PHASE: a randomised, controlled trial of supervised self-help cognitive behavioural therapy in primary care

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SUMMARY

Background: Common mental health problems account for up to 40% of all general practitioner (GP) consultations. Patients have limited access to evidence-based psychological therapies. Cognitive behavioural therapy self-help strategies offer one potential solution.

Aim: To determine differences in clinical outcome, patient satisfaction and costs, between a cognitive behavioural-based self-help package facilitated by practice nurses compared to ordinary care by GPs for mild to moderate anxiety and depression.

Design of study: Randomised controlled trial.

Setting: Seventeen primary healthcare teams.

Method: Patients presenting to their GP with mild to moderate anxiety and/or depression were recruited to the study and randomised to receive either a self-help intervention facilitated by practice nurses or ordinary care. The self-help intervention consisted of up to three appointments: two 1 week apart and a third 3 months later. There were no restrictions on ordinary care.

Results: Intention-to-treat analysis showed that patients treated with practice nurse-supported cognitive behavioural therapy self-help attained similar clinical outcomes for similar costs and were more satisfied than patients treated by GPs with ordinary care. On-treatment analysis showed patients receiving the facilitated cognitive behavioural therapy self-help were more likely to be below clinical threshold at 1 month compared to the ordinary care group (odds ratio [OR] = 3.65, 95% confidence interval [CI] = 1.87 to 4.37). This difference was less well marked at 3 months (OR = 1.36, 95% CI = 0.52 to 3.56).

Conclusion: Facilitated cognitive behavioural self-help may provide a short-term cost-effective clinical benefit for patients with mild to moderate anxiety and depression. This has the potential to help primary care provide a choice of effective psychological as well as pharmacological treatments for mental health problems.

Keywords: self-help groups; cognitive behaviour therapy; randomised controlled trials; mental health.

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Introduction

MENTAL health problems account for up to 40% of all general practitioner (GP) consultations,[1] costing primary care an estimated £76.1 million and the NHS £96 million for pharmaceutical therapies.[2] The most prevalent neurotic disorder within the week prior to interview in the Office of National Statistics' psychiatric morbidity study[3] was mixed anxiety and depressive disorder (88/1000 cases). Overall, the prevalence of neurotic disorder was 164/1000 cases. Although many patients prefer psychological treatment; for example, cognitive behavioural therapy, there is limited access to these therapies in primary care.[4,5] Self-help strategies based on similar principles enable people to make choices and take actions on their own behalf to improve health and wellbeing.[6] There is growing evidence that this approach can be successful for a range of mental health problems in primary care.[7]

The principal burden of mental health work falls to GPs, although practice nurses report seeing large numbers of patients both formally and informally for mental health problems.[8] Given the evidence that practice nurses are able to take on new and delegated roles in many areas of health care,[9] there is also potential to develop their role in mental health.[10] However, because the majority of practice nurses have little experience of formal mental health training, they themselves express reservations about their levels of skill in dealing with mental health problems.[11]

The PHASE programme, which focused on the psychological health (PH) of patients by assessing self-help education (ASE) delivered by practice nurses in primary care, targeted the high prevalence of mixed anxiety and depression within the general population.[3] This trial tested the clinical and economic effects of training practice nurses to facilitate cognitive behavioural-based self-help mental health care for people with mild to moderate common mental health problems compared to ordinary care by GPs.

Method

Trial objective

To determine differences in clinical outcome, patient satisfaction and costs between a self-help booklet based on cognitive behavioural therapy techniques and facilitated by practice nurses, compared to ordinary care by GPs for mild to moderate anxiety and depression.

Ethics

Ethical approval was granted by the Multiple Research Ethics Committee (Northern and Yorkshire) and subsequently from eight local research ethics committees.

Participants

Seventeen primary healthcare teams participated in the study. Twenty-three practice nurses from the 17 general practices represented a range of practices, from single-handed to large teams, situated in both urban and semi-rural locations in north-east England. The index of multiple deprivation scores, using a scale from 1 (least deprived) to 84 (most deprived), ranged from 16 to 70.[12] All patients aged 18 years and above consulting GPs with mild to moderate symptoms of anxiety and/or depression were eligible for the trial. GPs filled in a simple and easily completed severity matrix for each patient comprising four domains (wellbeing, problems, functioning, risk) and four levels of severity (no problem, slight, moderate, severe). Patients were included in the study if they were experiencing slight or moderate distress in one or more of the three domains of wellbeing, problems and functioning. Patients were excluded if they were assessed to be at a risk level of slight or above and/or to be experiencing severe distress in wellbeing, problems or functioning, or were judged to require immediate treatment with a new course of anti-depressants. GPs gave patients a consent form and information sheet. Completed forms were returned directly to the research team's base for randomisation.

Randomisation

Patients were randomised once consent had been given. Randomisation was independent of the research team and carried out using a computer-generated random numbers table with practices blind to the randomisation strategy. Block randomisation was utilised in blocks of four patients per practice to prevent practice nurse workload becoming unmanageable. Patients were informed of their randomly allocated group within 24 hours and were requested to make the appropriate appointment at their surgery.

Treatments

Practice nurse-facilitated self-help. Practice nurses assisted patients in using a self-help book — *Managing Anxiety and Depression*[13] — a booklet developed for primary care, based on cognitive behavioural therapy techniques and previously subject to an outcome study.[14] Practice nurses assisted patients in using the booklet both within and between sessions. The programme comprised up to three sessions based on a previous trial evaluating a 'two-plus-one'

session model.[15] The first two appointments, offered 1 week apart, focused on familiarisation with the booklet and applying it to samples of the patients' problems. Patients then used the booklet at home and were offered a third review appointment ('plus-one') 3 months later.

Practice nurses received 3 days training to support patients using the book in the form of a 'health technology'. The trainers had recognised qualifications in cognitive behavioural therapy as well as extensive experience of training in this area. Nurses were required to carry out an observed role play and complete a written task at the end of the 3 days. Supervision was provided either face to face or by telephone. A full account of the training has been reported elsewhere.[16]

Ordinary care. GPs treated patients assigned to them in their 'usual' way. There were no restrictions on the type of care delivered. Ordinary care might include continued prescription of medication, advice and reassurance, formal counselling or referral to counselling, and psychological therapy services.

Outcome measures and data collection

Baseline questionnaires were posted when patients were informed of their allocation. Follow-up measures were completed 1 and 3 months later. Primary outcome measures were patient self-report questionnaires:

- *CORE-OM*[17]: a 34-item scale measuring the domains of symptoms, functioning, wellbeing and risk (total mean score range 0 to 4. A high score represents increased problem severity. Cut-off scores differentiating clinical and non-clinical populations were 1.19 for males and 1.29 for females),
- *EuroQol-5D*[18]: a health-related quality-of-life measure quantifying health using a thermometer scale (range 0 to 100 with higher scores indicating greater positive health) and weighted health status (-0.59 to 1.00 with 1.00 being full health and -0.40 unconscious),
- *The consultation satisfaction questionnaire*[19]: measuring depth of relationship, professional care and perceived time (total mean score range 1 to 5).

The General Health Questionnaire-12 (GHQ-12)[20] was used to detect caseness at baseline using a cut-off score of 3 or above. GP records were accessed to collect demographic data on all participants as well as information on resource use, supplemented by information from patients obtained by questionnaire.

Sample size

Effect sizes ranging from 0.88[21] and 0.87 to 1.18[22] are recorded when self-report measures are used in self-help studies. Assuming an effect size of 0.80, 30 patients were required to be retained in each group, giving the study 80% power to detect a difference at the 0.05 confidence level. Mindful of the impact of drop-out rates following randomisation, as well as patient non-compliance with attendance, we set a recruiting-to-retention ratio target of 2:1 (i.e. a minimum of 60 patients recruited to each group to ensure retaining the required power).

Statistical methods

Data were analysed using SPSS for Windows version 9. Analyses of the CORE-OM and EuroQol at 1 and 3 months were conducted using baseline data as the last observation carried forward (LOCF) in an intention-to-treat analysis, with the baseline represented as a covariant.

Clinically significant changes were calculated by determining the parameters of reliable and clinically significant change,[23] which were applied to an on-treatment sample. Reliable and clinically significant change analyses concern the evaluation of change between two time points for each case, taking into account the relationship of the individual change scores to pre-treatment sample scores and the psychometric reliability of the outcome measure. It would therefore be inappropriate to use a LOCF sample when conducting these analyses. Odds ratios (ORs) and numbers needed to treat (NNT) were calculated. Levels of satisfaction were compared using full factorial analyses of variance (ANOVAS). Satisfaction data were analysed using an independent *t*-test applying a 1% significance level.

