Research protocol for GPs in the Intervention arm

Study Aim

The aim is to determine the clinical and cost effectiveness of the addition of primary care based debt counselling (provided by Citizens Advice Bureau counsellors) to usual care, for patients with depression and debt.

We hypothesise that outcomes can be improved by applying key principles of collaborative care:

- A shared understanding of how debt, depression and other problems relate to each other for each individual
- A plan agreed by patients, CAB and GP
- Structured communication between patients and the two main practitioners
- Proactive follow up to overcome shame, stigma or chaotic lives

Pre GP assessment appointment

Before seeing the GP, patients will have attended a research assessment and have been:

- Recruited to the study (via waiting room or record search, assessed as suitable, consented and baseline data collected)
- Allocated to treatment arm
- Phoned by practice staff to arrange an appointment to see an intervention GP (but they won't know they are in the intervention arm)

What happens at the GP assessment appointment?

The GP will assess both anxiety and depression, and need regarding medication and psychological therapy. They will, in partnership with the patient, agree future treatment in line with NICE guidance and also incorporate a psychosocial assessment and plan focused on debt and other social problems.

- The GP will complete the study-specific CAB referral and shared assessment form, including:
 - Main concerns (in patient's own words)
 - Diagnoses (ongoing/significant past), including alcohol
 - Psychological difficulties and their relationship to debt for the individual (e.g. tiredness, concentration, anger, fears)
 - Other social difficulties (e.g. housing, work/study, relationships, domestic violence/emotional abuse, gambling)
 - Patient's goals (immediate, medium-term and long-term)
 - Assessment of hopelessness/suicide risk
 - Provisional treatment plan (e.g. psychological therapy, exercise referral etc.)
- If deemed appropriate, GP may refer patient to IAPT services and other interventions and arrange to review the patient at ongoing appointments as required

- The GP will advise the patient that they have been allocated to receive debt advice from a CAB advisor and will be contacted by a CAB advisor
- The GP will confirm the patient's consent to CAB referral and their agreement to the sharing of their contact details and initial shared assessment with the CAB
- The GP will provide the patient with the study-specific debt advice leaflet and Royal College of Psychiatrists' Debt and Mental health leaflet
- The participant's written signed agreement to sharing contact details and specific information in the shared comprehensive assessment will be retained by the GP practice

Ongoing management of participants

- The CAB advisor will complete the assessment, send back the completed form to the GP/practice and give a copy to the participant
- Ongoing care will usually be managed and co-ordinated by the CAB advisor (in a small minority of cases this may be the GP) for the period of the intervention
- Ongoing pathways of care will include monthly progress reviews by the GP. On average this is likely to be 6 reviews, but could be up to 12 in line with NICE guidance. Progress reviews may also include checking participant progress with CAB and prompting non-attenders to return if they appear to be dropping out or have dropped out of CAB care
- Ongoing communication between GP and CAB advisor includes: 1-2 line summaries in the patient electronic record after each contact and a short summary of significant events when appropriate. Further liaison is facilitated by the co-location of CAB advisors in GP practices
- Optional pathways include:
 - k) referral to more intensive CAB debt counselling (if recommended and arranged by CAB advisor managing the case)
 - l) referral to other social inclusion services
 - m) referral to IAPT or other services for psychological therapy
 - n) sleep hygiene
 - o) active monitoring
 - p) structured Group Physical Activity
 - q) group Based Peer Support
 - r) community Mental Health Team
 - s) crisis resolution or Home Treatment teams
 - t) drug treatment e.g. SSRIs or other psychotropics
 - u) Support for addiction e.g. alcohol, drugs, gambling, smoking

Ongoing involvement in the research for participants

• Separately from the intervention, participants will continue to be followed up by researchers to collect outcome measures at 4 and 12 months

In the event that the participant refuses CAB referral:

- The GP will complete the relevant tick box informing the study team that the participant has declined CAB intervention
- The GP may continue to have further follow up appointments with the patient as required

Adverse event reporting

The following serious adverse events (SAE) should be reported to the Peninsula Clinical Trials Unit by faxing () the SAE form within 48 hours of becoming aware of the event:

- Death
- Immediately life-threatening illness
- Hospitalisation or prolongation of hospitalisation (this may include hospitalisation for self-harm/attempted suicide and depression)
- An event which results in persistent or significant disability or incapacity

If you have any queries about the study you can e-mail or call the research team:

Local Researcher:	Local PI:
Name:	Name:
Telephone:	Phone:
e-mail:	e-mail: