care organisation ○ Academic ○ Pharmaceutical industry ○ Medical device industry ○ Other

| | |
|---|---|
| Address | The Queen's Medical Research Instit<br>47 Little France Crescent<br>Edinburgh |

| | |
|---|---|
| Post Code | EH16 4TJ |
| Country | |
| Telephone | 0131 242 3330 |
| Fax | |
| Mobile | |
| Email | r&doffice@nhslothian.scot.nhs.uk |

**A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?**

○ Yes ◉ No

*Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.*

**A68. Give details of the lead NHS R&D contact for this research:**

| | Title | Forename/Initials | Surname |
|---|---|---|---|
| | MS | Tina | McLelland |
| Organisation | | | |
| Address | The Queen's Medical Research Instit | | |
| | 47 Little France Crescent | | |
| | Edinburgh | | |
| Post Code | EH16 4TJ | | |
| Work Email | | | |
| Telephone | 0131 242 3330 | | |
| Fax | | | |
| Mobile | | | |

*Details can be obtained from the NHS R&D Forum website: http://www.rdforum.nhs.uk*

**A69. How long do you expect the study to last?**

Planned start date: 01/04/2010
Planned end date: 02/08/2010
Duration:
Years: 0
Months: 4

**A71-1. Is this a single centre study?**

◉ Yes ○ No

**A71-2. Where will the research take place?** *(Tick as appropriate)*

- ☐ England
- ☑ Scotland
- ☐ Wales
- ☐ Northern Ireland

- ☐ Other states in European Union
- ☐ Other countries in European Economic Area
- ☐ USA
- ☐ Other international (please specify)

**A72. What host organisations (NHS or other) in the UK will be responsible for the research sites?** *Please indicate the type of organisation by ticking the box and give approximate numbers of planned research sites:*

| | |
|---|---|
| ☐ NHS organisations in England | |
| ☐ NHS organisations in Wales | |
| ☑ NHS organisations in Scotland | 1 |
| ☐ HSC organisations in Northern Ireland | |
| ☐ GP practices in England | |
| ☐ GP practices in Wales | |
| ☐ GP practices in Scotland | |
| ☐ GP practices in Northern Ireland | |
| ☐ Social care organisations | |
| ☐ Phase 1 trial units | |
| ☐ Prison establishments | |
| ☐ Probation areas | |
| ☐ Independent hospitals | |
| ☐ Educational establishments | |
| ☐ Independent research units | |
| ☐ Other (give details) | |
| Total UK sites in study: | 1 |

## A76. Insurance/ indemnity to meet potential legal liabilities

***Note:* in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland**

**A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research?** *Please tick box(es) as applicable.*

*Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.*

- ☑ NHS indemnity scheme will apply (NHS sponsors only)
- ☑ Other insurance or indemnity arrangements will apply (give details below)

The University of Edinburgh has a policy in place that provides indemnity against legal liability for non-negligent harm caused to a research subject, arising from the management of the research.

*Please enclose a copy of relevant documents.*

**A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research?** *Please tick box(es) as applicable.*

*Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided*

*through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.*

- [x] NHS indemnity scheme will apply (protocol authors with NHS contracts only)
- [x] Other insurance or indemnity arrangements will apply (give details below)

The University of Edinburgh has a policy in place that provides indemnity against legal liability for non-negligent harm caused to a research subject, arising from the design of the research.

*Please enclose a copy of relevant documents.*

**A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?**

*Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.*

- [ ] NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)
- [x] Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

The University has a policy in place that provides indemnity against legal liability for non negligent harm caused to a research subject, arising from the conduct of the research. This policy includes a no fault compensation section for accidental injury that is neither expected or intended when within the terms or instructions of the trial protocol.

*Please enclose a copy of relevant documents.*

## PART B: Additional information for specific study types

## PART B Section 1: Information on Investigational Medicinal Product(s) being used in the trial

***If the trial is performed with several investigational medicinal products, please open a separate set of the following questions for each product. Similarly, if the product is a combination product, please give separate information for each active substance.***

## PART C: Overview of research sites

**Please enter details of the host organisations (NHS or other) in the UK that will be responsible for the research sites.**

| Research site | PI/ local collaborator |
|---|---|

## PART D: Declarations

**D1. Declaration by Chief Investigator**

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.

2. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.

3. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.

4. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.

5. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.

6. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.

7. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.

8. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 1998.

9. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:

    - Will be held by the main REC or the GTAC (as applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
    - May be disclosed to the operational managers of review bodies, or the appointing authority for the main REC, in order to check that the application has been processed correctly or to investigate any complaint.
    - May be seen by auditors appointed to undertake accreditation of RECs.
    - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.

10. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.

11. I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

**Contact point for publication***(Not applicable for R&D Forms)*

*NRES would like to include a contact point with the published summary of the study for those wishing to seek further information. We would be grateful if you would indicate one of the contact points below.*

- [x] Chief Investigator
- [ ] Sponsor
- [ ] Study co-ordinator

☐ Student

☐ Other – please give details

☐ None

**Access to application for training purposes** *(Not applicable for R&D Forms)*

*Optional – please tick as appropriate:*

☑ I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

Signature: .....

Print Name: Emma Frances Harris

Date: 25/01/2010 *(dd/mm/yyyy)*

**D2. Declaration by the sponsor's representative**

*If there is more than one sponsor, this declaration should be signed on behalf of the co−sponsors by a representative of the lead sponsor named at A64-1.*

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.

2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.

3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.

4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.

5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.

6. The duties of sponsors set out in the Research Governance Framework for Health and Social Care will be undertaken in relation to this research.

7. I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

Signature: .....

Print Name:

Post:

Organisation:

Date: *(dd/mm/yyyy)*

**D3. Declaration for student projects by academic supervisor**

1. I have read and approved both the research proposal and this application. I am satisfied that the scientific content of the research is satisfactory for an educational qualification at this level.

2. I undertake to fulfil the responsibilities of the Chief Investigator and the supervisor for this study as set out in the Research Governance Framework for Health and Social Care.

3. I take responsibility for ensuring that this study is conducted in accordance with the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research, in conjunction with clinical supervisors as appropriate.

4. I take responsibility for ensuring that the applicant is up to date and complies with the requirements of the law and relevant guidelines relating to security and confidentiality of patient and other personal data, in conjunction with clinical supervisors as appropriate.

Signature: .....

Print Name:

Post:

Organisation:

Date: *(dd/mm/yyyy)*

Lothian NHS Board

South East Scotland Research Ethics Committee 02
Deaconess House
148 Pleasance
Edinburgh
EH8 9RS
Telephone 0131 536 9000
Fax 0131 536
www.nhslothian.scot.nhs.uk

Miss Emma F Harris
Specialist Psychological Practitioner
Older Adults Psychology Service
Jardine Clinic
Royal Edinburgh Hospital, Edinburgh
EH10 5HF

Date 24 March 2010
Our Ref
Enquiries to Lyndsay Baird
Extension 89061
Direct Line 0131 536 9061
Email lyndsay.baird@nhslothian.scot.nhs.uk

Dear Miss Harris

**Study Title:** **An exploration of the presence and nature of intrusive imagery in older people with Generalised Anxiety Disorder**
**REC reference number:** **10/S1102/9**
**Protocol number:** **v.1**

The Research Ethics Committee reviewed the above application at the meeting held on 10 March 2010. Thank you for attending to discuss the study.

**Documents reviewed**

The documents reviewed at the meeting were:

| *Document* | *Version* | *Date* |
|---|---|---|
| REC application | v.2. | 11 February 2010 |
| Protocol | v.1 | 25 January 2010 |
| Investigator CV | | 11 February 2010 |
| Participant Information Sheet | v.2 | 02 February 2010 |
| Participant Consent Form | v.2 | 02 February 2010 |
| Questionnaire: Geriatric Depression Questionnaire | | |
| Questionnaire: PSWQ Questionnaire | | |
| Questionnaire: AAQ Questionnaire | | |
| Questionnaire: Non Validated Questionnaire | | |
| Questionnaire: CFQ Questionnaire | | |
| Student C.V. | | |
| Advertisement | | 11 February 2010 |

**Provisional opinion**

This research aims to explore the possible role of intrusive imagery in Generalised Anxiety Disorder (GAD) in older adults, by comparing a group of older people with a diagnosis of GAD and a control group without a diagnosis of GAD. The Committee considered that the main ethical issues were the lack of information related to the processes the researcher would follow if participants become distressed or if the control group participants exhibited symptoms of GAD, the confidentiality of the Community Group interviews held in cafes and the system for secondary contact of the community group. After discussions with the researcher it was agreed that the participants General Practitioner should be informed of their participation in the study. The researcher informed the committee that a schedule for the proposed interview had been developed and she would submit this. The committee suggested that the Participant Information Sheet was a little vague and unhelpful and the researcher agrred to redraft the paperwork.

The Committee would be content to give a favourable ethical opinion of the research, subject to receiving a complete response to the request for further information set out below.

The Committee delegated authority to confirm its final opinion on the application to a meeting of the sub-committee of the REC.

**Further information or clarification required**

The Committee agreed to offer a favourable ethical opinion of the research, subject to receiving a complete response to the request for further information below. Authority to consider the response and to confirm the Committee's final opinion has been delegated to the Sub-Committee:

- Clarify what processes you will follow if a participant becomes distressed, the process for assisting control participants that may show symptoms of GAD, and what treatment would be recommended.
- Reassure the Committee that the Community Group interviews will be held in a private room including details of the sites.
- Produce a General Practitioners Letter or Information Sheet.
- Provide topic guides for your interview sessions.
- The consent form should include a specific sentence related to using audio visual equipment.
- As discussed at the meeting 'Geriatric' should be removed from title of the Depression Rating Scale if it does not conflict with copyright. The Patient name question should also be replaced with a coding system.
- Reassure the Committee that if a participant states that they do not hear voices they will move onto the appropriate questions rather than going through a large number of questions related to this subject.
- Add the site details into Part C the IRAS form.
- The Participant Information Sheet:
    - Is too vague, it should focus on will happen to the participant when they take part in the study.
    - Font size should be increased.
    - Should offer participants copies of the results of the research in lay language including contact details of where they can be obtained.
- As discussed at the meeting any secondary contact with the Community Group should be made through a general reminder through the Community Group.

