

The effectiveness of health assessments in primary care as a strategy for improving both physical and mental health in patients with schizophrenic illness.

A West Midlands Development and Evaluation Service Report

Authors: Lesley Roberts •, Lisa Gold*, David Moore & Karen Elley†**

• Department of Primary Care and General Practice
Division of Primary Care, Public and Occupational Health
University of Birmingham
Edgbaston
Birmingham
B15 2TT

* Health Economics Facility
Health Services Management Centre
University of Birmingham
Birmingham
B15 2RT

** Department of Public Health
Division of Primary Care, Public and Occupational Health
University of Birmingham
Edgbaston
Birmingham
B15 2TT

† Sandwell Health Authority
Kingston House
438 High Street
West Bromwich
B70 9LD

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CONCLUSION AND COMMENTARY

Question addressed by this review:

How effective is health assessment (opportunistic or systematic) in primary care as a strategy for improving or maintaining mental and physical health in patients with schizophrenic illness.

Conclusion: Despite the adoption of a wide search strategy only three papers were identified which met the inclusion criteria. No studies were of a high quality. All three studies tentatively supported the feasibility of undertaking routine health assessments of schizophrenic patients in primary care, although data on effectiveness and patient related outcomes are lacking. Studies to determine the effect of such a scheme on patient mental and physical health are needed before such schemes become widely introduced.

Expiry Date: 2004

Further research to determine effectiveness, cost-effectiveness and feasibility is recommended and any new data may alter the conclusions of this report. During the write-up phase of this review the authors became aware of the establishment of a scheme in Hammersmith and Fulham Primary Care Groups whereby a financial payment would be made to GPs for undertaking health reviews of patients with severe mental illness. There are plans to evaluate the scheme by comparing health status year on year and interviewing patients about their experience of the scheme. No results are expected from this project for some time (Personal communication). An update in four years time is therefore recommended to include any new data.

Contribution of Authors

Lesley Roberts undertook the collection and collation of evidence for this review and wrote the draft report. Lisa Gold and Karen Elley gave advice on the formulation of the question and the overall process of the review, helped with some of the writing and structuring of the report and read and commented on the draft report. David Moore provided duplicate data extraction, read and commented on the draft report and provided ongoing support.

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SUMMARY

Objective

To review the usefulness of offering routine or opportunistic health assessment in primary care to patients with schizophrenic illness.

Question addressed

How effective and cost-effective is the use of routine or opportunistic health assessment in primary care as a means of improving mental and physical health in patients with schizophrenic illness.

Methods

The literature on the use of health assessment in primary care for patients with schizophrenia was sought using structured searches in the internet, Medline, CINAHL and other medical databases. All study designs were included provided that assessment was undertaken by primary care providers. Papers that only reviewed other studies, described practice, offered only expert opinion or described results of included studies were excluded. The quality of included studies was assessed and relevant data extracted.

Results

Studies found: 4527 papers were originally identified. 4439 were excluded on the basis of title and abstract alone. 88 papers were obtained of which only 3 satisfied the inclusion criteria

Quality: The quality of all included studies was judged to be poor. All studies presented methodological problems or failed to fully report patient outcomes.

Effectiveness: The available data are insufficient to determine the effectiveness of health assessment for schizophrenic patients in primary care. This is due to a combination of factors: lack of relevant research, poor quality studies and the failure of studies to adopt patient centred measures of health improvement.

Conclusion

There is little evidence to suggest that undertaking health assessment of schizophrenic patients (outside of the usual health promotion activity of general practice) in primary care is an effective way of improving the mental or physical health of this patient group.

Practitioners planning on establishing routine clinics or operating an opportunistic assessment programme for patients with schizophrenic illness in primary care would need to fully evaluate their effectiveness in practice.

Aim of the Review

To review systematically the literature on the effectiveness of primary care assessment as a method of improving physical and mental health in patients with schizophrenic illness (or other enduring psychotic illness).

Background

Schizophrenia is a complex and poorly understood condition affecting about 1% of the population at some point in their lives¹. Onset is usually during young adulthood but can be later. Symptoms can typically be split into positive and negative symptoms^{2,3,4}. Principal positive symptoms are hallucinations (visual, auditory or tactile), disordered thinking, delusions (often the feeling of being persecuted), distortions of the person's understanding of their relationship to the outside world (e.g. thinking that thoughts are known to the outside world), disturbance of emotion (either blunted or inappropriate emotion). Negative symptoms include loss of motivation, withdrawal from social relationships and deterioration in self-care. Negative symptoms are less responsive to medical therapy and more likely to persist when other symptoms have been resolved⁵. Symptoms vary from patient to patient and few patients experience all of the above symptoms. Indeed it is generally accepted that there may be two main types of schizophrenic illness, commonly referred to as Type I and Type II, the first with a predominance of positive symptoms and the second with a more gradual onset and predominance of negative symptoms⁶. Other evidence has suggested that there may be 3 separate dimensions of schizophrenic symptomatology^{7,8}. Patients with schizophrenia often lack insight into the condition and experience distorted perceptions and visual and auditory hallucinations as reality. This can be extremely distressing for the patient and also means that patients find it difficult to perceive symptoms as evidence of illness. This means patients are often unable to seek appropriate help for their illness. Schizophrenia is often accompanied by depression, which may be resistant to antidepressant medication⁹ and which may worsen as quality of life decreases. The prognosis for first episode schizophrenia is difficult to predict. Some patients will make a good recovery, others may be able to manage symptoms with the help of drug therapy and/or psychiatric support, and a third group will experience frequent relapse or continual disablement and find quality of life and ability to function is seriously impaired. Much of the research relating to prognosis and outcome in schizophrenia is difficult to interpret due to poor methodology or the use of non-standardised diagnostic criteria. However Shepherd et al¹⁰ in a methodologically sound five year follow-up study, using accepted diagnostic criteria, reported that 22% of patients remained symptom free during follow-up, 35%

experienced discrete episodes with remission between each episode and 43% of patients experienced continual symptoms.

Treatment for schizophrenia usually involves anti-psychotic drugs either taken orally or administered as an intra muscular injection. These can be effective in the damping down of some of the more disturbing symptoms of schizophrenia. Patients may need to try several medications and doses before a successful therapy is found. Patients responding to medication are often advised to stay on a long-term maintenance dose, as this has been identified as the major factor in preventing relapse¹¹. Side effects of antipsychotic medication for some patients can be unpleasant and vary with the drug used. Common symptoms include dry mouth, blurred vision, akathisia (restlessness), tremor of the hands and feet, slurred speech, sensitivity to sunlight, drowsiness, constipation, stiffness of the joints, menstrual changes and weight gain. Clozapine (which is generally reserved for the treatment of severely ill patients who have failed to respond to usual antipsychotics) has the complication of reducing the white blood cell count, forcing patients to undergo regular monitoring for this, although it does have advantages in terms of a reduction in the other common side effects and increased efficacy in the treatment of severe schizophrenia. Some side effects can be controlled by the use of other drugs such as Procyclidine, an anti-Parkinsonian drug which helps prevent tremor and stiffness. Poor compliance with drug therapy (less than half of patients undergoing long-term treatment take their medication as directed¹² is undoubtedly due not only to the nature of the illness but also to the unwanted side effects. Other effective treatments include psychological therapy, and general support, although these usually supplement drug therapy.

It is therefore apparent that schizophrenia is a complex and distressing illness. The nature of the illness and lack of understanding of the behaviour exhibited by many sufferers has led to a degree of stigmatisation of the disease both by the general public and within the medical sector^{13,14}. Stigmatisation may lead to the discrimination of schizophrenic individuals in terms of educational and employment prospects and social opportunities. The Psychiatric Morbidity Surveys in the UK found that only 20% of people suffering from psychoses were in paid employment¹⁵. Poverty and poor housing are issues that many long-term mentally ill patients have to face and are factors commonly associated with poor health. Given the nature of the symptoms and the side effects of medication this patient group are often in need of support for both mental illness (during periods of relapse) and physical health (due to self neglect, side effects or even self inflicted injury).

The trend towards deinstitutionalisation has seen the transfer of care of patients with severe mental illness from hospital into the community. Many patients with psychotic illness, including schizophrenia, now live largely outside the psychiatric hospital setting in group homes, hostels or private accommodation¹⁶. Psychiatric services have responded to this move by the establishment of a more community based service, and the involvement of the primary care team in the care of the mentally ill has increased. Follow up studies of recently discharged schizophrenic patients reveal that many lose contact with the specialist services and depend on general practitioners for their medical and psychiatric care^{17,18,19}.

Given the relative youth of community care for mentally ill patients it is not surprising that there has been some confusion over the responsibilities of different health professionals in the care of these patients. Psychiatrists differ in the amount of responsibility that they accept for patients' physical health. Patients being admitted to psychiatric hospital will receive a physical health check and intervention where appropriate. Whilst an inpatient, the psychiatric team accept responsibility for the medical management of the patient including the identification of physical illness. However a study by McIntyre and Romano reported that only 10% of psychiatrists undertake physical health monitoring as a component of outpatient care²⁰. Given the increase in patients able to be managed successfully in the community (largely due to new drug interventions), many patients receive no physical health care from the psychiatric services. Most General Practitioners accept responsibility for the physical care of such patients but prefer to share psychiatric care with the psychiatric services²¹.

