The VIP trial PROTOCOL

Long title of the trial	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.
Short title of trial	The VIP trial.
Version and date of protocol	Version 12
Sponsor	UCL
Funder (s)	NIHR Public Health Research (PHR) Programme
Trial registration number	16929670
Phase of trial	Data collection
Chief investigator:	Dr Marc Serfaty
Sponsor Representative:	Suzanne Emerton

SIGNATURES

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

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

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

Chief Investigator: Prof Marc Serfaty

Sign: 

Date: 16/12/2021

Sponsor Representative: UCL

Sign:

Date:

For the purposes of this document, Priment is representing the Sponsor.

This Protocol template is intended for use with UK sites only.

VERSION HISTORY

Version number	Version date	Reason for Change
1	31/05/2016	To add further details of study procedures.
9	22/01/2019	Study amendment
10	20/12/2019	Changes to step 1 screening procedure and management of high suicide risk
10.1	1/04/2020	Minor corrections to version number, phase of trial and formatting of text and contents page.
11	10/12/2020	Substantial amendment to allow data collection to resume in a way that is Covid-19 secure requiring changes to trial documents and procedure for obtaining consent at steps 1 and 3. Listing of London Boroughs of Croydon, Sutton and Bromley as boroughs to consider expansion into if feasible. Inclusion of pre-approved MSc students, as part of the VIP trial team, to conduct secondary analysis on anonymous data in line with VIP trial aims and under the supervision of the trial manager and CI.
12	16/12/2021	Listing the London Boroughs of Waltham Forest, Redbridge, Barking & Dagenham, Brent, and Harrow as possible boroughs to expand into if feasible.

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3 TRIAL PERSONNEL

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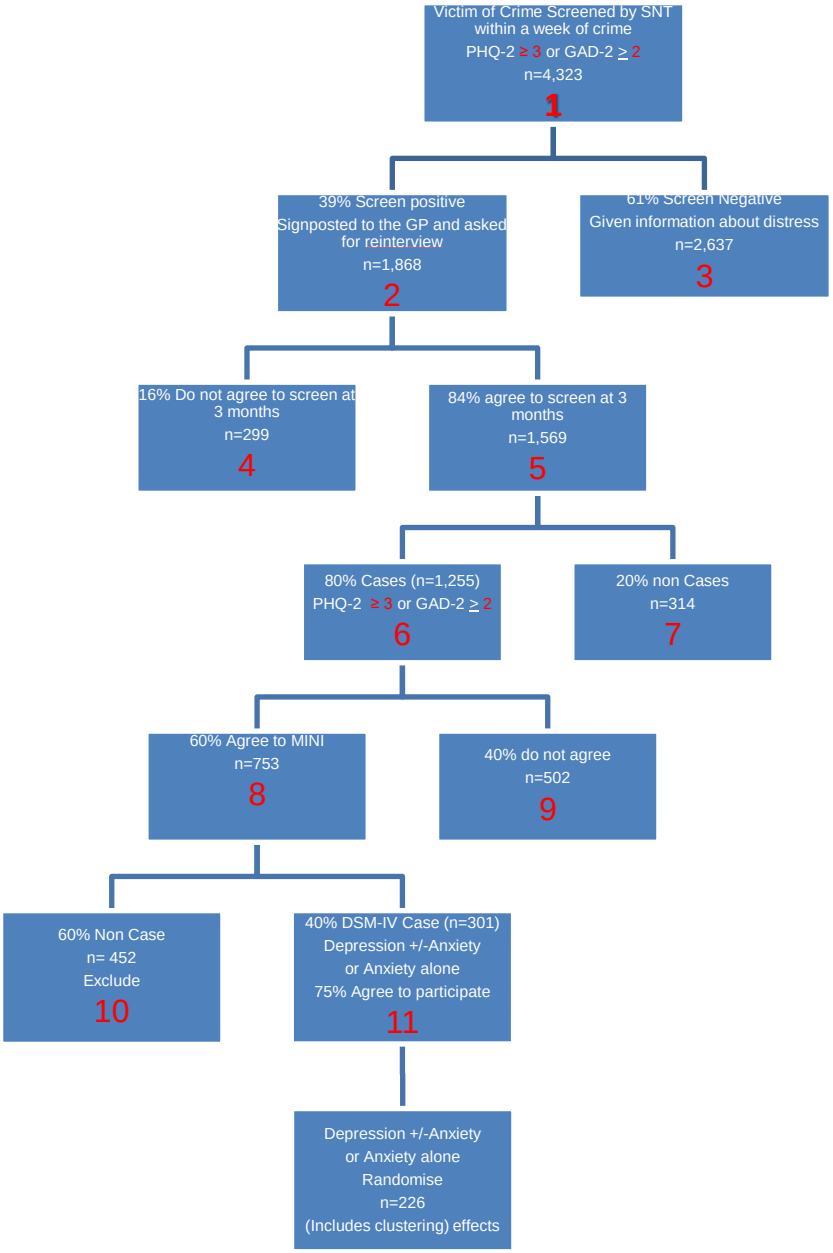
4 SUMMARY