When submitting your response to the Committee, please send revised documentation where appropriate underlining or otherwise highlighting the changes you have made and giving revised version numbers and dates.

If the committee has asked for clarification or changes to any answers given in the application form, please do not submit a revised copy of the application form; these can be addressed in a covering letter to the REC.

The Committee will confirm the final ethical opinion within a maximum of 60 days from the date of initial receipt of the application, excluding the time taken by you to respond fully to the above points. A response should be submitted by no later than 16 July 2010.

**Membership of the Committee**

The members of the Committee who were present at the meeting are listed on the attached sheet.

**Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

**10/S1102/9 Please quote this number on all correspondence**

Yours sincerely

**Professor Peter Hayes**
**Chair**

Email: lyndsay.baird@nhslothian.scot.nhs.uk

*Enclosures:* *List of names and professions of members who were present at the meeting and those who submitted written comments.*

*Copy to:* *Elspeth Currie*

**South East Scotland Research Ethics Committee 02**

**Attendance at Committee meeting on 10 March 2010**

**Committee Members:**

| *Name* | *Profession* | *Present* | *Notes* |
|---|---|---|---|
| Miss Sharon Cameron | Nurse | Yes | |
| Mrs O M A Chiswick | Nurse | Yes | |
| Professor Peter Hayes | Professor of Hepatology | Yes | |
| Dr Calum MacKellar | Director of Research | Yes | |
| Mr Lindsay Murray | Health & Safety Manager | Yes | |
| Mr Andy Neustein | Retired | No | |
| Dr Nigel Ostrowski | General Practitioner | Yes | |
| Mrs V Prosser | Not Known | No | |
| Mr Thomas Russell | Consultant Neurosurgeon | No | |
| Ms Tzyvia Rye | Medical Research | Yes | |
| Dr Lillian Schweizer | Geneticist | Yes | |
| Reverend Donald Stephen | Reverend | Yes | |
| Mr W O D Walker | Retired | Yes | |

**Also in attendance:**

| *Name* | *Position (or reason for attending)* |
|---|---|
| Dr Alex Bailey | Scientific Officer |
| Miss Lyndsay Baird | Committee Co-ordinator |

Lothian NHS Board

South East Scotland Research Ethics
Committee 02
Deaconess House
148 Pleasance
Edinburgh
EH8 9RS
Telephone 0131 536 9000
Fax 0131 536
www.nhslothian.scot.nhs.uk

NHS Lothian

Miss Emma F Harris
Specialist Psychological Practitioner
NHS Lothian
Older Adults Psychology Service
Jardine Clinic
Royal Edinburgh Hospital, Edinburgh
EH10 5HF

Date 18 May 2010
Our Ref
Enquiries to Lyndsay Baird
Extension 89061
Direct Line 0131 536 9061
Email lyndsay.baird@nhslothian.scot.nhs.uk

Dear Miss Harris

**Study Title:** **An exploration of the presence and nature of intrusive imagery in older people with Generalised Anxiety Disorder**
**REC reference number:** **10/S1102/9**
**Protocol number:** **v.1**

Thank you for your letter of 20 April 2010, responding to the Committee's request for further information on the above research and submitting revised documentation.

*The further information was considered in correspondence by a sub-committee of the REC. A list of the sub-committee members is attached.*

**Confirmation of ethical opinion**

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

**Ethical review of research sites**

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

**Conditions of the favourable opinion**

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk. *Where the only involvement of the NHS organisation is as a Participant Identification Centre, management permission for research is not required but the R&D office should be notified of the study. Guidance should be sought from the R&D office where necessary.*

*Sponsors are not required to notify the Committee of approvals from host organisations.*

**It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).**

**Approved documents**

The final list of documents reviewed and approved by the Committee is as follows:

| *Document* | *Version* | *Date* |
|---|---|---|
| REC application | v.2. | 11 February 2010 |
| Investigator CV | | 11 February 2010 |
| Questionnaire: Geriatric Depression Questionnaire | | |
| Questionnaire: PSWQ Questionnaire | | |
| Questionnaire: AAQ Questionnaire | | |
| Questionnaire: Non Validated Questionnaire | | |
| Questionnaire: CFQ Questionnaire | | |
| Student C.V. | | |
| Advertisement | | 11 February 2010 |
| Protocol | 2 | 15 April 2010 |
| Participant Information Sheet | 3 | 14 April 2010 |
| Participant Consent Form | 3 | 14 April 2010 |
| GP/Consultant Information Sheets | 1 | |
| Questionnaire: Mood Rating Scale | Validated | |
| SCID-I (for DSM-IV-TR) Screening Questions | Validated | |
| Structured interview covering letter | | |
| Response to Request for Further Information | | 20 April 2010 |

**Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

**After ethical review**

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

| | |
|---|---|
| **10/S1102/9** | **Please quote this number on all correspondence** |

Yours sincerely

**Professor Peter Hayes**
**Chair**

Email: lyndsay.baird@nhslothian.scot.nhs.uk

*Enclosures:* *List of names and professions of members who were present at the meeting and those who submitted written comments*

"After ethical review – guidance for researchers"

*Copy to:* *Elspeth Currie*

## Welcome to the Integrated Research Application System

## IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

**Please enter a short title for this project** (maximum 70 characters)
Exploring intrusive imagery in Generalised Anxiety Disorder -version 1

**1. Is your project an audit or service evaluation?**

○ Yes ◉ No

**2. Select one category from the list below:**

○ Clinical trial of an investigational medicinal product
○ Clinical investigation or other study of a medical device
○ Combined trial of an investigational medicinal product and an investigational medical device
○ Other clinical trial or clinical investigation
◉ Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
○ Study involving qualitative methods only
○ Study limited to working with human tissue samples, other human biological samples and/or data *(specific project only)*
○ Research tissue bank
○ Research database

**If your work does not fit any of these categories, select the option below:**

○ Other study

**2a. Please answer the following question(s):**

| | | |
|---|---|---|
| a) Does the study involve the use of any ionising radiation? | ○ Yes | ◉ No |
| b) Will you be taking new human tissue samples (or other human biological samples)? | ○ Yes | ◉ No |
| c) Will you be using existing human tissue samples (or other human biological samples)? | ○ Yes | ◉ No |

**3. In which countries of the UK will the research sites be located?***(Tick all that apply)*

☐ England
☑ Scotland
☐ Wales
☐ Northern Ireland

**3a. In which country of the UK will the lead R&D office be located?**

○ England
◉ Scotland

- ○ Wales
- ○ Northern Ireland

**4. Which review bodies are you applying to?**

- ☑ NHS/HSC Research and Development offices
- ☑ Research Ethics Committee
- ☐ National Information Governance Board for Health and Social Care (NIGB)
- ☐ Ministry of Justice (MoJ)

**5. Will any research sites in this study be NHS organisations?**

◉ Yes ○ No

**6. Do you plan to include any participants who are children?**

○ Yes ◉ No

**7. Do you plan to include any participants who are adults unable to consent for themselves through physical or mental incapacity?** *The guidance notes explain how an adult is defined for this purpose.*

○ Yes ◉ No

**8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service in England or Wales?**

○ Yes ◉ No

**9. Is the study, or any part of the study, being undertaken as an educational project?**

◉ Yes ○ No

**9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?**

◉ Yes ○ No

**10. Is this project financially supported by the United States Department for Health and Human Services?**

○ Yes ◉ No

## NOTICE OF SUBSTANTIAL AMENDMENT

*Please use this form to notify the main REC of substantial amendments to all research other than clinical trials of investigational medicinal products (CTIMPs). For CTIMPs, please use the European Commission notice of substantial amendment form at http://eudract.emea.europa.eu/document.html.*
*The form should be completed by the Chief Investigator using language comprehensible to a lay person. Support in principle should be sought from the study sponsor before the amendment is submitted.*

**Details of Chief Investigator:**


| | Title | Forename/Initials | Surname |
|---|---|---|---|
| | Mrs | Emma F | Miller |
| Work Address | Department of Clinical Psychology | | |
| | Health in Social Science, University of Edinburgh | | |
| | Medical School, Teviot Place, Edinburgh | | |
| PostCode | EH8 9AG | | |
| Email | e.f.miller@sms.ed.ac.uk | | |
| Telephone | 07920572878 | | |
| Fax | | | |


| | |
|---|---|
| **Full title of study:** | An exploration of the presence and nature of intrusive imagery in older people with Generalised Anxiety Disorder |
| **Lead sponsor:** | |
| **Name of REC:** | Lothian Research Ethics Committee 02 |
| **REC reference number:** | 10/S1102/9 |
| **Name of lead R&D office:** | |
| **Date study commenced:** | recommenced 01/08/12 |
| **Protocol reference (if applicable), current version and date:** | version 3, 01/08/12 |
| **Amendment number and date:** | 1, 01/08/12 |

**Type of amendment**

*(a) Amendment to information previously given in IRAS*

(●) Yes ( ) No

*If yes, please refer to relevant sections of IRAS in the "summary of changes" below.*

*(b) Amendment to the protocol*

(●) Yes ( ) No

*If yes, please submit either the revised protocol with a new version number and date, highlighting changes in bold, or a document listing the changes and giving both the previous and revised text.*

*(c) Amendment to the information sheet(s) and consent form(s) for participants, or to any other supporting documentation for the study*

(•) Yes ( ) No

*If yes, please submit all revised documents with new version numbers and dates, highlighting new text in bold.*

Changes to project title, contact details for chief investigator and supervisors.

**Is this a modified version of an amendment previously notified and not approved?**

( ) Yes (•) No

**Summary of changes**

*Briefly summarise the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study.*
*If this is a modified amendment, please explain how the modifications address the concerns raised previously by the ethics committee.*
*If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained.*

A-2.1/A.3.There is a change to my name and address, as I have married and moved house. There is also a change to my work address as my employment contract has now ended.
A-2.1. There has been a change of academic supervisor due to staffing changes.
A.1. The project title has changed to reflect a minor change in study design from a comparison of two groups (GAD and non GAD) to looking at the full cross section of experience from very low to very high levels of worry.
A.10. This has also necessitated a change in wording for the main research question: Do individuals with higher levels of worry experience more intrusive imagery?
A.59. Recruitment: in order to include individuals with high levels of worry, it is still necessary to recruit from clinical sources, however, lower numbers of clinical participants are now being sought (around 10 individuals instead of 26). The overall number of participants to be recruited is now around 60 (instead of 52) to reflect slight changes in the study design.
part C.Due to difficulties in recruiting participants with clinical levels of anxiety, it is hoped to add two further research sites, Psychological services for older people in Tayside and Fife. SSI's have been created for these sites.
A.28. A leaflet has also been developed as a first introduction to the study. Individuals indicating an interest in taking part are then given the full participant information.
A.18. There has been a minor change in the wording of the question relating to imagery in the intrusions interview and the addition of two closed questions
A.41. Storage of data: due to the investigators change of circumstances,anonymised data will be stored in the investigators home in a locked filing cabinet and anonymised data will be analysed in the investigators home on a laptop computer.
A.69. There is also a change to the dates for conducting the study which will now be from 01/09/12 to 01/12/12.

**Any other relevant information**

*Applicants may indicate any specific issues relating to the amendment, on which the opinion of a reviewing body is sought.*

**List of enclosed documents**

| *Document* | *Version* | *Date* |
|---|---|---|
| Participant Information Sheet | 4 | 01/04/2012 |
| Consent form | 4 | 01/04/2012 |
| Research Protocol | 3 | 01/08/2012 |
| Leaflet | 1 | 01/04/2012 |

**Declaration by Chief Investigator**

1. *I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.*
2. *I confirm that the study sponsor has been notified of the proposed amendment.*
3. *I consider that it would be reasonable for the proposed amendment to be implemented.*

**Date:**.....

**Lothian NHS Board**

**South East Scotland Research Ethics Committee 02**

Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG
Telephone 0131 536 9000
Fax 0131 465 5789

**www.nhslothian.scot.nhs.uk**

Date 13 December 2012
Your Ref
Our Ref

Enquiries to: Joyce Clearie
Extension: 35674
Direct Line: 0131 465 5674
Email: Joyce.Clearie@nhslothian.scot.nhs.uk

26 September 2012

Miss Emma F Harris
Specialist Psychological Practitioner
NHS Lothian
Older Adults Psychology Service
Jardine Clinic
Royal Edinburgh Hospital, Edinburgh
EH10 5HF

Dear Miss Harris

**Study title:** **An exploration of the presence and nature of intrusive imagery in older people with Generalised Anxiety Disorder**
**REC reference:** **10/S1102/9**
**Amendment number:**
**Amendment date:** **01 August 2012**

The above amendment was reviewed by the Sub-Committee in correspondence.

**Ethical opinion**

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

**Approved documents**

The documents reviewed and approved at the meeting were:

| Document | Version | Date |
|---|---|---|
| Leaflet | 1 | 01 April 2012 |

## Welcome to the Integrated Research Application System

## IRAS Project Filter

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**Please enter a short title for this project** (maximum 70 characters)
Exploring intrusive imagery in Generalised Anxiety Disorder -version 1

**1. Is your project an audit or service evaluation?**

○ Yes ◉ No

**2. Select one category from the list below:**

○ Clinical trial of an investigational medicinal product
○ Clinical investigation or other study of a medical device
○ Combined trial of an investigational medicinal product and an investigational medical device
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○ Study involving qualitative methods only
○ Study limited to working with human tissue samples, other human biological samples and/or data *(specific project only)*
○ Research tissue bank
○ Research database

**If your work does not fit any of these categories, select the option below:**

○ Other study

**2a. Please answer the following question(s):**

| | | |
|---|---|---|
| a) Does the study involve the use of any ionising radiation? | ○ Yes | ◉ No |
| b) Will you be taking new human tissue samples (or other human biological samples)? | ○ Yes | ◉ No |
| c) Will you be using existing human tissue samples (or other human biological samples)? | ○ Yes | ◉ No |

**3. In which countries of the UK will the research sites be located?***(Tick all that apply)*

☐ England
☑ Scotland
☐ Wales
☐ Northern Ireland

**4. Which review bodies are you applying to?**

☑ NHS/HSC Research and Development offices
☑ Research Ethics Committee

☐ Patient Information Advisory Group (PIAG)
☐ Ministry of Justice (MoJ)

**5. Will any research sites in this study be NHS organisations?**

◉ Yes ○ No

**6. Do you plan to include any participants who are children?**

○ Yes ◉ No

**7. Do you plan to include any participants who are adults unable to consent for themselves through physical or mental incapacity?** *The guidance notes explain how an adult is defined for this purpose.*

○ Yes ◉ No

**8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service in England or Wales?**

○ Yes ◉ No

**9. Is the study, or any part of the study, being undertaken as an educational project?**

◉ Yes ○ No

**9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?**

◉ Yes ○ No

## Site-Specific Information Form

**Is the site hosting this research a NHS site or a non-NHS site?** *NHS sites include Health and Social Care organisations in Northern Ireland. The sites hosting the research are the sites in which or through which research procedures are conducted. For NHS sites, this includes sites where NHS staff are participants.*

- (●) NHS site
- ( ) Non-NHS site

*This question must be completed before proceeding. The filter will customise the form, disabling questions which are not relevant to this application.*

*One Site-Specific Information Form should be completed for each research site and submitted to the relevant R&D office with the documents in the checklist. See guidance notes.*

*The data in this box is populated from Part A:*

Title of research:
An exploration of the presence and nature of intrusive imagery in older people with Generalised Anxiety Disorder

Short title: Exploring intrusive imagery in Generalised Anxiety Disorder -version 1

Chief Investigator:

| Title | Forename/Initials | Surname |
|---|---|---|
| Miss | Emma F | Harris |

Name of NHS Research Ethics Committee to which application for ethical review is being made:
Lothian Research Ethics Committee 02

Project reference number from above REC: 10/S1102/9

**1-1. Give the name of the NHS organisation responsible for this research site**

NHS Lothian

**1-2. In which country is the research site located?**

- ( ) England
- ( ) Wales
- (●) Scotland
- ( ) Northern Ireland

**1-3. Is the research site a GP practice or other Primary Care Organisation?**

( ) Yes (●) No

**2. Who is the Principal Investigator or Local Collaborator for this research at this site?**

Select the appropriate title: (•) Principal Investigator ( ) Local Collaborator

| | Title | Forename/Initials | Surname |
|---|---|---|---|
| | Miss | Emma F | Harris |
| Post | Specialist Psychological Practitioner | | |
| Qualifications | Bsc(hons) Psychology and Neuroscience | | |
| Organisation | NHS Lothian | | |
| Work Address | Older Peoples' Psychology Service | | |
| | Jardine Clinic | | |
| | Royal Edinburgh Hospital | | |
| PostCode | EH10 5HF | | |
| Work E-mail | emma.harris5@nhs.net | | |
| Work Telephone | 01315376614 | | |
| Mobile | | | |
| Fax | | | |

a) Approximately how much time will this person allocate to conducting this research? *Please provide your response in terms of Whole Time Equivalents (WTE).*
0.2wte

b) Does this person hold a current substantive employment contract, Honorary Clinical Contract or Honorary Research Contract with the NHS organisation or accepted by the NHS organisation? (•) Yes ( ) No

*A copy of a current CV for the Principal Investigator (maximum 2 pages of A4) must be submitted with this form.*

**3. Please give details of all locations, departments, groups or units at which or through which research procedures will be conducted at this site and describe the activity that will take place.**

*Please list all locations/departments etc where research procedures will be conducted within the NHS organisation, describing the involvement in a few words. Where access to specific facilities will be required these should also be listed for each location.*

*Name the main location/department first. Give details of any research procedures to be carried out off site, for example in participants' homes.*

| | Location | Activity/facilities |
|---|---|---|
| 1 | Royal Edinburgh Hospital | Clinicians working in care of the elderly will be asked to identify and seek consent to pass on details of patients meeting the inclusion criteria for the study |
| 2 | Royal Victoria Hospital | Clinicians working with patients over the age of 60 will be asked to identify and seek consent to pass on details of patients meeting the inclusion criteria for the study |

**5. Please give details of all other members of the research team at this site.**

**6. Does the Principal Investigator or any other member of the site research team have any direct personal involvement (e.g. financial, share-holding, personal relationship etc) in the organisation sponsoring or funding the research that may give rise to a possible conflict of interest?**

( ) Yes (•) No

**7. What is the proposed local start and end date for the research at this site?**

| | |
|---|---|
| Start date: | 01/03/2010 |
| End date: | 02/08/2010 |
| Duration (Months): | 5 |

**8-1. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol.** *(These include seeking consent, interviews, non-clinical observations and use of questionnaires.)*

*Columns 1-4 have been completed with information from A18 as below:*

1. *Total number of interventions/procedures to be received by each participant as part of the research protocol.*
2. *If this intervention would have been routinely given to participants as part of their care, how many of the total would have been routine?*
3. *Average time taken per intervention (minutes, hours or days)*
4. *Details of who will conduct the procedure, and where it will take place*

*Please complete Column 5 with details of the names of individuals or names of staff groups who will conduct the procedure at this site.*

| Intervention or procedure | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|
| Informed consent | 1 | 0 | up to 10 m | The researcher, NHS or community setting. | Emma Harris |
| SKID GAD | 1 | 0 | 15 mins | The researcher, NHS or community setting. | Emma Harris |
| Intrusions Interview | 1 | 0 | 30-40 mins | The researcher, NHS or community setting. | Emma Harris |
| Acceptance and Action Questionnaire | 1 | 0 | 5 minutes | self-report | Emma Harris |
| Penn-state worry inventory | 1 | 0 | up to 10 m | self-report | Emma Harris |
| Geriatric Depression Scale | 1 | 0 | up to 10 m | self-report | Emma Harris |
| Cognitive Fusion Questionnaire | 1 | 0 | up to 10 m | self-report | Emma Harris |

**8-2. Will any aspects of the research at this site be conducted in a different way to that described in Part A or the protocol?**

○ Yes ◉ No

*If Yes, please note any relevant changes to the information in the above table.*

*Are there any changes other than those noted in the table?*

**10. How many research participants/samples is it expected will be recruited/obtained from this site?**

a maximum of 26

**11. Give details of how potential participants will be identified locally and who will be making the first approach to them to take part in the study.**

Clinicians will be asked to identify and approach patients on their case load who meet the study inclusion criteria.

**12. Who will be responsible for obtaining informed consent at this site? What expertise and training do these persons have in obtaining consent for research purposes?**

| Name | Expertise/training |
|---|---|
| Emma Harris, chief investigator | The chief investigator is in the final year of a doctorate in clinical psychology and therefore has undertaken training to doctoral level in clinical and research skills. |

**15-1. Is there an independent contact point where potential participants can seek general advice about taking part in research?**

Yes, Dr Ken Laidlaw, Professional Lead for Older Peoples' Psychology Services in Edinburgh has agreed to act as an independent contact.

**15-2. Is there a contact point where potential participants can seek further details about this specific research project?**

Potential participants can seek further details from the chief investigator, academic supervisors or clinical supervisor.

**16. Are there any changes that should be made to the generic content of the information sheet to reflect site-specific issues in the conduct of the study?** *A substantial amendment may need to be discussed with the Chief Investigator and submitted to the main REC.*

No

*Please provide a copy on headed paper of the participant information sheet and consent form that will be used locally. Unless indicated above, this must be the same generic version submitted to/approved by the main REC for the study while including relevant local information about the site, investigator and contact points for participants (see guidance notes).*

**17. What local arrangements have been made for participants who might not adequately understand verbal explanations or written information given in English, or who have special communication needs?** *(e.g. translation, use of interpreters etc.)*

Due to the constraints of the study, it will not be possible to include participants who cannot communicate fluently in spoken and written English.

**18. What local arrangements will be made to inform the GP or other health care professionals responsible for the care of the participants?**

The participants' GP will be informed in writing should any concerns arise during participation in the study with regard to a participant's mood or safety.

**19. What arrangements (e.g. facilities, staffing, psychosocial support, emergency procedures) will be in place at the site, where appropriate, to minimise the risks to participants and staff and deal with the consequences of any harm?**

The chief investigator is in the final year of doctoral training to be a Clinical Psychologist and therefore has therapeutic skills necessary to deal with any distress arising during the study. In the event of an emergency, local procedures will apply.
In the event of a participant suffering any ongoing distress following participation in the study, they will be put in touch with the Older Peoples' Psychology Service and their GP will be contacted.

**20. What are the arrangements for the supervision of the conduct of the research at this site?** *Please give the name and contact details of any supervisor not already listed in the application.*

The academic aspects of the research will be supervised by:
Michael Hopley, University of Edinburgh email: mike.hopley@ed.ac.uk tel: 01316513972
David Gillanders, University of Edinburgh email: david.gillanders@ed.ac.uk tel: 01316513972

The clinical aspects of the research will be supervised by:
Elizabeth Baikie, Clinical Psychologist, Medicine of Old Age, Royal Victoria Hospital

email: elizabeth.baikie@nhslothian.scot.nhs.uk

**21. What external funding will be provided for the research at this site?**

- ○ Funded by commercial sponsor
- ○ Other funding
- ◉ No external funding

How will the costs of the research be covered?

**23. Authorisations required prior to R&D approval**

This section deals with authorisations by managers within the NHS organisation. It should be signed in accordance with the guidance provided by the NHS organisation. This may include authorisation by clinical supervisors, line managers, service managers, support department managers, pharmacy, data protection officers or finance managers, depending on the nature of the research. Managers completing this section should confirm in the text what the authorisation means, in accordance with the guidance provided by the NHS organisation.

This section may also be used by university employers or research support staff to provide authorisation to NHS organisations, in accordance with guidance from the university.

**Declaration by Principal Investigator or Local Collaborator**

1. The information in this form is accurate to the best of my knowledge and I take full responsibility for it.
2. I undertake to abide by the ethical principles underpinning the World Medical Association's Declaration of Helsinki and relevant good practice guidelines in the conduct of research.
3. If the research is approved by the main REC and NHS organisation, I undertake to adhere to the study protocol, the terms of the application of which the main REC has given a favourable opinion and the conditions requested by the NHS organisation, and to inform the NHS organisation within local timelines of any subsequent amendments to the protocol.
4. If the research is approved, I undertake to abide by the principles of the Research Governance Framework for Health and Social Care.
5. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to the conduct of research.
6. I undertake to disclose any conflicts of interest that may arise during the course of this research, and take responsibility for ensuring that all staff involved in the research are aware of their responsibilities to disclose conflicts of interest.
7. I understand and agree that study files, documents, research records and data may be subject to inspection by the NHS organisation, the sponsor or an independent body for monitoring, audit and inspection purposes.
8. I take responsibility for ensuring that staff involved in the research at this site hold appropriate contracts for the duration of the research, are familiar with the Research Governance Framework, the NHS organisation's Data Protection Policy and all other relevant policies and guidelines, and are appropriately trained and experienced.
9. I undertake to complete any progress and/or final reports as requested by the NHS organisation and understand that continuation of permission to conduct research within the NHS organisation is dependent on satisfactory completion of such reports.
10. I undertake to maintain a project file for this research in accordance with the NHS organisation's policy.
11. I take responsibility for ensuring that all serious adverse events are handled within the NHS organisation's policy for reporting and handling of adverse events.
12. I understand that information relating to this research, including the contact details on this application, will be held by the R&D office and may be held on national research information systems, and that this will be managed

according to the principles established in the Data Protection Act 1998.

13. I understand that the information contained in this application, any supporting documentation and all correspondence with the R&D office and/or the REC system relating to the application will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.

This section was signed electronically by MISS EMMA HARRIS on 15/02/2010 05:28.

| | |
|---|---|
| Job Title/Post: | Specialist Psychological Practitioner |
| Organisation: | NHS Lothian |
| Email: | emma.harris5@nhs.net |

| | | |
|---|---|---|
| Participant Consent Form: PCF | 4 | 01 April 2012 |
| Participant Information Sheet: PIS | 4 | 01 April 2012 |
| Interview Schedules/Topic Guides | 2 | 01 April 2012 |
| GP Letter /Cons Information | 2 | 01 April 2012 |
| Protocol | 3 | 01 August 2012 |
| Notice of Substantial Amendment (non-CTIMPs) | | 01 August 2012 |

**Membership of the Committee**

The members of the Committee who took part in the review are listed on the attached sheet.

**R&D approval**

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

**Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

**10/S1102/9: Please quote this number on all correspondence**

Yours sincerely

**Mr Thomas Russell**
**Chair**

E-mail: joyce.clearie@nhslothian.scot.nhs.uk

*Enclosures:* *List of names and professions of members who took part in the review*

**South East Scotland Research Ethics Committee 02**

**Attendance at Sub-Committee of the REC meeting 2 on September 2012**

| *Name* | *Profession* | *Capacity* |
|---|---|---|
| Mr Thomas Russell | Retired Consultant Neurosurgeon | Expert |
| Professor Lindsay Sawyer | University Lecturer | Lay |

Queen's Medical Research Institute
47 Little France Crescent, Edinburgh, EH16 4TJ

NHS Lothian

Research & Development
Room E1.12
Tel: 0131 242 3330
Fax: 0131 242 3343
Email:
R&DOffice@luht.scot.nhs.uk

Director:
Professor David E Newby

GEN/UK/approval

10 June 2010

Miss Emma Harris
Older Adults Psychology Service
Jardine Clinic
Royal Edinburgh Hospital
Edinburgh
EH10 5HF

Dear Miss Harris,

Lothian R&D Project No: **2010/P/PSY/07**

**Title of Research:** An exploration of the presence and nature of intrusive imagery in older people with Generalised Anxiety Disorder

MREC No: 10/S1102/09 **LREC No:** N/A

CTA No: N/A **Eudract:** N/A

PIS: Version 3 dated 14 April 2010 **Consent:** Version 3 dated 14 April 2010

Protocol No: Dated 15 April 2010

I am pleased to inform you that this study has been approved for NHS Lothian and you may proceed with your research, subject to the conditions below. This letter provides Site Specific approval for NHS Lothian.

Please note that the NHS Lothian R&D Office must be informed if there are any changes to the study such as amendments to the protocol, recruitment, funding, personnel or resource input required of NHS Lothian.

Substantial amendments to the protocol will require approval from the ethics committee which approved your study.

Please inform this office when recruitment has closed and when the study has been completed.

I wish you every success with your study.

Yours sincerely

Professor David E Newby
R&D Director

enc: Research Governance Certificate ☑ (to be signed and returned)

## Welcome to the Integrated Research Application System

## IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

**Please enter a short title for this project** (maximum 70 characters)
Exploring intrusive imagery in Generalised Anxiety Disorder -version 1

**1. Is your project an audit or service evaluation?**

○ Yes ◉ No

**2. Select one category from the list below:**

○ Clinical trial of an investigational medicinal product
○ Clinical investigation or other study of a medical device
○ Combined trial of an investigational medicinal product and an investigational medical device
○ Other clinical trial or clinical investigation
◉ Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
○ Study involving qualitative methods only
○ Study limited to working with human tissue samples, other human biological samples and/or data *(specific project only)*
○ Research tissue bank
○ Research database

**If your work does not fit any of these categories, select the option below:**

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**2a. Please answer the following question(s):**

| | | |
|---|---|---|
| a) Does the study involve the use of any ionising radiation? | ○ Yes | ◉ No |
| b) Will you be taking new human tissue samples (or other human biological samples)? | ○ Yes | ◉ No |
| c) Will you be using existing human tissue samples (or other human biological samples)? | ○ Yes | ◉ No |

**3. In which countries of the UK will the research sites be located?***(Tick all that apply)*

☐ England
☑ Scotland
☐ Wales
☐ Northern Ireland

**3a. In which country of the UK will the lead R&D office be located?**

○ England
◉ Scotland

- ○ Wales
- ○ Northern Ireland

**4. Which review bodies are you applying to?**

- ☑ NHS/HSC Research and Development offices
- ☑ Research Ethics Committee
- ☐ National Information Governance Board for Health and Social Care (NIGB)
- ☐ Ministry of Justice (MoJ)

**5. Will any research sites in this study be NHS organisations?**

◉ Yes ○ No

**6. Do you plan to include any participants who are children?**

○ Yes ◉ No

**7. Do you plan to include any participants who are adults unable to consent for themselves through physical or mental incapacity?** *The guidance notes explain how an adult is defined for this purpose.*

○ Yes ◉ No

**8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service in England or Wales?**

○ Yes ◉ No

**9. Is the study, or any part of the study, being undertaken as an educational project?**

◉ Yes ○ No

**9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?**

◉ Yes ○ No

**10. Is this project financially supported by the United States Department for Health and Human Services?**

○ Yes ◉ No

## Site-Specific Information Form (NHS sites)

**Is the site hosting this research a NHS site or a non-NHS site?** *NHS sites include Health and Social Care organisations in Northern Ireland. The sites hosting the research are the sites in which or through which research procedures are conducted. For NHS sites, this includes sites where NHS staff are participants.*

- (●) NHS site
- ( ) Non-NHS site

*This question must be completed before proceeding. The filter will customise the form, disabling questions which are not relevant to this application.*

*One Site-Specific Information Form should be completed for each research site and submitted to the relevant R&D office with the documents in the checklist. See guidance notes.*

*The data in this box is populated from Part A:*

Title of research:
An exploration of the presence and nature of intrusive imagery in older people with Generalised Anxiety Disorder

Short title: Exploring intrusive imagery in Generalised Anxiety Disorder -version 1

Chief Investigator:

| Title | Forename/Initials | Surname |
|---|---|---|
| Mrs | Emma F | Miller |

Name of NHS Research Ethics Committee to which application for ethical review is being made:
Lothian Research Ethics Committee 02

Project reference number from above REC: 10/S1102/9

**1-1. Give the name of the NHS organisation responsible for this research site**

NHS Fife

**1-2. In which country is the research site located?**

- ( ) England
- ( ) Wales
- (●) Scotland
- ( ) Northern Ireland

**1-3. Is the research site a GP practice or other Primary Care Organisation?**

( ) Yes (●) No

**2. Who is the Principal Investigator or Local Collaborator for this research at this site?**

Select the appropriate title: (•) Principal Investigator ( ) Local Collaborator

| | Title | Forename/Initials | Surname |
|---|---|---|---|
| | Mrs | Emma F | Miller |
| Post | Trainee Clinical Psychologist | | |
| Qualifications | Bsc(hons) Psychology and Neuroscience | | |
| Organisation | Clinical Psychology | | |
| Work Address | School of health in social science | | |
| | Medical School, Teviot Place | | |
| | Edinburgh | | |
| PostCode | EH8 9AG | | |
| Work E-mail | e.f.miller@sms.ed.ac.uk | | |
| Work Telephone | 07920572878 | | |
| Mobile | 07920572878 | | |
| Fax | | | |

a) Approximately how much time will this person allocate to conducting this research? *Please provide your response in terms of Whole Time Equivalents (WTE).*
0.2 WTE

b) Does this person hold a current substantive employment contract, Honorary Clinical Contract or Honorary Research Contract with the NHS organisation or accepted by the NHS organisation? ( ) Yes (•) No

*A copy of a current CV for the Principal Investigator (maximum 2 pages of A4) must be submitted with this form.*

**3. Please give details of all locations, departments, groups or units at which or through which research procedures will be conducted at this site and describe the activity that will take place.**

*Please list all locations/departments etc where research procedures will be conducted within the NHS organisation, describing the involvement in a few words. Where access to specific facilities will be required these should also be listed for each location.*

*Name the main location/department first. Give details of any research procedures to be carried out off site, for example in participants' homes.*

| | Location | Activity/facilities |
|---|---|---|
| 1 | Stratheden Hospital | leaflets given to patients meeting study criteria.<br>Interviews may take place on site or in participants' homes where appropriate. |
| 2 | Lynebank Hospital | leaflets given to patients meeting study criteria.<br>Interviews may take place on site or in participants' homes where appropriate. |
| 3 | Whyteman's Brae Hospital | leaflets given to patients meeting study criteria.<br>Interviews may take place on site or in participants' homes where appropriate. |

**5. Please give details of all other members of the research team at this site.**

**6. Does the Principal Investigator or any other member of the site research team have any direct personal involvement (e.g. financial, share-holding, personal relationship etc) in the organisation sponsoring or funding the research that may give rise to a possible conflict of interest?**

( ) Yes (•) No

**7. What is the proposed local start and end date for the research at this site?**

| | |
|---|---|
| Start date: | 03/09/2012 |
| End date: | 03/12/2012 |
| Duration (Months): | 3 |

**8-1. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol.** *(These include seeking consent, interviews, non-clinical observations and use of questionnaires.)*

*Columns 1-4 have been completed with information from A18 as below:*

1. *Total number of interventions/procedures to be received by each participant as part of the research protocol.*
2. *If this intervention would have been routinely given to participants as part of their care, how many of the total would have been routine?*
3. *Average time taken per intervention (minutes, hours or days)*
4. *Details of who will conduct the procedure, and where it will take place*

*Please complete Column 5 with details of the names of individuals or names of staff groups who will conduct the procedure at this site.*

| Intervention or procedure | 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|---|
| Informed consent | 1 | 0 | up to 10 minutes | The researcher, NHS or community setting. | Emma Miller |
| SKID GAD | 1 | 0 | 15 mins | The researcher, NHS or community setting. | Emma Miller |
| Intrusions Interview | 1 | 0 | 30-40 mins | The researcher, NHS or community setting. | Emma Miller |
| Acceptance and Action Questionnaire | 1 | 0 | 5 minutes | self-report | Emma Miller |
| Penn-state worry inventory | 1 | 0 | up to 10 minutes | self-report | Emma Miller |
| Geriatric Depression Scale | 1 | 0 | up to 10 minutes | self-report | Emma Miller |
| Cognitive Fusion Questionnaire | 1 | 0 | up to 10 minutes | self-report | Emma Miller |

**8-2. Will any aspects of the research at this site be conducted in a different way to that described in Part A or the protocol?**

○ Yes ◉ No

*If Yes, please note any relevant changes to the information in the above table.*

*Are there any changes other than those noted in the table?*

**10. How many research participants/samples is it expected will be recruited/obtained from this site?**

Up to 10

**11. Give details of how potential participants will be identified locally and who will be making the first approach to them to take part in the study.**

Potential participants will be identified and given an information leaflet by their clinician.

**12. Who will be responsible for obtaining informed consent at this site? What expertise and training do these persons have in obtaining consent for research purposes?**

| Name | Expertise/training |
|---|---|
| Emma Miller, chief investigator | The chief investigator is in the final year of a doctorate in clinical psychology and therefore has undertaken training to doctoral level in clinical and research skills. |

**15-1. Is there an independent contact point where potential participants can seek general advice about taking part in research?**

Ken Laidlaw, Clinical Lead for Older People's Psychology Service Edinburgh has agreed to act as an independent contact point.

**15-2. Is there a contact point where potential participants can seek further details about this specific research project?**

Further details can be obtained from the chief investigator, Academic or Clinical Supervisors

**16. Are there any changes that should be made to the generic content of the information sheet to reflect site-specific issues in the conduct of the study?** *A substantial amendment may need to be discussed with the Chief Investigator and submitted to the main REC.*

*Please provide a copy on headed paper of the participant information sheet and consent form that will be used locally. Unless indicated above, this must be the same generic version submitted to/approved by the main REC for the study while including relevant local information about the site, investigator and contact points for participants (see guidance notes).*

**17. What local arrangements have been made for participants who might not adequately understand verbal explanations or written information given in English, or who have special communication needs?** *(e.g. translation, use of interpreters etc.)*

Due to the constraints of the study it will not be possible to include participants who are not fluent in spoken and written English.

**18. What local arrangements will be made to inform the GP or other health care professionals responsible for the care of the participants?**

A letter will be sent to participants' GP to inform them of their patients' participation. Should a participant be found to be suffering from an undiagnosed condition or considered to be at risk in some way their GP will be informed, with the participant's consent where appropriate.

**19. What arrangements (e.g. facilities, staffing, psychosocial support, emergency procedures) will be in place at the site, where appropriate, to minimise the risks to participants and staff and deal with the consequences of any harm?**

The chief investigator is in the final year of a doctorate in Clinical Psychology and as such has training and experience necessary to manage any distress experienced by participants during the interview. In the unlikely event of ongoing distress arising from the research process the participant's GP would be informed and referral for Psychological support discussed.

**20. What are the arrangements for the supervision of the conduct of the research at this site?** *Please give the name and contact details of any supervisor not already listed in the application.*

The academic supervision will be undertaken by David Gillanders, University of Edinburgh
The clinical supervision will be undertaken by Elizabeth Baikie, NHS Lothian

**21. What external funding will be provided for the research at this site?**

- ○ Funded by commercial sponsor
- ○ Other funding
- ◉ No external funding

How will the costs of the research be covered?
by the researcher

**23. Authorisations required prior to R&D approval**

This section deals with authorisations by managers within the NHS organisation. It should be signed in accordance with the guidance provided by the NHS organisation. This may include authorisation by clinical supervisors, line managers, service managers, support department managers, pharmacy, data protection officers or finance managers, depending on the nature of the research. Managers completing this section should confirm in the text what the authorisation means, in accordance with the guidance provided by the NHS organisation.

This section may also be used by university employers or research support staff to provide authorisation to NHS organisations, in accordance with guidance from the university.

**Declaration by Principal Investigator or Local Collaborator**

1. The information in this form is accurate to the best of my knowledge and I take full responsibility for it.
2. I undertake to abide by the ethical principles underpinning the World Medical Association's Declaration of Helsinki and relevant good practice guidelines in the conduct of research.
3. If the research is approved by the main REC and NHS organisation, I undertake to adhere to the study protocol, the terms of the application of which the main REC has given a favourable opinion and the conditions requested by the NHS organisation, and to inform the NHS organisation within local timelines of any subsequent amendments to the protocol.
4. If the research is approved, I undertake to abide by the principles of the Research Governance Framework for Health and Social Care.
5. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to the conduct of research.
6. I undertake to disclose any conflicts of interest that may arise during the course of this research, and take responsibility for ensuring that all staff involved in the research are aware of their responsibilities to disclose conflicts of interest.
7. I understand and agree that study files, documents, research records and data may be subject to inspection by the NHS organisation, the sponsor or an independent body for monitoring, audit and inspection purposes.
8. I take responsibility for ensuring that staff involved in the research at this site hold appropriate contracts for the duration of the research, are familiar with the Research Governance Framework, the NHS organisation's Data Protection Policy and all other relevant policies and guidelines, and are appropriately trained and experienced.
9. I undertake to complete any progress and/or final reports as requested by the NHS organisation and understand that continuation of permission to conduct research within the NHS organisation is dependent on satisfactory completion of such reports.
10. I undertake to maintain a project file for this research in accordance with the NHS organisation's policy.
11. I take responsibility for ensuring that all serious adverse events are handled within the NHS organisation's policy for reporting and handling of adverse events.
12. I understand that information relating to this research, including the contact details on this application, will be held by the R&D office and may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.