Few GPs have received more than the most basic training in psychiatry, with less than 22% having experience of working in a hospital psychiatric post²¹, and may find this patient group particularly difficult to manage in the primary care system. A survey of General Practitioners conducted in 1991 reported that many mentally ill patients only come to the attention of the primary care team when there is a crisis²¹. In such a situation the priority is mental health care, which means that the physical health needs of this patient group can be overlooked. There may also be a general tendency to prioritise mental health care for this group of patients and given the limited time available in a primary care consultation, some may feel that any health monitoring activity is best invested in this area.

Previous work suggests that patients with long-term mental illness in the community are prone to undetected and sometimes severe physical disease. Honig²² reported that 53% of a sample of outpatients at an urban community mental health care service had one or more physical disease warranting further attention and that 7% had a severe disease. Brugha²³ reported that 41% of 145

people with a long term mental illness at a psychiatric day care facility were judged to have medical problems requiring care, and 44% had unmet needs according to pathological screening. Farmer²⁴ reported that 53% of 59 people with long term mental illness in a community support program had undiagnosed medical problems and 36% had problems requiring a change of management.

Unrecognised and under-treated illness is important because there is evidence of increased morbidity²⁵ and mortality^{26,27} in people with long term mental illness. Schizophrenia is associated with a significantly increased mortality from both natural and unnatural causes. Risk of death from unnatural causes has been demonstrated to be over four times that for the general population, with an 8 fold risk being attributable to suicide²⁸. Death from respiratory disease is twice the rate for the general population and increased risk has also been demonstrated from a range of physical health problems including cardiovascular disease, digestive disease and genito-urinary disease²⁸. Whilst a degree of excess mortality was historically attributable to the psychiatric hospital environment (e.g. increased respiratory infection), mentally ill patients within the community remain at increased risk of cardiovascular and respiratory illness²⁹. The observed high morbidity rate among the mentally ill may be related to higher rates of smoking, side effects of medication such as weight gain, and self neglect or poor living conditions outside hospital confines^{23,24}. Although these are contributory factors, it is possible that these issues are compounded by the mentally ill not receiving a level of physical health screening and education comparable with that received by other patient groups. This hypothesis is supported by evidence that although rates of smoking and hypertension are significantly higher among the mentally ill than among the general population, GPs make few attempts to tackle cardiovascular and respiratory risk factors in this patient population²⁹.

Given this increased morbidity and mortality, mechanisms for identifying and reducing both mental and physical risk factors should be a priority. Much recent research has focussed on the role of the general practitioner as the health professional most likely to be in contact with long term mentally ill patients, and the primary care team advised to make special efforts to tackle risk factors among this group²⁹.

A task force that reviewed literature and developed good practice guidelines for the care of schizophrenic patients in primary care recommended that a comprehensive assessment including mental state, social functioning, general health and medication is essential for effective care and propose guidelines for the care of schizophrenic patients in general practice which includes assessment of physical and mental health³⁰. However given the admission of the authors that entirely evidence

based guidelines cannot yet be derived for the management of schizophrenia in primary care, it is important to consider the effectiveness of assessments in primary care as a strategy for improving physical and mental health in schizophrenic patients. There are a wealth of questions which deserve to be addressed but which cannot all be dealt with within the scope of one review. It is important to question the assumption that primary care is the right environment for assessment, education and intervention designed to reduce risk factors in schizophrenic patients. Would the introduction of physical health monitoring into psychiatric outpatient care help address the increased risk of cardiovascular and respiratory disease? Assuming that primary care is a suitable environment, the nature of health care assessment and intervention needs to be determined. Will schizophrenic patients attend for systematic screening or would opportunistic assessment be feasible in this patient group in a primary care setting? Indeed given the issues of poor compliance, low motivation and tendency to disorganisation in the long term mentally ill, can assessment, intervention and education improve patient health and reduce mortality?

Proposed Service

The use of assessment programmes or routine clinics in general practice for conditions such as diabetes and asthma are widely accepted. The fact that patients with severe and enduring mental health problems experience excess mortality similar to that of patients with severe and enduring physical illness and have a less healthy lifestyle than the general population³¹ has led to the proposal by some that primary care clinics should be established for patients with long term mental health problems³². These clinics would be able to serve the dual purpose of monitoring and improving both physical and mental health parameters.

An alternative strategy to this, in operation informally in many practices, is the use of disease registers and opportunistic screening tools. It has been proposed that disease registers in general practice are needed to help identify and monitor patients with chronic mental illness and close potential gaps in their care³³. In this way patient's records may be tagged and the opportunity to run through an established check-list is acted upon when a patient spontaneously attends at surgery. In practice the formal procedure of tagging notes may be unnecessary as many of these patients are known personally to the GP.

Anticipated costs

Routine clinics or invitation to attend for assessment involves additional costs to the primary care team in the establishment and maintenance of a disease register and assessment schedules. Costs will also occur in the administration of such a programme: costs of letters to patients, reminder phone calls etc. and in the provision of additional practitioner time for clinics. Such costs may be expected to be higher than for a comparable service for a chronic physical illness as patients may need more prompts to attend due to their mental illness.

Both a systematic and opportunistic programme will involve additional costs to the primary care team in terms of GP and practice nurse time. Additionally, costs for screening may be elevated by such a programme as increased assessment will generate increased blood tests, cervical screens etc. However cost savings may occur if disease is prevented or identified earlier.

METHODS FOR REVIEWING EFFECTIVENESS

A systematic review was undertaken according to predetermined methods laid down in a protocol. Literature identified through an initial scoping review or already held by the lead author (LR), who has an interest in primary mental health care, was used as the basis of determining detailed strategies for the literature search, inclusion and exclusion criteria and quality assessment criteria.

Search Strategy

A broad comprehensive search strategy was developed which was designed to identify any potentially relevant material relating to primary care health activity with schizophrenic patients. Concern over the use of terms like 'long term mentally ill' and 'severe and enduring mental illness' to describe populations of patients with primarily schizophrenic or psychotic illness lead to the inclusion of such generic terms in the search strategy. Whilst attempts were made to reduce the quantity of literature identified by such broad terms by the exclusion of specific mental illnesses (eg alzheimer's and bulimia) it was accepted that large amounts of irrelevant literature would be located by such a search strategy.

The key elements of the strategy were:

- Electronic searches of the listed electronic databases using a combination of search terms to identify literature pertaining to schizophrenia, primary care and health assessment (Appendix 1)

MEDLINE

EMBASE

CINAHL

Healthstar

PsychLit

Evidence Based Mental Health

- Searches of the Cochrane Library Controlled Trials Register and search of the Cochrane Library for any relevant systematic reviews.
- Citation searching of all articles obtained.

All sources were searched as far back as the individual databases went and all searches were conducted in March 2000. No language restrictions were applied. Where non-English papers were identified,

abstracts not available in English were translated to allow inclusion decisions to be made. Full translations were obtained where abstract alone was insufficient for eligibility to be assessed.

Inclusion / Exclusion decisions

All inclusion and exclusion decisions were made by the lead author and were made independently of the detailed scrutiny of study results. All decisions were made according to predetermined criteria laid out in the study protocol.

Inclusion Criteria

Study design

The initial scoping review suggested that evidence on this topic would be scarce. It was therefore predetermined that all study designs would be considered unless four or more controlled trials were identified, in which case controlled trials would form the minimum level of evidence that would be accepted. It was therefore anticipated that non-controlled trials, cohort studies and comparative case series would also be included. Expert opinion and single case studies were excluded.

Study population

Studies relating to patients with schizophrenia or psychotic illness (excluding drug induced or transient psychosis) registered with a General Practitioner or using primary care (general medical) services were included. It was decided that studies where patients were described as 'long term mentally ill' or suffering from 'severe and enduring mental illness' would be included as the majority of such patients would be those with psychotic illness^{29,34}. Studies with mixed populations where more than 50% of patients met with the review criteria would also be included.

Intervention

Any assessment or monitoring programme undertaken by the primary care team for patients with schizophrenic illness would be included. It was decided that studies of both systematic strategies and opportunistic strategies would be included. As recent focus has been on the provision of care for the mentally ill by non-specialist staff (GPs and Practice Nurses)³², studies would not be included for the purpose of this review if they only evaluated the effectiveness of a psychiatric trained professional (psychiatrist, CPN etc.) in a primary care setting.

Outcomes

Any patient centred outcomes would be eligible for inclusion, including physical or mental health state (measured directly using any health status scale or indirectly via reporting of admission rates etc.), quality of life, and patient satisfaction.

Exclusion criteria

Studies were excluded if they only provided background information (description of a condition, service, treatment or experience) or gave only expert opinion. Exclusion was also applied if identified papers reported only methodology or a technique and did not report any results. Studies meeting the inclusion criteria for design, population and intervention, but reporting only process of care measures or only demographic data would be reported but not included in the review. Those studies which reported only interim results of included results would be read only in conjunction with the main study results and results only taken into consideration once.

Quality Assessment Strategy

The quality of included papers was assessed using criteria determined prior to the conduction of the review (*Appendix 2*). Quality assessment was undertaken independently by two reviewers (LR and DM) and discrepancies resolved by joint reference to the original paper. Where differences could not be resolved in this way, reference was made to a third person.

Data Abstraction Strategy

Data was extracted from all included studies independently by two reviewers (LR and DM) onto a data extraction form (*Appendix 3*). As for quality assessment, differences were resolved by discussion and reference to the paper with a third person being consulted where discrepancies remained.

Analysis

Characteristics of included studies were tabulated and results were qualitatively assessed. The quantity, quality and design of included studies prohibited any more formal quantitative analysis. No two studies utilised the same outcome measures and the conversion of data to generic scores was not deemed appropriate. No data pooling was therefore undertaken

Data relating to costs were extracted from identified papers and additional cost data obtained from nationally produced data³⁵. No formal economic analysis was possible given the quality of the data

obtained but costs of strategies reported in identified studies were estimated. Specific methods to identify cost-effectiveness data were not adopted.

RESULTS

Volume of research material available

The broadness of the search strategy meant that a large volume of irrelevant research was identified. Initially, 4527 references were identified by the formal search. 4439 were excluded on the basis of information contained in the title or abstract. 88 full text papers were obtained, either because a decision could not be made using the available information or because they were potentially relevant for inclusion. After application of the exclusion criteria, three studies remained which were included in the final analysis. The main reasons for exclusion were that papers were discussion articles or editorials with no additional data, or reported only inappropriate intervention or outcome measures.

Excluded studies

Details of the excluded studies and reasons for exclusions are provided in Table 1.

Four studies were identified that examined primary care assessment of schizophrenic or mentally ill patients but were excluded as they failed to report any patient centred outcomes. Burns and Cohen³⁶ undertook a pilot study of payment to General Practitioners for monitoring long-term mentally ill patients, but only reported on process of care. Holden³⁷ reported on an audit study of the care of schizophrenic patients in primary care. This resulted in improved levels of recording of patient care but again no patient outcome measures were used. Crews and colleagues³⁴ initiated primary care clinics exclusively for patients with severe and persistent mental illness but again report only on process of care measures (numbers of immunisations updated, cervical smears done, new diagnoses made etc). Whilst it appears logical to assume that identification and treatment of disease or provision of disease screening ultimately improves patient health and possibly quality of life, the aims of the review were to summarise effectiveness in terms of improvement in patient health and therefore evidence of changes in process of care alone whilst interesting were not sufficient for inclusion. Sokhela and Uys³⁸ also undertook a study in which primary care nurses were trained to provide rehabilitation to psychiatric patients. This study viewed clinics as cases and reported on the success of nurses in managing rehabilitation of these patients. Again no patient outcomes were reported.

It is worth noting that much literature relating to the provision of a psychiatric service in primary care exists but was largely excluded on the basis of the abstracts. Much of the existing research has explored the effect and feasibility of running psychiatric clinics in primary care, attaching Community Psychiatric Nurses to practices and providing regular Psychiatric contact for GPs managing mentally ill patients. Given that these strategies are all more labour intensive and costly than regular GP assessment it is perhaps surprising that this latter area has been so little researched. The review strategy also identified some studies looking at the effectiveness of providing routine assessment in primary care for patients with learning difficulties. It is not possible to comment on the breadth of such evidence as much of the literature relevant to this particular patient group would have been excluded by the adopted search strategy. It would be impossible to translate results from studies of this patient group to patients with schizophrenia or other severe mental illness as these patient groups can not be expected to react in similar ways. Components of the illness itself such as paranoia, lack of motivation, dependency etc will all affect the success and feasibility of interventions in this patient population and research is only therefore relevant if undertaken on a similar population.

Included studies

Three studies met the eligibility criteria for inclusion:

1. Nazareth and colleagues³⁹ – Nazareth I, King M, See Tai S. Monitoring psychosis in general practice: A controlled trial. *British Journal of Psychiatry* 1996; **169**: 475-483
2. Burns and colleagues⁴⁰ – Burns T, Millar E, Garland C, Kendrick T, Chisholm B, Ross F. Randomised controlled trial of teaching practice nurses to carry out structured assessments of patients receiving depot antipsychotic injections. *British Journal of General Practice* 1998; **48**: 1845-1848
3. Kendrick and colleagues⁴¹ – Kendrick T, Burns T, Freeling P. Randomised controlled trial of teaching general practitioners to carry out structured assessments of their long term mentally ill patients. *British Medical Journal* 1995; **311**: 93-98

Quality of included studies

Table 2 presents an assessment of the quality of included studies. There were only minor disagreements between reviewers on quality and these were all resolved on discussion. In general, the quality of included studies was poor.

Characteristics of included studies

The characteristics of included papers are summarised in

Table 3, Table 4 and Table 5

Interventions:

All included trials included the training of either GPs or Practice Nurses to carry out structured assessments of mentally ill patients in a primary care setting. Studies varied in the exact nature of the assessment, frequency and who was responsible for its delivery. All studies involved the use of a structured assessment or checklist with practitioners being trained in its use. One study (Nazareth) supplemented training with a manual which was designed to increase reliability of assessments and serve as a guide to the management of schizophrenia and other psychoses. This study outlined the content of the assessment, which included review of physical, psychological and social history, a health check, drug therapy review, and provision of information where necessary. The other two studies failed to document the content of the structured assessment.

Two of the included studies assessed the effectiveness of 3 monthly assessment (Nazareth and Burns) whilst one study considered a 6 monthly assessment schedule (Kendrick).

Populations:

Whilst location was similar in all three of the included studies (London area, UK) the populations differed in each study. All studies focussed on primary care patients or patients attending primary care clinics although mental health diagnoses differed between studies.

One study (Nazareth) focussed on patients with non-affective psychosis but does not report specific diagnoses for these patients.

The study by Burns and colleagues included only patients who received anti-psychotic depot medication in primary care of which 85% had a diagnosis of schizophrenia and only 2% had a non-psychotic diagnosis.

In their 1995 study Kendrick and colleagues used a broader population of patients with long-term mental illness which they clearly define in terms of level of disability, impairment of social behaviour

and diagnosis. Although they describe the diagnoses of included patients (253 had a psychotic disorder of which 204 had a diagnosis of schizophrenia) they do not provide outcome data by diagnostic group.

Outcomes:

Outcomes in the three trials varied greatly although two of the studies aimed to assess mental health / psychiatric state and social functioning (Nazareth and Burns). Kendrick and colleagues did not attempt to assess patient functioning or health directly but reported on numbers of psychiatric and general admissions, consultations, prescriptions etc; in both the intervention and control groups. These may be interpreted as proxy measures for wellbeing although the extent to which they are meaningful measures in this context is unclear.

Burns and colleagues used four separate tools to measure mental health and social functioning (Brief Psychiatric Rating Scale, Krawiecka-Manchester Scale for Clinical Status, Camberwell Assessment of Needs and the Abnormal Involuntary Movement Scale) and also reported numbers of psychiatric admissions and service contacts. Nazareth and colleagues utilised the Present State Examination, Targeting Abnormal Kinetic Effects and Abnormal Involuntary Movements Interviews, 20-item Medical Outcome Survey, Social Function Questionnaire and Global Assessment Scale to assess mental and physical health / wellbeing. This was the only study which reported any patient satisfaction outcomes as measured by the Client Satisfaction Questionnaire.

Follow up periods in all three trials were dissimilar and ranged from 6 months to 2 years.

Results of included studies

Due to the small numbers of studies included in this review the results of each study will be briefly summarised before discussing the overall meaning of these. Because of the differing outcome measures used in the trials, no pooling of data was possible. Results relating to the relevant outcome measures from each study are reported in Table 6.

Effectiveness

Nazareth and colleagues reported a significant improvement in both the Global Assessment Scale and the Behaviour, Speech and Other Syndromes (BSO) subscore of the Present State Examination in intervention patients. Changes in all other patient outcome measures failed to reach significance, including all other subscales of the Present State Examination (Assessment of Psychiatric State), global health measures and client satisfaction.

Burns and colleagues failed to demonstrate a significant effect using any of the health status measures used. They did however report a significant difference in the numbers of psychiatric admissions in favour of the intervention group (lower numbers of admissions in this group) although there was no significant difference in the number of inpatient days between the groups.

Kendrick and colleagues reported no significant difference in the numbers of psychiatric admissions, overdoses or referrals for physical ill health between intervention and control groups.

Other Reported Outcomes

Nazareth and colleagues reported that patients in the intervention group readily responded to the first clinic invitation (33/41) although follow-up at subsequent clinics was less consistent (13 at the second clinic and 22 at the third clinic). Poor follow-up at the second clinic led to an alteration of practice in one of the two study practices so that the third assessment was undertaken as an opportunistic rather than systematic assessment. Despite the numbers involved being very small this suggests that opportunistic assessment may allow for more complete patient follow-up than the adoption of a clinic or other systematic approach.

Staff in the intervention practices studied reported that the check-list was useful although found that the section on social functioning was too detailed and felt that when a patient's problems were recognised

at the first attendance and dealt with during subsequent consultations, the three month review became redundant. Staff, therefore, appear to favour a six monthly regime although evidence of the effectiveness of differing timescales is lacking.

Burns and colleagues also reported on process measures and the numbers of patients receiving various health prevention and promotion activities. Differences between intervention and control patients failed to reach significance. This is surprising as the intervention involved conducting structured assessments and would therefore be expected to inflate process measures. However, this unexpected outcome may partially be due to the design of the study where randomisation was by patient not practitioner. It is reasonable to expect nurses trained in the use of a structured assessment will transfer some of the skills and knowledge gained to the treatment of their control patients, hence confounding the measurement of health activity in the two groups. It is therefore unclear as to whether the structured assessment led to any gains in terms of health promotion activity.

Burns and colleagues report that in the intervention group all patients for whom a checklist was retrieved (63/79) received at least one assessment in the 12 month period of the study, and over one-third received three-monthly assessments. It therefore appears that in the context of this study a routine assessment programme in primary care was both feasible and acceptable to practice nurses and some patients.

