Debt **Co**unselling for **De**pression in Primary Care: An Adaptive **R**andomised Controlled Trial

Intervention Protocol

- Theory, Practice and Delivery -

CONTENTS

LIST OF ABBREVIATIONS

CAB Citizens Advice Bureau

DeCoDeR Debt Counselling for Depression: Randomised Controlled Trial

IAPT Improving Access to Psychological Therapies

NICE National Institute for Health and Clinical Excellence

PTSD Post-Traumatic Stress Disorder

SCA Shared Comprehensive Assessment

TAU Treatment As Usual

1 RATIONALE FOR HAVING AN INTERVENTION PROTOCOL

This protocol provides a description of the intervention as it is intended to be delivered by practitioners within general practice and CAB, the theory as to why it should make a difference, and the means for ensuring delivery: manuals, training and support.

The protocol serves several purposes:

- Provides a document stating what should be delivered for anyone to reference at a later stage
- Provides a reference – along with manuals for practitioners to use if they wish
- Provides a basis for assessing fidelity of actual delivery
- Provides a document which supports the process evaluation (not included in this document) – to understand problems with delivery and how intervention has its effect, if any.

2 BACKGROUND AND RATIONALE FOR THE INTERVENTION

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[1,2]. Alongside anxiety and stress it is considered the commonest cause for prolonged work absenteeism[3], as well as presenteeism (working below normal capacity when unwell). Mental ill health is estimated to cost the UK economy £40B per year overall[4,5]. Around 11% of the population are estimated to be struggling with personal debt, with evidence of increasing episodes of suicide associated with rising debt[6,7].

Most episodes of depression are managed in Primary Care, following the NICE recommended four-stepped approach[1]. 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.

Recognising the increasing burden of indebtedness and the link between debt and mental illness in the Foresight Report[8], 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,

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http://www.direct.gov.uk/en/MoneyTaxAndBenefits/ManagingDebt/PlanYourWayOutOfDebt/DG_10013291

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http://www.direct.gov.uk/en/MoneyTaxAndBenefits/ManagingDebt/PlanYourWayOutOfDebt/DG_187500

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 cost and/or low mood). Research suggests over 25% of depressed patients will have significant debt[9], 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[10,11]. 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[9,12]. 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.

2.1 Theoretical underpinnings of the intervention

The intervention is informed by the principles of collaborative care[13,14] which includes a multi-professional approach i.e. a GP plus at least one other, a structured management plan, scheduled patient follow ups and enhanced inter-professional communication.

The proposed intervention brings together two existing services:

1) debt counselling provided by third sector providers, such as 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 in Wales a variety of counselling and psychological therapies services.

Collaborative care has been shown to improve quality of life, healthy behaviours, self-efficacy and other health outcomes[15]. The intervention also aims to redress inequalities and promote social inclusion of marginalised groups[16]. It is based upon the assumption that social context plays an important role for mental illness onset and recovery, particularly in the case of debt and depression[10,17]. A shared comprehensive assessment will therefore combine social, psychological, environmental, economic and medical perspectives which will also incorporate personal goals and a bio-psycho-social management plan.

Liaison has been shown to be an important element of collaborative care and shared care more generally[18]. Communication will be enhanced by the sharing of, and co-creation between the patient, CAB worker and GP of the shared comprehensive assessment.

The active parts of the intervention as a whole: combining primary care treatment of depression with the addition of debt counselling and the comprehensive shared assessment, are supported by the co-location of GP and debt advisor in primary care, the additional pathways of care, enhanced communication between GP and debt advisor and case management for participants.