Economic analysis was carried out to compare the mean resource use for both groups. Direct costs, including contacts with the doctor and the nurse, purchase of the self-help manual, consultations with other mental health professionals, inpatient days and medication, were compared. Unit costs from the *Unit Costs of Health and Social Care*[24] were used for the contacts and from the *Monthly Index of Medical Specialities*[25] for medication costs.

Results

Sample

A total of 250 patients were recruited, of whom 140 returned their consent forms. One did not meet the inclusion criteria, leaving 139 eligible patients (see Figure 1). Sixty-four people were allocated to ordinary care and 75 to self-help, 47 of whom attended for one or more appointments. This group differential is owing not only to a combination of the small sample size and the imbalance of the block randomisation, but also to the fact that occasional errors were made at surgery level when patients were given an appointment to see the practice nurse when in fact they had been randomised to ordinary care. It was considered unethical to rectify the error once the patient had commenced treatment.

The mean age of the sample was 39.2 years (standard deviation [SD] = 12.6), and 84% were female. One hundred and twelve people (81%) returning consent forms completed the GHQ-12,[20] 108 (96%) meeting caseness.

Outcomes

There were no baseline differences between the two groups on any demographic or outcome variables. Table 1 shows the results at baseline, 1-month and 3-month follow-ups for the CORE-OM and EuroQol. At 1 month, both groups improved significantly over time: the CORE-OM, self-help group mean reduction was 0.28, *t* = 3.54, degrees of freedom (*df*) = 58, *P* = 0.001; the ordinary care group mean reduction was 0.17, *t* = 2.21, *df* = 46, *P* = 0.03; the EuroQol, self-help group mean increase was 6.63, *t* = 2.50, *df* = 58,
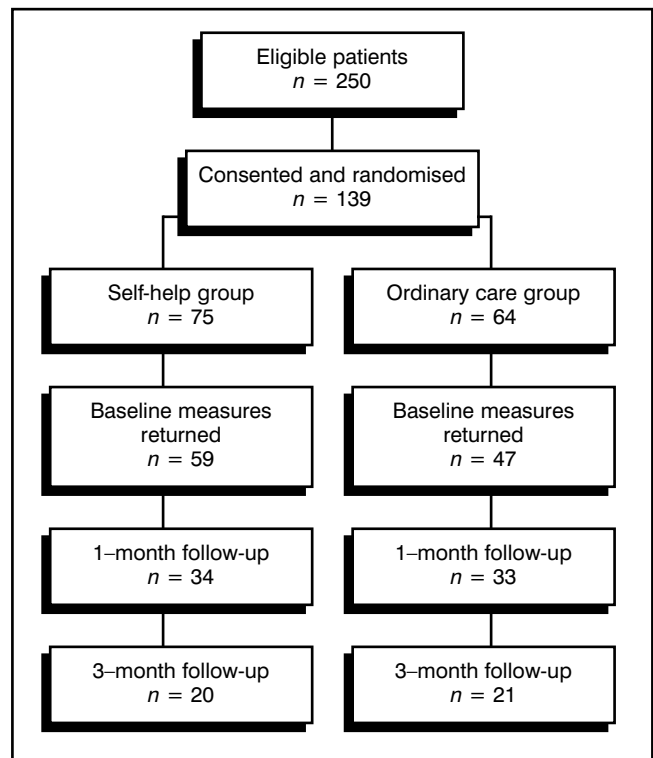

Figure 1. Trial profile.

P = 0.015; the ordinary care group mean increase 5.59, *t* = 3.12, *df* = 45, *P* = 0.003.

There were no between-group differences over time: CORE-OM, *F* = 1.01, *P* = 0.32; EuroQol thermometer, *F* = 0.03, *P* = 0.87; EuroQol weighted health status, *F* = 0.06, *P* = 0.80.

On the CORE-OM, 47% of the self-help group were below clinical cut-off at 1 month compared to 18% in the ordinary care group (OR = 3.65, 95% confidence interval [CI] = 1.87 to 4.37). The NNT equalled four patients in the self-help group for one additional patient to achieve a CORE-OM score below clinical cut-off compared to the ordinary care group.

