

1. Project Title:

The VIP trial: a randomised controlled trial of the clinical and cost effectiveness of a Victim Improvement Package (VIP) for the reduction of chronic symptoms of depression or anxiety in older victims of common crime.

2. Background:

2.1. Existing research :

Crime can affect anyone, and over 13 per cent of media outputs in the UK are dedicated to the topic (Curran et al 2010). Its behavioural and psychological effects on quality of life are severe: 51% of people may avoid going out alone following a 'common' serious crime (such as mugging, burglary or criminal damage) and 14% of all victims feel depressed (Morrall et al, 2010). Older people may be particularly vulnerable to crime because of concurrent major life events; family bereavements, physical ill health, disability, financial difficulties (Prince et al, 1995; Geerlings et al, 2000; Jackson, 2009). According to Age UK 1 in 3 pensioners (3 million) live in or on the brink of poverty (defined as 60% of median income, after housing costs) (Norton and West 2014). Cognitive models of trauma suggest that distress following adverse events, such as crime, may be more marked in people who, because of vulnerability and inadequate instrumental, social or family support, develop "negative cognitive coping responses" (Bifulco and Brown, 1996).

Our society continues to age. In 2007, for the first time in the UK, the number of people aged 65 or over was greater than those aged under 16, and by 2017 numbers will increase by another 15%, with people aged 85 or over estimated to reach 3.2 million by 2033 (Office of National Statistics, 2009). From the limited data on the impact of common serious crimes in older people, there appear to be increases in psychological distress, social care needs and mortality. Older victims of violence, have significant levels of depression and anxiety (n=36) (Gray and Acierno, 2002) and increased risk of placement in a care home within 10 years (n = 2,321,OR=2.1; 95% CI=1.0-4.6), even after controlling for other predictive effects (Lachs et al 2006). In older victims of burglary, depression and anxiety were present in 25 and 13 per cent respectively (n= 84) (McGraw and Drennan, 2006) and sheltered housing residents were 2.4 times more likely to have died or moved into a care home than their non-victimised neighbours within two years (n=56) (Donaldson 2003). Indeed it is recognized that psychological morbidity compounds age associated ill health and disability leading to higher use of social and healthcare services (Luber et al 2001).

Data provided by the Metropolitan Police (personal communication, 29th March 2011) indicates that in seven London boroughs selected for our pilot study, over 26,000 people aged over 55 years reported being victims of a common serious crime in the years 2009-10; this figure is likely to be considerably higher as over 60% of all crimes go unreported (MacDonald, 2002). In addition, only a small proportion of crime victims access formal support agencies, with most relying on networks of family and friends (McCart, Smith and Sawyer, 2010). Together, these data suggest, that there is a large group of older victims who never receive help.

Currently there exists a major health inequality for older people. Tens of thousands of over 65s miss out on vital support and risk serious deterioration in their mental health. Eighty five percent of depressed older people receive no treatment whatsoever; only 6% are referred to mental health services compared to 50% of younger adults, and only 3.7% of referrals for psychological therapies are for older people (Anderson et al, 2009). Very few older people are engaged into psychological therapies, even when they present with distress (Unutzer et al, 2003). Failure to treat depression and anxiety in older people often leads to chronicity of symptoms for months or years (Copeland et al, 1992).

Of the specific interventions for older victims, a small study of a video-based intervention for anxious or depressive symptoms showed no significant benefit (Acierno et al., 2004). Our RfPB funded Helping Aged Victims of Crime (HAVoC) study (Serfaty et al, 2015) on the impact of crime and its management in older people, confirms its significance as a public health issue; at 3 months after a serious common crime, 65% of victims felt it had affected their daily life, 27% were psychologically distressed with just under a half meeting DSM-IV criteria for a psychiatric disorder attributed to the crime. Our pilot RCT, using Safer Neighbourhood Teams (SNTs), small teams of police officers (usually 10-15 strong) dedicated to policing a certain community or area, successfully screened participants for distress; our subsequent management of this distress, using a Victim Improvement Package (VIP), appeared promising.

Equality requires care that suits older people and meets their age specific needs. Whilst identifying younger vulnerable people through their contact with Victim Support may work, this was not effective in older victims (Serfaty et al, 2015). Our new approach builds on an established partnership between the Metropolitan Police, a leading UK university and voluntary services, using an efficient system to identify and engage older victims in psychological care. It represents good value as such set up costs are a major component for any trial. It will hopefully provide a robust evidence base and method to redress some major inequalities of health and well-being. The trial is also consistent with guidance by the criminal justice system to address the needs of victims and increase social justice. If successful, this model of linking community policing and psychological services, Mind or Improving Access to Psychological Therapies (IAPT), could be used to prevent chronicity of symptoms in older victims of crime nationally.

2.2. Risks and benefits

Benefits of the study:

Reduction in inequalities in health: Depression and anxiety in older people, generally go undetected (Anderson et al 2009), impair quality of life, worsen the experience of concurrent physical symptoms, worsen disability and are strongly associated with suicide. Older people have limited access to psychological services and are less likely to discuss such problems, they tend to blame themselves (Acierno et al 2002; Adams-Price et al 2004) and rationalise that distress is normal. They tend not to use Victim Support or GP services (HAVoC study). Improving detection and recruitment of people with crime associated psychological distress through SNTs will facilitate engagement with services.

Prevention of chronic ill health: Depressive symptoms in community dwelling older people may remain for years (Copeland et al, 1992), but older people are rarely referred for treatment (Anderson et al, 2009). Identifying and treating symptoms early should reduce chronicity and improve the associated poor physical health. CBT, is an effective intervention for depression in older people (Serfaty et al 2009) which we have modified for older victims (Serfaty et al, 2013). A full trial will hopefully reduce morbidity and possibly mortality. Longer term follow-up of physical and psychosocial outcomes may be the subject of an MSc project.

Improve quality of life: with symptom reduction and any facilitation of a return to independent living (generally greatly valued by older people) the VIP will improve quality of life and may also defer residential care in some instances.

Building up an evidence base: of the NETSCC programmes currently underway, there are 3 studies on crime: two preventing offenders from re-offending, one on tackling alcohol and substance misuse, but none on victims of crime. Our pilot work was the first to link experts in criminology, the police, psychology, mental health users and the voluntary sector. We have established ways to identify, screen, recruit, and deliver our developed intervention (Serfaty et al, in press). The next step is to establish a robust evidence base using a fully powered RCT.

