STUDY PROTOCOL

Debt Counselling for Depression in Primary Care: An Adaptive Randomised Controlled Trial

(DeCoDer Study)

Version 3
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Chief Investigator: Professor Mark Gabbay
Professor of General Practice and HoD Health Services Research
Block B, Waterhouse Buildings
1-5 Brownlow St
Liverpool L69 3GL
Tel: 0151 794 5610

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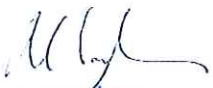
TABLE OF CONTENTS

1 SIGNATURE PAGE

Role	Name	Signature	Date
Chief Investigator	Professor Mark Gabbay		14/05/2015
Statistician	Professor Rod Taylor		14/05/2015
Sponsor's representative	Mr Alex Astor		15/05/15

2 KEY CONTACT DETAILS

Chief Investigator
Professor Mark Gabbay
Professor of General Practice and HoD Health Services Research
University of Liverpool
Block B, Waterhouse Buildings
1-5 Brownlow St
Liverpool
L69 3GL
0151 794 5610
mbg@liverpool.ac.uk

Sponsor Representative
Mr Alex Astor
Research Support Office
2nd Floor Block D Waterhouse Building
3 Brownlow Street
Liverpool
L69 3GL
Tel: 0151 794 8739
sponsor@liv.ac.uk

Statistician
Professor Rod Taylor
Chair of Health Services Research & Academic Lead, Exeter Clinical Trials Support Network
University of Exeter Medical School
Veysey Building
Salmon Pool Lane
Exeter
EX2 4SG
01392 726053
r.taylor@exeter.ac.uk

Trial Manager
Dr Adele Ring
University of Liverpool
Division of Public Health & Policy
Whelan Building
Quadrangle
Brownlow Hill
Liverpool
L69 3GB
0151 794 5739
adeler@liverpool.ac.uk

3 LIST OF ABBREVIATIONS

BAI	Beck Anxiety Inventory
BDI	Beck Depression Inventory
CAB	Citizens Advice Bureau
CI	Chief Investigator
CSRI	Client Service Receipt Inventory
EQ-5D-5L	EuroQol-5L
GP	General Practitioner
GSQ	General Satisfaction Questionnaire
LED-S	Short Life Events and Difficulties Schedule
LCRN	Local Clinical Research Network
MANSA	Manchester Short Assessment of Quality of Life questionnaire
OAS	Other as Shamer Scale
PCRN	Primary Care Research Network
PI	Principal Investigator
PPI	Patient and Public Involvement
RA	Research Assistant
RSQ	Response Style Questionnaire
SWEMWBS	Short form of the Warwick Edinburgh Mental Wellbeing Scale
TAU	Treatment as usual

4 STUDY SUMMARY

Title	**De**bt **Co**unselling for **De**pression in **P**rimary Care: An Adaptive Randomised Controlled Trial.
Study location	Primary care settings in England and Wales (lead site Liverpool)
Study aim	To determine the clinical and cost effectiveness of the addition of a Primary Care debt counselling advice service to usual care, for patients with depression and debt.
Study design	Adaptive parallel two group multi-centre randomised controlled trial with nested mixed methods process and economic evaluation. An internal pilot phase will be used to check intervention fidelity and need for cluster randomisation.
Planned number of sites	3 (Liverpool/Cheshire, Plymouth, Bridgend).
Study population	
Main inclusion criteria	Age ≥18; Scoring ≥14 on the Beck Depression Inventory; Self-identifying as having worries about debt.
Main exclusion criteria	Actively suicidal or psychotic and/or severely depressed and unresponsive to treatment; experiencing severe problems with addiction to alcohol or illicit drugs; unable or unwilling to give written informed consent to participate in study; currently participating in another research study including follow-up data collection phase; has received CAB debt advice in the past 12 months; do not want support about debt or money worries provided through GP practice.
Planned sample size	195 patients/arm across both feasibility and main trials if single randomisation or 235 patients/arm across both feasibility and main trials if cluster randomisation.
Study intervention	
Control arm	Debt advice leaflets provided by GP and treatment as usual (TAU).
Trial intervention	Debt advice leaflets provided by GP, debt counselling advice from a Citizens Advice Bureau Advisor and TAU.
Summary of Outcome Measures	
Primary	Beck Depression Inventory II
Secondary	Beck Anxiety Inventory (BAI), short form of the Warwick Edinburgh Mental Wellbeing Scale (SWEMWBS), EQ-5D-5L, Manchester Short Assessment of Quality of Life questionnaire (MANSA), adapted version of the Client Service Receipt Inventory (CSRI), Stanford presenteeism scale, general satisfaction questionnaire (GSQ), short Life Events and Difficulties Schedule (LED-S), The Adult Hope Scale, , Response Style Questionnaire - 24 (RSQ-24), Other as Shamer Scale (OAS), alcohol use Audit questionnaire, substance misuse screening tool (DAST).
Study schedule	
Duration of study	45 months
Study timelines	Set-up 3 months. Internal pilot 11 months. Full trial 25 months. Data cleaning, analysis, reporting 6 months. Total duration 45 months.

End of Trial	Completion of last follow-up visit of last participant

5 BACKGROUND AND RATIONALE

Depression is estimated to affect 5-10% of adults at any one time, and is a common presentation in Primary Care. However, research suggests that only around 2.5% of patients are formally recorded by GPs as having active depression or depressive symptoms [i,ii]. Alongside anxiety and stress it is considered the commonest cause for prolonged work absenteeism [iii], as well as presenteeism (working below normal capacity when unwell). Mental ill health is estimated to cost the UK economy £40B per year overall [iv,v]. Around 11% of the population are estimated to be struggling with personal debt, with evidence of increasing episodes of suicide associated with rising debt which is likely to increase with the worsening economic situation [vi,vii].

Most episodes of depression are managed in Primary Care, following the NICE recommended four-stepped approach[i]. This includes a range of low intensity interventions including short-term talking therapies, social prescribing to support lifestyle changes (e.g. for exercise), and antidepressants for more persistent symptoms. A recent HTA trial [viii] found a marginal benefit of SSRIs (antidepressants) for new cases of mild-moderate depression managed in Primary Care over treatment as usual (TAU), but many questions about the most cost effective ways to manage depression remain[i].

Recognising the increasing burden of indebtedness and the link between debt and mental illness in the Foresight Report[ix], the UK government provides web-based advice and guides on debt-management[†] highlighting a range of providers[††].Topping this list is the Citizen's Advice Bureau (CAB), a charity-based service which is widely available across the UK in over 3,500 locations, providing support to over 2M people per year. Their principal on-line recommended site is provided by government, funded by statutory levy from the financial services industry, backed by a national advertising campaign: the Money Advice Service website at www.moneyadviceservice.org.uk/. However, those with depression, particularly if from socio-economically deprived groups, may be particularly likely to find on-line services insufficient or inaccessible (due to travel costs and/or low mood), so a locally accessible, nationally provided, advice service may be an important alternative. Debt is commoner among poorer populations and around 1:4 among those experiencing mental health problems, who make up 50% of those with debt overall[x,xi]. The strategic & economic cases for providing debt advice for people experiencing mental health problems have been made in recent influential reports; and the intervention being proposed here falls within the suggested service provision costs and model[xii,xiii]. This study explores an intervention designed to provide enhanced access to timely support for people with depression and anxiety about indebtedness, and will provide robust information on its cost effectiveness and acceptability.

6 AIMS AND OBJECTIVES

6.1 Main trial

Aim:
To determine the clinical and cost effectiveness of the addition of a Primary Care debt counselling advice service to usual care, for patients with depression and debt.

[†] http://www.direct.gov.uk/en/MoneyTaxAndBenefits/ManagingDebt/PlanYourWayOutOfDebt/DG_10013291
[††] http://www.direct.gov.uk/en/MoneyTaxAndBenefits/ManagingDebt/PlanYourWayOutOfDebt/DG_187500

Specific objectives:
(i) To compare depression between intervention and control groups.
(ii) To compare anxiety, mental wellbeing, debt/financial status, satisfaction, health-related quality of life and societal costs between intervention and control groups.

(iii) To explore outcomes referred to in (i) and (ii) in terms of the following potential predictors - substance misuse problems, self-esteem, life events & difficulties, hope, optimism, resilience, and attribution style.

(iv) To determine core outcome domains and measures using the COMET Initiative approach to define a Standard Outcome Measure for mental health trials in deprived and hard to reach groups in primary care, adapted to this specific study.

(v) To manualise debt assessment and counselling intervention & joint comprehensive assessment (GP/patient/CAB) for use within the intervention.

(vi) To recruit new and chronic/recurrent cases from a variety of practices and populations to enhance generalisability.

(vii) To undertake a mixed method process evaluation to assess fidelity of intervention (using Normalisation Process Theory) and explore reasons for outcome differences and relationship between depression, anxiety, debt, stigma, shame & psychosocioeconomic factors triangulating economic, psychological factors analysis and qualitative interview data.

(viii) To undertake Knowledge Exchange events to inform adoption into care pathways (implementation).

(ix) To work closely with Service Users in Research/Patient and Public Involvement groups across the study sites to inform trial methodology, intervention development, aspects of analysis and the implementation of preparatory work.

(x) To recruit a virtual group of commissioners, providers and Health and Wellbeing board members to check willingness to commission intervention and advise on domains and measures.

(xi)To work with CAB leads, GPs and PPI advisors on developing the intervention and comprehensive assessment, qualitative topic guides and aspects of data analysis.

6.2 Internal pilot trial

The aim of the internal pilot phase is to test the procedures, recruitment processes and operational strategies that are planned for use in the main trial, identifying and resolving any problems and thereby assessing the feasibility of continuing with the main trial. Specific objectives are:-

1) to confirm methods for recruitment of practices
2) to confirm the ability to recruit patients via the proposed approaches
3) to confirm the acceptability of the study interventions
4) to confirm acceptability of data collection (outcome measures)
5) to assess contamination and confirm the randomisation method for the main trial
6) to assess the level of participant attrition
7) to check robustness of data collection systems

8) to identify and resolve potential difficulties in implementing the shared assessment
9) to assess intervention fidelity

7 TRIAL DESIGN

The study is an adaptive parallel two group pragmatic randomised controlled trial with 1:1 allocation to intervention or control with a nested mixed methods process and economic evaluation (Figure 1). Patients who have current depression and are worried about debt will be recruited through general practices in three areas of UK. After screening and consent, participants will be randomised to receive either General Practice treatment as usual (TAU) supplemented by debt management advice leaflets (control group) or General Practice treatment as usual supplemented with debt management advice leaflets and primary care based CAB debt advice including a shared GP/Advisor comprehensive assessment (intervention group). Primary (Beck Depression Inventory) and secondary (health-related quality of life, cost effectiveness, satisfaction, and explanatory factors) outcomes will be assessed in all participants at baseline, 4 and 12 months. In addition, qualitative in-depth interviews will be undertaken, to explore causal models of how debt counselling works.

The study includes an internal pilot phase in which intervention fidelity will be assessed and implementation problems identified and resolved without change to the intervention, so that data collected in this phase can be used in the final analysis. Both individual and cluster randomisation methods will be used in the pilot phase to assign participants to intervention or control arms with the aim of using individual level randomisation in the main trial if the pilot phase shows no strong evidence of contamination.

8 Trial ENDPOINTS

8.1 Main trial

8.1.1 Primary Outcome

The primary outcome measure is the Beck Depression Inventory II. This is a self-report measure commonly used in studies of depression.

8.1.2 Secondary Outcomes

Secondary outcomes are as follows, to be finalised during the internal pilot trial.

1. **Psychological wellbeing,** as measured by:
    - Beck Anxiety Inventory (BAI)
    - Short form of Warwick Edinburgh Mental Wellbeing Scale (SWEMWBS)

2. **Health-related Quality of Life,** as measured by:
    - EQ-5D-5L
    - Manchester Short Assessment of Quality of Life questionnaire (MANSA)

3. **Health and social care utilisation and employment factors,** as measured by:
    - adapted version of the Client Service Receipt Inventory (CSRI)
    - Fit Note self-reports

- Stanford presenteeism scale
- customised instrument to record personal debt issues

4. **Service satisfaction,** as measured by:

   - General Satisfaction Questionnaire (GSQ)

5. **Life Events**, as measured by:

   - short Life Events and Difficulties Schedule (LED-S)

6. **Substance Misuse,** as measured by:

   - Audit questionnaire (alcohol use)
   - Substance misuse screening tool (DAST)

7. **Explanatory measures**

Three psychological constructs will be assessed, each of which have been strongly associated with depression in previous work and which might reasonably be hypothesised to mediate the debt-depression relationship:

(i) **Hopelessness:** Adult Hope Scale (Snyder's State Hope Scale)
(ii) **Shame:** The Other as Shamer Scale (OAS)
(iii) **Rumination:** Response Style Questionnaire - 24 (RSQ-24)

The feasibility and acceptability of these outcome measures will be monitored in the internal pilot trial along with data utility in order to determine whether to maintain or reduce the full set of outcome, modifier and predictor variables in the main trial.

8.2 Pilot phase

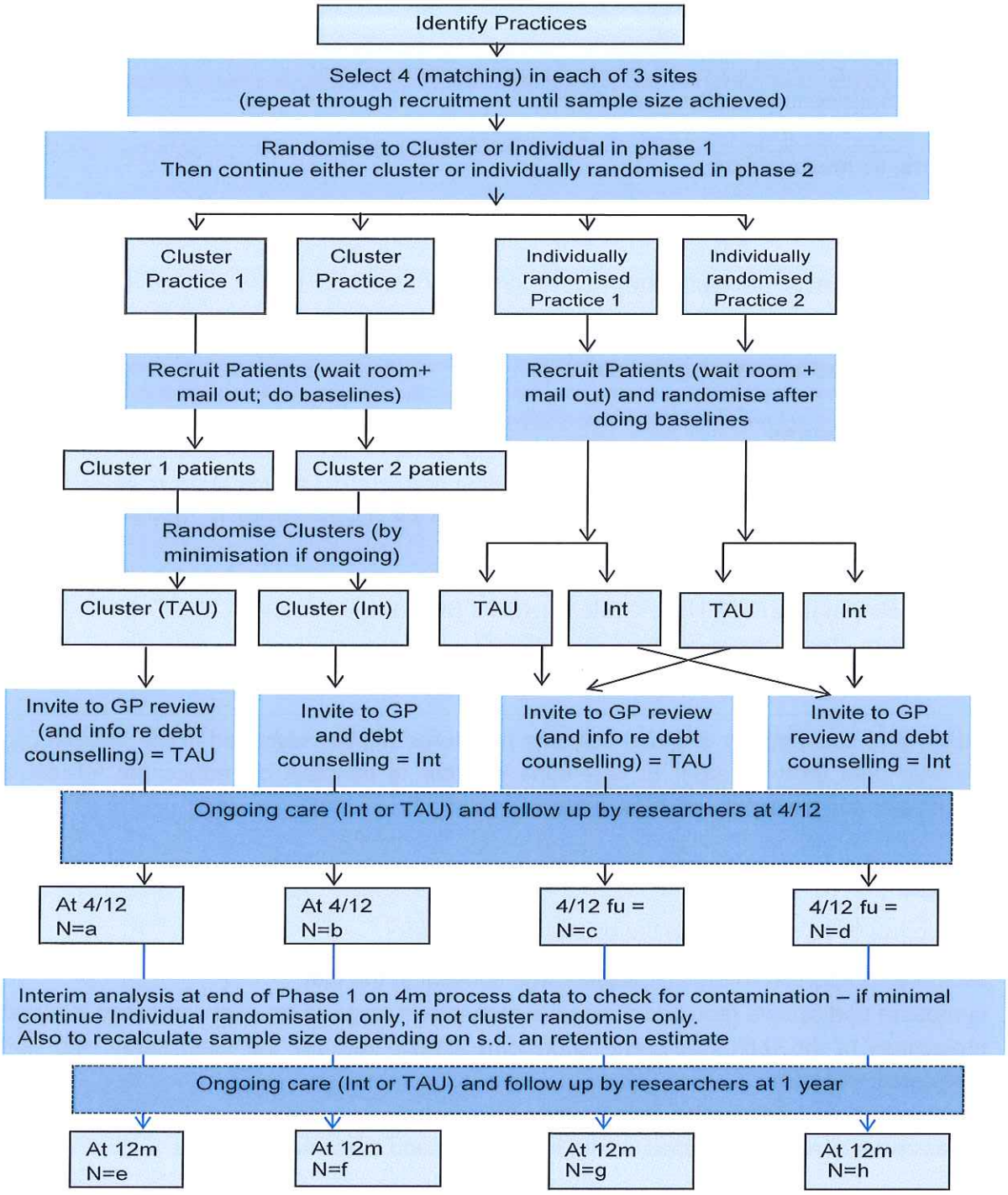
Specific outcomes to be measured in the pilot phase include:-

- estimated proportion of eligible patients who consent to the trial
- number of participants recruited during the recruitment stage of the pilot compared to target
- projections of the recruitment and short-term attrition rate for the main study with 95% confidence intervals
- assessment of contamination (see below)
- assessment of patient satisfaction with intervention and outcome measures

Assessment of contamination

The level of contamination in the control arm will be assessed by comparing individually randomised controls with cluster randomised control patients during the internal pilot trial. Uptake of any form of debt counselling by participants in control groups will be monitored at their follow-up visit, as this is the key measurable variable. An absolute and relative measure has been agreed to suggest important problems with contamination - 10 or more from among the 30 individually randomised control participants seeking debt advice, providing this is at least twice as common among individually versus cluster randomised controls. This evidence will be triangulated with evidence from qualitative interviews with participants that indicates their choice to do so was influenced by GP recommendation or more debt-focused assessments or consultations.

Figure.1: Overview of study



9 IDENTIFICATION AND RECRUITMENT OF GP PRACTICES

9.1 Identification of GP practices

Internal Pilot Phase: Twelve practices (average approximately 10,000 patients per site- using a 'hub and spoke' research practices approach if required in some sites) will be involved in this phase. Two of these practices will be those in which GP members of the research team are based. The remaining ten practices will be randomly selected from the full list of practices at each site. The practices will be matched according to high vs low deprivation and size (large/medium/small) before cluster randomisation. The aim will be to recruit a wide spectrum of communities.

Main study: Approximately 45 practices will be involved in the main trial, including the twelve from the pilot trial.

9.2 Recruitment of GP practices

The PI or other member of the research team at each site will send an invitation letter to the research GP lead and practice manager at each practice identified as being potentially suitable for the study. Invitation letters will include an information sheet about the study. Invitation letters will be followed up by a telephone call from a member of the research team to ascertain interest and if appropriate arrange a meeting at the practice to discuss the study in more detail. Local research teams will work closely with the Clinical Research Network (CRN) to recruit suitable practices.

10 PARTICIPANT SELECTION AND RECRUITMENT

Patients with a history of depression (with or without anxiety) within the last 12 months and who are worried about personal debt will be recruited through participating GP practices at the study sites. Depression at screening will be classified according to the Beck Depression Inventory (BDI) score where 14-19 = mild depression, 20-28 = moderate depression, >28 = severe depression.

10.1 Inclusion Criteria

- Age ≥18
- Scoring ≥14 on the BDI
- Self-identifying as having worries about debt

10.2 Exclusion Criteria

- Actively suicidal or psychotic and/or severely depressed and unresponsive to treatment
- Unlikely to comply with the intervention or follow-up e.g. experiencing severe problems with addiction to alcohol or illicit drugs
- Unable or unwilling to give written informed consent to participate in study
- Currently participating in another research study including follow-up data collection phase
- Has received CAB debt advice in the past 12 months

10.3 Identification and recruitment of participants

Participants will be identified and recruited via GP practices by two methods:

General Practice (GP) database searches

Supported by members of the local PI's research team and clinical research network staff, GP practices will identify adults potentially having current depression or depression related treatment in the last 12 months from practice database searches (use of antidepressants, diagnostic codes, QOF depression score codes). GPs may screen generated patient lists should they wish to do so to exclude any patients they deem it would be inappropriate to approach. Practices will then send out standard letters to potentially eligible patients, informing them of the study and inviting them to contact the research team. Practices will be offered Docmail service as an alternative to practice staff conducting mail out activities. Practices will be able to choose whether to use Docmail service or not.

Accompanying the trial invitation letter will be a flyer which provides a 'quick read', a participant information sheet, an expression of interest form and a Freepost envelope. The invitation letter will

ask patients to complete and return the expression of interest form in the Freepost envelope provided if they are interested in taking part in the study. On receipt of the completed form the local research assistant (RA) or other research team member will contact the individual by telephone, explain the study in detail, answer any questions the individual may have and assess initial eligibility (that they have worries about debt that they are personally responsible for, that they are not currently taking part in other research, that they have not had any advice from CAB in the past 12 months). If the person is still interested in taking part in the study and eligible at this point, the researcher will arrange a date and time to meet with the patient to complete the final stage of eligibility – Beck Depression Inventory. Should there be no response to the initial telephone call, the researcher will make reasonable further attempts to contact the individual, after which it will be assumed that the person is no longer interested in taking part.

Waiting room recruitment

Publicity posters will be displayed in the waiting rooms of participating GP practices and flyers outlining the study will be placed around the waiting room. Posters and flyers will be REC-approved and updated from time to time, as required. Flyers will include the contact details (telephone number/e-mail address) of the RA at the relevant site. Expression of interest forms and Freepost envelopes will also be freely available at the practice so that patients can choose to return an expression of interest form to the local research team (as described above), or telephone the research team for more information.

Clinical Research Network (CRN) researchers and the RA may also highlight the study to patients in the waiting room by handing out flyers and asking people to approach them or a member of the practice reception staff if they would like to discuss the study in more detail. Members of the GP practice staff may also highlight the study to patients by handing out flyers (with attached expression of interest forms) to patients when they are attending the practice. Where the researcher is available in the practice, patients registering their interest in the study will be taken into a side room to discuss the study in more detail and be handed the participant information sheet to read. The researcher will explain that patients will be screened for eligibility at their baseline data collection and consent visit. Patients interested in taking part in the study after discussion and reading of the participant information leaflet will be asked to complete an expression of interest form and the researcher will arrange a date and time to meet with the patient to complete the baseline assessment. In the event that a CRN researcher is present at the GP practice rather than the study RA the CRN researcher will explain that the completed expression of interest form will be passed to the study RA who will contact the patient to arrange a baseline assessment visit.

Some potential participants may opt to check eligibility there and then in the GP practice, so will complete the consent process at that point and complete their baseline BDI. Where people complete the BDI in their GP practice, they will be advised that the score will be carried over to the baseline assessment visit and will be the data used for the study, unless that visit takes place more than two weeks later, in which case, the participant would be asked to complete the BDI again at the baseline visit to determine eligibility and for use as baseline data for the study. Patients who are not eligible to take part (i.e. scoring <14) will be advised as to why they are not eligible to take part, thanked for their time and willingness to participate and given the same study-specific debt advice leaflet and the Royal College of Psychiatrists (RCPsych) 'Debt and mental health' advice leaflet as those given to people participating in the study. Ineligible patients will have no further involvement in the study.

Some patients may choose to take the expression of interest form away with them and return it completed to the research team in a Freepost envelope at a later date rather than completing

paperwork or booking an appointment at that time. On receipt of a completed form the local research assistant will contact the individual by telephone to book a baseline appointment.

10.4 Baseline assessment visit

The baseline visit will usually be held in the patient's home but otherwise will take place in a location convenient for the patient and researcher. At the start of this visit, patients will be asked to confirm that they continue to have worries about debt. The researcher will then obtain written consent to participate in the study (see below) - unless the participant has already given consent and had their eligibility to take part confirmed within the previous two weeks at their GP practice. Following consent, patients will complete the BDI to check eligibility to take part in the study and as baseline assessment data. Patients who are not eligible to take part (i.e. scoring <14) will be advised as to why they are not eligible to take part, thanked for their time and willingness to participate and given the same study-specific debt advice leaflet and RCPsych leaflet as those given to people participating in the study. Ineligible patients will have no further involvement in the study.