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.
Short title:	The VIP trial.
Phase of trial:	Full trial.
Primary Objective:	To determine whether older victims, with screen positive (≥3) PHQ-2 depression and/or (≥2) GAD-2 anxiety scores 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 Beck Depression Inventory-II and BAI.
Secondary objectives:	**a.** Symptom severity: as above, but measured at 9 months post crime (follow-up). **b.** To determine whether older victims with depression and/or anxiety present 3 months after a common crime, benefit from a VIP in terms of improving quality of life. **c.** Economic: to explore the costs of the VIP in older victims of crime with depression and/or anxiety. **d.** Health inequalities: to explore the likely impact on health inequalities. **e.** To explore the impact of signposting. **f.** Service delivery: to demonstrate that Safer Neighbourhood Teams (SNTs) can identify and recruit participants and that Mind therapists can deliver the VIP to reduce chronicity of depression and/or anxiety in older victims of crime.
Type of trial:	Single-blind randomised controlled trial.
Population:	Older victims of common serious crime with screen positive PHQ-2 depression and/or GAD-2 anxiety scores present 3 months after the crime.
Trial design and methods:	Participants randomised to treatment as usual or up to 10 individual sessions of modified Cognitive Behavioural Therapy (CBT) plus treatment as usual. The primary outcome, summed depression and anxiety, will be measured using the BDI-II and BAI at baseline (3 months post-crime) post-intervention (6-months post-crime), and follow-up (9-months post-crime).
Trial duration per participant:	6 months from baseline to final follow-up (9-months from initial screening to final follow-up).
Estimated total trial duration:	83 months.
Planned trial centres:	Multi-centre, to include nine planned centres.

Total number of participants planned:	226.
Main inclusion criteria:	Screen positive PHQ-2 depression and/or GAD-2 anxiety
Main exclusion criteria:	MINI diagnosis of schizophrenia, bipolar disorder, alcohol dependency or self-reported drug dependency. Receipt of CBT in the last 6 months. Inability to participate in CBT due language difficulties Significant cognitive impairment, indicated by a 6-item Cognitive Impairment Test score of 10 or more.
Statistical methodology and analysis:	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, comparing participants randomised to receive treatment as usual to those randomised to receive CBT, on an intention to treat basis.

5 TRIAL FLOW CHART



6 INTRODUCTION

6.1 BACKGROUND

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.

6.2 RISKS/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.

Therapist safety considerations: While the default location for therapy will be in the local MIND facilities, therapists may, at the therapists discretion, offer to conduct the therapy in the participants home provided they are satisfied that it is safe and they feel comfortable doing so. Each local MIND centre has in place a lone worker policy with contingencies for conducting therapy in a service-users' homes, and any visits to participant's homes will be conducted in accordance with these lone worker policies.

Safety during the Covid-19 pandemic: Covid-19 poses an infection risk to trial participants, researchers, MPS SNT officers, Mind therapists and the general public (as public transport is needed for data collection visits and travel to therapy sessions); face-to-face contact is needed to obtain signed consent, collect data and for delivery of therapy. Data collection was placed on pause during the outbreak to allow for full assessment of the risks and necessary adaptations needed for the trial to resume data collection in a safe and scientifically robust way.

ASSESSMENT AND MANAGEMENT OF RISK

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.

It is not 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), appropriate action will be determined in consultation with the PI including writing to their GP, arranging 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.

A separate suicidality SOP will be created to detail what constitutes a high risk of suicide and the actions that study staff will take in such instances. The Priment clinical trials unit will work with the study team to create a risk assessment for the study.

Covid-19 re-start risk log: has been created and will continue to be updated in line with key developments in the course of the pandemic and changes in government guidelines. The risk log details the changes that need to be made so that the trial can operate safely, and will be kept under review whilst the risk of infection remains high. The planned changes include: offering therapy remotely over telephone or video calling software (e.g. Microsoft Teams, Zoom), obtaining informed consent at step 3 verbally over the telephone or video calling (securely stored as audio files and electronic consent forms on Data Safe Haven), and collecting baseline, outcome and follow-up data at step 3 over the telephone or video calling software. A range of video calling platforms will be offered (e.g. Microsoft Teams, Zoom) so participants have a choice, as they may be more familiar with one platform than another. Signed consent at step 1 will continue to be obtained face-to-face as police SNT officers are front line workers; they will adhere to guidelines on PPE, social distancing, and the MPS telephone administrators will check that older victims are comfortable receiving a home visit before arranging the visit with the SNT officer.

This trial is categorised as: Type A = no higher than the risk of standard medical care

7 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.

Primary objective:

To determine whether older victims, with screen positive scores on the PHQ-2 (≥3) depression (and/or (≥2) GAD-2 anxiety) or (≥2) GAD-2 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.

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 screen positive scores on PHQ-2 (≥3) depression and/or (≥2) GAD-2 anxiety or GAD-2 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 screen positive (≥3) PHQ-2depression and/or (≥2) GAD-2 anxiety or (≥2) GAD-2 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 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 25-30 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.

8 OUTCOMES

8.1 PRIMARY OUTCOMES

(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.

8.2 SECONDARY OUTCOMES

The EuroQol (EQ5-D; Rabin 2001) is a 5 item generic utility measure of quality of life. It 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 el, 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) a modified version of the CSRI, developed for the present study, will be used to collect data on service use.

Generalised Anxiety Disorder Assessment (GAD-7) and Patient Health Questionnaire (PHQ-9) PHQ-9. The PHQ-9 and the GAD-7 are valid measures of depression and anxiety, respectively (Kroenke et al, 2001; Pinto-Meza et al, 2005) which are widely used in primary care settings.

Measures of 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 participants

(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 1 to 10

(iv) Treatment preference: Participants' treatment preference, collected on a tickbox

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 at 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.

vi) measures of satisfaction with treatment by rating on a 5 point scale (*not at all* to *very much*) whether the VIP was useful.

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		✓	

SAMPLE SIZE AND RECRUITMENT

8.3 SAMPLE SIZE CALCULATION

Sample size: Previous RfPB feasibility work on recruitment, delivery of the intervention, assessment and follow-up has informed this trial. We plan to use SNTs in each of the 9 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 a standardised combination of BAI and BDI-II scores. 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 that for moderate levels of symptoms the scores range from 20-28 and 16-25 for anxiety and depressive symptoms respectively.

9 TRIAL DESIGN

9.1 OVERALL DESIGN

General design: 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,

Step 3: diagnostic assessment and referral for an RCT to prevent continuing symptoms 3 months after the crime.

Step 1: the police, via Safer Neighbourhood Teams (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 written 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).

As individuals may experience high levels of distress immediately following a crime, any individual who is screened positive for depression and anxiety by the police within less than a week of the crime occurring will be re-screened by the UCL study team approximately 2 weeks after the crime.

A number of individuals who screen negative for anxiety and depression at step 1 will also be contacted again at step 2 to screen for anxiety and depression. All participants who screen negative at step 1 will be asked to provide consent to be re-contacted at 3 months. This will provide information on the proportion of individuals who initially appear to have been psychologically resilient to the impact of a crime may later go on to develop psychological symptoms. Individuals who screen negative at step 1 will not go on to be offered entry into step 3 of the study.

The trial will start with SNTs screening all suitable older victims for distress through home visits. However, as police resources are constrained, once we have established that SNTs can screen both positive and negative older victims, procedures will be adapted to screen older victims over the phone by dedicated administrators so that SNT officers visit only those who are screen positive or deemed vulnerable. This will ensure that police resources are targeted at distressed older victims only.

Step 2: Before step 2 of the study, we will send a letter to participants to inform them that we will be calling them to enquire about how they are doing. Older victims will be re-screened for continued symptoms at 3 months by a UCL researcher and if significant, screened for trial exclusion criteria (receipt of CBT in the previous 6 months, bipolar disorder, schizophrenia, alcohol dependency, cognitive impairment and insufficient command of English). Those suitable for the trial will be given verbal and written information with an adequate explanation of the aims, methods, anticipated benefits and potential hazards of the VIP trial. If agreeable, home visit appointments will be arranged for completion of step 3 baseline, and an appointment letter and a participant information sheet sent in the post. There will be at least 48 hours between step 2 re-screening and step 3 home appointments to allow the participant ample time to consider their participation in the trial. Whilst the risk of Covid-19 is ongoing, step 3 baseline appointments will be arranged as telephone appointments rather than home visits.

Step 3: Randomised controlled trial (RCT): Informed consent by a UCL researcher will be obtained in writing from each participant prior to participation in the trial. The researcher will record when the participant information sheet (PIS) has been given to the potential participant. The researcher will explain the participants 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. 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 not feasible for the researchers to meet the participant in person due to Covid-19, verbal consent will be taken over the telephone, which will be recorded using an encrypted Dictaphone. An electronic version of the consent form and the audio file of the consent will be uploaded to Data Safe Haven for secure storage. 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.

Consenting older victims will complete a battery of baseline measures: the Beck Anxiety Inventory, Beck Depression Inventory, a detailed assessment using the MINI (Sheehan et al., 1998) in according with the Diagnostic and Statistical Manual (4th Edition; DSM-IV), EQ5-D, CSRI, and therapy expectation.

Consenters will be allocated to the interventions described in section 11.2 below. We will record potential sources of bias (see section 8.2) known to predict outcome. The trial will be conducted and reported in accordance to the CONSORT guidelines.

9.2 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 9 boroughs to be active initially and for each to screen 10 participants during the start up. Thus our target would be to screen 40 x 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. Possible boroughs for expansion include the London Boroughs of Croydon, Sutton, Bromley, Waltham Forest, Redbridge, Barking & Dagenham, Harrow or Brent as Mind also has local centres in these areas so therapy can be delivered.

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:

9.3 INCLUSION CRITERIA

- Victims of reported common serious crime.
- Age 65 years or more. Symptoms of depression (indicated by a score of 3 or more on the PHQ-2 (Kroenke, Spitzer, & Williams, 2003) and / or symptoms of anxiety (indicated by a score of 2 or more on the GAD-2 (Kroenke, Spitzer, Williams, Monahan, & Löwe, 2007)

9.4 EXCLUSION CRITERIA

- Having ever been diagnosed with schizophrenia or bipolar disorder, assessed with simple yes/no questions, or a MINI diagnosis of alcohol 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.

- Significant cognitive impairment, indicated by a 6-item Cognitive Impairment Test score of 10 or more, 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 are focussing on common crime, rather than serious assaults associated with complex trauma and legal issues requiring specialist services.

† 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.

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

10 STUDY PROCEDURES AND SCHEDULE OF ASSESSMENTS

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. If this changes and once we have established that SNTs can screen both positive and negative older victims, procedures can be adapted to screen older victims over the phone by designated administrator(s) so that police SNTs visits are only to those who are screened positive or deemed vulnerable. This will ensure that police resources are targeted at distressed older victims only

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 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:

Before step 2 of the study, we will send a letter to participants to inform them that we will be calling them to enquire about how they are doing. 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: Older victims will be screened for their suitability for the trial. A yes / no checklist will be completed to confirm that they are ≥65, victim of a common serious crime, have English proficiency sufficient for engaging in CBT, have not received CBT in the previous 6 months or been diagnosed with schizophrenia or bipolar disorder. They will then be screened for alcohol dependency using module I of the MINI (Sheehan et al 1998) and significant cognitive impairment, indicated by a 6-item Cognitive Impairment Test score of 10 or moreIf they are a case of depression, with or without anxiety, or anxiety alone, and meet trial eligibility criteria, 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. If the participant is recruited whilst the Covid-19 pandemic present a risk, they will be asked whether they would prefer therapy to be delivered face-to-face (if feasible) or remotely over telephone or video calling (e.g. Microsoft Teams). Participants will also be asked whether they are comfortable receiving therapy over telephone or through video calling in case government restrictions mean it is not feasible for Mind to deliver therapy face-to-face.

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 25-30 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, crime types, 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 include 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 thematic analysis (Braun & Clark, 2006) 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 11. 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. All participants in step 3 of the trial will be given a £10.00 "love to shop" voucher, to compensate them for the time they take to complete the study questionnaires, after completion of the baseline, and after each of the two follow-up points. Thus the total payable if the participant completes all 3 time points will be £30.00.

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. The limited data available on remote therapy in older adults shows low drop-out rate, therefore attrition should not be affected by delivering the intervention over telephone or video calling software (e.g. Microsoft Teams) as a result of Covid-19.

10.1 RANDOMISATION PROCEDURES

Participants will be classified by their screening outcome on the GAD-2(Kroenke et al., 2007) and PHQ-2 (Kroenke et al 2007) (at baseline, just prior to randomisation and 3 months post-crime) as having either 'anxiety' (alone) or 'depression' (with or without anxiety), and the randomisation will be stratified by this primary diagnosis.

UCL researchers will provide participant details to the VIP trial administrator, who will use a web-based randomisation system and then 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 trial coordinator will track participants, notifying the research team when assessments are required.

10.2 TREATMENT PROCEDURES

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. If the victim has a preference to be treated in their own home, for example due to physical disability or if they fear leaving the house after the crime, they can, at the discretion of the MIND therapist, receive the therapy in their home. In this instance the local Mind centres lone working policy will be adhered to at all times while providing home therapy. If it is not safe to deliver therapy face-to-face due to the infection risk posed by Covid-19, therapy will be delivered over telephone or using video calling software instead, but the number and content of sessions will remain the same.