Kendrick and colleagues report that changes in neuroleptic medication and referrals to community psychiatric nurses were significantly more common in intervention patients than in controls. Changes in other treatments also tended to be more common in intervention patients although these trends failed to reach significance. The study also reported the numbers receiving assessments in the intervention groups to provide some evidence about acceptability and feasibility. 127/171 had at least one assessment in the two year period and only 29/171 received all four assessments.

This study also examined GPs views on the acceptability and usefulness of the assessment. Practitioners had undertaken assessments in different ways with 27/31 applying the assessment opportunistically when patients consulted, 5/31 reporting that they had written to patients, 5/31 had telephoned to encourage attendance and 5 had visited patients who had failed to attend. Most GPs reported that the assessment schedule was easy to use and acceptable to patients, although over half felt that there was sometimes or often not the time in the consultation to carry out the assessment. Few GPs felt that use of the assessment schedule had directly led to changes in treatment or referrals.

Economic analysis

None of the included studies included economic analysis or fully reported resource use data. Making assumptions about the resource utilisation of each intervention it was possible to produce cost estimates for the intervention strategies in the three studies to provide a rough estimate of the relative cost per patient per year of the three interventions (Table 7). All resources were estimated at 1999 costs.

Summary of results

In summary a wide search strategy was adopted but only three studies were included in the final review. The quality of these studies was poor and all contained methodological problems or failed to provide a full report of patient outcomes. All studies appeared to tentatively support the feasibility of undertaking routine assessments of patients with schizophrenia but more studies are needed to determine the effectiveness (ideally incorporating some measure of satisfaction) and most cost-effective method of undertaking assessment.

DISCUSSION

Many practices have in place procedures for reviewing patients with asthma, diabetes and other chronic physical conditions. It has been suggested that similar arrangements should be made for patients with chronic mental illness. The excess morbidity and mortality of these patients, especially those suffering from schizophrenia has been well documented. Whilst much of this excess mortality is due to increased rates of suicide or accidental death, a large proportion is due to increased rates of physical ill health, including cardiovascular and respiratory disease. Patients suffering from serious mental illness are also more likely to suffer from a variety of minor health problems, often caused by self-neglect or lack of insight, such as poor dental health and podiatric problems. It is therefore reasonable to assume that interventions aimed to increase healthy behaviours in this patient group may result in measurable improvements in physical health and quality of life. Increased physical wellbeing and improved quality of life would reasonably be expected to lead to improvement in mental health. It is also reasonable to assume that monitoring of mental health in a routine manner would enable early intervention to maintain mental wellbeing.

However despite all these assumptions, the need to determine the effectiveness of routine assessment of this patient group in primary care remains. A range of issues unique to the provision of care to the mentally ill mean that data relating to the effectiveness of primary care assessment and clinics for other patient populations is unlikely to reliably inform on treatment of the mentally ill. Patients with severe

mental illness are more likely to fail to keep clinic appointments, be unwilling to receive certain assessments and fail to fully understand health advice or alter their lifestyle accordingly. Therefore assessment strategies that work with other patient groups e.g. routine clinics may fail to be effective when adopted for the care of the mentally ill. It is therefore important that before advising practitioners to undertake routine assessment of their schizophrenic patients, that evidence relating to the effectiveness, cost-effectiveness and feasibility/acceptability of possible strategies is considered. A broad systematic review of this topic has identified only three studies, which differ widely in the strategies used and outcomes measured. No study demonstrates strong evidence on the effectiveness of routine assessments in a primary care setting.

There was little evidence overall to support the theory that assessment of patients with schizophrenia on a regular basis in primary care leads to improvements in their mental and/or physical health. One study (Nazareth) reported improvements in overall psychiatric and social functioning and in a measure of behaviour, speech and other syndromes, although failed to demonstrate significant differences on several other measures. This trend towards marginal improvement was further supported by Burns and colleague's study which failed to demonstrate a significant difference in any measure but found a difference in the numbers of psychiatric admissions (but not total time in hospital) in favour of the intervention group. This study failed to note any differences in processes of care, a fact that is possibly explained by poor study design. However it is important that the number of measures explored be taken into consideration when reporting a significant finding. The third study included in the review however did not report any significant effect on numbers of admissions, overdoses or referrals for physical ill health. This study did not formally measure functioning or other patient centred outcomes. Given that a difference was noted in numbers receiving changes to their medication or referrals to CPNs, it is unfortunate that no attempts were made to quantify patient satisfaction or measure quality of life.

It is however important to bear in mind that trials sized on a primary outcome rarely have the power to detect differences in secondary outcomes and the fact that the identified studies failed to identify differences in certain measures is not to say that the differences do not exist and would be identified by a larger trial powered specifically to detect differences on these measures.

Follow-up of patients for assessments was poor in the trial using a systematic approach (Nazareth) but improved once a more opportunistic method of assessment was adopted. Data from the other two trials (Burns and Kendrick) appears to favour Practice Nurses over GPs to improve patient follow up

although this difference may be due to differences in the designs of these two studies. GPs reported that it was sometimes difficult to undertake assessment during routine consultation. However Practice Nurses were undertaking assessment when administering depot medication and potentially had more flexibility in their appointment schedule.

It is also important when attempting to interpret the available data that the generalisability of the study populations be considered. The ability to generalise findings from a study of patients who are receiving depot medication in primary care, as in the study by Burns and colleagues, is questionable on two main grounds: firstly this patient group are unlikely to be representative of all schizophrenic patients as those receiving medication from psychiatric professionals are excluded (these potentially are the more severely ill or difficult to manage), and secondly the patient group are accustomed to regular attendance at the surgery for medication. A potential difficulty in the operation of services for those with mental health problems is ensuring attendance, the nature of the population studied in this trial means that acceptability to patients and likelihood of patients attending can not be generalised to all patients with psychotic illness

The failure of Kendrick and colleagues to provide outcome data by diagnostic group makes generalisation of results to a population of patients with psychotic illness difficult. 187 of the included patients in this study had a non-psychotic diagnosis, including anxiety/depression, agoraphobia, personality disorder and alcohol abuse. It is possible that such patients will respond to invitation for assessment, the assessment itself and health education in a dissimilar way to those with a psychotic illness.

Costs were approximated per patient / year and were heavily influenced by frequency of intervention (3 or 6 monthly). Nazareth and colleagues reported that practice staff in their sample felt that 6 monthly assessment was not necessary as many of the issues identified at initial assessment were subsequently dealt with during consultation, making review unnecessary. Involving both GPs and nurses and adopting a routine invitation system appears to inflate costs without additional benefit.

Given the increased ill health and morbidity suffered by the long-term mentally ill, it is important that strategies be developed to improve this. Research is needed to determine the most appropriate setting for such intervention – patients who are regularly in contact with members of the psychiatric team may prefer health intervention and promotion to be undertaken by these professionals who would need appropriate training, whilst others may prefer increased involvement of the primary care team. Further

research is also needed to determine the most effective and acceptable method of assessment, as well as to quantify the effect that this has on patient wellbeing.

CONCLUSIONS AND FURTHER COMMENTS

Both the quantity and quality of the effectiveness data is poor and fails to report on outcomes such as patient satisfaction and quality of life.

Poor quality evidence suggests a slight trend toward improvement in the mental health of patients who receive assessment by primary care practitioners.

Evidence to inform on a preferable strategy for undertaking routine assessment of schizophrenic patients in primary care is lacking although an opportunistic strategy appears to improve patient attendance and compliance with assessment, as well as being less costly.

Future research should focus on determining efficacy of assessment in terms of mental health, physical health and patient satisfaction or quality of life. Efficacy should ideally be assessed in a framework of opportunistic assessment (e.g. flagging of patient notes etc.) rather than a routine system (e.g. invitations / appointments to attend a clinic appointment).

Tables

Table 1 : Excluded studies

Author	Source	Reason for exclusion
Anonymous.	Mental health and primary medical care. Publication - Group for the Advancement of Psychiatry 10[105], 699-775. 1980.	Discussion article – Expert opinion with no additional data
Anonymous.	Mental health. Bridging psychiatric and primary care. Nurse Practitioner 8[3], 70-71. 1983.	Editorial – no additional data
Anonymous.	Shared care of patients with mental health problems. Report of a Joint Royal College Working Group. Occasional Paper - Royal College of General Practitioners [60], 1-10. 1993.	Discussion article – Expert opinion with no additional data
Baird, M. A. and Grant, W. D.	Remuneration of family physicians (II). Journal of Family Practice 30[5], 518-519. 1990.	Letter – no additional data
Berardi, D., Ferrari, G., Scaramelli, A. R., Scardovi, A., and Vittorangeli, M.	Psychiatry and general practice: Epidemiological studies and collaborative research projects in Italy. Epidemiologia e Psichiatria Sociale, Vol 5(3) (pp 164-167),1996 .	Discussion article – Expert opinion with no additional data
Bindman, J., Johnson, S., Wright, S., Szmukler, G. , Bebbington, P., Kuipers, E., and Thornicroft, G.	Integration between primary and secondary services in the care of the severely mentally ill: Patients' and general practitioners' views. British Journal of Psychiatry 171[AUG.], 169-174. 1997.	No appropriate intervention or outcome -Survey of G.P and patient views.
Brody, E. B.	Factors in the recognition and management of the nonhospitalized schizophrenic as a medical patient. Modern Treatment 6[4], 695-703. 1969.	Discussion article – Expert opinion with no additional data
Burns, T., and Kendrick, T.	The role of General Practitioners in the care of schizophrenia. Schizophrenia 1996 : Breaking down the	Duplicate of assessed publication