Participants who indicate that they are actively suicidal at the baseline visit will be encouraged to contact the study GP promptly, before any further participation in the study. The researcher will explain that the study GP or the on-call GP will be informed of the researcher's concerns about the participant's welfare and current risk – with or without the participant's permission. The visit will be brought to a close and the researcher will explain to the participant that he/she may continue with the study, if desired, once the current risk has been discussed with a GP. If so, the RA will explain that he/she will contact the GP in approximately two weeks to check if it would be appropriate to re-contact the participant. The purpose of the RA re-contacting the GP is to ensure that further participation in the study has been assessed as appropriate by a clinical expert.

10.4.1 Informed consent

Individuals who agree to take part in the study will provide written consent at the baseline assessment visit. The researcher will first confirm understanding of what will be involved in taking part in the study and go through the consent form with the patient – including an explanation of why the researcher wishes to audio record the LEDs component of the assessment visit, confidentiality, the right to withdraw from the study and consent to be contacted by a second researcher for subsequent qualitative interviews. Any questions will be answered before written consent to participate is taken. Two copies of the consent form will be completed and signed by both the participant and the researcher taking consent (one for the participant and one for the research file). A photocopy of one of the original signed copies of the consent form will be made by the researcher and scanned by a member of the practice staff in to the medical records of the participant at the GP practice.

10.4.2 Baseline data collection and assignment of study number

Baseline data (see Section 16) will be collected by a mixture of participant self-report and researcher-led questioning. The researcher will register the participant on the study database. The database will allocate the participant a unique trial number and randomise them to intervention or control (see 11.3), if they are a patient from an individual randomisation practice. The unique trial number will be used on all of the participant's data collection forms. It is anticipated that baseline data collection will take approximately two hours and will be completed in one visit. Should the participant become tired and wish to complete baseline questionnaires on a second occasion, this visit should be completed within a week of the first assessment visit. All participants who consent to do so will have the LEDs component of the data collection audio-recorded. Audio recordings of

the LEDs component will be stored on universities (Liverpool, Plymouth, Swansea) managed network server, not on a computer's own hard drive.

10.5 Notification of new participant to GP practice

The study database will generate an e-mail to the local site manager and to a designated member of the GP practice staff notifying him/her of the participant's consent, unique study number and allocation. The member of staff will forward the e-mail to the appropriate study GP who will be able to login directly via a link in the e-mail to the web-based password protected study database to view participant details. A copy of the participant's consent form will be sent to the practice (usually by post) by a member of the research team, following the baseline assessment visit and randomisation (see section 11.1/11.2).

11 RANDOMISATION

In the internal pilot trial, relevant GP practice demographic information will be sent to CTU/study statistician by CRN in England, this activity will be supported by ABMU Health Board in Wales. Four practices (matched on their size and deprivation index score) in each of the three trial localities will be randomised to intervention or control arms and cluster (practice) or individual (patient) level allocation such that six practices are randomised to cluster allocation and six practices to individual allocation. To achieve total population research practice sites may be combined using a hub and spoke approach where available. The randomisation sequences and matching will be computer generated undertaken by an independent statistician working with the CTU. The CTU programming team will run checks before and during the trial to verify the integrity of the randomisation system.

Should the internal pilot show contamination to be a problem, for the main trial, the remaining practices will be randomised to intervention or control stratified by size and the deprivation (higher vs lower) of the populations they serve. If contamination is not found to be a problem, participants would be individually randomised to intervention or control.
Additional practices for the main trial will be identified and recruited once a decision has been made at the end of the internal pilot whether randomisation will be individual or cluster.

11.1 Individual level randomisation procedure

Following informed consent, a member of the research team (usually the RA) will access the password-protected randomisation website and enter the required participant details, including GP practice and participating GP's e-mail address, in order to obtain the participant's allocation. This allocation will not appear on the randomisation screen, thereby maintaining assessor blinding, but the randomisation procedure will trigger an automatic email to the identified member of the practice staff informing him/her of the participant's allocation. This email will identify the participant by his/her initials and unique trial number which the member of staff and GP can link to the participant's personal details when they access the web-based password protected study database. The member of the practice staff will retrieve participant's personal details and call them to arrange an appointment with a named GP at the practice. For trial management purposes, automatic emails (blinded, i.e. not including allocation) will also be sent to relevant team members e.g. Chief Investigator, trial manager, local PI as appropriate.

11.2 Cluster level randomisation procedure

During the internal pilot trial (and main trial if cluster randomisation continues), participants recruited at cluster randomised practices will be registered on the main trial database as soon as possible following written consent. A member of the research team (usually the RA) will access the

password-protected registration website and enter the required participant details, including GP practice and identified staff member e-mail address, in order to register the participant on the trial. This process will trigger an automatic email to the relevant member of the practice staff confirming the participant's consent and registration. The member of staff will forward the e-mail to the appropriate study GP. Both the member of staff and the study GP will access the web-based database to obtain the participant's personal details. For trial management purposes, automatic confirmatory emails (not including allocation) will also be sent to relevant team members e.g. Chief Investigator, trial manager, local PI as appropriate.

11.3 Blinding

Researchers conducting assessment interviews will not be informed of participant allocation and participants will be asked not to reveal to these assessors what type of debt advice they have received. At each data collection visit researchers will record which arm they believe participants are in, and record inadvertent unblinding.

To reduce contamination, wherever possible GPs will see either 'control' or 'intervention arm' patients only.

12 TRIAL INTERVENTIONS

Trial interventions are (i) GP treatment as usual (TAU) supplemented by debt management advice leaflets (control) or (ii) GP treatment as usual supplemented by debt management advice leaflets and primary care based CAB debt advice, including a shared GP/CAB Advisor comprehensive assessment (intervention). Following the initial GP appointment after randomisation, to enhance consistency, participants should continue to see this nominated GP or their named deputy where possible.

The trial intervention brings together two existing services:

1) Debt counselling provided by third sector providers e.g. the Citizens Advice Bureau
2) Primary care mental health services provided by general practices, supplemented by Improving Access to Psychological Therapies (IAPT) Services in England, and a variety of counselling and psychological therapies services in Wales.

This combined assessment will combine social, psychological, environmental, economic and medical perspectives in a formulation which will incorporate personal goals and a bio-psycho-social management plan. The intervention as a whole will incorporate four organisational mechanisms to optimise utility of the comprehensive assessment and the debt counselling (Figure 2).

12.1 Treatment as usual

Individuals randomised to TAU will receive GP care, a study-specific debt advice leaflet and RCPsych debt advice leaflet. TAU will beginning with an initial consultation with a GP linked to the study. This initial GP assessment appointment should take place within a week of the participant being randomised. As with participants randomised to intervention arm, control arm participants will be contacted by a member of the practice staff to arrange an appointment with a named GP. The initial GP appointment will combine an assessment of both anxiety and depression, an assessment of need regarding medication and psychological therapy, and agreement regarding further treatment. This may include a referral to the local IAPT service and may normally include up to twelve further GP contacts. GPs may refer participants to IAPT services and other interventions as

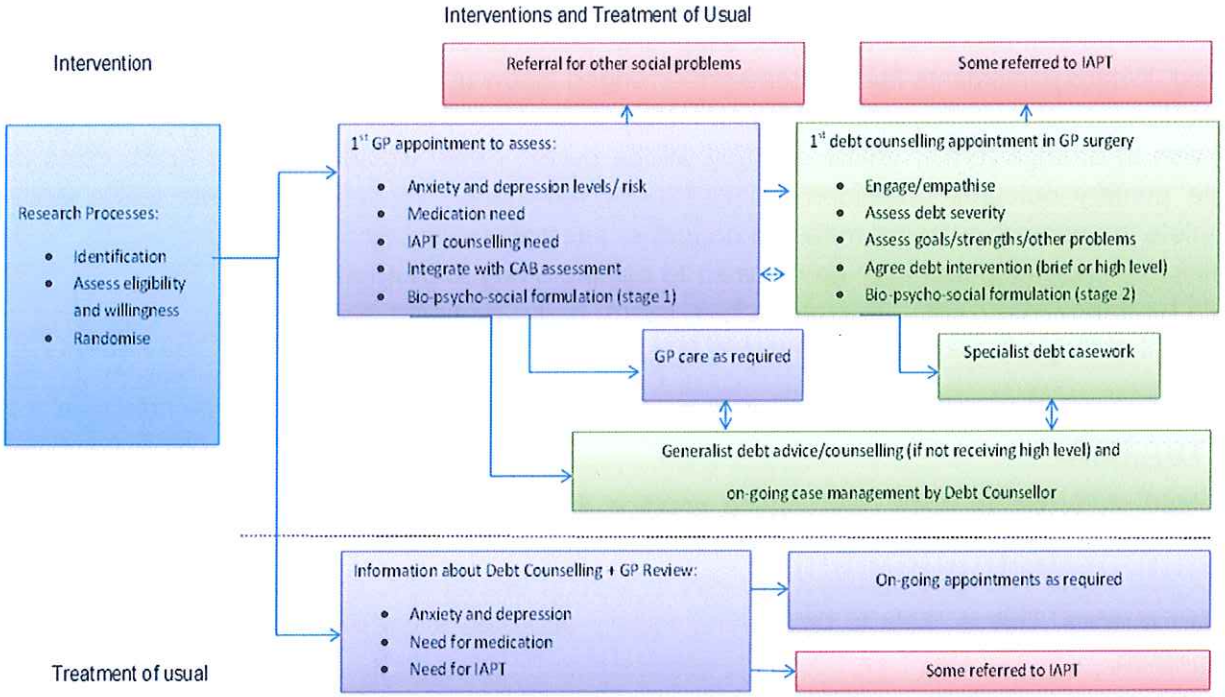
they please and may arrange to review participants at ongoing appointments as required. The GP will provide each participant with a study–specific debt advice leaflet at the initial consultation.

