Randomised controlled trial of tailored strategies to implement guidelines for the management of patients with depression in general practice

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SUMMARY

Background: *Various methods are available for implementing change in the clinical behaviour of general practitioners (GPs). Although passive dissemination of information is generally ineffective, other methods can be variably effective. Few studies have investigated the impact of tailored methods.*

Aim: *To determine whether methods tailored to overcome obstacles to change using psychological theories are more effective than dissemination alone in the implementation of guidelines for depression among GPs.*

Design of study: *Randomised controlled trial.*

Setting: *Sixty general practices in England; 30 GPs in the control group, 34 in the intervention group.*

Method: *Practitioners identified patients presenting with depression before and after the implementation of guidelines (control group* n = *192 in the first data collection,* n = *181 in the second; intervention group* n = *210 in the first data collection and* n = *197 in the second). The main outcome measures were: record of adherence to guideline recommendations in clinical records; proportion of patients with Beck Depression Inventory (BDI) score less than 11 at 16 weeks after diagnosis.*

Results: *In comparison with the control group, in the group of GPs receiving tailored implementation, there were increases in the proportions of patients assessed for suicide risk. In the intervention group, the proportion of patients with BDI scores of less than 11 at 16 weeks increased.*

Conclusion: *Obstacles to implementation can be identified and strategies tailored to address them. The findings indicate a new approach for research to understand and develop methods of implementation.*

Keywords: *randomised controlled trial; clinical behaviour; implementation of guidelines; depression; disease management.*

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Introduction

VARIOUS methods are available for implementing change in the clinical behaviour of general practitioners (GPs), including the dissemination of guidelines alone, or guidelines supplemented with audit and feedback, reminders, educational meetings, or the re-engineering of services. Although passive dissemination of information is generally ineffective, other methods can be variably effective. Therefore, it has been recommended that the selection of implementation methods should be guided by evidence on their effectiveness, the nature of the change being suggested, and an assessment of the obstacles to change.[1] The existence of obstacles to change offers a potential explanation for the variable effectiveness of implementation methods.[2,3] Different obstacles may be present in different settings at different times. If the implementation methods are tailored to overcome the obstacles, then change may be more likely to take place.[4,5]

Few studies have investigated the impact of tailored methods.[2] Several of these have involved educational outreach and included only limited assessment of the principal obstacles to change.[6,7] However, the effectiveness of tailored methods is likely to depend on the extent to which all important obstacles to change are identified. In addition, the approach used to match methods to obstacles should ensure the selection of methods most likely to be effective. Since empirical evidence to indicate which obstacles would be most likely to be overcome by particular implementation methods is limited, we have suggested that psychological theories could be used to guide the choice of methods to overcome obstacles facing individual practitioners, health care teams or health care organisations.[3] In this paper, we report a randomised trial in which such theories were used to tailor implementation methods to the obstacles facing GPs asked to implement guidelines for the management of patients with depression.

Depression is a common disorder among patients attending GPs.[8] However, although generally effective treatment is available[9] patients do not always receive adequate care. Some patients are not correctly diagnosed, some do not receive a therapeutic dose of antidepressant and some do not receive treatment for a sufficient length of time. The implementation of guidelines for depression could be one method for improving the care of depressed people. Our hypothesis was that implementation methods tailored, by reference to psychological theories, to the obstacles faced by individual practitioners would be more likely to improve adherence to guidelines and improve outcome than

HOW THIS FITS IN

What do we know?

- The effectiveness of strategies for implementing guidelines varies in different settings and circumstances and the explanation may be the local obstacles to change.
- Approaches for matching strategies to the identified obstacles are not well developed.

What does this paper add?

- the findings of this preliminary study suggest that the selection of implementation strategies through reference to psychological theories, and following investigation of the obstacles to change, can be an effective method.
- Use of psychological theory can assist in improving understanding of implementation and change. Further studies are required to determine whether this is a practical and cost-effective method for further use.

- The diagnosis of depression must be based on core symptoms as defined in the ICD-10 or DSM-IV (A).
- At diagnosis, the patient must be assessed for risk of suicide (A).
- Patients with major depression are treated with antidepressants and/or cognitive behaviour therapy (A).
- Antidepressants must be prescribed in therapeutic doses (A).
- After commencement of treatment, the patient should be reviewed within three weeks and the risk of suicide re-assessed (B).
- Patients who have responded fully in the acute phase of the treatment should be seen at least once every month during the maintenance of treatment (B).
- Drug treatment should be continued for at least four months after the episode of depression has resolved (A).

Box 1. The guideline recommendations (A = recommendation supported by strong evidence and having an important impact on outcome; B = recommendation supported by moderate evidence, or having a less strong impact on outcome).

dissemination of guidelines alone.

Method

A systematic method was used to develop the guidelines.[10] The key elements of care were identified from good quality guidelines[11] and reviews.[8,9] Additional focused literature reviews were undertaken to enable the guideline recommendations to be categorised into A or B, depending on the strength of evidence and impact on outcome. The guidelines had seven recommendations (Box 1).[12]

Assignment

All 1239 general practitioners in Leicestershire, Lincolnshire, Derbyshire, Northamptonshire, and north Nottinghamshire were invited to take part in the study. The practices of those GPs who agreed to take part were randomised using a table of random numbers to control and intervention groups. Thus, no practice included a doctor in both study groups. Practitioners in both control and intervention groups received a copy of the guidelines in single-page format, plus a booklet containing a summary of the relevant evidence for each recommendation.

Protocol

Each practitioner in the intervention group also took part in an in-depth interview six weeks after dissemination of the guidelines to identify their obstacles to implementing them. The interview was piloted with two GPs not taking part in the study. The interviews were between 25 and 45 minutes in duration. They were recorded and transcribed, and reviewed independently by four members of the research team (RB, SR, NR, HH) to identify comments that indicated particular obstacles to change. For each such comment, a psychological theory explaining aspects of individual behaviour change was suggested by the reviewer. In a series of meetings, the interview and data about the performance of each GP were discussed until consensus was reached about the particular psychological theory that best explained the observed obstacle. The theory was then used to select the implementation method. For example, if a GP reported anxiety about assessing suicide risk and uncertainty about the form of questions to use, the theory identified would be self-efficacy.[13] In this case, the implementation method might include the provision of scripts of questions for assessing suicide risk for the GP to use in consultations. The implementation methods were delivered to each practitioner approximately four to six weeks after their interview. If a practitioner faced several obstacles they also received several implementation methods, selected by reference to theory.

Data were collected twice, the first time before the interviews and interventions and the second 12 months later. In each data collection, the participating GPs were asked to identify consecutively and seek the consent to participation in the study of seven adult patients, aged 18 or above, attending for their first consultation with new episodes of depression. Patients were excluded if they would be unable to complete the outcome questionnaire because they could not read or write English, or if they had received treatment for depression in the previous six months.

Masking

Data about the process of care were used to check the extent to which care was in accordance with the guideline recommendations, and were collected from the clinical records of the enrolled patients 16 weeks after the initial consultation. Data collection was undertaken by two trained data collectors blind to practitioners' study groups, and inter-rater reliability was checked during both data collections by dual independent data collection from 20 records. Serial administration of the Beck Depression Inventory (BDI)[14] was used to collect data about the outcome of care. Patients were asked to complete the BDI following the initial consultation, then four and 16 weeks later. A score of 11 and above was used to define cases of depression. The interview of each practitioner in the intervention group took place at least 16 weeks after the recruitment of the practitioner's final patient included in the first data collection.

The sample size calculation took account of the cluster

randomised design.[15] To detect a difference in adherence to a guideline recommendation (the primary study outcome measure) of 15% (55% versus 70%) between control and intervention groups with a significance level of 5%, power of 80%, six patients in each cluster, and an estimated intra-cluster correlation coefficient of 0.02,[16] 30 GPs were required in each study group. In the analysis, the odds ratios of improvement in adherence to the guidelines or outcome between data collections within each study group were calculated. The ratios between study groups of the odds ratios within study groups were then calculated. For example, assume that the level of adherence with a recommendation in the control group is 100 out of 200 patients. In the intervention group, assume it is 95 out of 200. The odds of adherence in the control group is 100/100 and in the intervention group 95/105. Assume that at the second data collection, adherence is 130/70 in the control group and 135/65 in the intervention group. The odds ratio between data collections in the control group is (100/100)/(130/70) (here called *x*), and in the intervention group is (95/105)/(135/65) (here called *y*). The statistical analysis sought to explain the ratio *x*:*y*. Logistic regression was used to model the odds ratios, using the Statistical Analysis System (SAS) software[17] and employing logit transformation[18] with generalised estimating equations to allow for correlations between patients attending the same doctor. Interactions between variables were sought and accounted for.

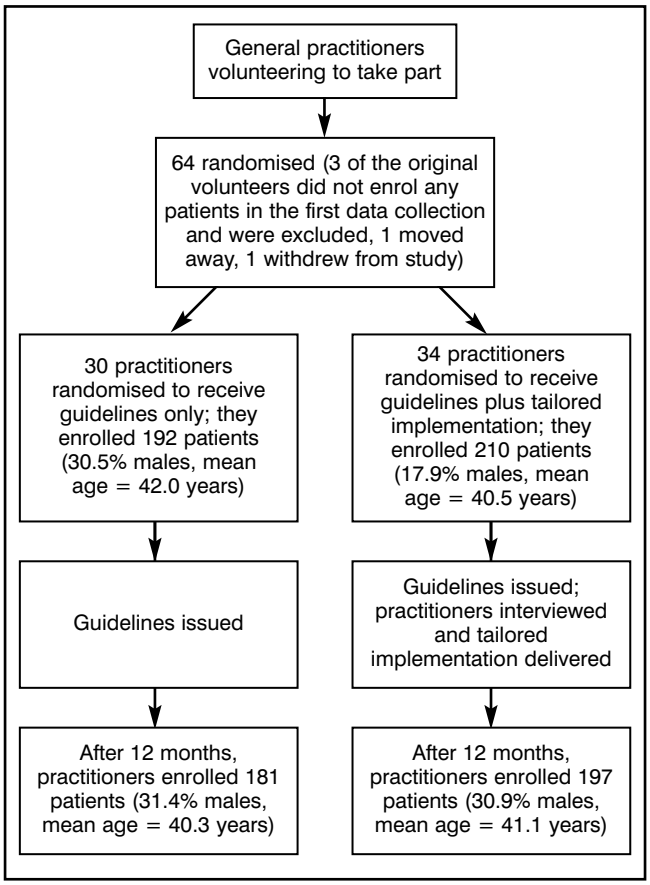

Figure 1. Outline of study showing numbers of GPs and patients in each study group.

Results

Participant flow

Sixty-four GPs took part in the study (Figure 1). Two were in solo practice, seven were from practices with more than one participating GP, and the remaining 55 were each from different group practices. Thirty-four were randomised to the intervention group and 30 to the control group. There were no significant differences in the age of patients in each study group, but there were fewer males in the intervention group in the first data collection ($P<0.05$). There were no significant differences between groups in adherence to the guideline recommendations at baseline (Table 2).

The obstacles to implementing the guidelines among the GPs in the intervention group and the theories that were identified as explaining them are shown in Table 1. The implementation methods were tailored for each individual and the table indicates only the general approach taken for each type of obstacle. The care of six GPs was found to adhere closely to the guidelines and their interviews indicated that they did not face obstacles. Therefore, they received feedback with encouragement to reinforce their pattern of care. The theories most commonly found to explain observed obstacles were preparedness to change,[19] typically relating to GPs who had not given thought to the need to change performance; and self-efficacy,[13] which typically related to GPs who did not feel able to ask about suicide risk or discuss compliance with medication with patients because they did not have confidence in their choice of words. Two GPs were themselves depressed; one had already been diagnosed as depressed and a second realised they were depressed during the interview. Both were encouraged to seek appropriate treatment.

Analysis

The levels of inter-rater reliability of the data collection for the variables to check adherence to the guidelines were all satisfactory (κ = 0.68–0.95). The findings are summarised in Table 3. Most patients received treatment for their depression (recommendation 3) and were followed up after three weeks (recommendation 5). However, levels of adherence to other guideline recommendations, such as assessment of suicide risk (recommendation 2) and prescription of therapeutic doses of antidepressant (recommendation 4) were lower. In comparison with the control group, the intervention increased the odds of assessment of suicide risk.

The numbers of patients completing the BDI in the first data collection in the control and intervention groups respectively were: at recruitment 156 (81%) and 172 (82%), after four weeks 123 (64%) and 138 (66%), and after 16 weeks 109 (56%) and 115 (55%). In the second data collection, the numbers in the control and intervention groups respectively were: at recruitment 155 (86%) and 160 (81%), at four weeks 127 (71%) and 143 (73%), at 16 weeks 113 (62%) and 126 (64%). The proportion of patients with a BDI score of less than 11 at 16 weeks increased in the intervention group.

Discussion

This study is the first to investigate the effectiveness of tai-

Table 1. Obstacles to change and methods tailored to overcome them, among the 34 GPs in the intervention group. A GP could have more than one obstacle to change.

Theories and obstacles	Number of GPs	Implementation strategies
Preparedness to change[19] — for example, failure to contemplate the need to change, or contemplating change but taking no action	15	Feedback with guidance tailored to the stage of contemplation; educational outreach
Self-efficacy[13] — for example, reluctance to ask about suicide risk because lack of confidence in ability to choose an appropriate form of words	15	Quotations from other GPs who felt able to assess suicide risk to enable modelling; educational outreach visit; feedback
Social influence theory[20] — for example, reliance on discussion with peers or guidance from local specialists in changing practice	9	Small group discussion with peers; educational outreach visit by an expert clinician; feedback to enable comparison of performance with others
None — performance in accordance with the guidelines, no obstacles identified in interviews	6	Feedback presented positively
Cognitive dissonance theory — for example, rejection of a guideline recommendation because it conflicted with current beliefs	3	Educational outreach visit; feedback accompanied by a reminder of the evidence
Organisational obstacles — for example, difficulty of some rural practitioners in getting to continuing education events; loss of confidence in local psychiatry services	3	None possible within the study; given feedback
Psychological illness — for example, depression	2	Encouragement to seek appropriate support and treatment; given feedback

Table 2. Changes in adherence of practitioners to guideline recommendations between data collections in the control and intervention groups, for male and female patients included together. Figures are numbers of patients (% of eligible patients).

	First data collection		Second data collection		Odds ratio[a] 95% CI
	Control	Intervention	Control	Intervention	
Total number of patients	192	210	181	197	
Diagnosis: 3 or more symptoms recorded	86 (44.8)	83 (39.5)	83 (45.9)	113 (57.4)	1.9 (0.9–3.8)
Suicide risk assessed at diagnosis	42 (21.9)	42 (20.0)	48 (26.5)	131 (66.5)	5.6 (2.8–11.3)
Treated with antidepressant or cognitive therapy	180 (93.8)	191 (91.0)	168 (92.8)	188 (95.4	2.5 (0.7–9.2)
Antidepressant in therapeutic dose	106 (69.7)	121 (73.3)	127 (78.9)	155 (87.6)	1.3 (0.6–3.2)
Reviewed at 3 weeks	127 (83.6)	139 (84.2)	129 (80.1)	146 (82.5)	1.1 (0.5–2.4)
Risk of suicide re-assessed at 3 weeks	4 (3.2)	14 (10.1)	13 (10.1)	31 (21.2)	0.7 (0.2–3.0)
Those treated are to have two or more follow-up consultations	83 (54.6)	85 (51.5)	75 (46.6)	108 (61.0)	2.0 (0.9–4.0)
Treated for 4 months	69 (45.4)	85 (51.5)	66 (41.0)	92 (52.0)	1.2 (0.6–2.4)
BDI <11 at diagnosis	7 (4.5)	8 (4.7)	6 (3.9)	4 (2.5)	0.6 (0.1–3.0)
BDI <11 at 4 weeks	22 (17.9)	24 (17.4)	30 (23.3)	27 (18.9)	0.8(0.4–1.8)
BDI <11 at 16 week	49 (45.0)	31 (27.0)	50 (42.0)	58 (45.0)	2.5 (1.2–5.2)