Improving public health: Despite changing demographics, the disproportionate impact of crime on physical and mental health in older people has yet to be addressed. If effective, our model used to screen and treat older victims could be applied to victims of all ages.

Cost considerations: A preliminary analysis on our HAVoC study data strongly suggests that the VIP intervention represents a cost-effective use of resources. Cost data will provide an accurate assessment of the associated costs of screening and the intervention. After a violent crime (Lachs et al 2006) or burglary (Donaldson 2003) there may be increased likelihood of moving into a nursing home. It is therefore hoped that the overall costs of the intervention may reduce in the medium to longer term.

Generating further interest: The lack of attention regarding the fate of older victims of crime (cf the fear of crime) is difficult to understand. Users of mental health services, victims, and the criminal justice department have all suggested that victims' needs should be a priority. Unmet needs created by acts of crime require more understanding and appropriate management as part of the general move towards greater social justice.

The risks of the study: *Clinical considerations:* As far as we know there are no risks from improved screening in high risk groups, provided that services are available to manage the condition, nor evidence that CBT does harm. Whilst people may be disappointed if allocated to a TAU group, we are adopting usual practice and they should not suffer adversely, indeed, all participants will benefit from information about crime, its effects, and sign-posting to available local services. *Cost considerations:*

Short term risks of the study include: increased direct costs associated with screening, delivering the intervention; hypothetical indirect costs from an increased demand for services.

2.3. Rationale for current study: The proposed research is not part of a wider study and the background and rationale has been already described.

3. Research objectives:

Our aim is to prevent chronicity of symptoms of psychological distress in older victims of common serious crime. We will use a three-step process to satisfy our main objective: to conduct an assessor blind, randomised controlled trial, comparing a manualised Victim Improvement Package (VIP; Serfaty et al 2013) plus Treatment as Usual (TAU) with TAU alone, stratified for a diagnosis of either depression with or without anxiety or anxiety alone.

Step 1: SNTs will screen and identify high risk individuals within a month of a crime, for possible depression and/or anxiety. Step 2: researchers will rescreen these for continuing distress at 3 months post crime, Step 3: we will randomise eligible participants into the VIP trial.

Primary objective:

To determine whether older victims, with DSM-IV depression (and/or anxiety) or anxiety alone (Sheehan et al 1998) present 3 months after a common serious crime, benefit from a VIP to reduce continued severity of symptoms (6 months post crime; post-intervention), measured with the BDI-II (Beck et al 1996) and BAI (Leyfer et al 2006) standardised for this purpose.

2. Secondary objectives:

a. Symptom severity: as above, but measured at 9 months post crime (followup) and 1-2 years post crime (longer followup (funding will be sought elsewhere)).

b. Social: to determine whether older victims with DSM-IV depression and/or anxiety or anxiety alone present 3 months after a common crime, benefit from a VIP in terms of improving quality of life at 6 and 9 months post crime, measured using the EQ5-D (Rabin 2001).

c. Economic: to explore the costs of the VIP in older victims of crime with DSM-IV depression and/or anxiety or anxiety alone, using the CSRI (Curtis 2008) at 6 and 9 months post crime.

d. Health inequalities: to explore the likely impact on health inequalities in a number of connected ways. This is described in detail in section 6 below. This will enable us to explore the relationship between inequalities in health and age and how these relate to improvement with our interventions.

e. The impact of signposting: for ethical reasons the SNTs will signpost older victims to their GP (see methods). Although we are not conducting an outcome study of signposting, we will collect data at 3 months post crime to see whether those with significant distress have acted on the materials provided. Our objectives are (i) Quantitative: We will collect data asking whether people have acted on the signposting and if so in what way. (ii) Qualitative: we will conduct semi-structured interviews with 24 people asking them why they have or have not acted on the information provided and how it could be improved (see methods).

f. Service delivery: to demonstrate that Safer Neighbourhood Teams (SNTs) can identify and recruit participants and that suitably trained Mind therapists can deliver the VIP to reduce chronicity of depression and/or anxiety in older victims of crime. We will establish a novel integrated model of care involving two large public service organisations, the Metropolitan Police and the voluntary organisation, Mind. If effective, these methods would be deliverable nationally and would have international significance.

4. Research design:

General design: Our RfPB funded HAVoC study has informed this VIP trial proposal (Serfaty et al in press). We have developed robust recruitment techniques and the VIP treatment manual. We have tested and selected appropriate screening tools and the diagnostic interview. The VIP trial consists of three steps Step 1: screening for potential depression and/or anxiety at the time of the crime. Step 2: re-screening, diagnostic assessment. Step 3: referral for an RCT to prevent continuing symptoms 3 months after the crime.

Step 1: the police, via SNTs, who routinely visit nearly all older victims within a month of the crime will add to their usual information and support, a brief screen to identify significant depressive or anxiety

symptoms; our pilot found that people with significant symptoms at one month are at risk of becoming chronically distressed sometimes with social repercussions. SNTs in boroughs representing different socio-demographic characteristics will be selected to ensure generalisability. With verbal agreement, those with significant distress (screen positive) will be signposted to local services for further care options, and notified to the research team for re-screening. Ideally we would hope that signposting will benefit screen positive participants, but in reality we anticipate that simply providing information and signposting will have little effect on outcome (Callahan et al, 1994).

Step 2: people will be re-screened for continued symptoms at 3 months by a UCL researcher and if significant, offered a fuller assessment using the MINI (Sheehan et al 1998). Those with a diagnosis of depression and/or anxiety (attributed to the crime) will be given verbal and written information with an adequate explanation of the aims, methods, anticipated benefits and potential hazards of the VIP trial. Forty eight hours will be given for consideration by the patient before randomisation into the controlled trial of VIP added to usual care (Treatment as Usual; TAU) compared to TAU alone.

Step 3: RCT: Informed consent by the CI, or a person delegated by the CI will be obtained in writing from each participant prior to participation in the trial. The Investigator will record when the patient information sheet (PIS) has been given to the patient. The Investigator or designee will explain the patients are under no obligation to enter the trial and that they can withdraw at any time during the trial, without having to give a reason. No clinical trial procedures will be conducted prior to taking consent from the participant. Consent will not denote enrolment into trial. A copy of the signed Informed Consent form will be given to the participant. The original signed form will be retained at the study site and a copy sent to their GP. If new safety information results in significant changes in the risk/benefit assessment, the consent form will be reviewed and updated if necessary and subjects will be re-consented as appropriate. Consenters will be allocated to the interventions described in section 7 below. We will record potential sources of bias (see section 9) known to predict outcome. The trial will be conducted and reported in accordance to the CONSORT guidelines.

Randomisation: UCL researchers will provide consenters details to PRIMENT, an independent clinical trials unit, who, using web based randomisation, will notify an independent trial coordinator in UCL of group allocation. The UCL coordinator will notify participants of their group allocation and also an administrator working in Mind who will arrange delivery of the VIP. Assessors will be kept blind where possible. The UCL trial coordinator will track participants, notifying the research team when assessments are required.

Clinical and economic evaluation: We will conduct a full clinical evaluation and cost assessment; described in sections 9 (outcomes) and 12 (analysis).

Stopping rules: We do not anticipate that our intervention will cause any harm, nor that there will be evidence of benefit so great that the study needs to be terminated. Individual discontinuation will be if a participant becomes so unwell that they are self-neglecting, or at risk of self-harm to a degree to require urgent assessment by their GP and/or local mental health services. This will be actioned with the participant by research workers and/or therapists.

Recruitment: Although we have conducted detailed feasibility work and do not anticipate major problems in recruitment, we have considered potential factors that may cause a shortfall. First, early signposting may marginally reduce morbidity at 3 months, thus reducing the numbers available to enter the trial. Secondly, the recruitment rate at the start of trials tends to be lower for the first 3 months, until SNTs get used to screening and referring.

We estimate that each SNT is able to screen an average of 15 older victims per month. We may expect 4 SNTs out of our 7 boroughs to be active initially and for each to screen 10 participants during the start up. Thus our target would be to screen $40 \times 3 = 120$ participants in the first 3 months. Screening and recruitment data will then allow us to make more accurate predictions about the number of SNTs required. We could always expand the number of boroughs or SNTs within each borough if necessary.

5. Study population:

Victims of reported common serious crime* aged 65 years⁺ or more, living in selected London boroughs who satisfy the following criteria will be eligible:

Inclusion: A MINI (Sheehan et al, 1998) DSM-IV diagnosis of depression[±] (with or without anxiety) or anxiety attributed to the crime.

Exclusion: MINI diagnosis of schizophrenia, bipolar disorder and/or alcohol or drug dependency as these are not targeted by the VIP but could affect outcome; receipt of Cognitive Behaviour Therapy (CBT) in the last 6 months, inability to participate in CBT because of language difficulties and/or Mini Mental State Score of ≤ 24 (significant cognitive impairment) as CBT is less likely to be effective.

* The police definition of common serious crimes includes: common assault, actual bodily harm, grievous bodily harm, harassment, racist crime, homophobic crime, false representation (deception), burglary, distraction burglary, criminal damage to property, theft including pick-pocketing and snatch.

† We have chosen people 65 years or more as they are more likely to be economically (retired), physically and socially compromised and experience marked inequalities; our cut off was determined by pilot work that generated few distressed victims aged 55-64.

* We are focussing on common crime, rather than serious assaults associated with complex trauma and legal issues requiring specialist services.

‡ Establishing a clear diagnosis is necessary as diagnostic severity predicts chronicity, enables case identification and determines which CBT model is used for treatment.

6. Socioeconomic position and inequalities:

Older people experience age and socioeconomic health related inequalities.

Age related inequalities: among over 65s, for every 1 million with depression, 850,000 receive no treatment whatsoever; referral to mental health services occurs for 50% of depressed younger adults and only 6% of older adults; a recent Healthcare Commission audit found that only 49/1300 referrals for psychological therapy were older people (Anderson et al, 2009). Whilst identifying younger people through contact through Victim Support may work, it was not effective in older victims (Serfaty et al 2015).

Socioeconomic inequalities: crime and the fear of crime: 1. Impacts significantly on psychological, physical and social wellbeing; 2. Worsen social isolation and exclusion. 3. Occur more frequently in poorer areas (Flatley et al 2010) where large numbers of older people live in or close to poverty (Norton and West 2014). 4. Social inequality is associated with poorer mental health and our HAVoC study found those with a previous psychiatric history were likely to become distressed following a crime. Public concerns about neighbourhood disorder, social cohesion and collective efficacy may impact disproportionately in deprived areas, however there are no data establishing a direct link examining the differential impact of socioeconomic status and crime on mental health. Persisting distress in victims may increase social exclusion and have a greater impact on the social capital within deprived areas (Taylor, 1995, 1996; Girling et al, 2000; Jackson, 2008).

How we will attempt to address inequalities: This is the first RCT to tackle an existing problem of distress in older victims of crime and failure to access psychological therapies. Our data will be some of the most comprehensive concerning psychological health consequences of crime in older people.

From these, we will be able to make inferences about age related health inequalities in the UK. Individual postcodes will allow us to examine the relationship between psychological distress and relative levels of deprivation using the Lower Layer Super Output Area (LSOA) data. (www.communities.gov.uk/corporate/researchandstatistics/statistics/subject/indicesdeprivation).

As a secondary trial outcome, we will explore differences in improvements in participants stratified by deprivation. Findings will enable us to inform local action as guided by the recent 2014 joint publication (on local action to tackle health inequalities) between Public Health England and Sir Michael Marmot's Centre for Health Equity (Marmot et al 2010).

HAVoC demonstrated that generic approaches, including Victim Support, were unable to meet the needs of older people. Equality requires care to suit older people's age specific needs and it is essential to develop services with these in mind. Our cross agency approach showed that older victims could be identified, recruited and engaged in treatment. With a full trial, we will generate an evidence base demonstrating that continued psychological distress can be prevented hopefully with associated positive changes in vulnerability, isolation, resilience, confidence and physical health. It will also provide an established model which can be rolled out through Public Health England.

7. Planned interventions:

I. The Victim Improvement Package (VIP):

Up to 10 manualised individual sessions of modified CBT, will be delivered, over 3 months, in community based Mind facilities. Full details of the VIP manual have been published and are available from the Chief Investigator (Serfaty et al, 2013) The VIP, tailored to the main presenting symptoms and used flexibly, will cover: Session 1: a narrative of the crime, underlying beliefs, behaviours and how these have changed; Session 2: psycho-education about crime and an introduction to CBT; Sessions 3-8: mood diaries to identify unhelpful thinking and behaviours; guided discovery to challenge beliefs about crime, personal vulnerability and safety; behavioural experiments to challenge unhealthy avoidances; Sessions 9-10: relapse prevention. Only Mind therapists previously trained in CBT techniques and with at least 2 years' experience in delivering CBT will be used. Therapists will be expected to be at a standard accreditable by the British Association of Behavioural and Cognitive Psychotherapists (BABCP). Mind therapists will be given a day of training on how to apply the VIP to their skill set.

All sessions will be audio-taped; treatment quality will be rated from a random sample of 1 in 10 tapes using the Cognitive Therapy Scale-Revised(Blackburn et al, 2001). A checklist will measure adherence to the manual.

II Treatment as Usual (TAU):

In older victims of common serious crime psychological distress is not usually detected and adequately treated (Unutzer et al 2003; Anderson et al 2009), although the following interventions may occur:

Informal support: provided by networks of friends and relatives, where available.

Voluntary agencies: Safer Neighbourhood Teams visit victims and routinely send information on how to contact Victim Support (VS), which relies on the victim proactively requesting assistance, which older people do not appear to do (Serfaty et al, in press). People may self-refer to Mind. In reality few older people take up offers of help when contacted by letter (Serfaty et al, 2015).

GP referral: Concerning older people, our qualitative work found that victims do not seek help from their general practitioner directly as they do not believe that the problem is "medical". When referred to the GP with depressive and anxiety symptoms they may not be managed according to NICE guidelines, especially when distress is seen as understandable or associated with ageing (Anderson et al 2009). A small number may be prescribed psychotropic medication, but many are reluctant to take these(Blanchard et al 1995). With anti-depressants there may be difficulties with compliance, fears of dependence, interactions and side effects.

Psychotherapy referral: A recent development has been Improving Access to Psychological Therapies (IAPT) where people may self-refer, or be referred by their GP. The IAPT/Wellbeing services use a stepped care model with provision for limited Cognitive Behaviour Therapy (CBT). CBT is recommended by the National Institute of Health and Clinical Excellence (NICE) as an effective treatment for anxiety and depression in people of all ages, but generally very few older people receive this (Anderson et al 2009). We will not exclude CBT from TAU for ethical reasons, we will however record any receipt of this and account for it in the analysis.

Traumatic Stress Clinics: these rarely see older adult victims and as a tertiary service, it may take people at least a year to gain access to treatment.

Access to independent practitioners: for economic reasons, older people are less likely to pursue privately financed options.

Where the patient is agreeable, the GP will be informed of the study and the diagnosis. We will not encourage use of CBT or starting or increasing psychotropic medication during the trial.

8. Methods proposed.

We have already piloted different approaches to identify significant distress in older victims; by writing, by telephone or direct screening through SNTs. Of the 1,058 people who agreed to be contacted, over 80% of respondents were identified through the police with only 15% from Victim Support, and none of the latter satisfied entry criteria for the trial. When approached directly through the Safer Neighbourhood Teams, over 90% of participants agreed to screening with 39% above a significant cut off on our screening tools. Assuming the project is successful, operationalisation in routine practice will be as follows:

Step 1:

Identification: the most pragmatic and cost efficient way to identify older victims, is via the police from victims date of birth collected during the reporting procedure (usually by telephone contact either directly from victims of crime, family or a friend), or for some crimes, theft, criminal damage and hate crime, online. We acknowledge that victims that do not report crime may present to A&E staff, GPs, or be brought to the attention of relatives and friends. We have consulted experts in research in A&E who suggest that A&E is pressured, has a significant turnover in staff and screening for social problems, such as domestic violence, is not practicable. Similarly our GP representative pointed out that in 30 years a patient has never disclosed being a victim of crime. Furthermore, our pilot work (HAVoC) demonstrated that advertising, flyers and posters were not successful, and the number of victims in each setting is so small that continuous education about the study would be costly and inefficient. If the VIP is shown to be of benefit, then effective dissemination of our findings and the development of management strategies will enhance screening in these other settings and development of a fuller public health prevention strategy. SNTs almost always visit older people after a crime to collect information and provide advice on crime prevention. In addition they will screen for symptoms of depression and/or anxiety.

Screening: This will be done by incorporating 4 brief questions with a pro forma, to determine cut offs on the PHQ-2 (Kroenke et al 2003) and the GAD-2 (Kroenke et al 2007) respectively. The use of the PHQ-2 and GAD-2 in older people as screening instruments has been validated as follows: 1. In other published studies: the PHQ-2 is a valid screening tool for major depression people of all ages (Arroll et al, 2010) and in older people providing it is followed by a more-comprehensive diagnostic process (Li et al, 2007; Lino et al 2014). The GAD-2 has been validated for use as a brief screening tool in older people (Wild et al, 2014). 2. Their use has also been demonstrated in our pilot HAVoC study (Serfaty et al, 2015).

A simple calculation, on the respective scales by adding up two numbers, will demonstrate casesness. Those below (screen negative) and above (screen positive) the cut offs will be managed as follows:

Screen negative: The older person given information about the potential impact of crime and how to access help through their GP or self-referral to local services if they feel that they have got worse.

Screen positive: the older victim will be: i) informed that the crime may have caused significant distress and that they could benefit from follow up and possible help ii) given a brief information leaflet about the impact of crime iii) given a letter to take to their GP practice at their next visit iv) asked for permission to be contacted again in three months to repeat screening and to ensure that they are managing, and for their details to be sent to a coordinator based at UCL.

We acknowledge the concern from the board that screening may influence outcomes. However: 1. Screening is required to identify victims at risk of chronic distress; 2. Longitudinal data, using repeated screening for depression in older residents in Liverpool, shows a marked chronicity of symptoms over years (Copeland et al, 1992); 3. Signposting older victims to GPs in similar populations with psychological distress had minimal effect (Callahan et al, 1994; Serfaty et al, 2009). We considered not signposting, however leaving distressed victims with no recourse to help would be unethical. Randomisation in step 3 should balance for known and unknown factors which predict outcome. Nevertheless, understanding the reasons for decision making and behaviour following signposting in this population is an important public health issue, and will be explored using qualitative methods and may provide an opportunity to improve future management for older victims (see below).