3 PROTOCOL

3.1 Debt counselling

Debt counsellors will provide debt counselling as per national CAB protocols with the added responsibilities laid out in CAB advisor summary protocol. The CAB advice will be provided by specialist CAB debt advisors, supported and case-supervised by senior CAB staff. The CAB Service will accept the referral and arrange the 1st appointment which will take the form of an assessment of the extent of debt, income and other financial circumstances. Prior to the financial statement being prepared with the client, action will be taken in relation to any emergency action (bailiff action) and prioritising the priority and non-priority debts. The second stage will be to explore the options for dealing with the debts and agree an action plan with the client. Such options may include: challenging liability for debt, token offers for repayment, pro-rata offers for repayment or legal remedies such as insolvency, debt relief orders or bankruptcy. Subsequent processes will include implementing or amending the action plan dependant on client circumstances. Those without 'priority debts' at assessment will be offered a session with a CAB money management advisor. The intervention is anticipated on average to consist of up to 3 post-assessment advice sessions plus case management support.

Debt counselling provided by the CAB is intended to educate participants, teach them skills to manage their own short term debt, avoid a worsening of both debt and depression (i.e. a downward spiral) and raise confidence to manage longer term finances.

3.2 GP Care

GPs will provide treatment in line with NICE guidance for depression. In addition GPs will carry out a biopsychosocial shared comprehensive assessment and monitor the participant in line with the GP summary of the intervention protocol.

3.3 Shared comprehensive assessment (see appendix SCA form)

Assessment will be carried out following randomization to the intervention, through two key consultations. One assessment will be carried out by the general practitioner linked to the study within two weeks of consent to participate in the trial. This consultation will combine an assessment of both anxiety and depression, as recommended by NICE guidance[1], and will include an assessment of need regarding medication and psychological therapy and agreement regarding further treatment which could include referrals to the local IAPT service.

The shared comprehensive form has been developed to assist with the sharing of information in a structured way. It is split into 2 main parts, the first section is the GP assessment and the second is the CAB assessment. The GP assessment includes subsections including the main concerns of the individual in their own words and diagnoses; psychological difficulties relevant to debt, including suicide risk; other social difficulties including housing, work/study, relationships and domestic abuse and lastly a subsection identifying goals for the future and any other current treatment.

The CAB part of the shared comprehensive assessment incorporates assessments normally carried out in the Citizen's Advice Bureau and will be further adapted and manualised to incorporate additional features. The primary aim is to assess severity of debt following initial engagement with the individual; the assessment will also incorporate an analysis of the individual's other social problems, their strengths and their key social and emotional goals. At the end of the consultation they will agree whether the individual requires a higher level debt counselling intervention, or the basic debt counselling provision.

Each assessment section has an area for the participant to sign to consent for their information to be shared with the CAB and GP respectively. With the appropriate consent, information from the GP assessment and CAB assessment will be shared with the Citizen's Advice Bureau advisor assigned to the patient's own general practice and the study general practitioner.

The shared comprehensive assessment is a protocolised system to share co-produced information between the GP, CAB advisor and patient in-line with the collaborative care model and shared decision making. It aims to improve communication between general practice and the CAB and facilitate continuity of care for the patient. It also aims to involve the patient in decisions about their care which has been shown to improve treatment adherence, self-efficacy and outcomes. The shared assessment also avoids the unnecessary burden of the patient having to tell what can sometimes be a painful story over and over again to staff and associated professionals[19].

Enhanced communication between primary care and CAB services is facilitated through the use of shared comprehensive assessment which is held on both the GP practice clinical notes and the CAB system and also by the patient.

3.4 Co-location

Co-location has been shown to improve liaison between the workers within services and can also help to improve access[20,21]. In this case the co-location of the CAB in primary care should enhance access to services[21] by overcoming elements of stigma which may be present for those not usually accessing CAB services[20,22].

It is anticipated that where possible CAB workers will see patients within their own practice, but in some instances of small practices, and where accommodation is problematic CAB workers may see patients at other venues, including neighbouring practices or nearby health centres. On occasions the more specialised intensive debt counselling services may be based within the usual CAB settings.

3.5 Pathways

The intervention incorporates two core pathways (3.1 and 3.2) as well as optional ones. The core pathways include being seen initially by the General Practitioner and following this by the CAB advisor. On-going pathways of care include progress reviews by the GP and the CAB worker.

Optional pathways 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 (NICE guidance for Depression ref).

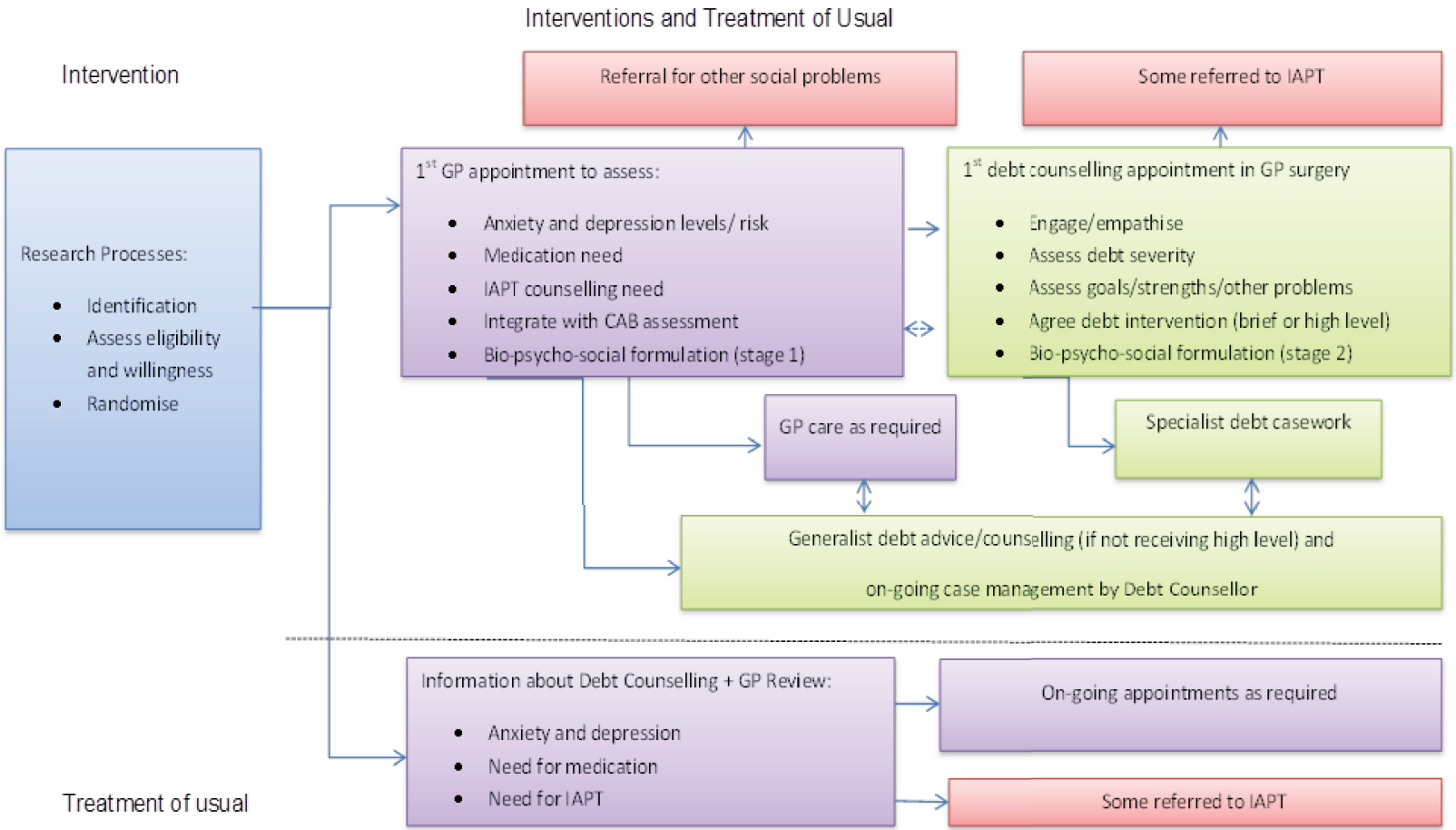
3.6 Liaison

Co-location is also anticipated to enhance the possibility of informal one-to-one discussion about individual cases. Organised formal liaison is encouraged between the GP and CAB worker in order to underpin enhanced communication where feasible, particularly for example where clients are more vulnerable and struggling to maintain contact with services and or having greater need and complexity. This enhanced liaison may include telephone catch-up calls between CAB advisor and GP, face-to-face meetings or occasional attendance at practice meetings by a CAB worker if appropriate.

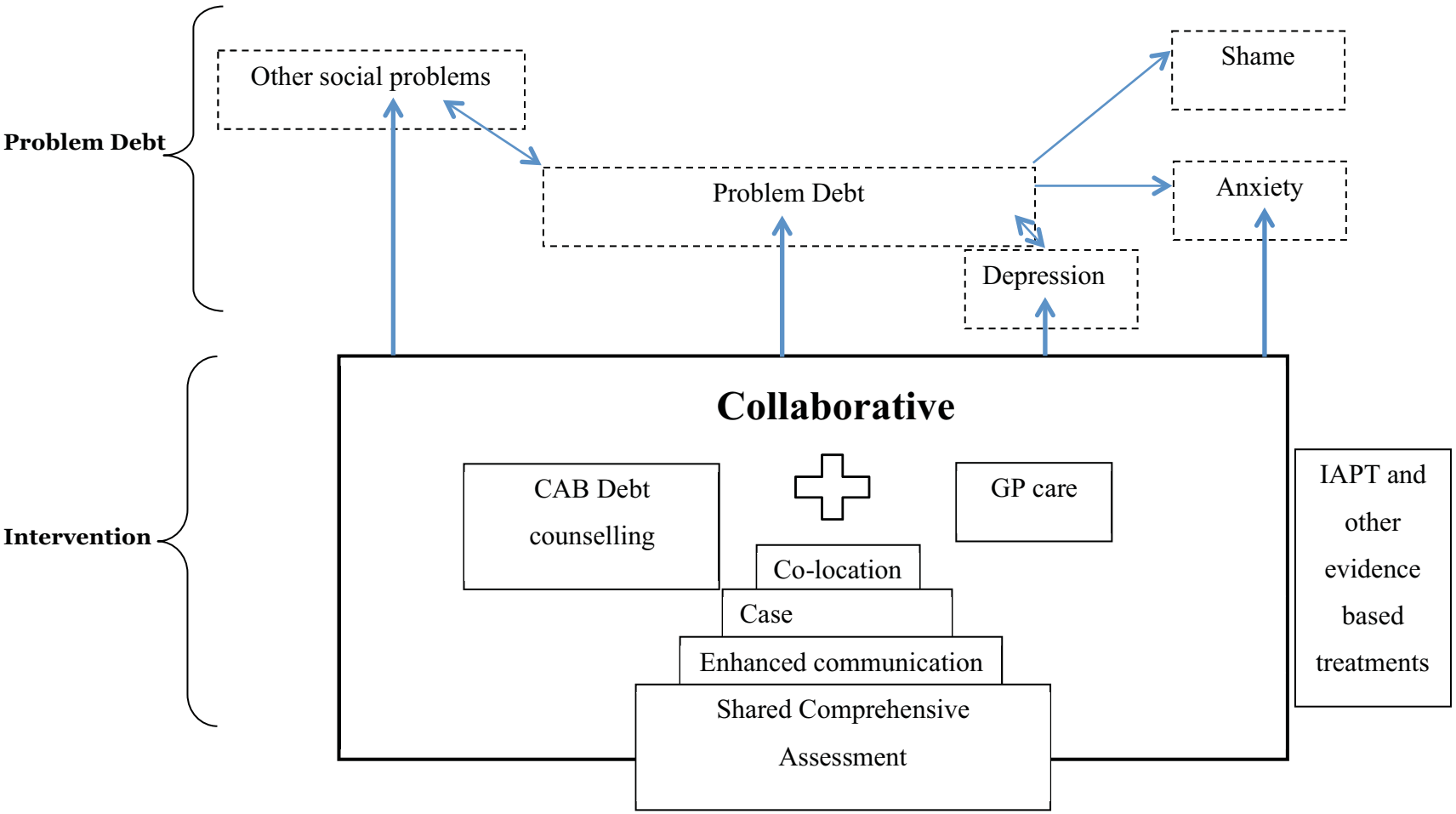
3.7 Case management

Case management is an important part of the collaborative care approach . For this intervention, for the majority of cases, the case manager will be the CAB worker. After the initial Comprehensive Shared Assessment, the case manager will maintain contact with the patient according to the most convenient method for each individual. This may be by telephone, e-mail, text, face-to-face review or a combination. The aim will be to ensure that an individual's progress is monitored and that individuals are enabled, prompted and empowered to attend appointments with the CAB workers, General Practice, IAPT and other social interventions as agreed in the management plan. If during the early stages of our feasibility trial attendance at appointments with CAB, GPs and other booked appointments remains low, we will enhance this aspect of our intervention. Case management, as a part of collaborative care, is an essential continuation of facilitating patient attendance, self-efficacy, patient-centred timing of progress and risk monitoring[23]. Care in a collaborative care model is a continuous process and not a one-off intervention that is responsive to changing needs and a changing evaluation of needs[24].

Flow chart overview of the trial, including Treatment of usual and Intervention



Concept Map of the Intervention and Potential Impact for Individuals



4 IMPLEMENTATION

Sections 2 and 3 have detailed how the intervention should be delivered in theory and in this research. However, changing existing practice requires a range of supportive mechanisms.

To help with this, the delivery of the intervention will be supported by:

- Training of GPs by the PI at each site arm (initial training)
- DeCoDeR Manual and mini-manual for GPs (see appendices
- Follow up review with GPs
- Training of CAB workers by the lead CAB study co-applicant
- Full manual and CAB summary protocol for CAB workers
- Supervision of CAB
- Fidelity review

4.1 What new thinking and behaviour is required of GPs and Cab advisors?

GP

1. Carry out part one of a Shared Comprehensive Assessment (this may take a double appointment slot, approx. 20 minutes).
2. Commitment to shared care with the CAB and shared decision making with the patient at the centre of care.
3. Share additional information with the CAB advisor as appropriate (using the 'Shared Comprehensive Assessment: GP Follow up Form') as part of a structured plan and also informally as part of enhanced communication.
4. Work with the patient and CAB advisor to encourage patient engagement and retention with CAB debt counselling in order to overcome shame, stigma or chaotic lives.

CAB advisor

1. Carry out the second part of the Shared Comprehensive Assessment.
2. Commitment to shared care with the GP and shared decision making, with the patient at the centre of care.
3. Working in a primary care location.
4. Work with the patient towards their personal debt goals taking into account mental health issues.
5. Share information with the GP practice as part of a structured plan (via CAB follow up form and arranged meetings) and informal liaison with GPs and practice staff as part of enhanced communication and colocation.
6. Case manage the patient and work with the GP to encourage patient engagement and retention with CAB debt counselling in order to overcome shame, stigma or chaotic lives.

4.2 Fidelity review during internal pilot trial

The proposed intervention is a complex intervention and will therefore need to be piloted. It is recognised that adaptations will be required and that a detailed implementation process will be needed to ensure the intervention is delivered optimally.

Fidelity will be assessed and qualitative interviews with GP and CAB advisors will be used to assess implementation problems and facilitators. Problems will be 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.

Fidelity Checklist

- Carry out Shared Comprehensive Assessment and share
- Provide participants with study debt leaflets
- Offer CAB appointments
- Provide an opportunity for co-location

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