12.2 Intervention arm

Participants in the intervention arm will undergo a shared comprehensive assessment, starting with an initial GP review which mirrors that of the control group. At that visit, the GP will advise the participant of the intention to refer the participant to a CAB advisor and the GP will confirm that the participant is happy for this to be done. The GP will complete an electronic referral form that will include a statement that confirms the participant's agreement to be contacted by a CAB advisor and their consent to sharing of specified information between the CAB and GP, for the purposes of the shared comprehensive assessment. Participant's written, signed agreement to sharing of contact details and specific information for the purpose of the shared comprehensive assessment between GP and CAB will be retained by the GP practice. All participants will receive the study-specific debt advice leaflet and the RCPsych debt advice leaflet. Participants who do not wish to be contacted by a CAB advisor will be followed up as planned (see section 13), if they are still willing to do so. The GP will inform the study team via the web-based database that the participant has declined CAB intervention.

Following the initial GP consultation and referral to CAB debt advice service, a CAB advisor will contact the participant to arrange an initial assessment appointment. Preferably this appointment will take place at the patient's own general practice to facilitate liaison between the two services. Wherever possible the first CAB assessment should take place within two weeks of GP referral. The primary aim of this initial CAB appointment will be to assess severity of debt, other social problems, individual's strengths and their key social and emotional goals. At the end of the assessment there will be an agreement as to whether the individual requires a higher level debt counselling intervention, or the basic debt counselling provision. The CAB intervention will be implemented utilising manuals, training and organisational agreements developed previously. Telephone liaison between the GP and CAB services may be required, along with occasional attendance at primary care meetings by a CAB advisor if appropriate. A shared comprehensive assessment sheet will be developed in the start-up phase of the study with GP, CAB and service user input. The assessment sheet will be a working document shared between the GP and CAB advisor - with participant consent. Participants will be able to have a printed copy of the completed assessment sheet should they wish to do so. CAB advisors will access the web-based password protected database to record study specific data.

Figure 2: Summary of trial interventions



12.3 Ongoing management of participants

Treatment as usual

GPs may arrange to review participants allocated to TAU at ongoing appointments as required.

Intervention arm

The case manager for participants in the intervention arm will usually be the CAB advisor (in a small minority of cases this may be the GP or nurse). Participant contact will be maintained through telephone, e-mail, text, face-to-face review or a combination of these methods. Contacts will be recorded by CAB advisors on the password protected study database.

On-going pathways of care will include progress reviews by the GP and the CAB advisor. Optional pathways will include a) referral on to more intensive CAB debt counselling services, b) to other social inclusion services based on assessment of problems within comprehensive assessment and c) referral on to IAPT services for psychological therapy.

13 PARTICIPANT FOLLOW-UP

Following the baseline visit, all participants will undertake two further assessment visits with a researcher - one four months post baseline visit and one 12 months post baseline visit. The researcher will arrange the dates for the four and 12 month follow up visits at the end of the baseline assessment and in addition will send a letter confirming the agreed dates to the participant. Participants will receive reminders of visit dates/times for follow up visits from the local research team no earlier than one week before the planned visit, to reduce risk of losses to follow up. Reminders will be sent out by text, telephone, e-mail or post (as preferred by participant). Researchers will arrange to meet participants in the participants' own homes or at alternative

venues (GP practice, local community premises or University sites) as appropriate and convenient in each case. Participants will receive reasonable travel expenses and a £10 shopping voucher for each completed data collection visit to defray their expenses and time. In the event that a face to face follow-up visit cannot be arranged, telephone, postal or on-line data collection options will be offered. Where participants fail to attend pre-arranged follow up meetings reasonable attempts will be made to contact participants to confirm if they wish to re-arrange the visit. Should participants not wish to arrange further follow up, they will be asked if they would be willing to complete the single primary outcome questionnaire (BDI-II) by telephone. Should participants prefer not to complete the primary outcome measure no further attempts to contact the participant will be made. Participants indicating that they do not wish to complete any further follow up will be asked if they would be happy to provide a reason (to help inform future research development), but will also be advised that they are under no obligation to do so.

14 TRAINING

The lead study GP in each participating practice and his/her nominated deputy will be trained before starting recruitment in the trial design, assessment protocol and NICE guided 'treatment as usual' pathways. The local manager will visit to support recruitment, check fidelity to protocol and answer queries. This is likely to be monthly initially and then every 6-8 weeks once the study is established.

Researchers conducting qualitative interviews (see section 16.2) will receive training from experienced CAB staff who work in the field of debt and mental health and from service user advisors. Specific training and supervision will be provided by senior academics to ensure researchers develop the relevant skills to conduct interviews effectively: both from an ethical and scientific standpoint. Participants may be particularly concerned about issues such as confidentiality and how their data are reported and handled and assurances will be given at the interview, alongside the information sheet and the consent process. All aspects of the interviews and topic guides will reflect these sensitivities.

15 SAFETY

Participants will be advised at the start of the baseline interview that if their answers indicate that they are currently at risk of serious harm to their health, or that their life may be at risk, the researcher will advise them to see their GP as a matter of urgency, and will inform the study GP that the participant has been given this advice.

Researchers will contact the study GP or the on-call GP if they have specific concerns about the participant's welfare and current risk, in particular, if participants indicate they are suicidal during data collection visits – either verbally or as indicated on the BDI-II. Participants who indicate that they are actively suicidal will be encouraged to contact the study GP promptly, and the researcher will explain that the study GP or the on-call GP will be informed of the researcher's concerns about their welfare and current risk – with or without participant's permission. The visit will be brought to a close at this point and it will be explained to the participant that should they wish to continue participation in the study they will be able to do so once they have discussed current risk with the participating GP or on-call GP. In this case, the RA will explain that they will contact the GP in approximately two weeks to check if it would be appropriate to re-contact the participant. The purpose of the RA re-contacting the GP is to ensure that further participation in the study has been assessed as appropriate by a clinical expert.

If a participant circles either statement 2 or 3 on item nine of the BDI II the participant will also be considered to be at significant risk. In such circumstances the researcher will inform the relevant participating GP or the on-call GP at the participant's GP practice and the assessment visit will be terminated as detailed above.

Researchers will receive training about assessment of risk from their local principal investigator (all senior clinicians) and will also be given a direct contact number for a senior mental health expert who can be contacted to discuss individual cases as and when necessary. The Principal Investigators will also liaise with the participating GPs as required. CAB advisors will follow CAB protocol and guidance regarding client risk and breaching confidentiality.

Researchers conducting assessment visits/qualitative interviews will follow a lone working protocol.

15.1 Adverse event reporting

There is no requirement to report non-serious adverse events in this study.