Step 2:

Older victims who screened positive at step 1 will be re-screened by a university researcher at 3 months after the crime, by telephone, in writing or internet, with the same questionnaires as in step 1. We will also ask participants whether they took the information letter to their GP and if anything was done.

Rescreen negative: people will be given the same information as for step 1 screen negative.

Rescreen positive: people will be offered a more detailed interview using the MINI (Sheehan et al 1998) to generate a diagnosis of depression and or anxiety according to criteria defined in the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV). If they are not a case on the MINI they will be given the same information as screen negative people. If they are a case of depression, with or without anxiety, or anxiety alone, then they will be given information about the trial

and 48 hours to consider whether or not to take part. Those who do not enter the trial will be offered a letter to take to their GP to explain the situation.

Qualitative information: Formal help-seeking behaviour by victims of crime is influenced by various demographic and socio-economic factors, as well as the type of crime (McCart et al, 2010). In order to understand participants' views about how signposting helped or not, we will undertake semi-structured interviews with a purposive sample of 15-24 participants at step 2 using a predefined sampling framework recommended by Flick and Saloman (2012), undertaken until saturation is achieved. Our population will include a balance of gender, people who screened negative or positive, and a diversity of people from ethnic and socio-economic backgrounds. At rescreening, potential participants will be asked if they agree to a recorded interview, given written information and at least 48 hours to consider. They will be offered the opportunity to be accompanied by a friend or relative at a time and place of their convenience. We will be sensitive to their reactions and allow them to withdraw from the interview at any time, although our previous work suggested that older victims found such interviews helpful (Serfaty et al, 2015).

The interview topic guide will begin by briefly discussing the crime and subsequent events, social support and formal and informal help-seeking. We will systematically explore the acceptability and acceptance of the relevant materials used in screening and signposting, whether the advice had been acted upon and any use of the referral letter given. Additionally, we will discuss their view of the response by healthcare and other professionals.

The data will be coded and managed in Nvivo software (Boyatzis, 1998). We will adopt a Framework approach (Gale et al, 2013), a method well-suited to studies such as ours where the areas and themes that we wish to examine have been, largely, identified in advance, but flexible enough to allow the inclusion of unanticipated topics. Two researchers will index and chart the data. The definitive thematic framework will be agreed by the social science leads and PI. The analysis will be structured primarily on the qualitative study questions and objectives – what aspects of this intervention work, for whom and why? Thus, we will analyse the data in order to illuminate the elements of the screening and signposting which facilitate appropriate and timely help-seeking, and those areas that may require alteration or enhancement.

Step 3:

Those who satisfy all entry criteria and consent will undergo a web based randomisation to either TAU or the addition of VIP to TAU described in section 7. Once they have completed the recommended course of treatment it will be up to the professional discretion of the therapist managing their care on how to proceed clinically. Those not randomised to the VIP will be asked for permission for us to inform their GP about the study and their current situation.

Attrition/Compliance: Our pilot work suggests that out of 581 victims interviewed within 1 month of a crime (not all positive), 486 (84%) agreed to be re-screened at 3 months. Of those screened who satisfied entry criteria and agreed to participate in the trial, 26 people were randomised, 12 to TAU and 14 to TAU plus CBT. Of these, all 12 in the TAU group were followed up post intervention at 6 months. Of the 14 randomised to the CBT group, 2 people withdrew just prior to being notified of their randomisation group. Of the remaining, 12 agreed to follow up and 3 declined therapy. Although caution is required when extrapolating retention rates generated from small numbers, our pilot data suggests a retention rate between 81-87% may be expected. This is consistent with a community study of individual CBT in depressed older people that had retention rates of 87% and 83% at 6 and 10 months (Serfaty et al 2009). The number of sessions attended will be an indirect measure of compliance with therapy.

9. Proposed outcome measures:

Baseline measures:

The primary outcome measures were selected after testing a range of measures in a similar population (Serfaty et al, 2009; Serfaty et al, in press). Data from our pilot work (HAVoC study) also helped inform our power analysis. We propose:

(a) The Beck Depression Inventory-II (BDI-II)(Beck et al 1996) and **(b) Beck Anxiety Inventory (BAI)**(Leyfer et al 2006) for those diagnosed with depression and anxiety respectively to measure participants' progress. These two scales, will be adjusted to enable us to compare improvements in depression or anxiety using "standardisation". Both the BDI-II and BAI are self-report, 21 item, 4

possible answer choices. They have good reliability and validity for measuring severity of depression and anxiety respectively. The BDI-II has the advantage over other scales because it includes a significant number of cognitive –affective as well as somatic dimensions. The BAI is composed of cognitive and somatic elements.

Additional baseline measures will include: basic demographic and clinical information; the type of crime (as described by the Metropolitan Police and provided in the VIP manual), its context; data on potential vulnerability factors e.g. recent life events and disability, and participants' perception of available support, previous history of depression or anxiety disorder.

We have chosen to confirm a DSM-IV diagnosis of depression or anxiety using the MINI (Sheehan et al 1998), as our work in a vulnerable, predominantly older population (CanTalk study), has found this scale brief and easy to use with minimal burden on participants.

The VIP offers weekly sessions for 3 months, this duration has been shown to be effective in community dwelling depressed older people (Serfaty et al 2009). Follow up will be immediate at the end of therapy (6 months after the crime) and then at 9 months after the crime. This time frame was chosen to balance longer term effects with the overall length and therefore cost of the study.

Secondary outcome measures:

The EuroQol (EQ5-D; Rabin 2001) is a 5 item generic utility measure of quality of life has been selected because: 1. It is brief, easy to use, minimizing attrition. 2. It compares favourably with other measures (Haywood et al, 2005; Makai et al 2014). 3. It has been used extensively in older people (Garratt et al, 2002). 4. We have used it in depressed older people (Serfaty et al, 2009; Holman et al, 2011) and older victims of crime (Serfaty et al, 2015). 5. It is recommended by NICE for health economics (NICE 2013), including trials with older people (Underwood et al 2013).

The Client Service Receipt Inventory: (CSRI; Curtis 2008) we have already used our modified version in a trial of CBT for older depressed people (Holman et al, 2011).

