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30-year follow-up of personality and clinical status of patients with anxiety and depression in the Nottingham Study of Neurotic Disorder

Submission date
18/06/2014

Recruitment status
No longer recruiting

Registration date
11/09/2014

Overall study status
Completed

Last Edited
03/01/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
The Nottingham study of neurotic disorder (NSND) was set up in 1983 to look at both the short and long term outcome of common anxiety and depressive disorders. In particular, it examined whether separately classifying individual neurotic disorders (for example into depression, bipolar affective disorder, social anxiety disorder) was actually helpful for either science or in treating sufferers of these conditions. Many patients were found to be have a mixed anxiety /depression disorder and could be considered to suffer from a general neurotic syndrome. The study investigated whether diagnosing a patient as suffering from a general neurotic disorder rather than making a conventional clinical diagnosis made any difference to predicting how the patient responded to treatment, or whether some modes of treatment (different treatments) were more successful than others. Data for the study has been collected on 9 further occasions since 1983, the last time being 12 years after the start of the trial. We are now repeating the assessments after 30 years as neurotic disorders can have some very long-term effects.

Who can participate?
Adults on no active treatment at the start of the study and diagnosed with generalized anxiety disorder, neurotic depression or panic disorder.

What does the study involve?
Participants are asked to attend a single follow up interview lasting about 85 minutes. The questions cover psychiatric diagnosis and symptoms, personality and social functioning, and service contacts. Written permission to access the patients' general practice medical notes is also requested at the beginning of the interview.

What are the possible benefits and risks of participating?
The patients have been followed up many times previously and have been seen by the same investigator, Dr Helen Tyrer, on the last occasion. Many look forward to the updated assessment and all of those approached at 12 years who gave consent to be seen at 30 years have been noted. At 12 years we had very positive views about the study and its progress. 4 patients who said they did not want to be followed up will not be seen at 30 years. We do not think there are

any particular risks of the study all data to be obtained have been asked about before. We will also be carrying out an interview to find out what major events have occurred over the past 30 years. This will include finding out how much each event has affected their mental health, and how it came about. This is part of a formal investigation into nidotherapy, the changing of the environment to better fit a person and their surroundings.

Where is the study run from?
Imperial College London (UK)

When is the study starting and how long is it expected to run for?
January 2014 to June 2017

Who is funding the study?
1. Department of Health Offender Health (UK)
2. Nicola Pigott Memorial Fund (UK)

Who is the main contact?
Professor Peter Tyrer
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Contact information

Type(s)
Scientific

Contact name
Prof Peter Tyrer

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Additional identifiers

Protocol serial number
16681

Study information

Scientific Title
30-year follow-up of personality and clinical status of patients with anxiety and depression in the Nottingham Study of Neurotic Disorder: an observational cohort study following a randomised trial

Acronym
Nott30

Study objectives
This is a long-term follow-up of patients recruited to a randomised controlled trial of cognitive behaviour therapy, drug therapy and self-help in 1988, and although this has now become a cohort study in the first two years of the trial the mode of therapy was kept the same as that randomised.

More details can be found here: http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=16681

Original trial can be found at: http://www.ncbi.nlm.nih.gov/pubmed/2899234

Ethics approval required
Old ethics approval format

Ethics approval(s)
12/EM/0331; First MREC approval date 21/11/2012

Study design
Randomised; Observational; Design type: Cohort study

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Mental Health; Subtopic: Anxiety, Depression; Disease: Depression, Anxiety

Interventions
In the original trial the patients were randomised to one of three drug treatments (diazepam, dothiepin and placebo), cognitive behaviour therapy or self-help, and most of the patients (70%) maintained this allocation for the first 2 years of this study.

1. Cognitive behaviour therapy: 3-6 sessions of treatment given by a trained nurse under supervision from an established therapist
2. Diazepam: matching tablets of diazepam (5-30 mg daily) with ascending dosage to preferred maximum over 6 weeks then reduction to zero by 10 weeks
3. Dothiepin, matching tablets of dothiepin (25-150 mg daily) with ascending dosage to preferred maximum over 6 weeks then reduction to zero by 10 weeks
4. Placebo: matching placebo medication
5. Self-help: relaxation tape and self-help instructions

Follow Up Length: 360 month(s); Study Entry : Registration only

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Comprehensive Psychopathological Rating Scale; Timepoint(s): baseline, 2, 4, 6, 10, 16, 32, 52, and 104 weeks, and follow-up at 5, 12 and 30 years

Key secondary outcome(s))
1. DSM diagnosis; Timepoint(s): baseline, 10, 16, 32, 52, and 104 weeks, and follow-up at 12 and 30 years
2. Hospital admission; Timepoint(s): baseline, 2, 4, 6, 10, 16, 32, 52, and 104 weeks, and follow-up at 5, 12 and 30 years
3. Hospital Anxiety and Depression Scale - Anxiety section; Timepoint(s): baseline, 2, 4, 6, 10, 16, 32, 52, and 104 weeks, and follow-up at 5, 12 and 30 years
4. Hospital Anxiety and Depression Scale - Depression Section; Timepoint(s): baseline, 2, 4, 6, 10, 16, 32, 52, and 104 weeks, and follow-up at 5, 12 and 30 years
5. Montgomery-Asberg Depression Rating Scale; Timepoint(s): baseline, 2, 4, 6, 10, 16, 32, 52, and 104 weeks, and follow-up at 5, 12 and 30 years
6. Neurotic Disorder Outcome Scale (NDOS); Timepoint(s): baseline, 5, 12 and 30 years
personality status; Timepoint(s): baseline, 2 years, 12 and 30 years
7. Social Functioning Questionnaire; Timepoint(s): 12 and 30 years
8. Suicidal behaviour; Timepoint(s): baseline, 2, 4, 6, 10, 16, 32, 52, and 104 weeks, and follow-up at 5, 12 and 30 years

Completion date
30/06/2019

Eligibility

Key inclusion criteria
1. On no active treatment at baseline
2. Satisfies diagnostic criteria for GAD, dysthymia or panic disorder
3. Target Gender: Male & Female

The participants to the original trial (Tyrer et al, 1988) were:
1. Aged between 18 and 65
2. Seen in general practice psychiatric clinics
3. Following the diagnostic criteria of the then new American diagnostic classification (DSM-III)) had a diagnosis of dysthymia (formerly neurotic depression), generalised anxiety disorder or panic disorder
4. Were not on any form of therapy for mental disorder at the time of randomisation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

Total final enrolment
210

Key exclusion criteria
Lack of informed consent

Date of first enrolment
01/01/2014

Date of final enrolment
30/06/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department of Psychological Medicine
London
United Kingdom
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Sponsor information

Organisation
Imperial College London (UK)

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Government

Funder Name
Department of Health Offender Health (UK)

Funder Name
Nicola Pigott Memorial Fund (UK)

Results and Publications

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?
Results article	30-year follow up	12/04/2021	18/05/2021	Yes	No
Results article		01/05/2022	03/01/2024	Yes	No
Results article		01/03/2022	03/01/2024	Yes	No
Results article		01/05/2022	03/01/2024	Yes	No
Results article		01/05/2022	03/01/2024	Yes	No
Results article		01/07/2023	03/01/2024	Yes	No
Other publications	mortality paper	01/02/2021	06/12/2019	Yes	No
Other publications	secondary analysis	01/05/2021	19/05/2021	Yes	No