For the purposes of this study, any event that falls into one of the following categories, or is a significant medical event in the opinion of the principal investigator, should be reported to PenCTU as a serious adverse event (SAE) as soon as possible after the event comes to light, regardless of whether the event is considered to be related to any of the trial interventions:

- Death
- Immediately life threatening illness
- Hospitalisation or prolongation of hospitalisation
- Results in persistent or significant disability or incapacity

GPs and researchers will be required to report any such event on a study-specific SAE form to PenCTU by fax within 48 hours of becoming aware of the event where possible. All SAEs will be reported onwards by PenCTU to the local PI, the CI and trial manager. The CI will report all SAEs to the study sponsor, the trial management group and the Trial Steering Committee. Any SAE considered by either the PI or the CI to be related to the administration of the trial procedures and unexpected will be notified to the REC. Expected SAEs would include hospitalisation for self-harm/attempted suicide and depression.

16 DATA COLLECTION

16.1 Data collection measures and timepoints

Participants will undertake three assessment visits with a researcher - at baseline, four and 12 months following the baseline visit. Follow up visits will take place at these timepoints regardless of the timing of the initial CAB assessment appointment. In addition to the assessment visits a purposive sample of participants will be invited to take part in two qualitative interviews (see section 16.2).

The data collection schedule for the internal pilot trial is shown in Table 1. The data collection schedule may be reduced for the main trial dependent on feasibility/acceptability of measures – determined during internal pilot trial.

Table 1: Data collection schedule

	Baseline	4 month	1 year
Demographic (Age, sex, deprivation score etc.)	✓		
BDI II	✓	✓	✓
Alcohol AUDIT & Substance Misuse Screen (DAST)	✓	✓	✓
BAI	✓	✓	✓
Short WEMWEBS	✓	✓	✓
CSRI (adapted for trial)	✓	✓	✓
EQ5D	✓	✓	✓
MANSA	✓	✓	✓
Stanford Presenteeism Scale	✓	✓	✓
CAB/Control debt assessment & outcomes Q	✓	✓	✓
GSQ		✓	
Hope Trait Scale	✓	✓	
LED-S	✓	✓	
OAS, RSQ	✓	✓	
Qualitative Interviews			
Participant Purposive Sample	✓	✓	
Professional (GP/CAB staff) purposive sample			(6-12 months)

16.2 Qualitative data collection

Internal Pilot Trial

Approximately 30-45 participants (10-15 at each site) purposively sampled for age, sex, geography, priority or non-priority debt and severity of depression will each undergo two interviews with a qualitative researcher. Participants who indicated on the baseline consent form that they would be happy to be contacted about taking part in qualitative interviews will be identified by research teams at each site and cross referenced with above variables on PenCTU database to identify a purposive sample of individuals for qualitative interviews.

The first interview will take place approximately 2-4 weeks after the baseline assessment visit and the second interview approximately four months later. The researchers conducting the qualitative interviews at each site will be different from the researchers undertaking assessment visits at each site in order to preserve blinding of assessors. . It is anticipated that these interviews will take place face to face and in a setting convenient for the participant, but if this cannot be organised, telephone interviews will be conducted, subject to participant consent. Interviews will be audio-recorded with participant consent and anonymised during transcription. A separate written consent form will be completed prior to the start of each qualitative interview. Transcripts will be identified by participant trial number and each will also be given a pseudonym.

The qualitative interview topic guides will be developed in conjunction with Service User advisors and will be adapted following initial analysis. The baseline narrative interview will explore participant's biographies of depression, anxiety and debt, the impact on participant's life (families, friends, work and other activities) and perceptions of practical aspects of debt (dealing with bailiffs, creditors, debt collectors and associated emotions e.g. fear). The follow-up semi-structured

interview four months later will enquire about developments since entering the trial, exploring the role of psychological, social and economic factors involved in recovery (or not) from debt and depression, including changes in employment, relationships with families, friends, and the connections with debt. The follow up interview will also check for evidence of contamination amongst controls (increased focus on debt in GP consultations, recommendation to attend or referrals for debt advice) and their experience of care and interventions (to check GPs concordance with trial protocols).

Anonymised electronic copies of transcripts will be stored on approved University computers at each site, which are password protected and virus checked. Data will only be stored on the University's managed network server and not on the computer's own hard drive. Any paper copies of participant transcripts will be stored separately to identifiable information (e.g. consent forms) and will be held in locked filing cabinets. Original audio files will be destroyed after four months – once transcripts have been checked for meaning or missing words. The qualitative researchers will keep field notes which will be stored and used according to standard confidentiality protocols.

Main trial

A further 30-45 interviews will be conducted in the main trial, with participants purposively sampled as above and concentrating on new sites (e.g. rural) in particular.

16.3 GP and CAB staff interviews

A process evaluation will be undertaken using semi-structured interviews with GPs and CAB staff participating in the study (10-15 of each). These findings will be triangulated with relevant CSRI data on appointments, process records from CAB visits and completed comprehensive assessments – which will be developed in consultation with GPs and CAB in the initial set up phase. GP and CAB staff interviews will be done once the participating practices have been involved in the trial for at least six months and will commence during the pilot trial. The purposive sampling frame will depend on whether the full trial is modified to a cluster design, but will seek to cover a range of sites and invite GP and CAB staff for interview after they've been participating for 6 – 12 months.

17 SUBJECT COMPLETION/WITHDRAWAL

The expected duration of participant involvement in the study is one year, with participants normally completing the study after the 12 month follow-up assessment. The trial itself will end on the date that the last participant undergoes his/her last study assessment. Participants who withdraw from the intervention and/or follow-up will not be replaced within the study. Data collected prior to withdrawal will be included in the study analysis unless a participant specifically requests that their data are removed from the database.

17.1 Withdrawal from intervention/discontinuation of follow-up

A participant may withdraw from the trial at any time, without being required to give a reason and without his/her care being affected.

The trial analysis is based on intention to treat, so all participants will be encouraged to continue with follow-up as per protocol even if, post-randomisation, they fail to attend any appointments with the GP or CAB advisor or the trial intervention is only partially completed. Participants who attend the assessment appointment with the GP but then refuse CAB contact or fail to have any contact with a CAB advisor following referral to CAB by GP, will be considered to have partially completed the intervention. Participants who refuse CAB referral and also indicate that they do not wish to complete follow-up visits with the researcher, will be withdrawn from the study at this point. Control

participants will be treated as this even if they attend CAB or debt advice through other means, and whether or not they attend the GP appointment for assessment and leaflets on debt.

Participants will also be withdrawn from the trial if they indicate during assessment/qualitative/CAB appointments that on-going participation would be likely to result in serious risk of harm to the participant themselves or to members of the study team or CAB service.

Withdrawal from trial follow-up, and the reason, if known, should be clearly documented in the participant's research/clinical records and the appropriate documentation should be completed and returned to the CTU as soon as possible as official notification of the withdrawal. Participants should be asked to explain their reason for withdrawing, but are under no obligation to do so.

17.2 Premature termination of the study

In the event that the Trial Steering Committee or Sponsor recommends early termination of the study for any reason, the Chief Investigator will notify the REC and will be responsible for informing participants of the premature termination of the study.

18 DATA MANAGEMENT

PenCTU will oversee the data management processes for quantitative data collection measures. The qualitative lead at each site will be responsible for management of qualitative data. All transcript data will be stored on the University of Liverpool's managed network server.

18.1 Subject numbering

Each participant will be allocated a unique trial number generated by computer following consent and will be identified in all study-related documentation by their trial number. A record of names, addresses and telephone numbers linked to participants' trial numbers will be stored securely for administrative purposes on the study database.

18.2 Data collection

Data will be recorded on study specific data collection forms (CRFs) at the study visits by the researcher. Participants will complete participant related outcome measures. Data will be collected on paper. All persons authorised to collect and record study data at each site will be listed on the study site delegation logs, signed by the relevant PI. A 20% random selection of anonymised CAB records of intervention participants will be checked against the debt advice protocol to check fidelity.

18.3 Data entry

Completed CRFs will be checked and signed at the research site before being sent to the CTU. Original CRF pages and questionnaires will be posted to the CTU at agreed time points for double-data entry on to a password protected database. Forms will be tracked using a web based trial management system. Double-entered data will be compared for discrepancies using a stored procedure. Discrepant data will be verified using the original paper data sheets.