	barriers, 4 th International Conference, Vancouver, B.C, Canada. 1996.	
Burns, T. and Kendrick, T.	Care of long-term mentally ill patients by British general practitioners. <i>Psychiatric Services</i> 48[12], 1586-1588. 1997.	Duplicate of assessed publication
Burns, T. and Cohen, A.	Item-of-service payments for general practitioner care of severely mentally ill persons: Does the money matter? <i>British Journal of General Practice</i> 48[432], 1415-1416. 1998.	No patient related outcomes
Burns, T.	Inner-city general practice population with schizophrenia [1]. <i>Psychiatric Bulletin</i> 22[10], 639. 1998.	No appropriate intervention or outcome
Butler, T., Glendinning, C., Gask, L., Rummery, K., Rogers, A., Lee, J., and Bower, P.	Mental health and primary care: an alternative policy agenda. <i>Journal of Mental Health</i> 6[4], 331-334. 1997.	Editorial – Expert opinion with no additional data
Cooper, B.	Psychiatric illness in general medical practice. An investigation in Mannheim. <i>International Journal of Rehabilitation Research</i> 4[1], 86-87. 1981.	Prevalence data only
Copolov, D. L.	Psychoses: A primary care perspective. <i>Medical Journal of Australia</i> 168[3], 129-135. 1998.	Discussion article – Expert opinion with no additional data
Corser, C. M. and Ryce, S. W.	Community mental health care: a model based on the primary care team. <i>British Medical Journal</i> 2[6092], 936-938. 8-10-1977	No appropriate intervention. Study of primary care based community psychiatric service
Cotroneo, M., Outlaw, F. H., King, J., and Brince, J.	Advanced practice psychiatric-mental health nursing in a community-based nurse-managed primary care program. <i>Journal of Psychosocial Nursing & Mental Health Services</i> 35 [11], 18-25. 1997.	Discussion article – Description of integrated primary and mental health service
Crammer, J.	GPs and long term mentally ill patients [15]. <i>British Medical Journal</i> 302[6782], 964. 1991.	Letter – Descriptive / prevalence data only
Craven, M. A. and Handfield-Jones, R.	Shared mental health care in Canada. Making a joint	Discussion article – Expert opinion with no additional

	effort to define our roles. Canadian Family Physician 43, 1785-1787. 1997.	data
Crews, C., Batal, H., Elasy, T., Casper, E., and Mehler, P. S.	Primary care for those with severe and persistent mental illness. Western Journal of Medicine 169[4], 245-250. 1998.	No patient related outcomes – process of care measures only
Danczak, A. and Hastings, S.	Chronic mental illness in general practice [4]. British Journal of General Practice 42[364], 491-492. 1992.	Letter – No appropriate intervention or outcome. Data on inequality of care only
Dowrick, C.	Improving mental health through primary care. British Journal of General Practice 42[362], 382-386. 1992.	Review article – background information and expert opinion with no additional data
Essex, B., Doig, R., and Renshaw, J.	Pilot study of records of shared care for people with mental illnesses. British Medical Journal 300[6737], 1442-1446. 1990.	Inappropriate intervention
Evans, P. and Lloyd, K.	Auditing the primary care of mental disorders. International Review of Psychiatry 10[2], 127-129. 1998.	No appropriate intervention or outcome.
Falloon, I. R., Shanahan, W., Laporta, M., and Krekorian, H. A.	Integrated family, general practice and mental health care in the management of schizophrenia. Journal of the Royal Society of Medicine 83[4], 225-228. 1990.	Review article – background information and expert opinion with no additional data
Fisher, N. and Roberts, J.	Primary health care service for long-stay psychiatric in-patients. Psychiatric Bulletin 22[10], 610-612. 1998.	Study based in secondary care setting
Gage, L. W. and Kline, N. W.	Improving mental health services in primary care: the nurse's role. Nurse Practitioner 11[7], 72-74. 1986.	Discussion article – Expert opinion with no additional data
Goldberg, D.	Mental health priorities in a primary care setting. Annals of the New York Academy of Sciences 310, 65-68. 21-6-1978.	Discussion article – no relevant data
Goldberg, D.	The treatment of mental disorders in general medicine settings. General Hospital Psychiatry 14[2], 83-85. 1992.	Editorial – Expert opinion with no additional data
Goldberg, D.	Training general practitioners in mental health skills.	Review article – no additional data

	International Review of Psychiatry 10[2], 102-105. 1998	
Gray, R. and Smedley, N.	Assessing primary nursing in mental health. Nursing Standard 12[21], 35-38. 11-2-1998.	No appropriate intervention. Based in psychiatric not primary care setting
Gmur, M.	The schizophrenic as a partner in his management in family practice. Schweiz Med Wochenschr. 112[48], 1735-1741. 1982.	Discussion article – expert opinion with no additional data
Gmur, M.	The schizophrenic patient and the general practitioner. Schweiz Rundsch Med. Prax. 72[43], 1355-1358. 1983.	Discussion article – expert opinion with no additional data
Herring, M. E. and Ross, J.	Detecting physical disorders in emotionally disturbed patients. Postgraduate Medicine 86[2], 135-142. 1989.	Discussion article – expert opinion with no additional data
Holden, J.	An audit of the care of 266 patients with schizophrenia in 16 general practices. Irish Journal of Psychological Medicine 15[2], 61-63. 1998.	Audit study to improve recording of care parameters – no patient outcomes
Honig, A., Tan, E. S., Pop, P., Philipsen, H., De Wit, R., and Van Pelt, P.	The influence of consensus on the assessment of physical disease in chronic community psychiatric patients. Psychotherapy & Psychosomatics 51[3], 142-149. 1989.	No appropriate intervention or outcome
Honig, A., Pop, P., Tan, E. S., Philipsen, H., and Romme, M. A. J.	Physical illness in chronic psychiatric patients from a community psychiatric unit. The implications for daily practice. British Journal of Psychiatry 155[JUL.], 58-64. 1989.	No appropriate intervention or outcome – Study of prevalence of physical disease in psychiatric population
Honig, A., Pop, P., De Kemp, E., Philipsen, H., and Romme, M. A. J.	Physical illness in chronic psychiatric patients from a community psychiatric unit revisited. A three-year follow-up study. British Journal of Psychiatry 161[JULY], 80-83. 1992.	No appropriate intervention or outcome – Study of prevalence of physical disease in psychiatric population
Hoult, J.	Comprehensive services for the mentally ill. Current Opinion in Psychiatry 6[2], 238-245. 1993	Discussion article – expert opinion with no additional data
Hustig, H. H. and Norrie, P. D.	MJA practice essentials. Managing schizophrenia in the	Discussion article – expert opinion with no additional

	community. Medical Journal of Australia 168[4], 186-71. 16-2-1998.	data
Johnstone, E. C., Owens, D. G. C., and Gold, A.	Schizophrenic patients discharged from hospital - A follow-up study. British Journal of Psychiatry 145[DEC.]. 1984.	No appropriate intervention or outcome – descriptive epidemiology only
Jones, L. R. and Knopke, H. J.	Educating family physicians to care for the chronically mentally ill. Journal of Family Practice 24[2]. 1987.	Discussion article – expert opinion with no additional data
Kaeser, A. C. and Cooper, B.	The psychiatric patient, the general practitioner, and the outpatient clinic: an operational study and a review. Psychological Medicine 1[4], 312-325. 1971.	No appropriate intervention or outcome
Keks, N. A., Altson, B. M., Sacks, T. L., Hustig, H. H., and Tanaghow, A.	Collaboration between general practice and community psychiatric services for people with chronic mental illness. Medical Journal of Australia 167[5], 266-271. 1997.	Discussion article – expert opinion with no additional data
Kendrick, T., Baptiste, J., Kerwin, R., Freeman, H., and Brooker, C.	The increasing role of the general practitioner in schizophrenia. Round Table Series - Royal Society of Medicine Issue 46[pp 15-23]. 1996.	Duplicate of assessed publication – Summary of included publication
Kendrick, T., Burns, T., Miller, E., and Garland, C.	The role of general practice nurses in the care of schizophrenia. Schizophrenia 1996 : Breaking down the barriers, 4 th International Conference, Vancouver, B.C, Canada. 1996.	Duplicate of assessed publication
Kendrick, T., Burns, T., Freeling, P., and Sibbald, B.	Provision of care to general practice patients with disabling long-term mental illness: A survey in 16 practices. British Journal of General Practice 44[384], 301-305. 1994.	No appropriate intervention or outcome – descriptive epidemiology only
Kendrick, T., Millar, E., Burns, T., and Ross, F.	Practice nurse involvement in giving depot neuroleptic injections: Development of a patient assessment and monitoring checklist. PRIM CARE PSYCHIATRY, Vol 4(3) (pp 149-154), 1998 .	No appropriate intervention or outcome

Kessler, L. G., Tessler, R. C., and Nycz, G. R.	Co-occurrence of psychiatric and medical morbidity in primary care. <i>Journal of Family Practice</i> 16[2]. 1983.	No appropriate intervention or outcome – Study of morbidity in mentally ill patients
Kisely, S. R. and Goldberg, D. P.	The effect of physical ill health on the course of psychiatric disorder in general practice. <i>British Journal of Psychiatry</i> 170[JUNE], 536-540. 1997.	No appropriate intervention or outcome – Study of effect of physical morbidity on psychiatric outcome
Kroon, H. and Hutschemaekers, G.	The role of general practitioners in the care of the chronic mentally ill; an epidemiological study. <i>Nederlands Tijdschrift voor Geneeskunde</i> 139[34], 1737-1741. 1995.	No appropriate intervention or outcome – Survey of GPs and Mental Health workers to determine numbers of mentally ill patients being care for by different services
Lang, F. H., Johnstone, E. C., and Murray, G. D.	Service provision for people with schizophrenia. II. Role of the general practitioner. <i>British Journal of Psychiatry</i> 171[AUG.], 165-168. 1997.	No appropriate intervention or outcome – Descriptive epidemiology and GP survey
Lehman, A. F.	Quality of care in mental health: the case of schizophrenia. <i>Health Affairs</i> 18[5], 52-65. 1999.	Discussion article – expert opinion with no additional data
Lima, B. R. and Brooks, M. L.	Coordination of services for outpatients under concurrent medical and psychiatric care. <i>General Hospital Psychiatry</i> 7[4]. 1985.	No appropriate intervention or outcome
Linsky, M. A.	Variables affecting compliance with treatment of post-hospitalized patients with chronic mental illness. <i>Public Health Reports</i> 96[2]. 1981.	No appropriate intervention or outcome
Livingston, M. G.	Management of schizophrenia. <i>Prescribers' Journal</i> 36[4], 206-215. 1996.	Discussion article – expert opinion with no additional data
Mak, K. Y.	Management of psychiatric disorder in primary care and family medical practice. <i>Hong Kong Pract</i> , Vol 21(8) (pp 345-346), 1999 .	Editorial – Expert opinion with no additional data
Malla, A. K., Norman, R. M., McLean, T. S., Cheng, S., Rickwood, A., McIntosh, E., Cortese, L., Diaz, K., and Voruganti, L. P.	An integrated medical and psychosocial treatment program for psychotic disorders: patient characteristics and outcome. <i>Canadian Journal of Psychiatry - Revue Canadienne de Psychiatrie</i> 43[7], 698-705. 1998.	No appropriate intervention - Study of case management

Maricle, R. A., Hoffman, W. F., Bloom, J. D., Faulkner, L. R., and Keepers, G. A.	The prevalence and significance of medical illness among chronically mentally ill outpatients. <i>Community Mental Health Journal</i> 23[2], 81-90. 1987.	No appropriate intervention or outcome – Study of prevalence of medical illness in a psychiatric population
Naji, S. A., Howie, F. L., Cameron, I. M., Walker, S. A., Andrew, J., and Eagles, J. M.	Discharging psychiatric in-patients back to primary care: A pragmatic randomized controlled trial of a novel discharge protocol. <i>Prim Care Psychiatry</i> , Vol 5(3) (pp 109-115), 1999 .	No appropriate intervention or outcome - Study of discharge protocols involving general practitioners
Nazareth, I., King, M., and Davies, S.	Care of schizophrenia in general practice: The general practitioner and the patient. <i>British Journal of General Practice</i> 45[396], 343-347. 1995.	No appropriate intervention or outcome – Study to determine use of primary care services by schizophrenic patients and assess GP and patient attitudes
Nazareth, I. D. and King, M. B.	Schizophrenia: Community care and the family physician. <i>International Review of Psychiatry</i> 4[3-4], 267-272. 1992.	Discussion article – expert opinion with no additional data
Nazareth, I. D. and King, M. B.	Controlled evaluation of management of schizophrenia in one general practice: a pilot study. <i>Family Practice</i> 9[2], 171-172. 1992.	No appropriate intervention or outcome – study to identify differences in service provision for schizophrenic and non-schizophrenic patients
Petersen, I.	Training for transformation: reorientating primary health care nurses for the provision of mental health care in South Africa. <i>Journal of Advanced Nursing</i> 30[4], 907-915. 1999.	No appropriate intervention or outcome and inadequate definition of population. Study to evaluate training primary care nurses in mental health issues.
Ramsay, A., Vredenburgh, J., and Gallagher, R. M., III.	Recognition of alcoholism among patients with psychiatric problems in a family practice clinic. <i>Journal of Family Practice</i> 17[5]. 1983.	No appropriate intervention or outcome – Study to determine whether GPs question psychiatric patients about alcohol intake
Regier, D. A., Burke, J. D. Jr, Manderscheid, R. W., and Burns, B. J.	The chronically mentally ill in primary care. <i>Psychological Medicine</i> 15[2], 265-273. 1985.	Discussion article – expert opinion with no additional data
Rohland, B. M., Rohrer, J. E., and Culica, D.	Substitution of psychiatric care by primary care physicians: Impact of the Iowa Medicaid managed mental health care plan. <i>Administration & Policy in Mental Health</i> 26[5], 369-371. 1999.	No appropriate intervention or outcome – survey to determine effects of recent policy change

Scher, M., Wilson, L., and Mason, J.	The management of chronic schizophrenia. Journal of Family Practice 11[3], 407-413. 1980.	No appropriate intervention or outcome – Study of effectiveness of a public mental health training programme
Shachor, S., Sive, P. H., and Telpaz, N.	Mental health care by a family oriented general practice team. International Journal of Social Psychiatry 22[2], 96-100. 1976.	Description of a service only
Smith, V. P.	Resettling long stay psychiatric patients in the community [15]. British Medical Journal 305[6863], 1229. 1992.	Letter – No additional data
Sokhela, N. E. and Uys, L. R.	The integration of the rehabilitation of psychiatric patients into the primary health care system. Curationis: South African Journal of Nursing 21[4], 8-13. 1998.	No patient related outcome - Outcomes were changes in nurses performance
Sokhela, N. E.	The integration of comprehensive psychiatric/mental health care into the primary health system: diagnosis and treatment. Journal of Advanced Nursing 30[1], 229-237. 1999.	No appropriate intervention or outcome – Study to evaluate training of primary care nurses in mental health – no patient outcomes
Stanley, A. and Macmillan, F.	Physical health in a chronic psychotic population: community management and training opportunities. Primary Care Psychiatry, Vol 2(4) (pp 249-252), 1996 .	No appropriate intervention or outcome – Study of patients moving from hospital to hostel accommodation.
Steiner, J. L., Hoff, R. A., Moffett, C., Reynolds, H., Mitchell, M., and Rosenheck, R.	Preventive health care for mentally ill women. Psychiatric Services 49[5], 696-698. 1998.	No appropriate intervention or outcome – study to identify differences in care between patient groups.
Tanielian, T. L., Cohen, H. L., Marcus, S. C., and Pincus, H. A.	General medical care for psychiatric patients. Psychiatric Services 50[5], 637. 1999.	No appropriate intervention or outcome – Survey to establish numbers of psychiatric patients having access to general medical care
Tansella, M. and Bellantuono, C.	Provision of mental health care in general practice in Italy. British Journal of General Practice 41[352], 468-471. 1991.	Discussion article – expert opinion with no additional data
Taube, C. A. and Burns, B. J.	Mental health services system research: the National Institute of Mental Health Program. Health Services	Description of National Institute of Mental Health's work and research priorities

	Research 22[6], 837-855. 1988.	
Thomas, C. W., Guy, S. M. and Ogilvie, L. P.	An evaluation of a practitioner training program designed to assist families of people with severe psychiatric disorders. <i>Psychiatric Rehabilitation Journal</i> 23[1], 34-41. 1999.	Discussion article – expert opinion with no additional data
Tribolet, S. and Laemmer, J. N.	Management of schizophrenics in the general practice setting. <i>Presse Medicale</i> 27[40], 2190-2197. 1998.	Discussion article – expert opinion with no additional data
Van Os, J. and Neeleman, J.	Caring for mentally ill people. <i>British Medical Journal</i> 309[6963], 1218-1221. 1994.	Discussion article – expert opinion with no additional data
Wagner, D. L.	Issues in the provision of health care for all. <i>American Journal of Public Health</i> 63[6], 481-485. 1973.	Discussion article – expert opinion with no additional data
Wallot, H.	Follow-up of the schizophrenic patient by the general practitioner. <i>Union Med Can</i> 112[3], 268-271. 1983.	Discussion article – expert opinion with no additional data
Watson, C. M.	Chronic psychosis and reproductive health. <i>British Journal of Family Planning</i> 20[4], 117-120. 1995.	Discussion article – expert opinion with no additional data
Wear, A. N. and Peveler, R. C.	Use of primary care services by chronically mentally ill patients. <i>Journal of Mental Health</i> 4[2], 199-204. 1995.	No appropriate intervention or outcome – Study to compare primary care service use by chronically mentally ill and non-mentally ill patients
Wilkes, J.	Primary care of patients with schizophrenia [1]. <i>British Journal of General Practice</i> 48[426], 920. 1998.	Letter – No additional data
Wood, K., and Anderson, J.	The effect on hospital admissions of psychiatric case management involving general practitioners: preliminary results. <i>Aust N.Z Journal Psychiatry</i> 29[2], 223-229. 1995.	No appropriate intervention – Study to evaluate new psychiatric cases management system

Table 2 : Quality indicators for included studies

	Nazareth and colleagues	Burns and colleagues	Kendrick and colleagues
Trial described as randomised	No	Yes	Yes
Assignment truly random	N/A	Yes	No
If not truly random, description randomisation	N/A	N/A	Quasi randomisation by practice with minimisation used to balance for number of partners, list size and numbers of mentally ill patients.
Description of allocation	N/A	Adequate	N/A
Outcome assessor blinded to allocation	No	Unclear	Unclear
Groups comparable at entry	No – no significant characteristics in demographics or disease characteristics, but significant differences in number of GP consultations between groups.	No – significantly higher proportion of males in control group.	Yes
Relatively complete follow-up (>80%)	Yes	Unclear	Yes
Outcomes of withdrawals described and included	Unclear	Unclear	N/A
Groups treated identically apart from intervention	Yes	Yes	Yes
Comments	Non-randomised trial with practices selecting to be control or intervention. Practices with GPs interested or knowledgeable in mental health are possibly more likely to have become intervention practices hence introduction of confounding variables is suspected.	Unit of randomisation was the patient. Nurses were therefore trained in an assessment technique but expected to only implement this with intervention patients. The potential for cross-contamination was therefore deemed to be high.	