[a]Ratio between study groups of the odds ratios within study groups of change in compliance with guidelines (or outcome) between data collections.

loring implementation methods to identified individual obstacles guided by psychological theory. A 'diagnostic' model was used in which theories were used to interpret observed performance and interviews of GPs and guide the selection of particular implementation methods. The findings suggest that this approach to implementation may be effective and should be further investigated.

The findings demonstrate that GPs do face obstacles in implementing guidelines and that at least some of these obstacles can be identified in interviews and understood in terms of psychological theories. We cannot determine from this study whether reference to psychological theories was essential in selecting implementation methods. However, we did find that reference to theories enabled us to explain the selection and this approach should facilitate future research in this field. Reliance on personal judgement alone would not have had this benefit.

The practitioners who took part in this study were self-selected and the obstacles they faced may not represent the obstacles faced by most GPs. Nevertheless, the obstacles we identified do have some implications for quality improvement programmes, such as clinical governance. For example, some practitioners may lack the language to use in consultations, such as assessing suicide risk or advising about taking medication. This problem may be best addressed through consultation training.[21]

The intervention did not increase adherence to all guideline recommendations, and some improvements also occurred in the control group. There are several possible explanations. Adherence to some guideline recommendations, such as treatment with an antidepressant or cognitive therapy, was already high and further improvement would have been unlikely. We did not seek to identify obstacles at the level of the team or organisation since we did not have

methods available to address them. However, such obstacles may have a major impact on the ability of practitioners to apply the guidelines. Although we did not seek information about organisational obstacles, some practitioners did describe them. Furthermore, some individual obstacles may have been overlooked despite the care taken in conducting and analysing the interviews and it is also possible that the obstacles faced by a practitioner may have changed over time. It is also possible that we could have chosen other implementation methods that would have been more effective or delivered them more intensively. Also, this was a relatively small study and it may only have detected large intervention effects. The intra-cluster correlation coefficients for the eight guideline recommendations and the three BDI measurements ranged from 0.01 to 0.25, with eight being of a value less than 0.1. Therefore, our study may have been insufficiently powered to detect an effect owing to the intervention for some of the recommendations.

Some of the changes in performance may have been owing to improved recording only. However, this is unlikely to adequately explain the findings. GPs disclosed in interviews their difficulties in assessing suicide risk, indicating that the low level of recording of suicide risk assessment in the first data collection was not simply failure to enter information in the records. Furthermore, information about prescribed treatment and follow-up appointments are unlikely to be omitted from records. The participating practitioners recruited patients and it is therefore possible that they may have excluded certain patients, but this would not have been more likely in either study group and therefore is unlikely to explain the differences in the intervention group.

We did not investigate the cost of the intervention in this study. It is possible that the costs would be relatively high in comparison with other implementation methods since the identification of obstacles is not usually a component of other methods. However, even audit and feedback, a commonly used method in the United Kingdom, have cost consequences and an increase in costs might be justified if our new approach was more effective.

Several issues remain to be addressed in further research. Future studies should provide information on how obstacles should be identified and which set of theories best predict which methods to choose. The validity of different methods of identifying obstacles requires investigating, and the relative importance of individual, team, and organisational obstacles to change should be assessed. Research is also required to develop methods for identifying and addressing obstacles at the level of the team, and the organisation.

Future studies of implementation methods should include identification of the prevailing obstacles. Only in this way will it become possible to determine which methods are most effective in the presence of particular obstacles. Furthermore, if future studies relate observed obstacles to psychological or other behavioural theories, our understanding of the process of change in clinical performance of professionals will gradually improve. Therefore, this study should not be regarded as providing a new implementation method for immediate general use. It does, however, indicate a new avenue for research to improve understanding of, and develop methods to promote, change in the clinical behaviour of practitioners, teams, and health care organisations.

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