Protocol investigating the clinical outcomes and cost-effectiveness of cognitive–behavioural therapy delivered remotely for unscheduled care users with health anxiety: randomised controlled trial

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Background
Health anxiety and medically unexplained symptoms cost the National Health Service (NHS) an estimated £3 billion per year in unnecessary costs with little evidence of patient benefit. Effective treatment is rarely taken up due to issues such as stigma or previous negative experiences with mental health services. An approach to overcome this might be to offer remotely delivered psychological therapy, which can be just as effective as face-to-face therapy and may be more accessible and suitable.

Aims
To investigate the clinical outcomes and cost-effectiveness of remotely delivered cognitive–behavioural therapy (CBT) to people with high health anxiety repeatedly accessing unscheduled care (trial registration: NCT02298036).

Method
A multicentre randomised controlled trial (RCT) will be undertaken in primary and secondary care providers of unscheduled care across the East Midlands. One hundred and forty-four eligible participants will be equally randomised to receive either remote CBT (6–12 sessions) or treatment as usual (TAU). Two doctoral research studies will investigate the barriers and facilitators to delivering the intervention and the factors contributing to the optimisation of therapeutic outcome.

Results
This trial will be the first to test the clinical outcomes and cost-effectiveness of remotely delivered CBT for the treatment of high health anxiety.

Conclusions
The findings will enable an understanding as to how this intervention might fit into a wider care pathway to enhance patient experience of care.

Declaration of interest
None.

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Medically unexplained symptoms cost an estimated £3 billion per year of incremental unnecessary costs to the National Health Service (NHS) in England.[1] Much of this is consumed through in-patient admission, general practitioner (GP) consultations, prescriptions and unscheduled care use. Health anxiety often contributes to an increased use of services[2,3] because it results in increased reassurance seeking behaviour which in turn can maintain health anxiety.[4] Reducing costs of unscheduled emergency care, particularly admissions to acute hospitals, is part of the quality premium for each clinical commissioning group (CCG).[5]

In a recent meta-analysis of seven randomised controlled trials (RCTs) comparing cognitive–behavioural therapy (CBT) v. treatment as usual (TAU) with follow-up, CBT was effective on health anxiety and depression, and the results were robust to publication bias.[6] Most RCTs were conducted in psychological treatment or medical out-patient clinic settings. A recent large multicentre RCT found reductions in health anxiety that were maintained for at least 2 years.[7] Furthermore, the reduction in care use covered the cost of therapy provision, although the additional costs of screening for 28 000 people with health anxiety in medical clinics were not covered.[8]

The focus of Department of Health CCG policy and Improving Access to Psychological Therapies (IAPT) work is to prevent emergency care use through action in primary care[5,9] or failing that by preventing emergency hospital admissions through alternative service provision enacted through emergency care services.[5] Currently, there are no RCTs of the clinical or cost-effectiveness of CBT for health anxiety in patients seeking urgent treatment from primary or emergency care settings despite there being a high prevalence of health anxiety in these settings and health-anxious patients representing a significant proportion of emergency care users.[10] At present IAPT provides CBT for health anxiety but only 0.1–0.4% of patients seen by IAPT services in England have health anxiety[11,12] suggesting a low uptake of these services by patients and referrers. Recently completed work from the Collaboration for Leadership in Applied Health Research and Care Nottinghamshire, Derbyshire and Lincolnshire (CLAHRC-NDL) regular attenders' project provides an explanation. The project interviewed 15 participants with health anxiety or related problems, 33 GPs and other members of primary care staff and 3 CBT therapists. This work found that there was considerable stigma among these participants in relation to attending mental health services. The stigma was such that some GPs would not refer some patients.

When patients did go, they reported that mental health services were inflexible, made little attempt to engage them and were unable or unwilling to meet their needs (M. Stubley, personal communication, 2015).

Remotely delivered psychological therapy is a more accessible approach that has been used to address health anxiety effectively.[13,14] Increasingly, remote delivery of psychological treatment by telephone or the internet can be a successful way of engaging groups of patients with mental health problems where either anxiety or stigma among groups with physical and mental health problems prevents their attendance at IAPT or mental health services.[13–15] Potentially it is an efficient use of time and resources because neither the therapists nor the patients have to travel to appointments, it is easy to arrange at a mutually convenient time and even people living in remote areas can receive treatment. On the other hand, there are potentially a range of challenges with such an approach such as lack of access to or confidence with technology, reliability of connectivity, data protection and privacy.[15] A systematic review showed that for people with depression and anxiety, telephone-delivered or internet-delivered psychological treatment can be just as effective as face-to-face treatment, although some techniques require adaptation.[16] At present, remotely delivered therapy over the internet tends to be computer-led self-help therapy for volunteers with health anxiety with minimal therapist contact.[13] People who attend urgent care with health anxiety often do not understand that they may have health anxiety when they would meet diagnostic criteria for it so they are very unlikely to make use of computer-led self-help therapy. Therefore, there is a need to develop interventions that could be delivered to people who attend unscheduled care with health anxiety. The effectiveness of the treatment delivered through technology is thought to be dependent on the same factors that generally determine the outcome of psychological therapy, the quality of the therapeutic relationship between therapist and patient, competency and adherence to the therapeutic approach, pace and duration of treatment.[16–17] This highlights the significance of a strong therapeutic relationship. Video-conferencing software may be an approach that enables an experience closer to face to face than most computer-oriented therapy. As such, there is potential for closer therapeutic relationships and, possibly, better or more cost-effective outcomes.

The primary aim of the study was to test the clinical outcomes and cost-effectiveness of remotely delivered CBT to repeat users of unscheduled care services who have severe health anxiety. The findings will inform whether remotely delivered CBT is effective in reducing health anxiety and use of health services. Given that there is already evidence that the participants in the current study would usually be unwilling to attend face-to-face treatment, the design of choice is a comparison of remotely delivered CBT *v.* TAU rather than face-to-face delivered CBT. Thus the study consists of the following objectives:

1   To determine the clinical outcomes and cost-effectiveness of offering 6–12 sessions of remotely delivered CBT for health anxiety in repeated users of unscheduled primary or secondary care for physical symptoms without an underlying physical health cause who have high health anxiety *v.* TAU.
2   To explore the feasibility and usefulness of research on implementation processes by identifying the barriers and enablers to delivering such remote treatment and how such treatment might fit into a wider care pathway to enhance patient experience of care.

Method

Study design

The study is a two-arm parallel group, longitudinal, mixed methods, single-masked, multicentre RCT investigating the clinical outcomes and cost-effectiveness of remotely delivered CBT intervention *v.* TAU. Participants randomised to the trial will be allocated to one of two arms:

1   In the remote CBT intervention arm participants will receive 6–12 sessions of CBT delivered remotely; this will be via video calling or over the telephone in addition to the usual care they receive.
2   In the TAU arm participants will continue to consult with their GP and other health providers they would normally approach.

Participants in both arms will be followed up 3, 6, 9 and 12 months after the baseline assessment.
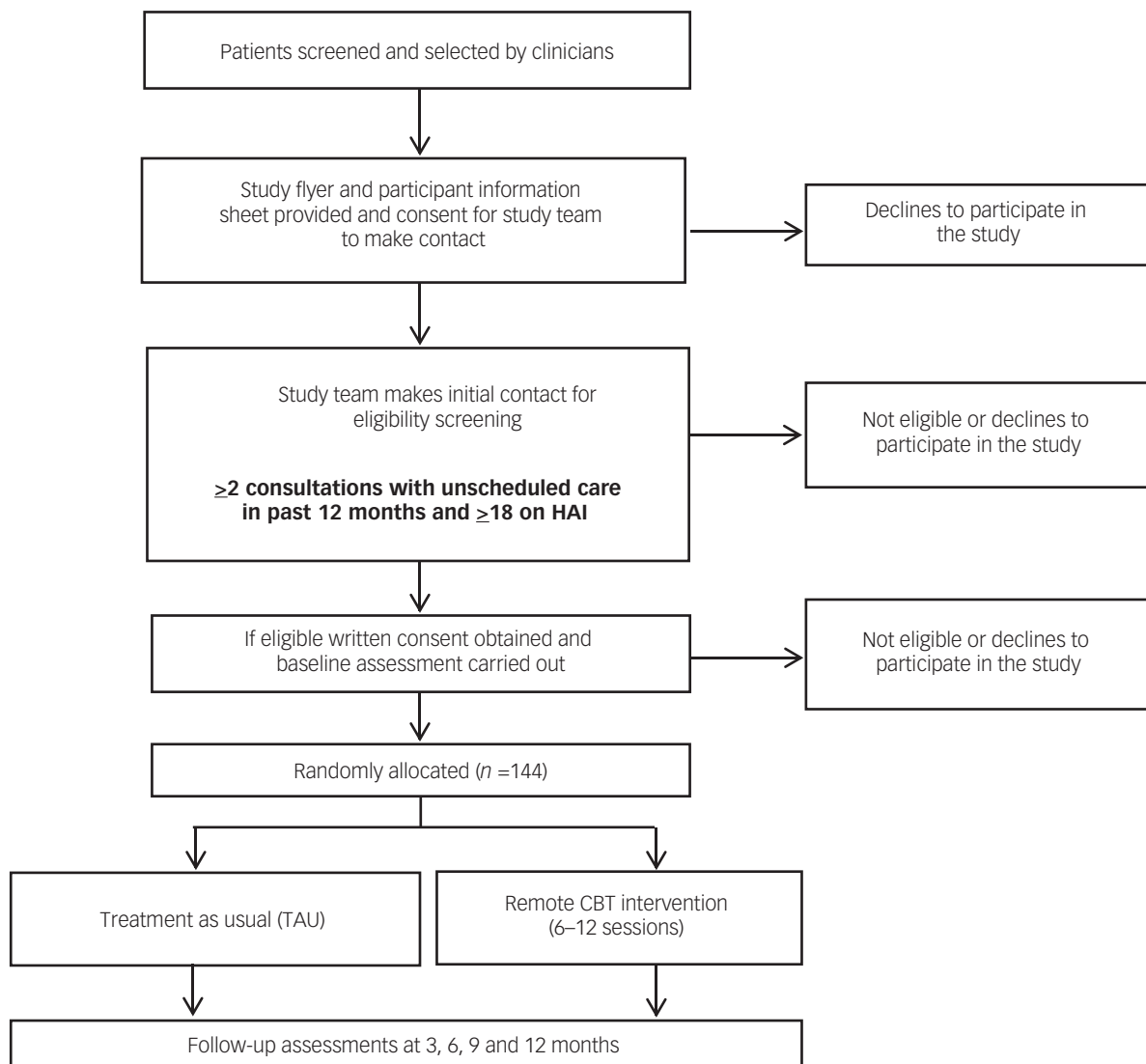
Participants

The study will be a multicentre study undertaken in primary and secondary care centres across five regions in the East Midlands: Nottinghamshire, Leicestershire, Derbyshire, Northamptonshire and Lincolnshire. Participants will be recruited from unscheduled primary and secondary care services in each centre. This will include emergency departments and GP practices where same-day urgent appointments are offered. This may also extend to recruiting from walk-in centres, out-of-hours services and out-patient clinics. Participants will be selected based on the criteria below.

Inclusion criteria

- Two or more consultations, referrals or hospital admissions with any provider of unscheduled care (including urgent same-day appointments at their general practice) in the past 12 months for symptoms such as cardiac, respiratory, neurological, gastrointestinal or genitourinary problems not attributed to identified pathology.
- A score of 18 or above on the Health Anxiety Inventory (HAI).[18] This is the clinical cut off for severe health anxiety.
- Aged 18 years and over.
- Sufficient understanding of English (spoken and written) to enable full engagement in the intervention.
- Able and willing to give oral and written informed consent to participate in the study (Fig.1).

Exclusion criteria

- Presence of a pathological medical condition requiring further assessment or acute management. This criterion aims to prevent obstruction of medical treatment through the addition of psychological therapy, where the cause of symptoms or outcome of investigations remains unclear. However, those with a diagnosed ongoing chronic medical condition would not be excluded.
- Pregnancy.
- Severe mental illness such as schizophrenia, bipolar disorder, severe major depressive episode or eating disorder.
- At immediate risk of harm to themselves or other people through their mental state.
- A diagnosis of organic mental disorder such as dementia, delirium, substance use disorder or organic mood disorder.
- Receiving specialist mental health intervention or have done within the past 6 months. This will enable a clearer indication

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│        Patients screened and selected by clinicians │
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┌──────────────────────────────────────┐       ┌────────────────────────┐
│   Study flyer and participant information │──────▶│  Declines to participate in │
│   sheet provided and consent for study team │      │        the study         │
│          to make contact                │       └────────────────────────┘
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│   Study team makes initial contact for    │──────▶│  Not eligible or declines to │
│        eligibility screening              │      │  participate in the study │
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│   >2 consultations with unscheduled care  │
│     in past 12 months and >18 on HAI      │
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│   If eligible written consent obtained and │──────▶│  Not eligible or declines to │
│     baseline assessment carried out       │      │  participate in the study │
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│         Randomly allocated (n =144)       │
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│ Treatment as usual (TAU) │  │  Remote CBT intervention │
│                     │  │    (6–12 sessions)      │
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│  Follow-up assessments at 3, 6, 9 and 12 months │
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Fig. 1 Study flow chart comparing remotely delivered cognitive–behavioural therapy (CBT) *v.* treatment as usual (TAU) for high utilisers of healthcare with high health anxiety. HAI, Health Anxiety Inventory.

of the intervention's impact on functioning over and above other treatments.

- Significant intellectual disability that is moderate to severe or to the extent that engagement in the intervention is not possible.

Referring clinicians will approach patients meeting eligibility criteria, and seek consent to be contacted by the study researchers. Potential participants who provide written or verbal consent to be contacted by the research team will then be telephoned by a researcher. Information will be provided about the study and consent to carry out eligibility screening will be sought. If the potential participant wishes to continue, an eligibility screening will be carried out. A person will be deemed eligible if they have had two or more consultations with any provider of unscheduled services in the past 12 months and a score of 18 or more on the HAI. If eligible, the researcher will then arrange an assessment interview with the potential participant. At the interview, oral and written consent will be sought and the baseline assessment conducted. A brief explanation of health anxiety and its impact on psychological and physical health will be given to participants following screening. More detailed explanation is given to those in the treatment arm or if

specifically requested by any participant. Individuals will be participating in the study for 12 months from the date of randomisation. For the implementation analysis, participants will be interviewed separately within 18 months of their randomisation. Staff participation will end with completion of a qualitative interview.

Randomisation

Following eligibility screening and baseline assessment the researcher will enter the participant's details onto a web-based randomisation system. The arm to which a participant is assigned will be determined by a computer-generated pseudo random code using random permuted blocks of varying size, created by the Nottingham Clinical Trials Unit (CTU) in accordance with their standard operating procedure and held on a secure server. Participants will be allocated with equal probability to each treatment arm with stratification by region. Only the trials manager, or their nominee, will have password access to the unmasked randomisation data. The researchers responsible for collecting the baseline and outcome data will remain masked to randomisation

until data collection has been completed. Participants themselves and the CBT practitioners will not be masked to treatment group. Investigators may identify the treatment of participants through password-protected access; however, this will only be done at the end of the trial or in the event of a medical emergency or serious adverse event. Participants may also accidentally reveal to the researcher when obtaining outcome data that they have been receiving the remote CBT intervention. If this occurs then any case of un-masking will be reported and a written account of the reason for un-masking will also be made. Following data collection an analysis will be completed to determine if incidences of un-masking were equal in the two treatment groups.

Recruitment of staff

Health professionals and managers of services from different service settings and localities who are involved in the study will be approached by a doctoral researcher and asked whether they wish to participate in a qualitative interview.

Interventions

Following baseline assessment and confirmation of eligibility, participants will be randomly allocated to one of two treatment arms: (1) remote CBT intervention (in addition to usual treatment) or (2) TAU only.

Remotely delivered CBT intervention

Participants allocated to the remote CBT intervention will be provided with a detailed information sheet about the remote CBT intervention and contacted by a CBT practitioner within 10 days of randomisation. A team of experienced CBT practitioners will deliver CBT for health anxiety remotely using a treatment manual developed from the CHAMP study.[7] Clinical supervision will be facilitated by the lead therapist from the CHAMP study (H.T.) trained and experienced in the engagement of high service utilisers and delivery of CBT for health anxiety. The Revised Cognitive Therapy Scale (CTS-R)[19] will be used to assess therapist competence and treatment integrity. It will also be used to maintain the standard of therapy provided, as assessment results will inform supervision. Two randomly selected sessions will be assessed for each therapist by the supervisor (H.T.) and feedback given for areas of strength and areas for development. Six to twelve sessions will be offered, with the addition of follow-up sessions if required. The number of sessions will be dependent on the pace of engagement with the participant and in line with patient need. The intervention will address the symptoms of health anxiety from a cognitive–behavioural perspective. This will include undoing patterns of thought and behaviour that maintain health anxiety. For example, safety-seeking behaviours such as reassurance-seeking or phobic avoidance aim to reduce worry, but can often fuel health anxiety.

The CBT intervention will be delivered remotely via video-calling or over the telephone depending on the participant's preference. Participants may also receive text message/email reminders of CBT sessions. The system used for video-calling was deemed to offer a secure connection and user-friendly interface following a pilot review of available services. A contingency management plan has been put in place to address all potential failures in the technology. Permission will be sought to audio/video record treatment sessions. These will be made available to all participants as a means of consolidating learning from each session. They will also be used for assessments of therapeutic quality and reflection in clinical supervision meetings. Supervisory records will also help establish any adjustments required for effective remote delivery of therapy.

Participants will be free to continue to consult clinicians and other healthcare providers other than the CBT therapist throughout the intervention and after treatment completion. A discharge plan will be developed before treatment completion. A summary of the discharge plan will be distributed to the participant, their GP and any other relevant healthcare providers with the participant's consent. Outcome data will continue to be collected after the CBT sessions are completed until the end of the follow-up period.

TAU

Usual treatment will constitute a care plan decided by the patient and any healthcare providers involved in their care, including their GP. TAU will be unconstrained other than it will not be provided by the treatment intervention therapists.

Measures

Primary outcome

The primary clinical outcome will be longitudinal change on the short form 14-item HAI from baseline to 6 months.[18]

Secondary outcomes

Secondary outcomes will be any change in the following measures from baseline to 12 months:

- Short form 14-item HAI.[18]
- 7-item Generalised Anxiety Disorder (GAD)[20] for anxiety.
- 15-item Patient Health Questionnaire (PHQ-15)[21] for somatic distress.
- 9-item Patient Health Questionnaire (PHQ-9)[22] for depression.
- 8-item Work and Social Adjustment Scale (WSAS)[23] for social function.
- 5-item quality of life on the EQ5D-5L.[24]
- 36-item Short Form Health Survey (SF-36).[25]
- Change in the number of contacts with unscheduled or emergency care established through an adapted and stylised Client Service Receipt Inventory (CSRI).[26]

Other measures

At the baseline assessment only, the participant will also be interviewed using the research version of the Structured Clinical Interview for DSM-5 (SCID-5).[27] This will determine if people have mental disorders that exclude participation in the study and record the absence or presence of somatisation disorders, depressive disorders and anxiety disorders.

To elicit the participant's views of treatment, a modified version of a self-rated 5-item scale will be given at completion of treatment,[28] along with some semi-structured questions about the remote CBT to evaluate treatment satisfaction. The questionnaire will be posted out to all participants who receive any CBT sessions including those who complete the treatment and those who terminate treatment before completion. The questionnaire will be sent out by the project administrative support officer who will not be masked to treatment allocation.

All baseline assessments will be carried out face to face or over the telephone (if requested by the participant) by the study researchers. All the measures have established reliability, validity and history of use in clinical NHS settings. Follow-up assessments will be carried out over the telephone, email, via video-calling or by post at all time points depending on the participant's preference. A copy of the baseline assessments and follow-up questionnaires can be provided by contacting the corresponding author.

Outcomes collated by CBT practitioners

The CBT practitioners will collate brief measures of outcome, patient experience and therapist experience at each session of therapy:

- Short Form HAI[18]
- Outcome Rating Scale (ORS)[29]
- Session Rating Scale (SRS)[30]
- Working Alliance Inventory-Short Revised (WAI-SR).[31]

CBT practitioners will collate and have access to data collated from patients allocated to the remote CBT arm.

Statistical analysis

The analysis will be conducted on an intention-to-treat basis. Exploratory analysis for both primary and secondary outcomes will be conducted first. Given that the primary outcome variable will be repeatedly measured, multilevel modelling will be performed to quantify the treatment effects with patient as a level 2 unit. The time, treatment status and treatment × time interactions and baseline measurements will be included as covariate. Secondary outcomes will be analysed in a similar way. Any skewed outcome variables will be transformed for multilevel modelling. The analysis will thus broadly follow the same approach as the CHAMP study.[7]

Missing values in all outcomes will be checked and reported across treatment group and follow-up time. As the outcome will be repeatedly measured, a two-level logistic regression with patients as level 2 unit will be performed to test the influence of treatment status and baseline measures on outcome missingness. The missing value patterns and the results from multilevel logistic regression modelling will be used to inform missing value imputation under missing at random (MAR) assumption. Because multilevel modelling will be used to test treatment effects for all outcome variables that will be repeatedly measured, missing values could be automatically taken into account under MAR assumption to give sensible results. Nevertheless, as sensitivity analysis of the result robustness to missing value, the missing values will be imputed using multilevel modelling[32] and the results based on imputed data will be presented additionally. STATA 14 and REALCOM-IMPUTE software will be used to impute missing values by means of the Markov chain Monte Carlo (MCMC) approach for multilevel data.

Previously identified mediators and moderators of face-to-face delivered CBT will be examined including the presence or absence of depression, other comorbid mental and physical disorders, gender and severity of health anxiety at baseline.[6] In addition we will examine factors considered to affect utilisation and confidence in the use of internet technology such as age and socioeconomic deprivation.

Sample size and calculation

Based on the CHAMP study results, which showed that the mean HAI score for CBT and TAU groups were 24.9 (s.d.=4.2) and 25.1 (s.d.=4.5) respectively at baseline and 17.7 (s.d.=8.0) and 22.6 (s.d.=6.8) respectively at 6 months, 114 participants are required to detect such a difference in HAI score at 6 months for a 90% power at two-tailed significance at 0.05 level, assuming equal s.d. (8.0) for both groups and null correlation between baseline and follow-up measures for the purpose of being conservative. After taking into account a 20% loss to follow-up rate, a sample size of 144 is required. Stata 13 was used to perform the power analysis.

To achieve this target sample size several strategies will be implemented. These include the option of providing various locations for the completion of the baseline assessments including NHS sites, university sites and the participant's home. Participants will also be given various options for completing outcome measures; this will include returning questionnaires by post, email, telephone and video-calling.

Data monitoring

The trial will be overseen by an independent CLAHRC scientific committee. The chief investigator has overall responsibility for the study and shall oversee all study management.

Data on the impact of the intervention on reduction in health anxiety and other outcome measures will not be analysed until the end of the study period and therefore will not inform decisions to stop the research. However, serious adverse events will be reviewed and if there is any indication that these are linked to the intervention consideration will be given to stopping on the advice of the scientific committee.

Health economics

The study will be conducted from a health service and societal perspective. It will measure patient outcome using the EQ5D-5L and clinical outcomes where appropriate. This will enable the study results to be reported in terms of cost utility and cost-effectiveness. Detailed resource costing will be undertaken from a health service, patient and societal perspective. Cost utility and cost-effectiveness will compare remotely delivered CBT v. TAU. A detailed resource profile will be established for the intervention v. TAU. The resource profile will include capital cost, for example the technology and staff, time to deliver the intervention and patient costs in each arm; this will further include effects on employment and absence from work because of the health anxiety and it will seek to apply an average wage rate based on type of employment. It will in addition record any opportunity cost in terms of time incurred by carers. This will enable a cost profile to be calculated for each arm of the trial. Patients with health anxiety are often high utilisers of healthcare services and hence resources. Economic data will be collected at the same time as the collection of self-rated questionnaires from an adapted CSRI.[26] The resource pro forma used in this study when having the CSRI at its origin has been totally modified and custom designed to address the needs, key issues and cost drivers in this study. The form used in this work builds on the original CSRI and using a similar pro forma successfully employed in a study on mood disorder.[33] Economic interviews will be conducted at baseline, 3, 6, 9 and 12 months, as the costs measured will all be accrued in a 12-month period, discounting of costs and benefits would be unnecessary. An incremental cost-effectiveness ratio (ICER) and cost-effectiveness acceptability curves (CEAC) will be produced for the remote intervention v. TAU including the joint uncertainty in differential costs and effects from the cost-effectiveness plane. The use of both the ICER and the CEAC enables useful information to be presented to the decision-maker in terms of the uncertainty of the intervention. The ICER provides a ratio measure of incremental costs and effects of the intervention over TAU, whereas the CEAC charts the probability that the intervention will be considered cost-effective at different thresholds of cost-effectiveness.

Implementation analysis

The implementation analysis will provide important information on barriers and enablers to the delivery and implementation of the intervention. It will provide specific information about the challenges likely to be faced if the intervention is to be put into wider practice, as well as devise specific solutions to meet these challenges. To carry out the implementation analysis we will utilise an organisational learning approach and develop a network of practice, consisting of service users, the research team, GPs

interested or involved in the study, therapists and other practitioners involved in unscheduled care or psychological therapy from participating NHS trusts.[34]

The analysis will be primarily qualitative with referrers and non-referrers to the study and completers and non-completers of treatment. A small number of additional interviews with commissioners who might purchase the intervention as a service and ecological data collected from observation and minutes from network of practice meetings will be thematically analysed.[35] Quantitative data will be utilised to inform the analysis by potentially highlighting issues such as rates of recruitment and attendance at treatment sessions that may inform the analysis of barriers and drivers to the intervention. Data on these barriers and drivers will be fed back at the network of practice meetings so that they are addressed allowing the process of organisational learning to optimise the intervention during the course of the study without compromising or altering those parts of the study outlined in the protocol that are fixed.

Results

The study has been given research ethics committee approval by the London Riverside Ethics Committee. We currently have obtained site approvals for Nottingham City and Nottingham County CCG's, Nottingham University Hospitals, Nottinghamshire Healthcare NHS Foundation Trust, Nene and Corby CCG's and Northamptonshire Healthcare NHS Foundation Trust and have commenced recruitment. We may recruit from other sites outside of the East Midlands to meet recruitment targets.

Discussion

The study is funded by the National Institute of Health Research (NIHR) Collaboration Leadership in Applied Health Research and Care (CLAHRC) East Midlands and matched funding from NHS Partners. The funding allows a unique opportunity to be able to carry out an RCT to test the clinical outcomes and cost-effectiveness of remotely delivered CBT for repeated users of unscheduled care. There are no previous trials which have incorporated the use of video conferencing CBT for the treatment of health anxiety. CLAHRC East Midlands identified that reduction in primary and secondary unscheduled care use was an NHS priority. The CHAMP study provided evidence that CBT for health anxiety was effective for at least 2 years,[7] but the screening of patients they employed was impractical. However, patients with health anxiety do not use readily available conventional face-to-face CBT services for health anxiety but in other research have engaged with remotely delivered CBT.[13–14]

Through previous work with people who have medically unexplained symptoms in primary care and with persistent frequent attenders in primary care[36] the research team recognised that with careful use of language for both patients and clinicians it may be possible to find an acceptable form of words to recruit high utilisers of urgent care with high health anxiety. The research team constructed a network of practice from the outset of the study including a number of service users and members of the public with and without health anxiety and a variety of clinicians from the East Midlands and nationally who refer or manage people with health anxiety either face to face or remotely. Through an iterative process of using expertise by experience, we have found ways of describing the study in a way that has enabled us to recruit both referrers and patients into the study.

A CLAHRC study such as this must evaluate interventions as they would be delivered in clinical practice if they were to be adopted as part of routine care. As a result the design of the study examines clinical outcomes and cost-effectiveness compared with any routine care offered rather than efficacy of the intervention by utilising a control for attentional effects of a therapist or one that prevents the control group receiving any intervention that the health service wishes to offer. However, should remotely delivered CBT be effective compared with TAU, a non-inferiority RCT comparing it with face-to-face delivered CBT in those people with health anxiety willing to receive either approach may be warranted to determine the relative merits of both approaches. The outcome measures were selected to include those that IAPT services would routinely employ for patients with health anxiety as well as those examining cost-effectiveness and for the completion of the doctoral research. Thus the estimates of the clinical outcomes and cost-effectiveness as well as the implementation analysis will provide a direct estimate of the overall benefits and drawbacks of the approach should it be delivered routinely, allow a comparison with the outcomes of people with health anxiety who do receive routine IAPT treatment as well as provide data on challenges that remain to be addressed. The approach also requires proficiency in English and may need to be adapted for non-English speakers. A pragmatic RCT would have as few exclusion criteria as possible, yet the study excludes people with serious mental illness, eating disorder and substance use disorders; all of the above require a different clinical approach to the treatments being tested in the study. Unipolar, mild-to-moderate depressive episodes, other anxiety disorders or stable physical illnesses are not exclusions to the study as they are readily addressed by the intervention and are necessary to include if the study is pragmatic enough for use in clinical practice.

The study is multicentre but medium sized. A larger sample recruited from areas outside the East Midlands might increase the precision of our estimates of the effectiveness of the intervention *v.* TAU and the generalisability of the findings, but there are finite resources restricting the size of the study but not necessarily recruitment from outside the East Midlands. Thus the study has been adopted by the Clinical Research Network, and there are ongoing discussions with some more geographically distant sites in England; such recruitment will help the study to achieve its recruitment targets and increase the generalisability of its findings to routine healthcare across England.

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