Table 3 : Characteristics of included studies (population)

Study	Nazareth and colleagues	Burns and colleagues	Kendrick and colleagues
n	67	149	440
Number of practices or practitioners	4 practices 9 GPs	Number of practices not stated 46 practice nurses	16 practices 70 GPs
Location	Central London	Merton, Sutton and Wandsworth Health Authority	South Thames (west) Region
Population	Primary care patients with non-affective psychoses.	Primary care patients aged 18 and over receiving depot anti-psychotic medication in general practice. Included 126 patients with schizophrenia. Only 3 patients had a non-psychotic disorder.	Primary care patients aged 16 – 65 with long term mental illness. Included 253 patients with a psychotic disorder of which 204 had a diagnosis of schizophrenia.
Inclusion criteria	Diagnosis as above	Receiving depot anti-psychotic medication in general practice Aged 18+ Practice nurses had to be treating 4+ such patients.	More than 2 years disability due to impaired behaviour as a consequence of mental illness Aged 16-65 No dementia or organic brain disorder No learning disability
Study design	Non randomised controlled trial (unit of allocation – Practice)	Randomised controlled trial (unit of randomisation – patient)	Randomised controlled trial (unit of randomisation – practice)
Study strengths / weaknesses	Non-randomised study – practices chose to be intervention or control practices. 67 patients invited for assessment, 53 provided baseline data and 49 final outcome data. Follow up varied for different outcomes and were not complete (see table 5 for numbers). Large numbers of outcome measures and statistical testing undertaken	Unit of randomisation was the patient – all practice nurses were instructed in use of the assessment but were asked to continue ‘usual practice’ with control patients. Potential for contamination is therefore high.	Appropriate unit of randomisation (practice). Study fails to report any patient outcome scores – comparisons of numbers requiring admission etc is a poor proxy for wellbeing.

Table 4 : Characteristics of included studies (interventions)

Study	Nazareth and colleagues	Burns and colleagues	Kendrick and colleagues
Intervention	Primary care professionals trained in use of a structured checklist and provided with a manual. Clinics were established and patients invited by letter. Reminders were sent or telephone contact made as appropriate.	Nurses instructed to use structured assessment cards with patients.	GPs received training to improve understanding of long-term mental illness and instruction in use of assessment schedule. Schedule cards placed in the notes of patients – each practice chose how to organise reviews: 27/31 GPs chose opportunistic assessment; 5/31 wrote to patients; 3/31 telephoned to encourage attendance and 5/31 visited patients who failed to attend.
Professional implementing	Each assessment involved both the practice nurse and General Practitioner	Practice Nurse	General Practitioner
Frequency	3 monthly	3 monthly	6 monthly
Follow-up period	6 months	12 months	24 months

Table 5 : Characteristics of included studies (outcomes)

Nazareth and colleagues		Burns and colleagues		Kendrick and colleagues	
Outcome	n (I:C)	Outcome	n	Outcome	n
Present State Examination (Psychiatric state)	27:22	Brief Psychiatric Rating Scale	n/s	Numbers of psychiatric admissions	184:189
Targeting Abnormal Kinetic Effects interview	27:21	Krawiecka-Manchester scale for clinical status	n/s	Numbers of drug overdoses	184:189
Abnormal Involuntary Movements interview	27:21	Camberwell Assessment of Needs	n/s	Numbers of admissions for physical illness	184:189
Client Satisfaction Questionnaire	23:21	Abnormal Involuntary Movement Scale	n/s		
20-item Medical Outcome Survey	25:22	Numbers of psychiatric admissions and inpatient days	79:70		
Social Function Questionnaire	25:22				
Global Assessment Scale	27:21				
Data relating to interventions offered at assessment and numbers of GP or outpatient attendances was reported but was not relevant to the aims of this review. These are however discussed in the text.		Data relating to interventions offered and numbers of GP or outpatient attendances was reported but was not relevant to the aims of this review. These are however discussed in the text.		Data relating to changes in treatments was reported but is not of relevance to the aims of this review. These are however discussed in the text.	

Table 6 : Outcome data for principal study outcome measures

Nazareth and colleagues			Burns and colleagues			Kendrick and colleagues		
Outcome	Intervention Group	Control Group	Outcome	Intervention Group	Control Group	Outcome (no outcome measures but admission data is proxy for health status)	Intervention Group	Control Group
Present State Examination (Data for all 6 sub scores is provided – BSO was significant)	Baseline median 14.5 Endpoint median 11 Median change 1 (-9.8,8.4)	Baseline median 10 Endpoint median 15 Median change 2.5 (-9.7,8.7) p = 0.7	Brief Psychiatric Rating Scale (End point means only)	10.0 (SD 6.2)	10.7 (SD 5.8) p not significant	Admissions to psychiatric hospital	32	28 p not significant
Social Function Questionnaire	Baseline median 6 Endpoint median 6 Median change 0 (-2,2)	Baseline median 5 Endpoint median 5.5 Median change -1 (-2,0) p=0.4	Krawiecka Scores (End point means only)	6.9 (SD 3.7)	7.5 (SD 3.8) p not significant	Admissions under the mental health act	12	10 p not significant
Global Assessment Scale	Baseline median 60 Endpoint median 60 Median change 0 (0,10)	Baseline median 60 Endpoint median 60 Median change 0 (-10,0) p=0.04	Abnormal Involuntary Movement Scale (End point means only)	1.5 (SD 0.2)	1.4 (SD 2.2) p not significant	Overdose	1	4 p not significant
Targeting Abnormal Kinetic Effects	Baseline median 0 Endpoint median 0 Median change 0 (0,0)	Baseline median 2.5 Endpoint median 3.5 Median change 2 (0,4) p=0.2	Camberwell Assessment of Needs (End point means only)	3.9 (SD 2.6)	4.6 (SD 2.2) p not significant	Physical referrals	69	58 p not significant
Abnormal Involuntary Movement Interview	Baseline median 1 Endpoint median 1 Median change 0 (0,1)	Baseline median 3 Endpoint median 2.5 Median change 0 (-4,3) p = 0.6	Psychiatric admissions	6/79	15/70 p<0.01	Primary care consultations (mean)	13.8	17.1 p not significant
Client Satisfaction Questionnaire	Baseline median 28 Endpoint median 30.5 Median change 1	Baseline median 29 Endpoint median 31 Median change 0	Inpatient days	42.6 (SD 27.1)	41.3 (SD 35.0) p not significant			

	(0,3)	(-1,3) p=0.2						
Medical Outcome Survey	Baseline median 70.5 Endpoint median 65.75 Median change 0 (-5,5)	Baseline median 65.25 Endpoint median 69 Median change 2.25 (-5,4)						
Psychiatric attendances	Baseline median 0 Endpoint median 0 Median change 0	Baseline median 0 Endpoint median 0 Median change 0 p=0.08						

Table 7 : Economic evaluation of study interventions

	Nazareth and colleagues	Burns and colleagues	Kendrick and colleagues
Number in intervention group providing full process data	41	79	171
Number of assessments	3 in 9 months	4 in 12 months	4 in 24 months
Staff requirement	<i>Initial assessment:</i> Practice nurse – 20 minutes GP – 10 minutes <i>Subsequent assessment:</i> Practice nurse – 5 minutes GP – 10 minutes	Practice nurse – length of assessment not stated – assume cost as per additional practice nurse consultation.	GP – length of assessment not stated – assume cost as per additional consultation.
Staff cost	Initial assessment: £21.03 Subsequent assessment: £15.53	£7.58	£13.00
Additional costs (See comment below*)	Letters to invite or remind patients about assessment – Cost £0.59 per letter (Ref – Breast Screening Study).	Patients attending for depot injection, therefore assume no additional cost in generating attendance.	Assessment done opportunistically during routine surgery, therefore assume no additional cost in generating attendance.†
Costs per study	<i>Initial assessment: (33 undertaken)</i> £693.99 <i>Subsequent assessment: (35 undertaken)</i> £543.55 <i>Letters to patients: (Min of 126 sent *)</i> £74.34 TOTAL: £1311.88	<i>Assessments: (191 undertaken)</i> £1447.78 TOTAL: £1447.78	<i>Assessments: (286 undertaken)</i> £3718.00 TOTAL: £3718.00
(Cost per intervention patient)	£32.00	£18.32	£21.74
Cost per patient standardised to 12 months	£42.67	£18.32	£10.87

† Note: In some practices GP's reported writing, phoning and visiting patients to conduct assessment but numbers were not stated and therefore unable to adequately cost

* Costs of interventions, screening procedures and tests etc happening as consequence of assessment have not be included due to lack of data to quantify / specify these. All studies used a GP / Practice nurse training session which has not been included in the costs. This should be a one off-cost and therefore per patient/year should be negligible.