13. I understand that the information contained in this application, any supporting documentation and all correspondence with the R&D office and/or the REC system relating to the application will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.

This section was signed electronically by MISS EMMA Miller on 26/09/2012 11:56.


| | |
|---|---|
| Job Title/Post: | Trainee Clinical Psychologist |
| Organisation: | University of Edinburgh |
| Email: | e.f.miller@sms.ed.ac.uk |

Mrs Emma Miller
Department of Clinical Psychology
Health in Social Science
University of Edinburgh
Medical School
Teviot Place
EDINBURGH
EH8 9AG

Medical Director, Primary Care
Room 313
Hayfield House
Hayfield Road
KIRKCALDY
Fife KY2 5AH
Tel 01592 643355
www.show.scot.nhs.uk/fpct

Date
Our Ref 12-063 NRS12/MH83
10/S1102/9
Enquiries to Aileen Yell
Tel No 01383 565110
Email aileenyell@nhs.net

Dear Mrs Miller

**Project Title: 'An exploration of the presence and nature of intrusive imagery in older people with Generalised Anxiety Disorder'**

Thank you for your application to carry out the above project. Your project documentation (detailed below) has been reviewed for resource and financial implications for NHS Fife and I am happy to inform you that NHS permission for the above research has been granted on the basis described in the application form, protocol and supporting documentation. The documents reviewed were:

| Document | Version | Date |
|---|---|---|
| REC provisional favourable opinion letter | | 24 March 2010 |
| IRAS R&D Form | 2.0 | 26 April 2010 |
| GP Letter | 2 | |
| REC final favourable opinion letter | | 18 May 2010 |
| Protocol | 3 | 1 August 2012 |
| Participant Information Sheet | 4 | 1 April 2012 |
| Participant Consent Form | 4 | 1 April 2012 |
| Leaflet | 1 | 1 April 2012 |
| REC favourable opinion for amendment dated 01.08.12 | | 26 September 2012 |
| IRAS SSI Form | | 26 September 2012 |
| NRS-PCC Certificate of Compliance | | 24 December 2012 |

The terms of the approval state that you are the Principal Investigator authorised to undertake this study within NHS Fife. Your point of contact will be Dr Sheena Bailey, Psychology Department.

I note that the favourable ethical opinion applies to all NHS sites taking part in the study therefore no separate Site Specific Review is required in this case.

The joint sponsors for this study are NHS Lothian and University of Edinburgh.

Details of our participation in studies will be included in annual returns we are expected to complete as part of our agreement with the Chief Scientist Office. Regular reports of the study require to be submitted. Your first report should be submitted to Dr A Wood, R&D Manager, R&D Resource Centre, Lynebank Hospital, Halbeath Rd, Dunfermline, KY11 4UW (Amanda.wood3@nhs.net) in 12 months time and subsequently at yearly intervals until the work is completed. A Lay Summary will also be required upon completion of the project.

In addition, approval is granted subject to the following conditions:-

- All research activity must comply with the standards detailed in the Research Governance Framework for Health & Community Care (http://www.cso.scot.nhs.uk/publications/resgov/resgov.htm), health & safety regulations, data protection principles, other appropriate statutory legislation and in accordance with Good Clinical Practice (GCP).

- Any amendments which may subsequently be made to the study should also be notified to Aileen Yell, Research Governance Officer (aileenyell@nhs.net) , as well as the appropriate regulatory authorities. Notification should also be given of any new research team members post approval and/or any changes to the status of the project.

- This organisation is required to monitor research to ensure compliance with the Research Governance Framework and other legal and regulatory requirements. This is achieved by random audit of research. You will be required to assist with and provide information in regard to monitoring and study outcomes (including providing recruitment figures to the R&D office as and when required).

- As custodian of the information collated during this research project you are responsible for ensuring the security of all personal information collected in line with NHS Scotland IT Security Policies, until the destruction of this data.

- Permission is only granted for the activities for which a favourable opinion has been given by the REC (and which have been authorised by the MHRA where appropriate).

- The research sponsor or the Chief Investigator or local Principal Investigator at a research site may take appropriate urgent safety measures in order to protect research participants against any immediate hazard to their health or safety. The R&D office (aileenyell@nhs.net) should be notified that such measures have been taken. The notification should also include the reasons why the measures were taken and the plan for further action. The R&D office should be notified within the same time frame of notifying the REC and any other regulatory bodies.

I would like to wish you every success with your study and look forward to receiving a summary of the findings for dissemination once the project is complete.

Yours sincerely

Stella Clark

**DR STELLA CLARK**
Medical Director, Primary Care
NHS Fife

*Cc : Aileen Yell, Research Governance Officer, NHS Fife, Lynebank Hospital, Dunfermline*
*NRSPCC, R&D Office, Foresterhill House Annex, Foresterhil, AberdeenAB25 2ZB*

University Hospitals Division

NHS
Lothian

**Queen's Medical Research Institute**
**47 Little France Crescent, Edinburgh, EH16 4TJ**

RESEARCH &
DEVELOPMENT
Room E1.12
Tel: 0131 242 3330
Fax: 0131 242 3343
Email:
R&DOffice@luht.scot.nhs.uk

Director:
Professor David E Newby

KM/JK

14 December 2012

Mrs Emma Miller
Older Adults Psychology Service
Jardine Clinic
Royal Edinburgh Hospital
Edinburgh
EH10 5HF

Dear Mrs Miller

| | |
|---|---|
| **REC No:** | 10/S1102/9 |
| **R&D Project ID No:** | 2010/P/PSY/07 |
| **Amendment:** | Substantial amendment No.1 dated 1 August 2012 |
| **Title of Research** | An exploration of the presence and nature of intrusive imagery in older people with Generalised Anxiety Disorder |

I am writing in reply to recent correspondence in relation to an amendment(s) to the above project and the subsequent updated documents as follows.

- Protocol, dated 1 August 2012
- Participant information sheet, version 4 dated 1 April 2012
- Consent form, version 4 dated 1 April 2012
- Leaflet, version 1 dated 1 April 2012
- GP letter, version 2 dated 1 April 2012
- Full intrusions questionnaire, version 2 dated 1 April 2012

We have now assessed any consequential changes and can confirm that NHS Lothian management approval is extended to cover the specific changes intimated

Yours sincerely

**Mrs Karen Maitland**
**Research Governance Manager**

University Hospitals Division

**Queen's Medical Research Institute**
**47 Little France Crescent, Edinburgh, EH16 4TJ**

NHS Lothian

RESEARCH & DEVELOPMENT
Room E1.12
Tel: 0131 242 3330
Fax: 0131 242 3343
Email:
R&DOffice@luht.scot.nhs.uk

Director:
Professor David E Newby

LAC/LM

16 January 2013

Mrs Emma Miller
Specialist Psychological Practitioner
Older Adults Psychology Service
Jardine Clinic
Royal Edinburgh Hospital
Edinburgh
EH10 5HF

Dear Mrs Miller

| | |
|---|---|
| **REC No:** | **10/S1102/9** |
| **R&D Project ID No:** | **2010/P/PSY/07** |
| **Amendment:** | **30/06/2013 / Active** |
| **Title of Research** | **An exploration of the presence and nature of intrusive imagery in older people with Generalised Anxiety Disorder** |

Thank you for submitting the 'Confirmation of End of Study Date' form in respect of the above research project.

The extension to your study date(s) and/or the change to your study status (i.e. continuing to recruit or in follow up) notification has been noted by our department. A copy of this letter and your form is being sent to the parties mentioned below. If necessary, they will contact you regarding any further information they may require.

Please remember if your extension involves a change of date only, it should be listed in your annual progress report as a minor amendment. If the extension does involve other changes to the protocol e.g. increase in number of study participants, change in protocol definition of the end of study date, change of IMP exposure, addition of a new procedure, a substantial amendment may be required, and you should follow the appropriate procedure.

Yours sincerely

**Lynda Campbell**
**Research Governance Manager**

**cc:** *Sheevaun McIntyre, Accountant, Finance Dept. ACCORD*

## FULL INTRUSIONS INTERVIEW

### 1. MEMORIES

1. **In the last week have you had any particular memories from a particular episode or event in your past that keeps coming back into your mind?** *(If last week was exceptional then ask about a typical week).*

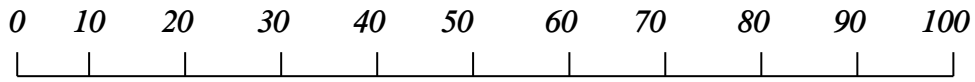
   **YES/NO**
   **(Prompts – When you were feeling the most depressed or memories of particular negative events)**

2. **What are the two most distressing memories?** *(If more than 2 then inform the patient that we will just be concentrating on the two most distressing memories).*

**Memory 1 -**
***When did this episode happen? How old were you at the time of this memory?***

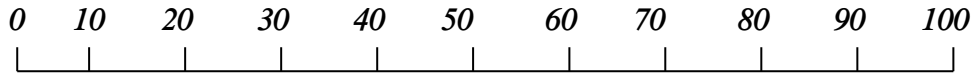
***Can you briefly describe the memory that you have?***

***Please rate the vividness of your memory for the experience:***




**Hazy memory** **Normal memory** **Very clear & vivid memory** **Most clear & vivid memory**

***What are the emotions that you associate with this memory?***

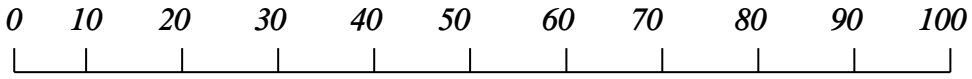



**Not at all** **A little** **Somewhat** **Very much so**

**Sad:** **Guilty:** **Ashamed:** **Other *(specify):***

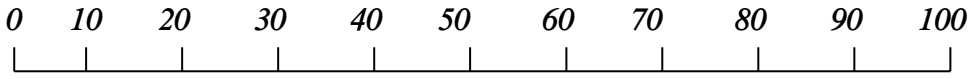
**Angry:** **Anxious:** **Helpless:**

***When you have this memory, does it feel like it is not just a past event but is happening all over again right now?***



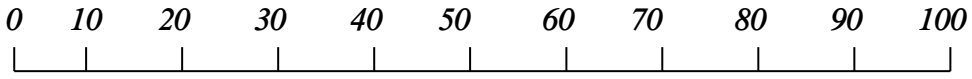

**Not at all** **A little** **Somewhat** **Very much so**

***When you remember the event do you re-experience emotions the same as, or very similar to, those that were felt in the actual event?***



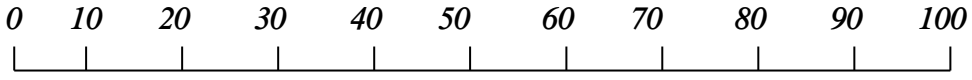

**Not at all** **A little** **Somewhat** **Very much so**

***When you remember the event do you re-experience physical feelings the same as, or very similar to, those that were felt in the actual event?***




**Not at all** **A little** **Somewhat** **Very much so**

**How many times did you experience the intrusive memory in the last week?**

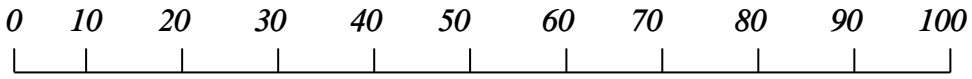



**None of the time** **Half the the time** **All of the time**

**When you experience the intrusive memory on average how long does it last?**

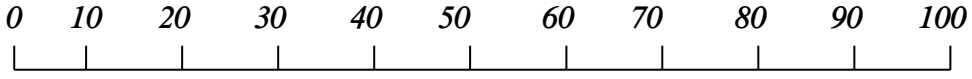
***seconds/minutes/hours***

**How much did the intrusive memory interfere with your daily life?**



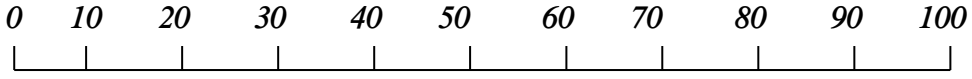

**Not at all** **Moderately** **Severely**

**How uncontrollable was your intrusive memory in the last week?**




**Not at all** **Moderately** **Completely**

**How distressing was your intrusive memory?**

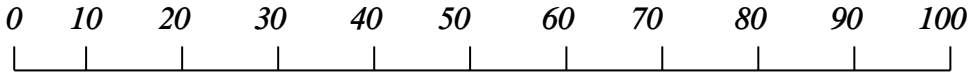



**Not at all** **Moderately** **Severely**

**Memory 2 -**
*When did this episode happen? How old were you at the time of this memory?*

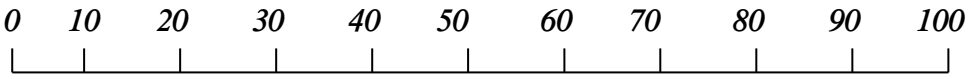
*Can you briefly describe the memory?*

*Please rate the vividness of your memory for the experience:*




**Hazy memory** **Normal memory** **Very clear & vivid memory** **Most clear & vivid memory**

*What are the emotions that you associate with this memory?*

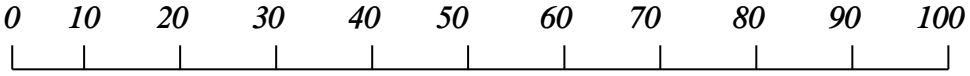



**Not at all** **A little** **Somewhat** **Very much so**

**Sad:** **Guilty:** **Ashamed:** **Other** ***(specify):***

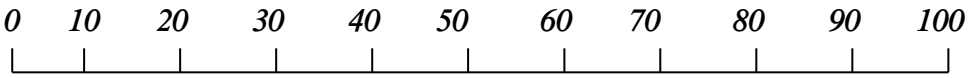
**Angry:** **Anxious:** **Helpless:**

*When you have this memory, does it feel like it is not just a past event but is happening all over again right now?*



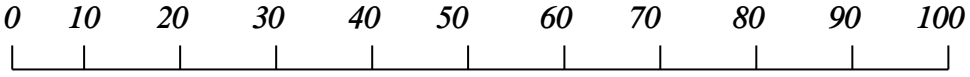

**Not at all** **A little** **Somewhat** **Very much so**

*When you remember the event do you re-experience emotions the same as, or very similar to, those that were felt in the actual event?*



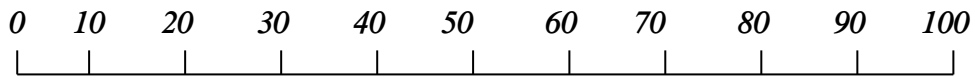

**Not at all** **A little** **Somewhat** **Very much so**

*When you remember the event do you re-experience physical feelings the same as, or very similar to, those that were felt in the actual event?*




**Not at all** **A little** **Somewhat** **Very much so**

**How many times did you experience the intrusive memory in the last week?**

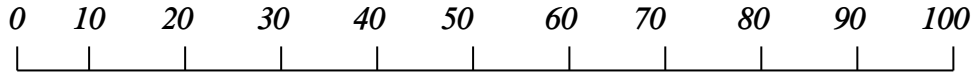



**None of the time** **Half the the time** **All of the time**

**When you experience the intrusive memory on average how long does it last?**

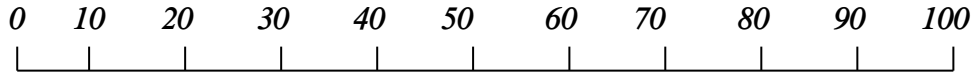
*seconds/minutes/hours*

**How much did the intrusive memory interfere with your daily life?**



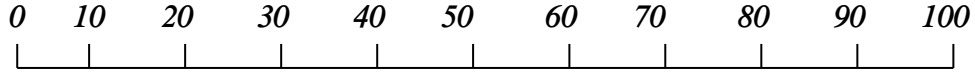

**Not at all** **Moderately** **Severely**

**How uncontrollable was your intrusive memory in the last week?**




**Not at all** **Moderately** **Completely**

**How distressing was your intrusive memory?**




**Not at all** **Moderately** **Severely**

3. **IMAGES**
   **[are you aware that your thinking often consists of mental images or pictures? If no, are you aware that your thinking ever consists of mental images or pictures? If no, discontinue images section]**

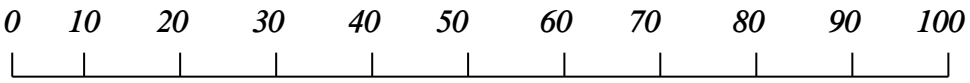
1. **In the last week have you had any other mental pictures or images that [have come spontaneously to mind?** *(If last week was exceptional then ask about a typical week).*

   **YES/NO**

2. **What are the two most distressing images?** *(If more than 2 then inform the patient that we will just be concentrating on the two most distressing images).*

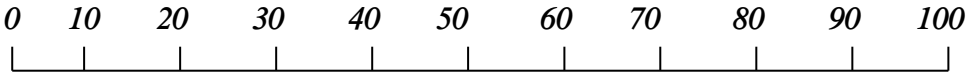
**Image 1 -**
***Can you briefly describe what you see in the image?***

*Please rate the vividness of your image:*



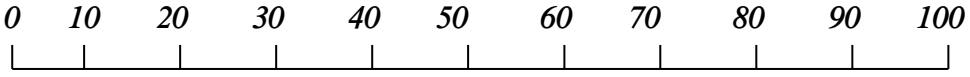

**Hazy memory** **Normal memory** **Very clear & vivid memory** **Most clear & vivid memory**

*Do you experience physical sensations when you have this image?*




**Not at all** **A little** **Somewhat** **Very much so**

*What are the emotions that you associate with this image?*

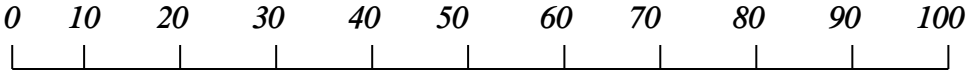



**Not at all** **A little** **Somewhat** **Very much so**

**Sad:** **Guilty:** **Ashamed:** **Other** ***(specify):***

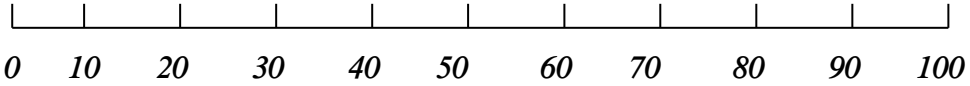
**Angry:** **Anxious:** **Helpless:**

***When you have this image, does it feel like it is not just a past event but is happening all over again right now?***




**Not at all** **A little** **Somewhat** **Very much so**

**How many times did you experience the intrusive image in the last week?**

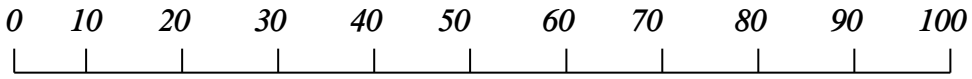



**None of the time** **Half the the time** **All of the time**

**When you experience the intrusive image on average how long does it last?**

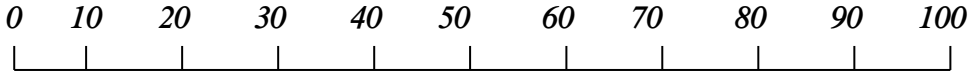
*seconds/minutes/hours*

**How much did the intrusive image interfere with your daily life?**



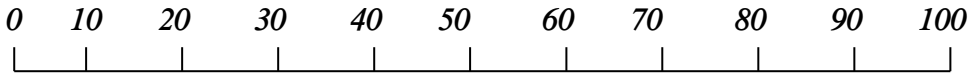

**Not at all** **Moderately** **Severely**

**How uncontrollable was your intrusive image in the last week?**




**Not at all** **Moderately** **Completely**

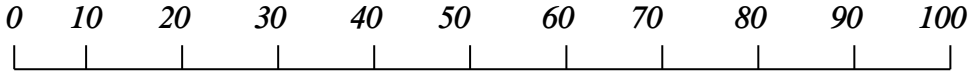
**How distressing was your intrusive image?**




**Not at all** **Moderately** **Severely**

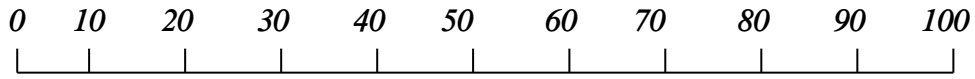
**Image 2 -**
*Can you briefly describe what you see in the image?*