Potential biases:

Sources of bias during the course of the trial:

At baseline (3 months post crime): (i) Prescribed antidepressants/anxiolytics: name, dose, and any recent changes, of medication. Doses will be standardised against imipramine/diazepam respectively to ensure that they are equivalent in both trial arms. (ii) Other psychological therapies reported by patients. (iii) Expectations at baseline: Participants will be asked to predict the degree of expected improvement, or not, on a 7 point Likert scale ranging from -3 to +3 (iv) Treatment preference: Patients' treatment preference, collected on a four point Likert scale (0-3).

At follow up: i) measures of attrition and engagement with therapy: during the course of the study we expect few deaths and this is likely to be a random. Additionally we will record change of residence, illness, geographical distance from therapy, did not attend rates and reason for not doing so;

ii) assessment of "blindness" by rater; iii) changes in prescribed psychotropic medication; iv) other psychological treatments received; v) measures of fidelity to treatment (Section, 7, Intervention). vi) measures of satisfaction with treatment by rating on a 5 point scale (not at all to very much) whether the VIP was useful.

10. Assessment and follow up:

Timing of Assessments: The main measures, (see 9. outcomes section) will be collected at 3 months post crime (baseline), 6 months post crime (post-intervention; primary end point) and 9 months post crime (follow up), in addition to a longer follow up (see below).

Post intervention: will include the outcome measures, including the MINI, previously described to determine the immediate effects and cost of the intervention.

Follow up (9 months post crime): we will exclude therapy related measures, but look for maintenance of any psychological improvement and related behaviour/social changes.

Longer term follow up: We appreciate that attrition over the longer term may not be random, and that the study is not powered to answer whether there are significant psychological differences between the intervention and control group. However, the wealth of data generated from the VIP trial will enable us to see what happens over a longer time frame. We plan for an MSc student (UCL postgraduate training MSc research thesis) to contact people at between 2 and 3 years to see whether any improvements are

sustained in the BDI-II and BAI, and whether there are differences in physical health status and/or accommodation.

Maximising followup: Steps will be taken to give us the best chance of collecting the primary outcome variables, BAI and BDI-II, at the principal time-point (6 months post-crime) using assiduous data collection; face to face, writing on at least 2 occasions, phone and online.

Summary of main measures (all with reference to post crime)	Baseline (3 months)	Post intervention (6 months)	Follow-up (9 Months)
BDI-II	✓	✓	✓
BAI	✓	✓	✓
MINI (caseness)	Yes/No	Yes/No	
EQ5-D	✓	✓	✓
CSRI	✓	✓	✓
Satisfaction with VIP		✓	
Expectation of therapy	✓		
Blindness assessment by RA		✓	✓
Attrition and reason		✓	✓
Fidelity: Adherence and CTS-R		✓	

10.1. Assessment of efficacy/effectiveness:

Participants will be cases of depression and /or anxiety according to DSM-IV guidelines as per the MINI (Sheehan et al 1998) and effect will be demonstrated by differential change in level of symptoms as recorded by a research interviewer blind to participant intervention status using the BDI-II or BAI, the score of which will be standardised (statistical analysis section). Symptoms will be measured with diagnosis at 3 months post crime (baseline), and at 6 months post crime (post intervention) and 9 months post crime (follow up).

Analysis will only occur once all data has been collected at the nine month post crime follow up- there will be no interim analyses as it is felt that there will be no ethical reason to stop the trial for reasons of efficacy.

10.2. Assessment of harms:

As this is not a drug trial, our main concern is whether people with depressive or anxiety symptoms are at immediate risk of self-neglect or self-harm, which would be considered a Serious Adverse Event (SAE). Whilst there is no significant evidence to date that CBT is harmful, all people receiving the VIP will be monitored clinically. Standard operating procedures for SAEs, already used successfully in an ongoing trial, will be applied to this study.

It is not be realistic for SNTs to conduct mental health risk assessments on those screened for potential distress at step 1. However SNTs will encourage people who score above a cut off, to take a letter to their GP. If a member of the SNT team believes that an individual is in immediate harm, then good practice would apply and arrangements for a GP visit or visit to A&E could be made. The Mental Capacity Act or Mental Health Law will be employed as usual.

For people in step 2 of the study, all participants will be screened at baseline for risk of self-harm. For those identified as high risk on the MINI (range: low, medium or high) or for those who score 3 on question 9 of the BDI-II (I would kill myself if I had the chance), arrangements will be made for an urgent assessment with a GP or at A&E where people are willing, or by use of Mental Health Law or the Mental Capacity Act if necessary. In step 3, any increase in suicide risk during the course of the study will not necessarily exclude people from continuing in the RCT, as participants may have an established therapeutic relationship in which clinical assessment and discussion will determine the appropriate management.

Mind therapists will be very familiar with procedures of managing people with suicidal thoughts. Where necessary, a further mental health assessment will take place, either through the GP or the local CMHT. We are aware that ending therapy may be distressing for the patient and liaison will be made with the patient's GP to ensure continued support is available if required.

If any participant is noted at any time point to be reclassified as high risk of self-harm, arrangements will be made in accordance with the governance procedures above and the increase in risk recorded. Any reports of self-harm considered a SAE, will also be recorded and the CI notified. All these data will be fed back to the DMC. SAEs will not exclude people from the trial and we will ensure that an assessment has been done by mainstream services (e.g. Mind, crisis team, CMHT, GP) and, where clinically acceptable, we will follow up all participants randomised.

11. Proposed sample size:

Sample size: Previous RfPB feasibility work on recruitment, delivery of the intervention, assessment and follow-up has informed this trial. We plan to use 2 SNTs in each of the 7 boroughs selected to recruit a total of 226 participants.

Power: Participants will be classified by their primary diagnosis of 'anxiety' or 'depression'. The main efficacy analysis (to inform any decision to roll out the program) will use changes from baseline to the end of the intervention period in BAI for 'anxiety' participants, and in BDI-II for those with 'depression'. To facilitate the combination of information across these scales, each will be standardised by its residual standard deviation after the full model has been fitted. Although there is little evidence to what constitutes a clinically meaningful difference (Seggar et al, 2002), consensus between experts in the field suggest that a change of 0.5 of a standard deviation, 3 or more on the BDI, is considered a NICE approved clinically important change (NICE, 2004). It is feasible to detect a ('true') average difference of 0.5 on the standardised joint scale with 90% power at $p < 0.05$ (2-sided) requires a total sample-size (N) of 168. (Calculations here were based on the normal distribution - an assumption justified by the central limit theorem). Applying an overall 'cluster-adjustment' for therapist effects, assuming a cluster-size of 8 and ICC=0.02, and 15% allowance for dropout, increases this to N=226. Using data from the pilot study, the 'target' standardised difference of 0.5 implies changes in both BAI and BDI-II of about 4 and this is valuable clinically, given the scales show the for moderate levels of symptoms the scores range from 20-28 and 16-25 for anxiety and depressive symptoms respectively.

12. Statistical analysis:

Clinical effectiveness analysis: We will follow a pre-specified plan for statistical analysis and reporting which will be finalised before database lock, and which adheres to the CONSORT guidelines. This includes presenting a table of summary statistics for those outcome variables collected at baseline, showing clinical characteristics for each group, along with (baseline) demographic characteristics. We will create a flow chart that will provide the number of potential participants that were screened, eligible, randomised and followed up at each time point.

The principal analyses: these will be based upon available data and conducted according to the intention to treat principle, using mixed models accounting for clustering of therapist effects (as random effects) and a limited number of pre-specified patient level factors including relevant baseline scores. Participants will be classified by their primary diagnosis (at baseline, just prior to randomisation and 3 months post-crime) as having either 'anxiety' (alone) or 'depression' (with or without anxiety). The randomisation will be stratified by this primary diagnosis and separate analyses, comparing TAU plus VIP vs TAU, will be conducted to see how the intervention performs according to diagnostic group. However, the primary efficacy analysis will be an overall analysis of all participants, using the outcome measure (BAI or BDI-II) pertinent to their baseline diagnosis in each case. To facilitate the combination of information across these scales, each will be standardised by its residual standard deviation after the full model has been fitted. The purpose of this overall analysis (on which the sample size was based) is to inform any decision to roll out the program, as it would then be offered to future participants irrespective of primary diagnosis but be expected to affect different symptoms according to diagnosis.

Supportive analyses: these will examine the extent to which the primary analysis is robust to the challenge presented by the observed loss to follow up. They will include an analysis using multiple imputation to adjust for the missing data. To accommodate any differential attrition across socio-economic groups that occurs, using the Lower Layer Super Output Area (LSOA) data, will be part of the predictor in the multiple

imputation model. There will also be a 'worst case' analysis where drop-outs from the intervention group would be assumed to have shown no change from baseline (or the average change seen in the control group, should this actually be a decline), whilst drop-outs from the control group would be assumed to have achieved the average benefit seen in the intervention group. Since the time interval between randomisation and the primary outcome is relatively small (3 months), the number of deaths should be small also and, since it is reasonable to assume these will occur at random with respect to treatment allocation, they will be simply excluded from all analyses as being 'missing at random'.

Exploratory analyses: exploratory analyses will be carried out to describe how a limited number of pre-specified characteristics of participants may modify treatment effects. These will include patient preferences, relative levels of deprivation (LSOA data) and non-compliance with treatment: the latter being addressed using compliers' average causal effects (CACE) analysis.

Secondary outcome variables: these will be analysed using the same general framework as for the principle analyses. However, the presentation of the results will be restricted to the confidence intervals that come out of the analysis, rather than the p-values.

Economic analysis: unit costs will be attached to resource use, using the best available estimates to obtain a cost per patient over the entire period of participation in the trial. Total costs will be linked to the main outcome variables for each group. We will explore data to see whether findings are consistent with any previously published material determining cost per quality-adjusted-life-years.

13. Ethical arrangements:

Section 4 provides a description of the consent procedure and information about benefit and harm. Informed consent is an entry criterion for the trial. We will be screening and recruiting newly identified participants with full capacity only, using methods similar to those developed in our pilot study and approved by Camden & Islington Community Research Ethics Committee reference 08/H0722/85. The trial team will comply fully with the requirements laid down by the National Research Ethics Service (www.nres.npsa.nhs.uk). All older victims will benefit given that in older victims morbidity is high and distress not routinely identified. Self-referral for help rarely occurs. All those screened as distressed may benefit from their GP being notified. All participants consenting to the trial will benefit from continued monitoring of symptoms, including suicidal intent.

Our pilot work suggests that the VIP was well received, potentially beneficial and did no harm. Although we predict that persistence of symptoms will be reduced by the VIP, this cannot be assumed. An RCT is ethical because it would not be appropriate long term to refer patients for an ineffective intervention nor would it be justified on costs. Participants will also benefit from risk assessments undertaken by Mind therapists and researchers who can then direct/refer patients to appropriate care pathways if necessary. Where risk is considered significant, the management is described clearly.

We do not foresee any difficulties with this trial however University College London holds insurance against claims from participants for injury caused by their participation in this clinical study. Participants may be able to claim compensation if they can prove that UCL has been negligent. However, as this clinical study is being carried through SNTs and Mind, they have a duty of care to the participant of the clinical study. University College London does not accept responsibility for any breach in the SNT's or MIND's duty of care, or any negligence in the part of the Metropolitan Police or Mind's employees. SNTs and Mind centres selected to participate in this clinical trial have their own negligence insurance cover for harm caused by their employees and a copy of the relevant insurance policy or summary can be provided on request.

14. Research Governance:

The nominated sponsor is University College London. There will be a Study Steering Committee (SSC) (to be appointed) consisting of an independent chair, at least two other independent members, the chief investigator and one other investigator plus user representatives. Observers from the NIHR-PHA programme will be invited to all SSC meetings. The trial will be run in accordance with GCP guidelines.

There will be a separate Data Monitoring and Ethics Committee (DMEC) reporting to the SSC which will consist of a clinician and a statistician, to ensure that no harm results from the intervention and that numbers are being achieved.

The SSC and DMEC will meet once before the start of a trial (month 3), then once during the screening phase stage (Month 9), then 4 monthly until the last follow-up (months 13, 17, 21, 25, 29, 33, 37).