Appendices

Appendix 1 : Electronic search strategies

MEDLINE 1966 TO April 2000

exp Primary health care/

(Primary adj5 care).mp

(Primary adj5 health adj5 care).mp

exp Family practice/

(Family adj5 practice).mp

exp General practice/

(General adj5 practi\$).mp

(Daily adj5 practice\$).mp

exp Physicians, family/

(Family adj5 physician\$).mp

(Family adj5 doctor\$).mp

(Family adj5 medic\$).mp

(Practice adj5 nurse\$).mp

(Nurse\$ adj5 practi\$).mp

1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 [Primary care]

exp Schizophrenia/

Schizophreni\$.mp

exp Psychotic disorders/

Psychotic.mp

Psychosis.mp

exp Schizophrenia and disorders with psychotic features/

Community psychiatry or Orthopsychiatry or Psychiatric nursing

((Mental\$ adj ill\$) not depressi\$ not anorexi\$ not bullimi\$ not alcohol\$ not stress\$ not tourette\$).mp

(Psychiatr\$ not depressi\$ not anorexi\$ not bullimi\$ not alcohol\$ not stress\$ not tourette\$).mp

16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 [Schizophrenia / Psychosis]

(Health adj5 check\$).mp

(Health adj5 surve\$).mp

(Health adj5 monitor\$).mp

(Health adj5 education).mp

(Health adj5 care).mp

(Check adj up\$).mp

Monitor\$.mp

Review\$.mp

Opportunistic\$.mp

Systematic\$.mp

(Physical adj5 health).mp

(Mental adj5 health).mp

Routine.mp

Medical.mp

Assessment.mp

Appointment.mp

Screen\$.mp

26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42

[Health assessments]

CINAHL 1982 TO DECEMBER 1999

exp Primary health care/

(Primary adj5 care).mp

(Primary adj5 health adj5 care).mp

exp Family practice/

(Family adj5 practice).mp

exp General practice/

(General adj5 practi\$.mp

(Daily adj5 practice\$.mp

exp Physicians, family/

(Family adj5 physician\$.mp

(Family adj5 doctor\$.mp

(Family adj5 medic\$.mp

(Practice adj5 nurse\$.mp

(Nurse\$ adj5 practi\$.mp

1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 [Primary care]

exp Schizophrenia/

Schizophreni\$.mp

exp Psychotic disorders/

Psychotic.mp

Psychosis.mp

exp Schizophrenia and disorders with psychotic features/

Community psychiatry or Orthopsychiatry or Psychiatric nursing

((Mental\$ adj ill\$) not depressi\$ not anorexi\$ not bullimi\$ not alcohol\$ not stress\$ not tourette\$.mp

(Psychiatr\$ not depressi\$ not anorexi\$ not bullimi\$ not alcohol\$ not stress\$ not tourette\$.mp

16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 [Schizophrenia / Psychosis]

(Health adj5 check\$.mp

(Health adj5 surve\$.mp

(Health adj5 monitor\$.mp

(Health adj5 education).mp

(Health adj5 care).mp

(Check adj up\$.mp

Monitor\$.mp

Review\$.mp

Opportunistic\$.mp

Systematic\$.mp

(Physical adj5 health).mp

(Mental adj5 health).mp

Routine.mp

Medical.mp

Assessment.mp

Appointment.mp

Screen\$.mp

26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42

[Health assessments]

EMBASE 1980-April 2000

exp Primary health care/

(Primary adj5 care).mp

(Primary adj5 health adj5 care).mp

exp General practice/

(Family adj5 practice).mp

(General adj5 practi\$).mp

(Daily adj5 practice\$).mp

exp General Practitioner/

(Family adj5 physician\$).mp

(Family adj5 doctor\$).mp

(Family adj5 medic\$).mp

(Practice adj5 nurse\$).mp

(Nurse\$ adj5 practi\$).mp

1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 [Primary care]

exp Schizophrenia/

Schizophreni\$.mp

exp Psychosis/

Psychotic.mp

Psychosis.mp

exp Psychiatry/

((Mental\$ adj ill\$) not depressi\$ not anorexi\$ not bullimi\$ not alcohol\$ not stress\$ not tourette\$).mp

(Psychiatr\$ not depressi\$ not anorexi\$ not bullimi\$ not alcohol\$ not stress\$ not tourette\$).mp

15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 [Schizophrenia / Psychosis]

(Health adj5 check\$).mp

(Health adj5 surve\$).mp

(Health adj5 monitor\$.mp

(Health adj5 education).mp

(Health adj5 care).mp

(Check adj up\$.mp

Monitor\$.mp

Review\$.mp

Opportunistic\$.mp

Systematic\$.mp

(Physical adj5 health).mp

(Mental adj5 health).mp

Routine.mp

Medical.mp

Assessment.mp

Appointment.mp

Screen\$.mp

24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40

[Health assessments]

HEALTHSTAR AND HEALTHSTAR 75 1975 - April 2000

Explode primary health care

OR physicians, family (mh)

OR primary nursing care (mh)

OR family practice (mh)

OR family practice (mh) and practice (tw) or General practice (kw)

OR physicians, family (mh) and practitioner (tw) or General practitioner (kw)

OR nurse practitioners (mh)

Explode schizophrenia

OR explode psychotic disorders

OR paranoid disorders (mh)

Explode delivery of health care

OR explode primary prevention

OR explode health education

Combination of the above

PSYCHLIT – 1990-April 2000

'primary health care' or (primary near/2 care) or (primary near/2 health near/2 care) or 'family practice' or (family near/2 practi*) or 'general practice' or (general near/2 practi*) or (daily near/2 practi*) or (family near/2 physician*) or (family near/2 doctor) or (family near/2 medic*) or (practice near/2 nurse*) or (nurse near/2 practi*)

schizophreni* or psychos?s or psychotic or ((mental* adj ill*) not depressi* not anorexi* not bulimi* not alcohol* not stress* not tourette* not alzheimer* not dement*)

'health check' or (health adj surve*) or (health adj monitor*) or 'health education' or 'health care' or (check adj up*) or monitor* or 'physical health' or 'mental health' or medical or routine or assessment or appointment or screen*

Appendix 2 : Checklist for quality assessment

NB: Checklists were developed for different study designs prior to searching. All studies meeting eligibility criteria were controlled trials therefore no other checklist was utilised

Reference Number:

First Author:

Date:

Please complete one checklist as appropriate to study design

Study Design	Checklist			
Controlled Trial	<ul style="list-style-type: none"> • Was trial described as randomised? • Was the assignment of the treatment groups truly random? If no how could randomisation be described? • Describe allocation concealment • Was outcome assessor blinded to treatment allocation? • Were control and treatment groups comparable at entry? • Was relatively complete follow-up achieved? • Were outcomes of people who withdrew described and included in analysis? • Were groups treated identically other than for the named intervention? 	Y	N	
		Y	N	U
		Quasi	Systematic	U
		Adequate	Inadequate	U
		Y	N	U
		Y	N	U
		Y	N	U
		Y	N	U
		Y	N	U

Cohort Studies	<ul style="list-style-type: none"> • Are exposed people representative of the standard users of the intervention? • Was the non-exposed cohort selected from the same population as the exposed? • Was exposure reliably ascertained and verified? • Were cohorts comparable on identified confounding factors? • Was there adequate adjustment for the effects of confounding variables? • Was a dose-response relationship between exposure and outcome demonstrated? • Was outcome assessment blind to exposure status? • Was follow-up long enough for the outcomes to occur? • Was an adequate proportion of the cohort followed-up? 	Y	N	U
Case Series	<ul style="list-style-type: none"> • Is the study based on a random sample selected from a suitable sampling frame? • Is there evidence that the sample is representative of standard users of the intervention? • Are the criteria for inclusion in the sample clearly defined? • Was follow-up long enough for important events to occur? 	Y	N	U

	<ul style="list-style-type: none"> • Were outcomes assessed using objective criteria? • If comparisons of series are being made was there sufficient description of the series and the distribution of prognostic factors? 	Y	N	U
		Y	N	U

Y – Yes, N- No, U – Unclear from the paper

Appendix 3 : Data extraction form

Primary Care Assessment of Patients with Schizophrenia

Reference Number:

First Author:

Date / Year:

STUDY DESIGN

Type of study: *please circle*

RCT

Clinical Trial (Not RCT)

Cohort

Cases Series

Other (please specify)

Trial design:

Parallel

Y

N

U

Crossover

Y

N

U

Blinded

Y

N

U

Who blinded?

Location:

Number of practices / centres:

Locations:

POPULATION

Inclusion Criteria

Exclusion Criteria

Number included in study

Total Approached

Total Excluded

Total Included

Number lost to follow up

ITT analysis

Y N U

Group			
	1	2	3
Description of intervention:			
Who implemented:			
Systematic or opportunistic:			
Frequency:			
Description:			
Number:			
Age Range:			
Mean Age:			
Male : Female ratio			

OUTCOMES

Outcome	Measurement tool	When recorded	Who recorded

ANALYSIS

Statistical tests used:

GROUP			
	1	2	3
Outcome 1 (<i>please state</i>) Baseline mean: End point mean: Mean change: P values:			
Outcome 2 (<i>please state</i>)			

Baseline mean: End point mean: Mean change: P values:			
Outcome 3 (please state) Baseline mean: End point mean: Mean change: P values:			
Outcome 4 (please state) Baseline mean: End point mean: Mean change: P values:			

COMMENTS:

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