

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

Submission date 19/05/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 19/05/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 11/07/2014	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Graham Thornicroft

Contact details

P029 Health Services Research Department
Institute of Psychiatry
Kings College London
University of London
De Crespigny Park
Camberwell
London
United Kingdom
SE5 8AF
+44 (0)20 7848 0851
J.Bindman@iop.kcl.ac.uk

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

London

United Kingdom

SE5 8AF

Sponsor information

Organisation

King's College London (UK)

Sponsor details

Institute of Psychiatry

De Crespigny Park

London

England

United Kingdom

SE5 8AF

G.Dale@iop.kcl.ac.uk

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