

# Debt Counselling for Depression in Primary Care: an adaptive randomised controlled pilot trial (DeCoDer study)

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**Disclaimer:** This report contains transcripts of interviews conducted in the course of the research and contains language that may offend some readers.

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## Scientific summary

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# Scientific summary

## Background

Depression is estimated to affect 5–19% of adults at any one time, is a common presentation to primary care and, as part of the mild to moderate mental health problems category, is a major contribution to absenteeism. It is estimated that 16% of the UK population is struggling with debt, and debt is particularly common among people with depression. The pilot trial reported here was the first phase of an adaptive trial funded by the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme to investigate the clinical effectiveness and cost-effectiveness of specialist debt counselling in primary care over usual care for adults with depression and debt. As the study failed to reach its recruitment target, it was terminated early during the internal pilot phase and, therefore, did not progress to the main trial. This report describes the study rationale, methods and findings of the pilot phase of this study, and implications for future research in this area.

## Objectives

The aim of the pilot trial was to test the procedures, recruitment processes and operational strategies that were planned for use in the main trial: identifying and resolving any problems, and thereby assessing the feasibility of continuing with the main trial. The specific objectives of the pilot trial were:

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 the 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 the robustness of data collection systems
8. to identify and resolve potential difficulties in implementing the shared assessment
9. to assess intervention fidelity.

## Methods

We conducted an adaptive, parallel, two-group, pragmatic randomised controlled pilot trial with 1 : 1 allocation to intervention or control treatment as usual (TAU). The participants allocated to the intervention received a shared biopsychosocial assessment from the general practitioner (GP) and Citizens Advice Bureau (CAB) advisor, debt advice leaflets and debt counselling from a CAB specialist debt advisor based in the practice. The control participants received TAU and debt advice leaflets only at a GP appointment. A nested mixed-methods process and economic evaluations were undertaken.

Patients who had current depression and were worried about debt were recruited through general practices in three regions of the UK (north-west England, south-west England and south Wales). Participants were recruited to the study via two approaches: (1) waiting room recruitment – publicity posters displayed in the waiting rooms of participating general practices and flyers with attached expressions of interest forms placed around the waiting room and handed out by study research assistants and practice staff; and (2) practice database searches and mail-outs – patients' records were screened for current depression or depression-related treatment in the last 12 months. GPs reviewed lists to exclude patients with other significant conditions that, in their opinion, made them unsuitable for invitation to the

study. Those remaining on the list were sent an introductory pack that comprised an explanatory letter from the practice, an expression of interest form and a freepost envelope.

Patients were eligible for the study if they were aged  $\geq 18$  years, scored  $\geq 14$  on the Beck Depression Inventory II (BDI-II) and self-identified as having worries about debt. The main exclusion criteria were being actively suicidal or psychotic and/or severely depressed and unresponsive to treatment; having severe problems with addiction to alcohol or illicit drugs; being unable or unwilling to give written informed consent; currently participating in another research study including a follow-up data collection phase; having received CAB debt advice in the past 12 months; or not wanting to receive support about debt or money worries provided via the general practice.

Outcomes of the pilot trial included the proportion of eligible patients who consented, the number of participants recruited during the recruitment stage of pilot compared with the target, an assessment of contamination, and an assessment of patient satisfaction with intervention and outcome measures.

The primary participant outcome was BDI-II score. Secondary outcomes included psychological well-being, health-related quality of life, health and social care utilisation and employment factors, and substance misuse at 4 months. Life events and difficulties data, service satisfaction, hopelessness, shame and rumination were also reported. Outcomes were collected at baseline (pre randomisation) and at 4 months post randomisation.

### **Quantitative data analysis**

Given that the study did not progress to a full trial and achieved a reduced sample size in the pilot trial phase, we were not powered to undertake an inferential statistical comparison of outcomes between intervention and control groups. Instead, outcomes findings are reported descriptively (means and standard deviation, or numbers and percentages) for primary and secondary outcomes for the two groups at baseline and at 4 and 12 months post randomisation.

### **Health economic data analysis**

As with the quantitative data analysis, given that the study did not progress to a full trial and achieved a reduced sample size in the pilot trial phase, we were not able to undertake an inferential statistical comparison of health-related quality of life or service use between the intervention and control groups, or to undertake an economic evaluation. Instead, the findings are reported descriptively (means and standard deviation, or numbers and percentages) for the two groups at baseline and at 4 and 12 months post randomisation.

### **Qualitative data collection and analysis**

In-depth, semistructured, topic-guided interviews were completed with a subset of consenting participants. Baseline qualitative interviews explored the participant's narrative biographies of depression, anxiety and debt, focusing on impacts on the participant's life and their perceptions of practical aspects of debt. A further qualitative interview at 4 months enquired about developments since the participant's entry into the trial, exploring the possible psychological, social and economic factors involved in recovery (or not) from debt and depression. The 4-month interviews also assessed concordance with trial protocols, acceptability of intervention and assessment measures, and the participant's experience of participating in the trial.

## **Results**

Sixty-seven practices were approached about the study; 12 were recruited as study sites but two were not able to recruit participants before the pilot closed. A total of 7874 patients were identified on practice computer systems as having markers of depression. In some practices, when  $> 300$  patients were identified who were potentially suitable for the trial, mail-outs were limited by random sampling from the total

population. Consequently, 4121 letters were sent out after screening by GPs, resulting in 138 expressions of interest. Researchers spent 170 hours in waiting room recruitment and 3367 leaflets were left in practices, resulting in 100 expressions of interest. From the 238 expressions of interest screened, 61 participants (26%) were recruited and randomised across the three research sites. Of those randomised, 18 were recruited from the waiting room and 43 were recruited from database searches. Of the 61 participants recruited, 32 were allocated to the intervention arm of the study and 29 were allocated to the control arm, and 28 and 24, respectively, completed the 4-month follow-up. When the pilot was stopped, only 22 participants had completed the 12-month follow-up.

In sites where participants were individually randomised, we found no evidence that participants in the TAU arm were accessing CAB debt advice more often than participants in cluster control (TAU) sites.

As a result of the small sample size, we can report only descriptive data. The groups were relatively well balanced, but > 50% of the recruitment was at one of the three sites. Most participants scored > 28 on the BDI-II (severe depression) at baseline, with an overall mean score of 35.2. The intervention group contained a higher proportion of dependent drinkers as classified by the Alcohol Use Disorders Identification Test.

We undertook in-depth, semistructured interviews with 23 participants (12 in the intervention arm and 11 in the control arm) and 11 professionals (GPs and CAB advisors). Participants' experiences of the intervention were largely positive, with those receiving CAB debt advice identifying two main benefits of advice: first, support in engaging with a range of agencies about debt issues and, second, identifying sources of additional financial support.

Participants also indicated benefits of participating in the research process. A number described the opportunity to discuss their lived experience during interviews with research staff as a kind of therapy. Although participants' experiences of involvement in the research were, therefore, largely positive, there were aspects of the research that participants highlighted as requiring further consideration. These included the form and content of questionnaires, the length of interviews and the complexity of language in some questionnaires, with the 'force choice' response style coming under criticism from some respondents. Both the complexity of language and the sheer number of questionnaires to be completed resulted in some overly long interviews; therefore, it was not surprising that some participants highlighted the need for interviews to be shortened.

The intervention process evaluation (using the normalisation process theory approach) with GPs and CAB advisors found that the co-location of the CAB service within primary care was viewed as beneficial and workable by both GPs and CAB advisors. However, there were caveats to some elements of the intervention. Although the psychosocial assessment undertaken by GPs as part of the shared comprehensive assessment was normalised within usual clinical practice, the time required to collect detailed information for sharing with CAB advisors was viewed as potentially prohibitive by GPs. A key element of the intervention was collaborative care through opportunities for informal communication, facilitated by the co-location of services. However, there was little evidence of any opportunities for such communication. This was thought, in part, to reflect the sporadic nature of CAB attendance at practices due to the small number of participants, but also working practices and competing workload priorities within general practice.

Participant stories of debt and depression reflected considerable complexity. These highlighted the myriad of concomitant psychological, social and contextual difficulties that acted and interacted to influence individual experiences of psychological distress in the context of unmanageable debt. Contextual influences included participants' experiences with debt collection organisations and benefits agencies and their systems and processes. Although employment was highlighted as a potential route out of debt and associated worry, considerable barriers to employment were also identified. These included, in particular, the current employment climate, the poverty trap (due to loss of benefits once in work), and physical and psychological health difficulties.

## Conclusions

The relationship between debt and depression is highly complex. A multitude of psychological, social and contextual influences acted and interacted to influence participants' experiences of psychological distress in the context of unmanageable debt. The contribution of debt and benefit organisations, through their systems and processes, to some participants' psychological distress, highlights the need to widen the focus of research investigation to determine the mechanisms of psychological distress in the context of debt. A number of participants highlighted specific benefits of debt advice, including helping them to engage with agencies about debt issues and providing additional financial support. Although a collaborative approach to care between GPs and CAB advisors for patients with debt and depression may be advocated, achieving this requires more than simple co-location of services. Some of the challenges we experienced reflect the difficulties of utilising an adaptive design in the tight time frame of a pilot trial, where the requirement for a sequential pathway of permissions for protocol amendments prohibits immediate adaptations. It is likely that the slow recruitment was at least partly a result of the complexity of psychosocial problems, making it harder for participants to engage with the research. Our internal pilot trial indicates, therefore, that it is likely that randomised controlled trials involving groups with complex social problems, including debt, are likely to be feasible within the current primary care environment in England and Wales (in the face of significant NHS reorganisations and stretched resources) only if additional investment is available to support and sustain participant and site recruitment.

## Trial registration

This trial is registered as ISRCTN79705874.

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## This report

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