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A randomised controlled trial of a computerised clinical decision support system for the management of psychiatric disorder in primary care.

Submission date
23/01/2004

Recruitment status
No longer recruiting

Registration date
23/01/2004

Overall study status
Completed

Last Edited
21/12/2009

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

Protocol serial number
PSI02-58

Study information

Scientific Title

Study objectives
To evaluate the cost-effectiveness, under service conditions, of case finding followed by computer-generated patient-specific clinical practice guidelines, compared with locally-agreed guidelines only, for the management of common mental disorders in primary care. The self-administered computerised assessment included
1. The Revised Clinical Interview Schedule (CIS-R), and
2. A social assessment covering sociodemographic characteristics, any current difficulties in housing, employment, finance and personal relationships, and the availability of social support.
In the course of this project, the previous version of the computer program entitled PROQSY (PROgrammable Questionnaire System) was upgraded so as to be compatible with Windows 95 and subsequent versions. Further modifications were also made. These included a method for detecting errors in the questionnaire files (or scripts), an integral randomisation command and new commands to provide more variety in the type face when generating the output for clinicians. The clinical practice guidelines were based on those developed by the World Health Organisation (WHO) for the management of psychiatric disorders in primary care (ICD10-PHC, Goldberg, 1994). These guidelines were discussed with the GPs in all 5 practices and they were given opportunities to alter any of the advice given in the guidelines. We also provided them with a list of local voluntary sector organisations and self-help groups and established whether the GPs regarded these as a useful organisations for patients. These groups were then incorporated in the guidelines.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Other

Health condition(s) or problem(s) studied
Schizophrenia and other psychoses

Interventions
Cases of common mental disorder were identified by case-finding questionnaire and then randomly allocated within practices to
1. An intervention group, in which the GP was given the results of a detailed self-administered computerised psycho-social assessment, combined with patient-specific treatment recommendations, or
2. A control group, in which the GP was not given any additional information or advice, but who had access to a copy of locally agreed clinical practice guidelines.
Randomisation was performed by the computer which administered the questionnaires and

generated the advice for the GP. The randomisation was therefore concealed from the research assistant and the subject.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
12-item General Health Questionnaire (GHQ12)

Outcome was assessed at 6 weeks and 6 months. The subjects were sent the questionnaires by post and were reminded by telephone if they did not respond.

Key secondary outcome(s)
1. Quality of life assessed with 6 questions
2. Satisfaction with treatment assessed with 1 question: If a friend were in need of similar help from a general practitioner would you recommend your GP to him/her?
3. Number of consultations in primary care assessed both by asking the subjects, and also by recording the number of consultations in the primary care notes of the subjects
4. In 2 of the practices we recorded the psychotropic medication prescriptions for all those in the trial.

Completion date
01/01/2001

Eligibility

Key inclusion criteria
1. Five general practices in Bristol and Cardiff participated in the study.
2. Eligible subjects were consecutive general practitioner (GP) attenders who were aged 16 years and over who completed the general health questionnaire (GHQ-12).
3. Subjects who had a positive GHQ score (i.e. >3) and who achieved a score of 12 or more on the CIS-R (Computerised Interview Schedule [Reduced]) were randomised.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 Years

Sex
All

Key exclusion criteria
1. A previous diagnosis of a psychotic illness
2. A mental handicap or cognitive impairment
3. Language or literacy difficulties
4. A severe or terminal physical illness

Date of first enrolment
01/12/1996

Date of final enrolment
01/01/2001

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Psychological Medicine
Cardiff
United Kingdom
CF14 4XN

Sponsor information

Organisation
Record Provided by the NHS R&D 'Time-Limited' National Programme Register - Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
NHS Primary and Secondary Care Interface National Research and Development Programme (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	results	01/11/2004		Yes	No