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Quality of Life following Adherence Therapy for People Disabled by Schizophrenia and their Carers

Submission date
19/05/2003

Recruitment status
No longer recruiting

Registration date
19/05/2003

Overall study status
Completed

Last Edited
11/07/2014

Condition category
Mental and Behavioural Disorders

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

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
EU Contract: QLG4-CT-2001-01734.

Study information

Scientific Title

Acronym
QUATRO

Study objectives
Adherence therapy will improve quality of life for patients, be cost effective, and reduce carer burden.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Schizophrenia

Interventions
Patients will receive 8 sessions of either adherence therapy or health education delivered by a trained therapist in each of the five sites. Fidelity will be maintained by group and individual supervision and monitored by examination of transcripts and recordings of interventions.

Adherence therapy
Adherence therapy is a pragmatic structured intervention drawing on the work of Kemp et al

(1996; 1998) and Gray (2001). It has an emphasis on patients' personal choice and responsibility. Initially the therapist will undertake an assessment of the patient's views of their medication. The therapist and patient will then develop an individually tailored plan of therapeutic activities that they will then undertake. The intervention will conclude with a reassessment of the patients' view of medication. The intervention is manualised.

Health education
Health education draws on the work on medication education of Macpherson et al (1996) and represents best current practice. Trials are consistent in demonstrating that medication education is largely inert in terms of its effect on compliance. The control intervention is a structured intervention with the aim of increasing patients understanding of treatment. While its function in this trial is to control for therapist time, it is also necessary from an ethical standpoint that the intervention is useful, and perceived to be so by subjects, and without adverse effects. The therapist will begin by assessing patients' knowledge about medication. They will then deliver a set series of educational sessions about schizophrenia and its treatment, which do not use the techniques of the experimental intervention. The sessions are didactic rather than patient centred. The intervention is manualised.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The primary outcome measure for the primary hypothesis is the Mental Component Summary Score (MCS) of the SF-36.

Secondary outcome measures
Other scales to be measured at baseline and 12 months include the following:

Socio-demographic: CSRI-EU
Psychopathology: BPRS
Quality of Life: MANSA, EQ5D, SF36
Disability: WHO DAS II
Clinical status: GAF, Calgary Depression Scale
Carers QoL : EQ-EU
Insight: SAI-E
Drug attitude: DAI, Moriskey
Adherence: Adherence scale
Treatment: Medication qs from CSSRI-EU
Side effects: LUNSERS
Clinical course: Clinical course schedule
Costs: CSSRI-EU

Treatment fidelity will be assessed directly at 3 months: adherence therapists in the study will be asked to tape record sessions with patients in the intervention group, and these will be rated for treatment fidelity (according to the adherence intervention protocol) by the Study Co-ordinating Centre. A random sample of control group sessions will also be recorded and examined for fidelity.

Overall study start date
01/01/2002

Completion date
28/02/2005

Eligibility

Key inclusion criteria
1. International Statistical Classification of Diseases and Related Health Problems, Tenth edition (ICD-10) schizophrenia

2. In the judgement of the responsible clinician are in need of maintenance anti-psychotic treatment for at least a year after entry to the study

3. Clear evidence of clinical instability in the previous year, defined by one or more of the following:
a. Hospital admission on clinical (mental health) grounds
b. A change in anti-psychotic medication
c. Increased frequency of contact (planned or actual)
d. Indications of clinical instability from relatives or carers
e. Indications of clinical instability from clinical team

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
400

Key exclusion criteria
1. Patients suffering from moderate or severe learning disabilities concurrent with schizophrenia
2. Patients suffering from organic brain disorders
3. Patients being treated by forensic psychiatric services
4. Dependence on alcohol or illicit substances
5. Unable to speak language of host country to a sufficient standard to receive intervention
6. Involved in other studies which are agreed locally to preclude inclusion
7. Lack of capacity to consent to inclusion

Date of first enrolment
01/01/2002

Date of final enrolment
28/02/2005

Locations

Countries of recruitment
England

Germany

Italy

Netherlands

United Kingdom

Study participating centre
P029 Health Services Research Department
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Sponsor information

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King's College London (UK)

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Sponsor type
University/education

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
Research organisation

Funder Name
European Union (Action Line: Quality of Life-2000- Public Health). European Union contract no. QLG4-CT-2001-01734.

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?
Results article	results	01/05/2009		Yes	No
Results article	results	25/05/2013		Yes	No