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

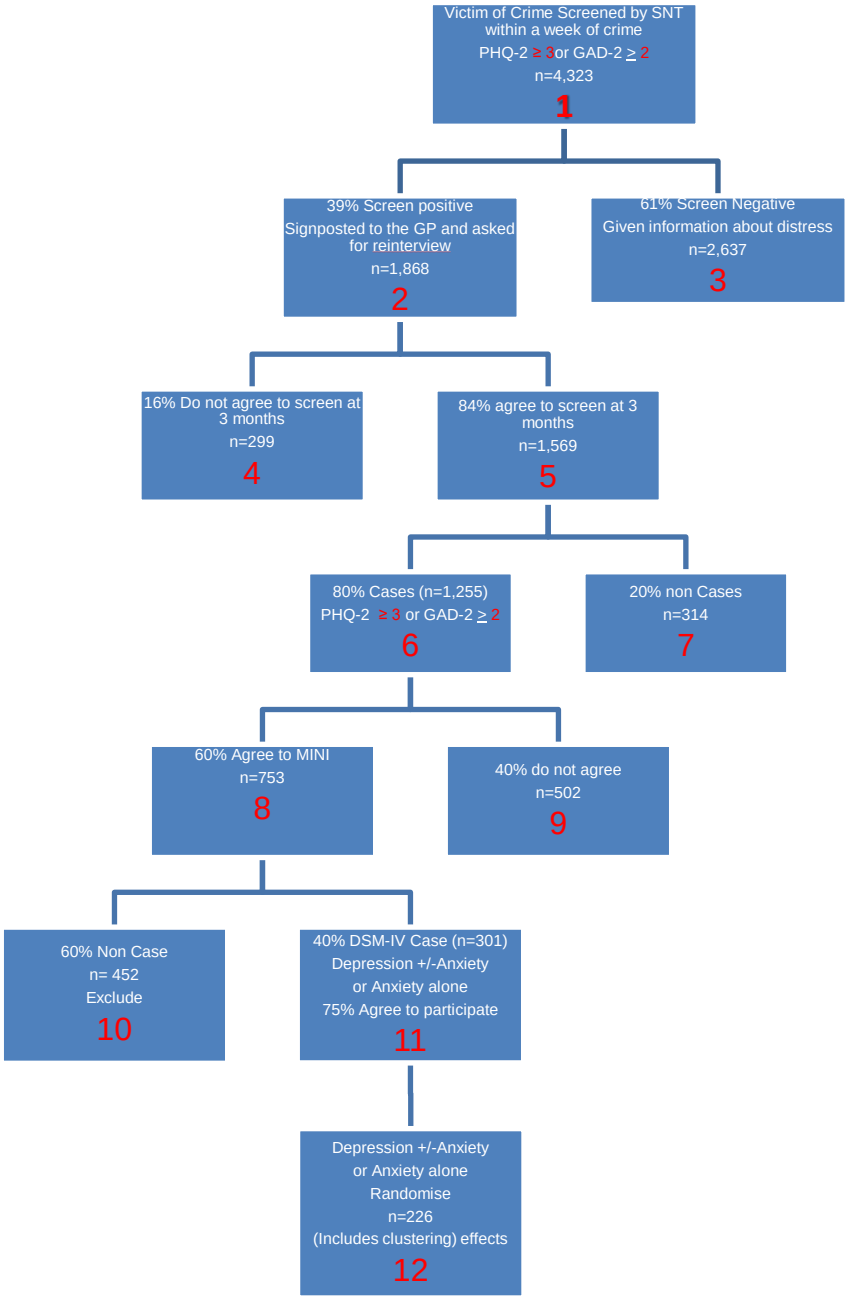
National Institute of Health and Clinical Excellence (NICE) as an effective treatment for anxiety and depression in people of all ages, but generally very few older people receive this (Anderson et al 2009). We will not exclude CBT from TAU for ethical reasons, we will however record any receipt of this 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 participant 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.

10.3 FLOWCHART OF STUDY ASSESSMENTS



	Document name	Version number
1	VIP-PIS-step 1	V7.1
1	Demographics sheet step 1 with flowchart with consent form	V2
2	GP Screen positive letter step 1	2.0
2	VIP Agreement to contact step 1	8.1
3	GP Screen negative letter step 1	3.0
4	No documents	
5	VIP-PIS-step 2	No longer used
5	VIP Consent step 2	No longer used
11	VIP trial Demographics step 2	7.0
5	PHQ-2	
5	GAD-2	
6	GP Screen positive letter step 2	3.0
7	No documents	
8	MINI (depression and anxiety sections)	
9	No documents	
10	No documents	
11	VIP-PIS-step 3	2.1
11	VIP Consent step 3	5.1
12	Step 3: Randomised Controlled Trial	

10.4 DEFINITION OF END OF TRIAL

The end of the trial will be the last follow-up point with the last participant of the study.

10.5 DISCONTINUATION/WITHDRAWAL OF PARTICIPANTS AND '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.

10.6 CONCOMITANT MEDICATION

Individuals will be excluded from participating in the trial if they have received CBT within the 6-month period preceding the step 2 screening (screening for entry into the RCT), as described in the trial exclusion criteria.

10.7 POST-TRIAL ARRANGEMENTS

We will not be providing treatment to participants after the end of the trial treatment period. Participants are free to seek CBT treatment themselves at any time post-trial through the normal means of obtaining this treatment. Should a mind therapist and participant agree that further sessions above those provided as part of the trial would be beneficial for the participant , then they will be free to carry on treating the participant as a Mind service-user , outside of the remit of the study, after the final follow-up is completed for that patient.

11 DATA MANAGEMENT AND QUALITY ASSURANCE

11.1 CONFIDENTIALITY

The CRFs will not bear the participant's name, but their initials, date of birth and trial identification number to allow for necessary checks during the data collection stage.

For the purposes of following-up participants and informing them of the results of the study, participants' name, address and contact details will be collected. This information on paper will be stored securely and locked away if unattended. In addition these directly identifiable data will be stored securely electronically and be kept separate from the clinical study data.

11.2 DATA COLLECTION TOOLS AND SOURCE DOCUMENT IDENTIFICATION

All participant outcomes will be recorded directly onto case report forms (CRFs).

It will be the responsibility of the investigator to ensure the accuracy of all data entered in the CRFs. The study delegation log will identify all personnel with responsibility for data handling and data entry, including those who have access to the trial database.

11.3 DATA HANDLING AND ANALYSIS

The trial database will be provided by Sealed Envelope with support from Priment CTU that will include facility for data entry via a secure website. CRF data will be entered by the VIP research assistant or the VIP administrator.

All data will be handled according to the Data Protection Act 1998 as well as UCL Information Security Policy.

Data analysis will be performed under the supervision of the trial statistician. Data analysis will be completed independently from data entry. A data analysis plan will be agreed before the database is locked.

11.4 DATA OWNERSHIP

At the end of the trial, the data belongs to UCL.

12 RECORD KEEPING AND ARCHIVING

The pCRFs, as part of the TMF, must be managed as essential trial documents with respect to storage. The Trial Manager or delegate will ensure that pCRFs and other essential documentation are kept securely with authorised access in acceptable environmental conditions. This applies to storage during the trial as well as after the trial closure.

The directly identifiable data necessary for following-up participants will be stored on UCL Data Safe Haven with access only to individuals who strictly need to see it for the purposes of managing the trial.

All essential documents will be archived for a minimum of 5 years after completion of trial.

Destruction of essential documents will require authorisation from the Sponsor.

At the end of the study the Priment Senior Data Manager will store a copy of the data which were captured electronically in the database in an access restricted folder.

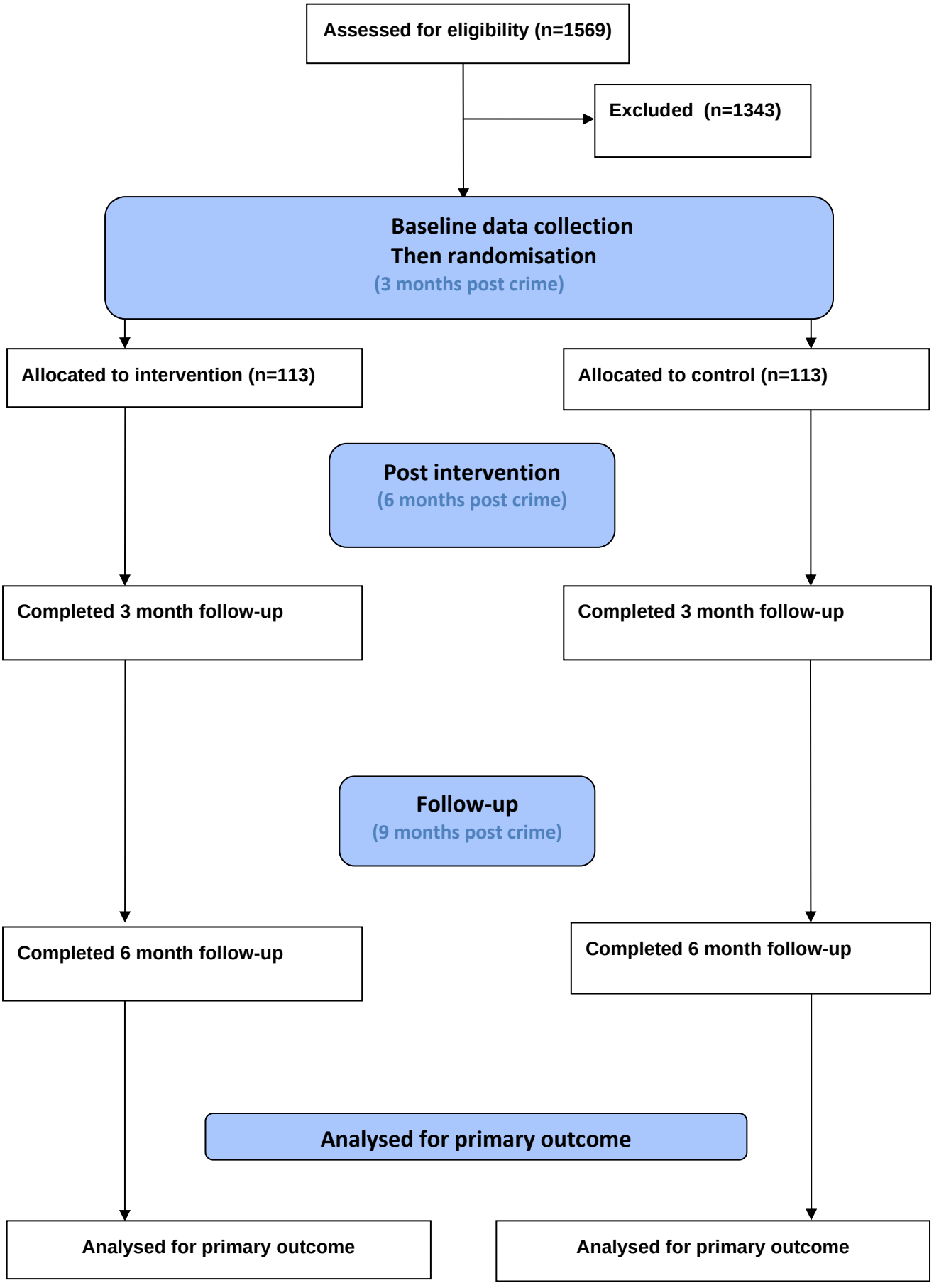
13 STATISTICAL CONSIDERATIONS

John Wood is the trial statistician who will be responsible for all statistical aspects of the trial from design through to analysis and dissemination.

13.1 STATISTICAL ANALYSES

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.

13.1.1 VIP CONSORT FLOW DIAGRAM (BDI-II AND BAI) WITH PREDICTED NUMBERS



13.1.2 PRINCIPLE 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 participant 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.

13.1.3 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'.

13.2 EXPLORATORY ANALYSIS

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), whether therapy was received remotely or face-to-face and non-compliance with treatment: the latter being addressed using compliers' average causal effects (CACE) analysis.

13.3 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.

13.4 ECONOMIC ANALYSIS

14 QUALITATIVE METHODS

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 25-304 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 thematic analysis (Braun & Clarke, 2006)), 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.

15 ECONOMIC EVALUATION

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.

16 NAME OF COMMITTEES INVOLVED IN TRIAL

A Trial Management Group (TMG), consisting of trial personnel, including Priment personnel assigned to the trial and researchers directly employed on the trial, as well as the chief-investigator and co-investigators, will meet every one to two months.

A Data Monitoring Committee (DMC) will meet at least once every year over the duration of the trial.

Trial Steering Committee (TSC) will meet at least once every year over the duration of the trial.

17 RECORDING AND REPORTING OF ADVERSE EVENTS AND REACTIONS

17.1 DEFINITIONS

Term	Definition
Adverse Event (AE)	Any untoward medical occurrence in a patient or clinical trial participant administered a medicinal product and which does not necessarily have a causal relationship with this treatment.
Adverse Reaction (AR)	Any untoward and unintended response in a participant to an investigational medicinal product which **is related** to any dose administered to that participant. *This includes medication errors, uses outside of protocol (including misuse and abuse of product)*
Serious adverse event (SAE), serious adverse reaction (SAR) or unexpected serious adverse reaction	Any adverse event, adverse reaction or unexpected adverse reaction, respectively, that: • results in death, • is life-threatening, • requires hospitalisation or prolongation of existing hospitalisation, • results in persistent or significant disability or incapacity, or consists of a congenital anomaly or birth defect
Important Medical Event	These events may jeopardize the participant or may require an intervention to prevent one of the above characteristics/consequences. Such events should also be considered 'serious'.
Unexpected adverse reaction	An adverse reaction the nature and severity of which is not consistent with the information about the medicinal product in question set out: (a) in the case of a product with a marketing authorization, in the summary of product characteristics for that product. (b) in the case of any other investigational medicinal product, in the investigator's brochure relating to the trial in question.
SUSAR	Suspected Unexpected Serious Adverse Reaction

17.2 RECORDING ADVERSE EVENTS

As the population participating in this research are over the age of 65, instances of physical illness, hospitalisation, and death are likely to occur over the duration of the study. As these events are expected

in this population and are not likely to be related to the intervention, they will not be recorded as adverse events.

Given that those participating in the study will be suffering from poor mental health, we will record any instances of suicide or attempted suicide, any increase in suicidality, or instance of self-harm as adverse events. These adverse events will be recorded in the CRFs following consent.

All adverse events will be recorded and accompanied with a simple, brief description of the event, including dates as appropriate.

All adverse events will be recorded until the last study follow-up.

17.3 ASSESMENTS OF ADVERSE EVENTS

Each adverse event will be assessed for the following criteria A-D;

A. SEVERITY

Category	Definition
Mild	The adverse event does not interfere with the volunteer's daily routine, and does not require intervention; it causes slight discomfort
Moderate	The adverse event interferes with some aspects of the volunteer's routine, or requires intervention, but is not damaging to health; it causes moderate discomfort
Severe	The adverse event results in alteration, discomfort or disability which is clearly damaging to health

B. CASUALTY

The assessment of relationship of adverse events to the administration of the intervention is a clinical decision based on all available information at the time of the completion of the case report form. The following categories will be used to define the causality of the adverse event:

Category	Definition
Definitely:	There is clear evidence to suggest a causal relationship, and other possible contributing factors can be ruled out.
Probably:	There is evidence to suggest a causal relationship, and the influence of other factors is unlikely
Possibly	There is some evidence to suggest a causal relationship (e.g. the event occurred within a reasonable time after administration of the trial medication). However, the influence of other factors may have contributed to the event (e.g. the patient's clinical condition, other concomitant events).
Unlikely	There is little evidence to suggest there is a causal relationship (e.g. the event did not occur within a reasonable time after administration of the trial medication). There is another reasonable explanation for the event (e.g. the patient's clinical condition, other concomitant treatments).
Not related	There is no evidence of any causal relationship.
Not Assessable	Unable to assess on information available.

C. EXPECTEDNESS

Category	Definition
Expected	An adverse event which is consistent with the information about the intervention.
Unexpected	An adverse event which is not consistent with the information about the intervention.

D. SERIOUSNESS

17.4 PROCEDURES FOR RECORDING AND REPORTING SERIOUS ADVERSE EVENTS

Serious adverse events will be recorded in the CRF, and in the Priment SAE log. The SAE log will be reported to Priment.

All serious adverse events that are related to the intervention and unexpected will need to be reported to Priment unless stated in the protocol that some expected SAEs will not be reported.

For participants on the control arm of a trial, SAEs do not have to be reported but will be recorded in the CRF.

The Chief or Principal Investigator will complete the sponsor's serious adverse event form and the form will be emailed to Priment primentsafetyreport@ucl.ac.uk within 24 hours of becoming aware of the event. The Chief or Principal Investigator will respond to any SAE queries raised as soon as possible.

Reporting to Priment will be completed using the Priment SAE form.

17.5 NOTIFICATION OF DEATHS

Only deaths that are assessed to be caused by suicide or self-harm will be reported to Priment.

17.6 NOTIFICATION OF SERIOUS BREACHES TO GCP AND/OR THE PROTOCOL

A "serious breach" is a breach which is likely to affect to a significant degree –

(a) The safety or physical or mental integrity of the participants of the trial; or

(b) The scientific value of the trial.

Priment will be notified of any case where the above definition applies during the trial conduct phase.

18 MONITORING AND INSPECTION

A monitoring plan will be established for the trial based on the risk assessment. The trial will be monitored with the agreed plan.

The investigator(s)/ institution(s) will permit trial-related monitoring, audits, and regulatory inspection(s), providing direct access to source data/documents.

19 FINANCE

This trial is funded by the National Institute of Health Research Public Health Research (PHR) Programme.

20 INSURANCE

University College London holds insurance against claims from participants for injury caused by their participation in the clinical trial. Participants may be able to claim compensation if they can prove that UCL has been negligent.

Participants may also be able to claim compensation for injury caused by participation in this clinical trial without the need to prove negligence on the part of University College London or another party. Participants who sustain injury and wish to make a claim for compensation should do so in writing in the first instance to the Chief Investigator, who will pass the claim to the Sponsor's Insurers, via the Sponsor's office.

21 STATEMENT OF COMPLIANCE

The trial will be conducted in compliance with the approved protocol, the UK Regulations, EU GCP and the applicable regulatory requirement(s).

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