*Please rate the vividness of your image:*



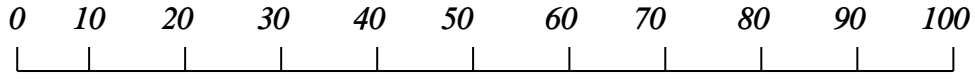

**Hazy memory** **Normal memory** **Very clear & vivid memory** **Most clear & vivid memory**

*Do you experience physical sensations when you have this image?*




**Not at all** **A little** **Somewhat** **Very much so**

*What are the emotions that you associate with this image?*

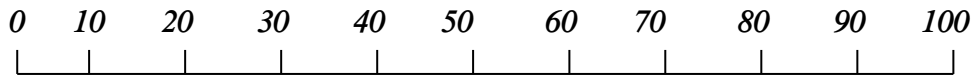



**Not at all** **A little** **Somewhat** **Very much so**

**Sad:** **Guilty:** **Ashamed:** **Other** ***(specify):***

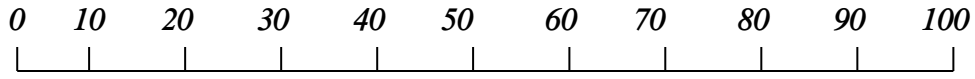
**Angry:** **Anxious:** **Helpless:**

***When you have this image, does it feel like it is not just a past event but is happening all over again right now?***




**Not at all** **A little** **Somewhat** **Very much so**

**How many times did you experience the intrusive image in the last week?**

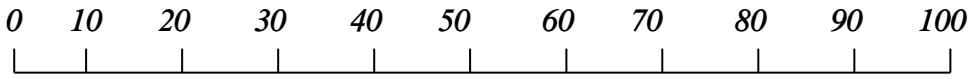



**None of the time** **Half the the time** **All of the time**

**When you experience the intrusive image on average how long does it last?**

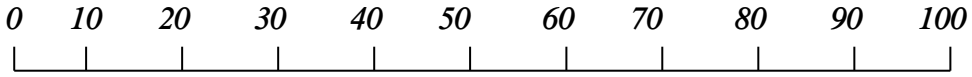
*seconds/minutes/hours*

**How much did the intrusive image interfere with your daily life?**



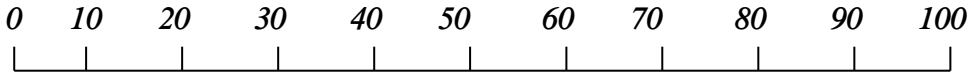

**Not at all** **Moderately** **Severely**

**How uncontrollable was your intrusive image in the last week?**




**Not at all** **Moderately** **Completely**

**How distressing was your intrusive image?**




**Not at all** **Moderately** **Severely**

**3. THOUGHT STREAM**

**Have you been aware in the past week of thoughts that keep coming spontaneously into your mind, giving you a similar message each time? Sometimes the thoughts may just comment, or give instructions, or say if something is good or bad.** *(If last week was exceptional then ask about a typical week).*
***(N.B. emphasise that this is perfectly normal and is not a sign of madness)***

**YES/NO**

**A) Do you experience any of this as like a 'voice' speaking to you? YES/NO**

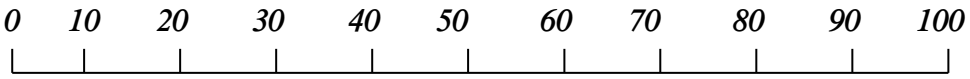
***(N.B. From now on use* 'voice' *or* 'stream of thoughts' *or other term, depending on the way the respondent prefers to describe it).***

**B) Is there just one 'voice' or are you aware of more than one?** ***(record the number of voices).***
**C) What are the two most distressing voices?** *(If more than 2 then inform the patient that we will just be concentrating on the two most distressing voices).*

**Voice One -**
What kinds of things does this 'voice' say? *(record examples)*
**OR** ***What kind of spontaneous intrusive thoughts do you have?***

Does the 'voice' use your **name** ***or refer to you as*** **'I', 'you' or 'he/she'***?*

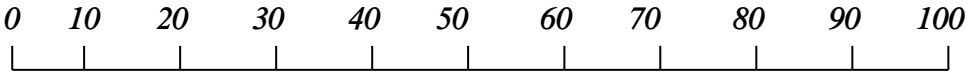
***Does its message tend to be the same or does it vary?***
**OR** ***Are your thoughts always the same or do they vary?***




**Always different** **Mostly different** **Mostly the same** **Always the same**

Is it the 'voice' of someone you know? ***(If so, who?)***

***What adjectives would you use to describe the voice?***

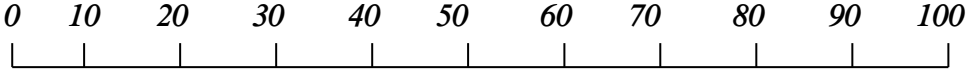



**Not at all** **A little** **Somewhat** **Very much so**

**Encouraging:** **Rational:** **Welcoming:**

**Critical:** **Intimidating:** **Pessimistic:**

***What emotions do you associate with these thoughts/voices?***

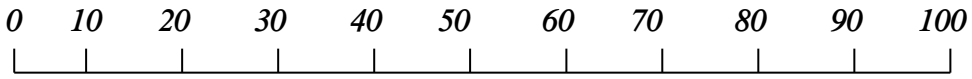



**Not at all** **A little** **Somewhat** **Very much so**

**Sad:** **Guilty:** **Ashamed:** **Other** ***(specify):***

**Angry:** **Anxious:** **Helpless:**

**How many times did you experience the thoughts/voice in the past week?**

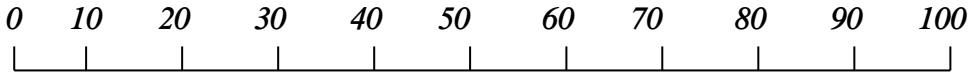



**None of the time** **Half the the time** **All of the time**

**On the last few occasions you heard it, how long did the thoughts/voice speak to you on average?**

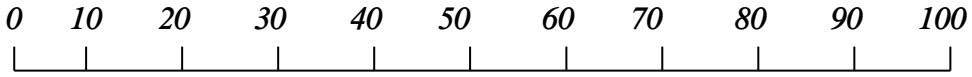
*seconds/minutes/hours*

**How much did the thoughts/voice interfere with your daily life?**



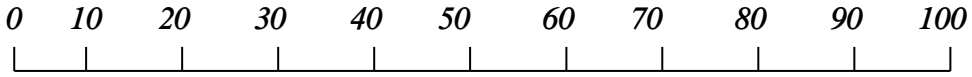

**Not at all** **Moderately** **Severely**

**How uncontrollable were the thoughts/voice in the last week?**




**Not at all** **Moderately** **Completely**

**How distressing were the thoughts/voice?**

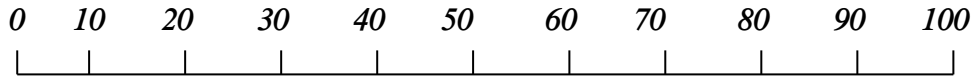



**Not at all** **Moderately** **Severely**

**Voice 2 -**
What kinds of things does this 'voice' say? *(record examples)*
**OR** ***What kind of thoughts do you have?***

Does the 'voice' use your **name** ***or refer to you as*** **'I', 'you' or 'he/she'***?*

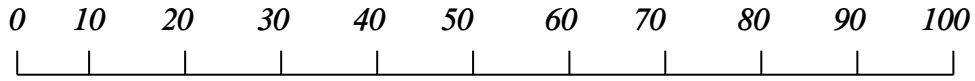
*Does its message tend to be the same or does it vary?*
**OR** *Are your thoughts always the same or do they vary?*




**Always different** **Mostly different** **Mostly the same** **Always the same**

Is it the 'voice' of someone you know? ***(If so, who?)***

*What adjectives would you use to describe the voice?*

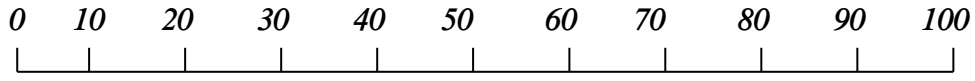



**Not at all** **A little** **Somewhat** **Very much so**

**Encouraging:** **Rational:** **Welcoming:**

**Critical:** **Intimidating:** **Pessimistic:**

*What emotions do you associate with these thoughts/voices?*

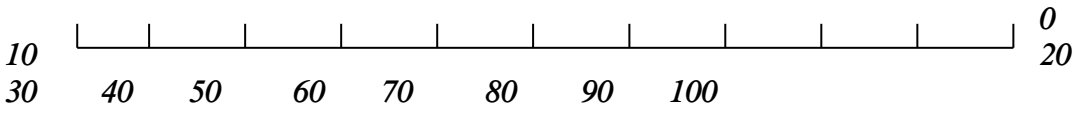



**Not at all** **A little** **Somewhat** **Very much so**

**Sad:** **Guilty:** **Ashamed:** **Other** ***(specify):***

**Angry:** **Anxious:** **Helpless:**

**How many times did you experience the thoughts/voice in the past week?**

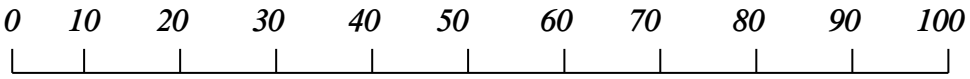



**None of the time** **Half the the time** **All of the time**

**On the last few occasions you heard it, how long did the thoughts/voice speak to you on average?**

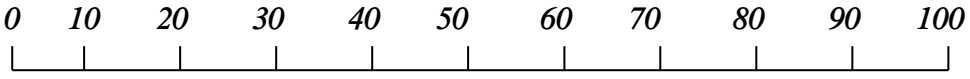
*seconds/minutes/hours*

**How much did the thoughts/voice interfere with your daily life?**



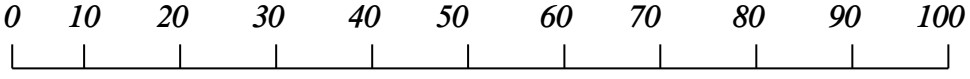

**Not at all** **Moderately** **Severely**

**How uncontrollable were the thoughts/voice in the last week?**




**Not at all** **Moderately** **Completely**

**How distressing were the thoughts/voice?**




**Not at all** **Moderately** **Severely**