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A pilot study of cognitive analytic therapy (CAT) in stressed pregnant women with underlying anxiety and depression

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Registration date 28/09/2007	**Overall study status** Completed	
Last Edited 29/06/2016	**Condition category** Mental and Behavioural Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0071183793

Study information

Scientific Title
A pilot study of cognitive analytic therapy (CAT) in stressed pregnant women with underlying anxiety and depression

Study objectives
It is hypothesised primarily that treatment with CAT for a group of pregnant women with stressful anxiety, either alone or in conjunction with, depressive disorders will:
1. Result in a reduction of psychological distress and disability as measured by standard psychometric instruments and also
2. In a biological marker of stress as measured by salivary cortisol levels when compared to an untreated control group with similar disorders

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Pragmatic randomised controlled pilot study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Mental and Behavioural Disorders: Depression

Interventions
We propose to conduct an essentially pragmatic, randomised, controlled pilot aiming to evaluate the treatment effects of a brief (16-session) treatment with CAT in addition to treatment as usual in two maternal mental health outpatient settings (Sheffield Care Trust and St Thomas Hospital, London). This intervention would be compared to treatment as usual provided by primary care (e.g. GPs, midwives, health visitors) and secondary mental health services (e.g. community mental health teams, peri-natal psychiatric services).

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The principal screening and outcome measure will be the Spielberger State/Trait Anxiety Measure which has been used in previous studies in this patient group as indicator of stress (Glover 2002).

Secondary outcome measures
Secondary standard outcome measures will include the Edinburgh Post Natal Depression Questionnaire (EPDS - a measure specifically validated for use in pregnancy as well as post-partum), the CORE brief routine outcome battery (an increasingly widely used general baseline indicator of subjective well being, risk of self harm, symptoms and functioning (Barkham et al 1998)) and the SF 36 short form of the Duke social support questionnaire. The latter will also be used in the economic evaluation. Use of self-report measures will minimise interviewer bias. In addition, sequential salivary cortisol levels will be used as secondary biological outcome measure. These will be sampled at the time points described above. They will be collected by obtaining samples of saliva 4 times per day (waking, after 30 minutes, after 3 hours, after 12 hours), on 2 days running in order to minimise day to day and diurnal variation. These samples will be collected on Salivette dental rolls, stored in a fridge and posted on to the laboratory (VG) at Imperial College. It is well established that cortisol is stable under such conditions.

Data on the prevalence of mother-infant interaction difficulties using a 5 minute video recording of mother-infant interaction (Murray et al 1996) will also be collected as well as any reductions observed in such difficulties in the treatment group. This will generate data on their prevalence initially and also enable future more extended studies to be planned if indicated. Similarly data will be collected on the incidence of subsequent post-natal psychiatric morbidity in these patient groups along with any change observed in the treatment group. This would similarly inform for further extended study of interventions aimed at reducing such morbidity.

Overall study start date
01/07/2006

Completion date
30/06/2009

Eligibility

Key inclusion criteria
Patients between 18 and 65 being referred from adult health services to perinatal psychiatric services (e.g. by midwives, obstetricians, GPs or mental health professionals) who appear at clinical diagnostic interview to be suffering from stress in the context of underlying anxiety, with or without associated depressive disorders will be offered entry into the trial at initial assessment.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Female

Target number of participants
76 patients: 38 in both the TAU group and in the TAU plus CAT group

Key exclusion criteria
1. Serious active substance abuse
2. Active psychotic symptoms
3. Age under 18 years old

Date of first enrolment
01/07/2006

Date of final enrolment
30/06/2009

Locations

Countries of recruitment
United Kingdom

Study participating centre
Adult Mental Health/ Psychotherapy
Sheffield
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Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details
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Sponsor type
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Funder(s)

Funder type
Government

Funder Name
Sheffield Health and Social Research Consortium

Funder Name
NHS R&D Support Funding

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration