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Tavistock Adult Depression Study: Comparing the effectiveness of usual GP care with once weekly psychoanalytic psychotherapy for people suffering from chronic, treatment-resistant depression

Submission date
18/11/2011

Recruitment status
No longer recruiting

Registration date
11/01/2012

Overall study status
Completed

Last Edited
02/10/2017

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and Study Aims
Most depressions get better on their own or with some help from a counselling, a form of talking treatment called cognitive behavioural therapy or anti-depressant tablets. But chronic or so-called treatment-resistant depression (TRD), can be more difficult to help. Many people suffer from it all around the world. Its symptoms include feeling very low or without energy over many years. It is difficult to feel pleasure, enjoyment or satisfaction. Sleep may be poor. There may be chronic feelings of worry and stress. Sometimes there are attacks of panic or of anger that feel out of place. You may also worry about your health and feel aches and pains for which no physical cause can be found. There may be personal difficulties in your close relationships, and unhappiness when you were growing up. Unfortunately, with this kind of depression the treatments we have now often cannot help that much.

We are trying to find out whether a talking treatment called psychoanalytic psychotherapy can help this kind of depression. We also want to find out about the kind of treatments that are being used at the moment, and how much they help. As well, we want to understand more about the illness, about its causes and why it lasts for such a long time.

Who Can Take Part?
Men and women, between 18 and 65 years old, who have been depressed for more than two years. To be eligible it is necessary to have received antidepressant treatment or cognitive therapy at least twice without real improvement.

What Does The Study Involve?
We are comparing sixty sessions of weekly individual psychoanalytic psychotherapy (PP) with treatment as it is normally offered. This is known as treatment as usual (TAU). Half of those in the research are offered the psychoanalytic treatment. It is possible to continue to receive

treatment with anti-depressants if you wish. If you are in the treatment as usual group you receive any treatment recommended by your GP. We ask consent to review your GP medical records. Any personal information in the trial is confidential.

The trial uses questionnaires and interviews to assess the benefits of the treatment. These cover diagnostic issues, your symptoms, personal functioning and quality of life. At first, there is an initial assessment which involves three interviews. A member of the research team will then meet with you every three months for the year and a half in which you will be attending for psychotherapy sessions or in the treatment as usual group. Over the next two years we ask to see you on three more occasions. The total time in which you will be involved in the trial is three and a half years.

What are the possible benefits and risks of participating?

Psychoanalytic psychotherapy involves speaking about the very personal kind of issues that can underlie depression. This can bring relief from the distressing symptoms of depression. It can help people feel more comfortable with some of the big issues in life. This may reduce the likelihood of becoming depressed again in the future especially when there are difficult or painful experiences such as job loss, relationship break-up, bereavement or physical illness.

The therapy can be emotionally painful. Some people find that the prospect of looking at what they feel inside frightening. Others worry about becoming too attached to the therapist or not feeling understood by them. Being open about these worries can usually help. The end of the weekly therapy sessions can be a difficult time because feelings of loss become more intense. This is an expected part of the treatment. We will always try to find ways of helping you come through these feelings.

This kind therapy may not be advisable for some people. In this case we will tell you about other treatments which are more likely to be of help to you.

There are no physical risks to participants in the study. But people with chronic depression often feel suicidal. Unfortunately some may act upon this. We carefully monitor the safety of everyone taking part in the research. The Senior Research Clinician and the Researchs Clinical Director hold a responsibility for patient safety. Whenever we identify a high risk of suicide we seek to arrange the help needed to reduce this.

If you happen to be allocated to receive treatment as usual, we ask you not to have psychoanalytic treatments while you are in the Study. However, when your period in the research comes to an end if you want the psychoanalytic therapy we will help you get it. While the regular research appointments take time, they also provide valuable support.

Where is the study run from?
All the people taking part in the Study come to the Tavistock Clinic. This is at 120 Belsize Lane, London, NW3 5BA which is near Swiss Cottage in North-West London. Those receiving psychoanalytic psychotherapy come for weekly sessions which are at the same time each week apart from breaks for holidays. Each persons therapist is the same throughout the sessions. All are qualified and experienced psychoanalytic psychotherapists.

When is the study starting and how long is it expected to run for?
The Study began in 2002 and it will end in 2014. The recruitment of new participants stopped in 2010.

Who is funding the study?
The study is funded by The Tavistock Clinic Charitable Foundation and by the Tavistock & Portman NHS Foundation Mental Health Trust. We have received three small grants from the International Psychoanalytic Association.
Who is the main contact?
Ms Felicitas Rost, TADS Project Coordinator, Psychotherapy Evaluation Research Unit, The Tavistock and Portman NHS Foundation Trust,
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Study website
http://www.tavistockandportman.nhs.uk/adultdepressionstudy

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Randomised Controlled Trial comparing the effectiveness of usual GP care with once weekly psychoanalytic psychotherapy in cases of refractory depression

Acronym

TADS

Study objectives
The condition under study is chronic, treatment-resistant depression, which represents a significant mental health problem worldwide. Approximately 12% of depressed patients experience these long-term, relapsing and complex forms of depression with significant impact on their work functioning, interpersonal relationships and quality of life. Until recently, there has been a shortage of research to guide the clinical management of these patients. There is a considerable lack of effective evidence-based treatment available to date.

Patients treated with once weekly, individual psychoanalytic psychotherapy will show improvements relative to baseline on the measures chosen. They will show greater benefits than patients who are treated with usual GP care (the TAU group).

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands Research Ethics Committee approved on 28th May 2002, reference number: MREC/0/7/35

Study design
Intention-to-treat pragmatic single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Patient information material can be found at http://www.tavistockandportman.nhs.uk/sites/default/files//Information for patients interested in taking part.pdf

Health condition(s) or problem(s) studied
Treatment-resistant depression

Interventions
Intervention group: individual psychoanalytic psychotherapy for depression (PPD), carried out once weekly for 18 months by senior clinicians from the Tavistock Clinic, adult department.

Control group: Treatment-as-usual as provided and managed by the referring primary care practitioner.

Total duration of treatment or review period is 18 months. Follow-up period is 2 years.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Change in depression severity as indicated by the independent, double-rated Hamilton Rating Scale of Depression (HRSD, Hamilton, 1967) at baseline, 3 months, 6 months, 9 months, 12 months, 15 months, 18 months, 6 months follow-up, 12 months follow-up and 24 months follow-up. It is a semi-structured interview consisting of 21 depression items, which yield a range of scores from 0 - 62.

Secondary outcome measures
1. Self-report depression severity: assessed using the Beck Depression Inventory (BDI II, Beck et al, 1996). It consists of 21 items, which yield a range of scores from 0 to 63. Each items is to be scored on a Likert-scale ranging from 0-3 (0 = depression symptom not present, 3 depression symptom severe). It is assessed at baseline, 3 months, 6 months, 9 months, 12 months, 15 months, 18 months,6 months follow-up, 12 months follow-up and 24 months follow-up
2. Axis I disorders: assessed using the Structured Clinical Interview for DSM IV, research version (SCID-I, First et al, 2001). This semi-structured clinical interview assesses subjects on all five axes of DSM IV diagnosis. The diagnoses assessed in the TADS trial are Major depressive disorder (MDD), dysthymia, alcohol abuse/dependency, drug abuse/dependency, anxiety disorders, obsessivecompulsive disorder (OCD), and eating disorders. It is assessed and blindly double-rated at baseline, 18 months, 6 months follow-up, 12 months follow-up and 24 months follow-up
3. Axis II personality disorders (PD): the Structured Clinical Interview for DSM IV Personality Disorders Questionnaire (SCID-II-PQ. First et al., 1997)) is used to identify patients with probable Axis II disorders. It is a self-report measure asking for a yes or no response to 104 questions. It is assessed and blindly double-rated at baseline, 18 months, 6 months follow-up, 12 months follow-up and 24 months follow-up
4. Personality functioning: the information yielded by the Tavistock Psychodynamic Interview (TPI) carried at baseline and six-months follow-up allows Axis-II pathology to be assessed with the Shedler-Westen Q-Sort, Shedler and Westen, 2004. The information also permits the assessment of personality pathology according to the revised criteria of the proposed DSM-V. Will be assessed and blindly double-rated at baseline and 6 months follow-up
5. Object relations: assessed using the Persons Relating to Others Questionnaire (PROQ2a, Birtchnell, 1999). It is a 48-item self-report questionnaire, which evaluates style of personal relating in terms of close (involving) vs. distant (seeking separation) and upper (relating from above downwards) vs. lower (relating from below upwards). The measure uses eight scales which are structured around these two axes. Participants are asked to tick against 48 statements whether there are "nearly always true", "quite often true", "sometimes true" or "rarely true". It is assessed at baseline, 3 months, 6 months, 9 months, 12 months, 15 months, 18 months, 6 months follow-up, 12 months follow-up and 24 months follow-up
6. Social functioning: the Global Assessment of Functioning scale (GAF, Hilsenroth et al., 2000) is used to assess psychological, social and occupational functioning positioned on a hypothetical, 0 to 100 continuum of mental health - illness. It also comprises Axis V of the DSM-IV. GAF scores are made on the basis of the aggregated total of information available on the subject. It is assessed by the researcher and double-rated at baseline, 18 months, 6 months follow-up, 12 months follow-up and 24 months follow-up
7. Subjective well-being: is assessed using the Clinical Outcomes in Routine Evaluation Outcome

Measure (CORE-OM, Evans et al., 2000). This 34-item self-report instrument assesses subjective well-being, symptoms, function, and risk. Participants are asked to rate whether 34 statements are "not at all true", "only occasionally true", "sometimes true", "often true" or "most or all of the time true". It is assessed at baseline, 3 months, 6 months, 9 months, 12 months, 15 months, 18 months, 6 months follow-up, 12 months follow-up and 24 months follow-up
8. Quality of life: is assessed using the Quality of Life Enjoyment and Satisfaction Questionnaire (Q-LES-Q, Endicott et al., 1993) . It is a self-report instrument consisting of 93 items grouped into eight quality of life areas - physical health, subjective feelings, work, household duties, school, leisure activities, social relationships, and general activities. Participant rate each item on a 5-point scale of enjoyment/satisfaction over the previous week (0 = not at all or never, 5 = frequently or all the time). Mean scores can be derived from the eight summary scales with a range from 0-100, with higher scores indicating better quality of life. It is assessed at baseline, 3 months, 6 months, 9 months, 12 months, 15 months, 18 months, 6 months follow-up, 12 months follow-up and 24 months follow-up
9. Number of depression-free days: at baseline, and at all subsequent review/ follow-up interviews, participants are asked to estimate the number of depression-free days experienced in the preceding month

Overall study start date
01/06/2002

Completion date
31/12/2004

Eligibility

Key inclusion criteria
1. Male and female primary care patients between 18 to 65 years of age
2. Major depressive disorder or dysthymia based on Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV) criteria and minimum symptom severity on the Beck Depression Inventory (BDI) of 21 or above and 14 or above on the Hamilton Rating Scale for Depression (HRSD)
3. Minimum of a two-year history of depression
4. Atleast two previous failed treatment attempts, one of which was with an anti-depressant
5. Able to speak conversational English and be seen at the Tavistock Clinic, London
6. Willing to enter a randomised controlled trial

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

129 participants across both arms

Key exclusion criteria
Primary care patients with:
1. Recent (previous five years) history of psychosis
2. Recent (previous five year) history of bi-polar disorder
3. Moderate or severe learning disabilities
4. Recent history (previous two years) of psychiatric input for, or diagnosis of, substance dependency (alcohol abuse more than 21 units/week; drug abuse more than 4/week)
5. Patients currently in psychological therapy
6. Patients who have received psychoanalytic psychotherapy in the previous two years

Date of first enrolment
01/06/2002

Date of final enrolment
31/12/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University College London
Psychoanalysis Unit
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Sponsor information

Organisation
The Tavistock Charitable Foundation (UK)

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Sponsor type
Charity

Website
http://opencharities.org/charities/1049530

Funder(s)

Funder type
Charity

Funder Name
Tavistock Charitable Foundation (UK)

Funder Name
Evaluation of Research Proposals and Results Subcommittee (CERP) of the International Psychoanalytic Association (IPA) (UK)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	11/06/2012		Yes	No
Results article	results	01/10/2015		Yes	No