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

Submission date	<b>Recruitment status</b> No longer recruiting	Prospectively registered	
19/05/2003		☐ Protocol	
Registration date 19/05/2003	Overall study status Completed	Statistical analysis plan	
		[X] Results	
<b>Last Edited</b> 11/07/2014	Condition category  Mental and Behavioural Disorders	Individual participant data	

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

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# Additional identifiers

#### Protocol serial number

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

## Study type(s)

Quality of life

# 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(s)

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

# Key secondary outcome(s))

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 Coordinating Centre. A random sample of control group sessions will also be recorded and examined for fidelity.

# 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** 

# Healthy volunteers allowed

No

## Age group

Adult

#### Sex

All

#### 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

United Kingdom

England

Germany

Italy

Netherlands

Study participating centre
P029 Health Services Research Department
London
United Kingdom
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# Sponsor information

# Organisation

King's College London (UK)

#### **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**

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