



## Tailored online cognitive behavioural therapy with or without therapist support calls to target psychological distress in adults receiving haemodialysis: A feasibility randomised controlled trial



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### ABSTRACT

**Background:** Psychological distress is prevalent in haemodialysis (HD) patients yet access to psychotherapy remains limited. This study assessed the feasibility and acceptability of online cognitive-behavioural therapy (CBT) tailored for HD patients, with or without therapist support, for managing psychological distress.

**Methods:** This feasibility randomised controlled trial recruited patients from a UK HD centre. Following psychological distress screens, patients with mild-moderate psychological distress (Patient Health Questionnaire PHQ-9; score: 5–19 and/or Generalised Anxiety Disorder; GAD-7 score: 5–14) who met remaining inclusion criteria were approached for consent. Consenters were individually randomised (1:1) to online-CBT or online-CBT plus three therapist support calls. Outcomes included recruitment, retention, and adherence rates. Exploratory change analyses were performed for: psychological distress, quality of life (QoL), illness perceptions, and costs. The statistician was blinded to allocation.

**Results:** 182 (44%) out of 410 patients approached completed psychological distress screens. 26% found screening unacceptable; a further 30% found it unfeasible. Psychological distress was detected in 101 (55%) patients, 60 of these met remaining inclusion criteria. The primary reason for ineligibility was poor computer literacy (N = 17, 53%). Twenty-five patients were randomised to the supported (N = 18) or unsupported arm (N = 7); 92% were retained at follow-up. No differences in psychological distress or cost-effectiveness were observed. No trial adverse events occurred.

**Conclusion:** Online CBT appears feasible but only for computer literate patients who identify with the label *psychological distress*. A definitive trial using the current methods for psychological distress screening and online care delivery is unfeasible.

[ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT02352870) Identifier: NCT02352870

### 1. Introduction

Self-reported psychological distress, including symptoms of depression [1] and anxiety [2], affects approximately 39% of people living with end-stage renal disease (ESRD) treated with dialysis [1] and

is associated with increased morbidity [3], mortality [4–6], and health care utilisation rates [7]. Identifying and treating psychological distress in haemodialysis (HD) patients remains a challenge [8] because effective and pragmatic ways of delivering integrated mental and physical care are yet to be established in this setting.

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Identifying psychological distress in HD patients is the first challenge. Implementing thorough psychological assessment interviews is unfeasible with scarce resource [9]. Specific self-report screens for psychological distress are validated for use in physical long-term conditions (LTCs) [10] and offer a practical solution for routine assessment. However, screening alone is insufficient. Integrated support with evidence-based treatment pathways are required to ensure patients' in need of support are effectively managed at the appropriate level of care [11].

Cognitive behavioural therapy (CBT) is an effective psychotherapy for the treatment of psychological distress [12–14]. Three relatively small studies found CBT improved psychological distress outcomes in HD patients [15–17]. However, meta-analyses report small effect sizes for CBT in people with LTCs [18,19]. One reason for these small effects may be because CBT treatments were originally developed to treat primary mental health conditions [19,20]. The application of CBT to people with physical LTCs may require tailoring to ensure that factors unique to chronic illness, including maladaptive and/or erroneous perceptions of illness [21] and poor coping skills in response to illness [9] are targeted. NHS England pathfinder work conducted within existing Improving Access to Psychological Therapy (IAPT) services suggested that integrating LTC self-management needs alongside more traditional methods of treating anxiety and depression obtained larger treatment effects [22]. The *improving Distress in Dialysis* (iDiD) treatment is a tailored CBT protocol designed to manage psychological distress by providing patients with CBT skills which address the psychological mechanisms that perpetuate distress in response to haemodialysis specific symptom and self-management challenges [23]. However, access to skilled psychotherapists to support the implementation of CBT in physical health contexts is limited [24].

One method of increasing access to CBT is via tailored online self-help programmes. Therapist supported online CBT demonstrates equivalent efficacy to face-to-face CBT for the management of psychological distress [25]. In addition, online CBT has comparable adherence rates to psychotherapy treatment sessions when compared with face-to-face CBT [26]. Online CBT can be delivered using a stepped-care health service delivery model [27]. According to this model, individuals identified as having psychological distress are offered the least restrictive, yet most effective treatment first. The term least restrictive applies to the intensity of support provided. Thus type, duration, and frequency of patient-psychotherapist contact is titrated to individual need.

HD patients face a considerable treatment burden, thus offering online CBT as a first-line treatment is a pragmatic solution for resource limited patients and health services. Systematic reviews suggest that providing therapist support alongside online CBT improves outcomes, thus a degree of therapist input is likely required [28,29]. To inform a future full-scale randomised controlled trial (RCT), this feasibility study evaluated if HD specific online CBT (iDiD), with or without telephone therapist support, is a feasible and acceptable treatment for mild to moderate psychological distress in HD patients. This feasibility RCT addressed the below quantitative objectives to determine the appropriateness of the study design for a definitive RCT:

- i) Assess the feasibility and acceptability of online screening for symptoms of psychological distress in all patients attending for HD.
- ii) Explore trial recruitment and retention rates.
- iii) Explore adherence to online CBT sessions and therapist support calls (for the purpose of this feasibility study adherence is defined as engagement with scheduled psychotherapy treatments sessions and does not refer to adherence to dialysis or other treatment schedules).
- iv) Examine the potential efficacy of therapist supported online CBT in lowering symptoms of psychological distress and improving quality of life when compared with online CBT only. This will allow an estimate of the standard deviation of outcomes to inform a future

power calculation for a definitive trial.

- v) Study whether illness perceptions differ post-intervention between the supported and unsupported online CBT arms. This will allow an estimate of the standard deviation of illness perceptions to inform a future power calculation for a definitive trial.
- vi) Examine preliminary cost-effectiveness of therapist supported online CBT compared with online CBT only.

## 2. Subjects and methods

### 2.1. Study design and participants

This two-arm parallel group feasibility RCT was conducted at Guy's and St Thomas NHS Trust (GSTT; London, UK) HD units which treat approximately 600 HD patients. NHS ethical approval for this feasibility study was granted in December 2014 (reference: 14/LO/1934). Our full study protocol is published elsewhere [30]. Patients were recruited and individually randomised to therapist supported online CBT or online CBT only (no therapist support) between February 2015 and January 2016.

Patients were eligible for inclusion if they were  $\geq 18$  years old, received in-centre HD, and had co-morbid psychological distress, defined as mild to moderately severe symptoms of depression and/or anxiety. This included a score ranging from 5 to 19 on the Patient Health Questionnaire (PHQ-9) [31] and/or a score ranging from 5 to 14 on the Generalised Anxiety Disorder questionnaire (GAD-7) [32]. Patients needed to speak English well and have a basic understanding of the internet and email address to remain eligible. Patients were ineligible if they were receiving treatment for psychological distress (active psychotherapy or commenced pharmacotherapy within the last three months), had a severe mental health disorder (e.g. psychosis), or had current suicidal ideation.

Inclusion criteria were modified after three months of recruitment. Incident HD patients were found to have greater motivation to participate. Our original protocol ([ClinicalTrials.gov Identifier: NCT02352870](https://clinicaltrials.gov/ct2/show/study/NCT02352870))<sup>1</sup> had the following two exclusion criteria: i) dialysis vintage of  $\leq$  three months and ii) hospitalised one month prior to completing self-report screen. These criteria were removed to increase recruitment, which is acceptable given the nature of the study is to assess feasibility.

Potential patients completed online self-report psychological distress screens [31,32] whilst attending for HD. This occurred as part of the Integrating Mental and Physical healthcare: research, training, and services initiative (IMPARTS) [33]. Online screens were completed, either alone or with nurse/researcher, using iPads. The screening process asked potential patients for permission to contact them about study participation. Patients who: i) had mild-moderately severe psychological distress symptoms, ii) gave permission for research contact, and iii) met remaining inclusion criteria were approached for consent. If severe psychological distress was detected during screening, then the appropriate health care professional was informed. Fig. 1 details the stepped-care model with psychological distress thresholds applied in this study for onward referral.

### 2.2. Randomisation, allocation concealment, and blinding

Consenting patients were individually randomised after completing the online baseline questionnaire. Simple randomisation occurred via Lifeguide [34] which is a software used to program online interventions. An automated random number generator with a 1:1 ratio was

<sup>1</sup> Please note: Owing to a clerical error the study was originally registered as an interventional trial in [clinicaltrials.gov](https://clinicaltrials.gov). The correct option should have been to list this trial as 'other' to match the content of the registration document that fully indicates that the design of the study is a feasibility trial.

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