18.4 Data confidentiality and security

The research teams will ensure that participants' anonymity is maintained on all documents. Data will be collected and stored in accordance with the Data Protection Act, 1998. Electronic records will be stored in a SQL Server database, stored on a restricted access, secure server maintained by Plymouth University. The website will be encrypted using Secure Sockets Layer (SSL). Direct access to the trial data will be restricted to members of the research team and the CTU, with

access granted to others on request. Access to the database will be overseen by the CTU data manager and trial manager.

18.5 Archiving

Following completion of trial data analysis, the Sponsor will be responsible for archiving the study data and essential documentation in a secure location for a period of 10 years after the end of the trial. No trial-related records should be destroyed unless or until the Sponsor gives authorisation to do so. Medical case notes containing source data or other trial-related information should be identified by a label "Keep until dd/mm/yyyy" where the date given is 15 years after the last participant's final study visit.

19 DATA MONITORING AND QUALITY ASSURANCE

The RA or other member of the research team will check any researcher-completed data collection forms for missing data or obvious errors before the forms are sent to the CTU. Data will be monitored centrally for quality and completeness by the CTU and every effort will be made to recover data from incomplete forms where possible. The CTU data manager will oversee data tracking and data entry and initiate processes to resolve data queries where necessary. The trial manager will consider and implement central and local monitoring strategies as appropriate.

All trial procedures will be conducted in compliance with the protocol and according to the principles of Good Clinical Practice. Procedures specifically conducted by the CTU team (e.g. randomisation and data management) will be conducted in compliance with CTU standard operating procedures (SOPs). As necessary, the Principal Investigators and the participating GP surgeries will be required to permit delegated member of the research team or sponsor representative to undertake trial-related monitoring to ensure compliance with the approved trial protocol, providing direct access to source data and documents as requested.

20 TRIAL OVERSIGHT

20.1 Trial Management Group

The Trial Management Group will oversee the day to day conduct of the trial including study planning, ethics submissions, contractual agreements and issues, monitoring recruitment, preparing relevant progress reports, organising steering committee meetings, monitoring any serious adverse events and being responsible for the Trial Master File and administration of the trial budget. The trial management group members will include the CI, the local PIs from each site/representative from each site, the CAB lead, the PPI lead, the trial health economist, the trial statistician, PenCTU data manager, a qualitative lead and the trial manager. Invited observers will include a representative of the CRN. Trial management meetings will take place on a monthly basis initially, moving to bi-monthly or quarterly meetings in the main trial phase of the study if appropriate.

20.2 Trial Steering Committee

The Trial Steering Committee will oversee the conduct, progress and safety of the trial and will provide advice to the Trial Management Group. Terms of reference for the TSC will be developed and forwarded to the study sponsor. The TSC will include the CI, an independent trial statistician,

an independent health economist and a service user representative. The committee will include an independent chair. Invited observers will include the trial statistician, the trial health economist, trial manager and a representative from the research sponsor. The Trial Steering Committee will meet at the beginning of the trial, at the end of the internal pilot trial and thereafter as required, at least annually.

21 STATISTICAL CONSIDERATIONS

21.1 Sample size

We require 135 patients/arm to have 90% power to detect a clinically meaningful difference in the primary outcome of 3.5 BDI units between groups at 5% two-sided alpha (based on standard deviation (SD) of 9)[xiv, xv]. Given our analysis of covariance analysis approach to data analysis (see below) this sample size is likely to be conservative. To allow for a cluster allocation, we need to inflate the sample size by a design effect of 1.45 (assuming an intracluster correlation coefficient (ICC) of 0.05 and average cluster size of 10) [xvi]. In the pilot trial, we will recruit and randomise 120 patients to intervention and control arms nested by individual or cluster randomisation. If the pilot trial demonstrates no strong evidence of contamination (see section 8.2), main trial allocation will proceed at an individual level and we will require a total of 195 patients/arm across both pilot and main trials (allowing for 20% attrition and clustering in pilot trial). If pilot demonstrates strong evidence of contamination, full trial allocation will proceed at a practice level and we will require a total of 235 patients/arm across both pilot and main trials (allowing for 20% attrition and clustering in pilot and full trial). Should the level of outcome clustering within and between practices be higher (i.e. an ICC of 0.10) these sample sizes will provide 80% power (at 5% alpha).

21.2 Statistical analysis

As the trial protocol (other than the method of allocation) will remain consistent across pilot and main trial, outcome data from both trials will be aggregated into a single data analysis at the end of the main trial:

The primary analysis will compare primary and secondary outcomes at 12 months according to the intention-to-treat principle i.e. according to random allocation. Regression based analyses will adjust for baseline score and take account of data clustering. Outcomes will be analysed by locality to explore any effects on outcomes of CAB advisor approach regionally. Secondary analyses will be undertaken with repeated measures comparison of outcomes at both 4 and 12 month follow up time points. Sensitivity analyses will be under taken to examine the effects of missing data and differing imputation strategies. Interaction analyses will explore the potential impact of a limited number of pre-specified (moderator variables) subgroups (i.e. severity of depression (BDI <20 v rest), severity of debt- priority v non-priority, employed v unemployed, and hopelessness rating) as interaction terms. If there is a switch to individual randomisation after pilot, we will implement minimisation on the variables: severity of depression (i.e. BDI <20 vs >=20); severity of debt (priority vs non priority); employment status (employed vs unemployed); and level of hopelessness. If after pilot, it is decided that we need to go with cluster randomisation, then we will not implement this minimisation. No interim analyses are planned.

Contemporary mediational analysis methods will be used to explore the impact of treatment adherence/non-attendance and potential causal mechanisms [xvii]. A full statistical analysis plan will be developed before the end of data collection and agreed with the TMG and TSC in accord with CONSORT recommendations.

21.3 Economic evaluation

Economic analysis will be conducted from the UK NHS perspective. Incremental cost-effectiveness ratios will be generated based on the primary and secondary outcomes and will include an assessment of cost-utility as part of the cost-consequences analysis. Two time durations will be employed: a within-trial assessment and a longer-term time horizon assessment based on decision-analytic modelling- ensuring that good practice is adopted-and populated from parameter estimates derived from the trial and from information from literature sources relating to long-term effects of depression, anxiety and mental wellbeing. These time periods offer a longer duration than previous studies and will be used, alongside other sources, to arrive at more meaningful estimates of cost-effectiveness.

The costs associated with debt advice and counselling integrated with general practice (using data from CSRI and CAB process record summaries) will be estimated and compared to NICE guided treatment as usual and leaflet advice. The differences will be combined with differences in costs between intervention and control group to determine overall costs associated with the intervention. The health care resource utilisation of both groups (e.g. community based health care professional consultations, community care, anxiety and depression related prescriptions, secondary care contacts etc.) will be assessed through the completion at baseline, 4 and 12 months follow-up of the CSRI adapted for this study. These will be translated into costs using appropriate published unit costs (e.g. Curtis, 2011) [xviii]
The difference in overall costs between groups will be compared with differences in outcomes – as specified above – and including quality adjusted life years (QALYs). NICE recommended QALYs should be computed from EQ-5D[xix], and in the study we will use the recent five level update, EQ-5D-5L[xx].

A series of one-way sensitivity analyses will be conducted to assess the impact of parameter variation on baseline estimates of the range of incremental cost-effectiveness ratios, and a probabilistic sensitivity analysis will be undertaken to determine the extent to which the intervention can be regarded as representing value for money using the incremental cost/QALY as the metric for this assessment; measured against the NICE range of 'willingness to pay' thresholds between £20k and £30k per incremental QALY gained.

21.4 Qualitative analysis

Robust theoretical approaches to qualitative data analyse and interpretation will be employed. Narrative and constant comparative approaches will be used to develop the thematic analysis[xxi, xxii].
Service User advisors will be involved in the process of analysing anonymised patient transcripts to provide their perspectives on data interpretation.
Semi-structured interviews with a sample of GPs and CAB advisors participating in the trial will be conducted to check fidelity and the impact of participation on attitudes and practice (using Normalisation Process Theory - NPT)[xxiii]. Normalization Process Theory will underpin the exploration of the behavioural mechanisms that will or inhibit the routine incorporation of the intervention (GP assessment, CAB advice and shared comprehensive assessment) in everyday practice. It provides a rigorous conceptual framework to identify, describe, and understand interactions between participants' contributions (the things that they do) with the capabilities offered by the intervention - focusing attention on the intervention's workability and integration in workflow and context.

These findings will be triangulated with relevant CSRI data on appointments and process records from CAB visits and completed comprehensive assessments.

22 TESTING FEASIBILITY OF THE TRIAL AND DESIGN ADAPTATION

In addition to testing the feasibility of our trial design, we will also collect specific data to inform our response to the stopping and design adaptation rules (detailed below), prior to rolling out the full trial. We have constrained our design adaptation rules, by ensuring there are no changes to the intervention, to reduce the potential loss of data from the pilot trial to the overall trial.

22.1 Piloting the intervention

The proposed intervention is a complex intervention and will therefore need to be piloted. The four organisational elements are well established and it is not anticipated that there will be major theoretical changes to the intervention; however, it is recognised firstly that adaptations will be required and secondly that a detailed implementation process will be needed to ensure the intervention is delivered optimally. Fidelity will be assessed and qualitative interviews will be used to assess implementation problems and facilitators, and problems resolved to ensure the intervention is implemented as closely to the model as possible. Refinements to training and the manual may be made to help ensure fidelity to the original model. During the main trial the intervention will continue to be implemented with any additional procedures developed in the pilot trial to ensure closer fidelity to the model.

22.2 Design adaptation rules

Commissioners' willingness to pay

We intend to test commissioners' opinions about our proposed intervention and RCT. We will recruit a closed virtual group communicating via an email discussion forum. We will invite the relevant CCGs and Health and Wellbeing Boards in England and ABM University Health Board R&D department in Wales plus key providers (statutory and 3rd sector) to nominate senior representatives for this group. We propose to ask them to advise on the domains and measures of cost effectiveness that are most relevant to commissioning decisions in this area of service provision, using a Delphi technique. This will take place in the pre-trial period and after the internal pilot and before the full trial. We will also canvass their views on their potential willingness to commission this approach to debt advice in the future, informed by our pilot data.

Testing participant recruitment

We propose to compare our two recruitment methods. 1) Supported by ourselves, the networks and service support cost funding, practices will identify adults potentially having current depression or treatment for depression in the last 12 months from GP database searches (use of antidepressants, diagnostic codes, QOF depression score codes), and send out letters informing them of the study and inviting them to contact the research team. 2) We will also recruit direct from general practice waiting rooms supplemented by publicity material at reception and waiting areas. Our experience of consultation-based recruitment is that it is relatively inefficient in primary care mental health trials[viii]. At the end of the internal pilot trial we will compare key characteristics (demographics, debt and depression severity) of those recruited through mailshots versus direct contact, and within cluster versus individually randomised sites, to look for evidence of imbalances between the approaches that might introduce significant bias. We will also consider the relative resources required per recruit in terms of recruitment rate, staff resources associated with them, participant feedback on acceptability, refusal rates and practice teams' attitudes to mailshots v waiting room recruitment. This will supplement active recruitment monitoring throughout the trial to identify barriers to, and solutions for facilitating, recruitment. In the absence of clear evidence that individual factors such as sex, age, severity of debt or depression will have a substantially greater impact on outcome than other variations we do not intend to stratify our recruitment.

Acceptability of intervention and trial

Data will be used from qualitative interviews about participants' experiences of the trial and intervention and which with data on appointment attendance rates will be used to assess acceptability in the internal pilot trial. We intend to monitor attendance rates overall at assessment and advice sessions, and relative rates according to deprivation.

23 STOPPING RULES GOVERNING PROGRESSION TO MAIN TRIAL

At the end of the pilot trial a range of parameters will be assessed to inform decisions about stopping rules or adaptations to the main RCT design. The decision to progress to the main trial and modify the trial design will be made in close liaison with the Trial Steering Committee and in discussion with HTA. The following stopping rules will be used to inform a decision whether or not to progress to the main trial:

1. Failure to recruit to pilot trial

The aim is to recruit 120 patients from twelve GP practices in the pilot trial over a period of six months (i.e. approximately 10 patients per practice - 2 cluster and 2 individual randomisation sites in each of three localities). If recruitment is <50% of target at the end of the pilot trial despite intense efforts, appropriate CRN support and in the absence of any exceptional or unforeseen barriers that can be overcome through design adaptations, we will propose to the HTA that the trial is not feasible and should be stopped.

2. Lack of acceptability

The number of participants attending one, two or three meetings with a CAB advisor (intervention contacts) and the proportion of these from the most vulnerable populations will be monitored. Based upon our acceptability data outlined above, should attendance rates for un-cancelled CAB appointments fall below 60% overall at the end of the pilot trial, with no evidence of significant improvement as the trial settled in, we would recommend that the intervention is unlikely to be considered to be cost-effective by commissioners, particularly if triangulating data from qualitative interviews & CSRI/service satisfaction measures suggest that many potential clients find it irrelevant or unacceptable.

3. Uncertain commissioning environment

The findings from the pilot trial in terms of assessing the potential value of the intervention, its acceptability and other key markers identified by the commissioning stakeholders will be used to reaffirm their current interest in both supporting the ongoing trial and utilising the results in the future.

24 DESIGN ADAPTATION AT END OF PILOT TRIAL

Assuming the decision to progress to the main trial, our adaptive design allows us to revisit four elements of the main trial design following the completion of pilot trial:-

1. Sample size and power

We will estimate the standard deviation of the primary outcome (BDI) at the end of pilot trial and check this in accord with the sample standard deviation of a BDI score of 9. With only 12 practices, we are unlikely to estimate the outcome ICC with precision. However, we will check the ICC for primary outcome at the end of pilot trial and check that our assumed ICC (i.e. 0.01 to 0.05) falls within the 95% confidence interval of our observed estimate. We will check the SD of the BDI (and secondary outcomes) at the end of the pilot phase and therefore check our sample size assumptions. We will estimate the primary outcome standard deviations on the 120 patients recruited in the pilot stage. We have based our ICC estimate on the Ward et al study (xv). As the project progresses, and as part of the TMG regular evidence horizon scanning, we will also be scanning the literature for any new additional (large) published data sets that might provide a better (more precise) estimate of the BDI ICC at the practice level (and reflecting if they would have any impact on the proposed power). If necessary, we will adjust our sample size calculations for the main trial.

2. Participant recruitment

While it is anticipated that both methods will contribute significantly and will also widen the range of participant sample, it is possible that the trial could continue with one or other rather than both methods if one of the methods is either not cost effective, achieving only minimal numbers or introducing significant distortions in the sampling.

3. Contamination arising from randomisation method

We plan to check for evidence of significant contamination when participants are randomised individually rather than through cluster practices. While the numbers of patients involved in the pilot trial will not allow us to detect small differences we believe it will be possible to detect differences that reflect important levels of contamination (which might be considered to threaten trial reliability). To check for this we will monitor how many participants from control groups have taken up any form of debt counselling at their follow-up visit, as this is the key measurable variable. We have agreed an absolute and relative measure for this (see section 8.2). If we find strong evidence of contamination we would recommend that the full trial should switch to a full cluster randomised allocation.

25 ETHICS AND REGULATORY APPROVALS

25.1 Study sponsor

The study sponsor is the University of Liverpool.

25.2 Research governance

The trial will be undertaken within a primary care setting in three localities, subject to appropriate Research Ethics Committee (REC) approval and local NHS Research & Development approvals. The trial will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with GCP. Any amendments to the protocol will be submitted for REC approval as appropriate.

26 STATEMENTS OF INDEMNITY

The University of Liverpool holds indemnity and insurance cover with Marsh UK LTD, which applies to this study.

The CAB operates a robust documented complaints procedure. Any concerns will be dealt with by senior CAB managers within 1 week (to allow time for preliminary investigation within the CAB team).

27 PUBLICATION POLICY

The study team will prepare a plain English summary of the study findings. Participants and participating practices will be sent this lay summary by post or e-mail at the end of the study and will also be directed to relevant web pages, including the trial website, for further information.

The CI and grant holders will establish a writing group which will be responsible for preparing the final HTA report and a series of peer reviewed publications for submission to international journals in primary care, mental and public health.

The study findings will also be disseminated via presentations at key academic and professional conferences, supported by press releases. It is anticipated that a national launch event will be held in conjunction with the Citizens Advice Bureau at the end of the trial to publicise the findings.

28 FINANCE

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