A Trial Management Group will consist of the Chief Investigator (CI), co-applicants, representatives from the Metropolitan Police and Mind respectively, a trial manager and statisticians, and it will meet at least three times a year to discuss the progression and day to day management issues of the trial. The CI will be responsible for the overall leadership, management and outputs of the study and will maintain a log of the key milestones to be achieved against a timetable. The trial manager (TM) will be responsible for the day to day running and coordination of the study and will be accountable to Dr Serfaty (CI). The management role will include obtaining ethics and research governance approval, coordinating the collection of data, preparation of meetings and assisting with the writing and execution of the procedures and policies for the trial and disseminating the study's findings. The TM will also be responsible for ensuring recruitment is on target by collating monthly reports to the CI. The SNTs will report directly to their line managers. Administrators will report to the TM. The TM will be responsible for recruitment and assessment.

15. Project timetable and milestones:

The timetable and milestones in the GANNT chart are summarised below:

Date	Milestones
4 th Oct 2016 – 31 st March 2017 (Months 1-6) Setting up of project: (6 months)	Advertise and appoint clinical trial manager and 2 research assistants for London. Apply for ethics and research governance approval for all sites. Purchase equipment. Registration of the projects with ISRCTN, Clinicaltrials.gov. Develop procedures and policies for the conduct of the trial. Conduct training for SNTs to screen participants in step 1 and for researchers to rescreen and assess for step 2, undertake baseline and follow up assessments. Update literature. Appoint members to the trial steering committee and DMEC. Engage Mind centres and identify therapists for training. Set up web based randomisation.
1 st April 2017 – 30 th June 2017 (Months 7-9) Screening stage (3 months)	Step 1: SNTs to start Screening older victims of crime across all participating sites. Complete the training for therapists in the use of the VIP manual. Minor amendments if necessary to materials to be used in step 2 of the trial. Ask about whether acted on signposting.
1 st July 2017 – 30 th Sept 2019 (Months 10- 36) Ongoing trial (27 months)	Step 2: Re-screening, recruitment, intervention and follow up of patients. Assess for suitability, consent, undertake baseline measures. Randomise, deliver intervention, collect measures post intervention and at 9 months post crime follow up. Collect qualitative data about signposting.
1 st Oct 2019 – 31 st December 2019 (Months 37-39) Follow up post intervention (3 months)	Follow-up only and also analyse qualitative experience of signposting and whether people acted on this and if not why not.
1 st Jan 2020 – 30 th June 2020 (Months 40-45 end) Analysis of data, rate therapy, update literature search, dissemination and write up (6 months) End date: 30 th June 2020.	Data cleaning. Break blindness. Statistical and economic analysis. Rate CBT tapes using cognitive therapy scale. Discuss findings with research team. Update literature search. Write up of complete study findings. Offer results to surviving study participants. Present findings at National and International conferences. Use conference feedback to prepare final report. Prepare report for funders and information to be placed on NIHR-PHR and public Health England and Ministry of Justice web sites. Complete paper for publication in peer reviewed journal.

Months	1-3	4-6	7-9	10-12	13-15	16-18	19-21	22-24	25-27	28-30	31-33	34-36	37-39	40-42	43-45
Orientation															
Screen															
Recruitment															
Intervention															
Follow-up															
Analysis															
Write up															

16. Expertise:

Supervision arrangements are detailed in the clinical governance section. We will be working closely with PRIMENT, an independent Clinical Trials Unit,

Co-applicants Profs: Brewin, Kessel, Leavey, Drennan; Drs Serfaty (CI), Blanchard, were core members of the HAVoC Study; contributed to the VIP proposal.

Dr Serfaty (Psychiatrist/CBT therapist) will: train and supervise therapists; analyse, write up and disseminate findings. **Prof Kessel** (Public Health Specialist), Director of International Public Health and Responsible Officer, Public Health England. Previously a member of the HTA-PHA board, will help: develop and improve public mental health. **Commander Watson**, (Metropolitan Police Service), TP - Crime, Criminal Justice, Roads and Transport Policing, helped with: MPS involvement, and will help identify and coordinate SNTs; trial management. **Dr Blanchard** (Psychiatrist of old age) will: contribute to recruitment; analysis; write up. **Prof Laycock** (Criminologist), Jill Dando Institute of Crime Science: to advise on policy/ crime related issues. **Prof Brewin** (Traumatologist): ensure smooth running of trial and help with write up. **Dr Buszewicz** (General Practitioner)/trialist for independent CTU, and RDS, will assist with: trial management; write up from a GP perspective; ethical issues. **Prof Drennan** (Nurse) will help with: potential recruitment problems; contribute to social policy. **Ms Hunter** (Health Economist), contributed to: health-economics; will assist with analysis and write up. **Prof Leavy** (Sociologist), Head for Mental Health and Wellbeing in Northern Ireland, will help with: social aspects of crime; translation of research into studies of victims of crime in N.Ireland. **Mr Wood** (Statistician), Principal Research Associate in Statistics, contributed to: design, power calculation and will: provide the statistical input for the analysis; write up. **Mr Higgs**, (strategy and development manager, Mind), will help: recruit Mind therapists. **Ms Riveros** (Service Manager Age UK Camden), contributed to the PPI; will help identify additional users of services. **Mr Andrew** (User/Collaborator) assisted with the VIP proposal; will: contribute to steering groups; help with write up.

17. Partner Collaboration

We have liaised with a number of partner organisations who have been and will be involved in this application:

1. Metropolitan Police: we have a close working relationship with their operational unit and their SNTs will be doing the step 1 screening and will help with dissemination and policy development.
2. Mind: this Mental Health Charity, will provide an administrative input and the intervention, which they will fund.
3. Age UK Camden: will participate in our trial management group and dissemination of the findings to umbrella organisation, Age UK, for the benefit of older people.
5. Public Health England: Prof Kessel (co-applicant) is Director of International Public Health and is the responsible officer for Public Health England and the findings will be used to inform Public Health Policy.
6. SURF: Services Users Research Forum based in Camden and Islington Foundation Trust has helped develop the study and will participate in write up and dissemination.
7. Research & Development Central and North West London NHS Trust: a longstanding collaboration with Ms Lynis Lewis, Associate Director, who was actively involved in this application.
8. Jill Dando Institute of Security and Crime Science, UCL: the, has been involved in the HAVoC study and the VIP proposal. Prof Laycock (co-applicant) will form part of the TMG and also has links with the Ministry of Justice where the needs of victims can be represented.
9. Victim Support (VS). We have been involved with the VS Research Unit in the pilot Helping Aged Victims of Crime study and the findings will help inform how victims' needs are best addressed.

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