At 3 months both groups showed significant improvement on the CORE-OM and the EuroQol thermometer compared to baseline. On CORE-OM, the self-help group mean reduction was 0.34, *t* = 3.94, *df* = 58, *P* < 0.001; for the ordinary care group the mean reduction was 0.41, *t* = 4.14, *df* = 45, *P* < 0.001; on EuroQol, the self-help group mean increase was 8.24, *t* = 2.74, *df* = 58, *P* = 0.008; the ordinary care group mean increase was 7.96, *t* = 3.64, *df* = 45, *P* = 0.001.

There were no between-group differences in the amount of change over time: CORE-OM, *F* = 0.32, *P* = 0.57; EuroQol thermometer, *F* = 0.22, *P* = 0.64; EuroQol weighted status, *F* = 0.06, *P* = 0.81.

On the CORE-OM, 50% of the self-help group were below clinical cut-off at 3 months compared to 42% in the ordinary care group (odds ratio: 1.36, 95% CI = 0.52 to 3.56). The NNT equalled 12.5 patients in the self-help group for one additional patient to achieve a CORE-OM score below clinical cut-off compared to the ordinary care group at 3 months.

Table 2 summarises patient outcome data at both 1– and

Table 1. Outcome data.

Measure	Self-help group		Ordinary care group		Mean difference[a]	95% CI	Significance
	n	Mean (SD)	n	Mean (SD)			
CORE-OM[b] all items actual[c]							
Baseline	59	1.94 (0.51)	47	1.97 (0.54)			
1 month	34	1.38 (0.77)	33	1.74 (0.69)	0.26	-0.05 to 0.58	0.10
3 months	20	1.24 (0.82)	21	1.51 (0.87)	0.12	-0.36 to 0.61	0.62
CORE-OM[b] all non-risk items actual[c]							
Baseline	59	2.26 (0.55)	47	2.27 (0.55)			
1 month	34	1.55 (0.85)	33	1.92 (0.75)	0.28	-0.65 to 0.63	0.11
3 months	20	1.45 (0.91)	21	1.72 (0.88)	0.15	-0.41 to 0.71	0.59
CORE-OM[b] all items LOCF[d]							
Baseline	59	1.94 (0.51)	47	1.97 (0.54)			
1 month	59	1.67 (0.72)	47	1.80 (0.64)	0.11	-0.11 to 0.33	0.32
3 months	59	1.60 (0.80)	47	1.55 (0.77)	0.07	-0.18 to 0.33	0.57
CORE-OM[b] all non-risk items LOCF[d]							
Baseline	59	2.26 (0.55)	47	2.27 (0.55)			
1 month	59	1.91 (0.84)	47	2.01 (0.71)	0.09	-0.15 to 0.33	0.47
3 months	59	1.86 (0.91)	47	1.77 (0.85)	0.10	-0.38 to 0.19	0.50
EuroQol thermometer score[e] actual[c]							
Baseline	59	49.08 (18.44)	46	53.57 (21.60)			
1 month	32	62.03 (20.78)	30	59.53 (22.46)	3.08	-12.89 to 6.72	0.53
3 months	17	71.53 (16.65)	20	61.20 (22.87)	9.37	-2.71 to 21.45	0.12
EuroQol thermometer score[e] LOCF[d]							
Baseline	59	49.08 (18.44)	46	53.57 (21.60)			
1 Month	59	55.02 (21.29)	46	59.15 (21.07)	0.52	-5.89 to 6.94	0.87
3 Months	59	56.63 (22.00)	46	61.52 (22.09)	1.72	-5.56 to 9.01	0.64
EuroQol weighted health status[f] actual[c]							
Baseline	59	0.62 (0.28)	46	0.52 (0.30)			
1 Month	33	0.69 (0.30)	33	0.58 (0.32)	0.05	-0.18 to 0.09	0.50
3 Months	18	0.73 (0.26)	21	0.60 (0.34)	0.04	-0.21 to 0.14	0.67
EuroQol Weighted Health Status[f] LOCF[d]							
Baseline	59	0.62 (0.28)	46	0.52 (0.30)			
1 Month	59	0.65 (0.30)	46	0.57 (0.32)	0.01	-0.10 to 0.08	0.80
3 Months	59	0.66 (0.29)	46	0.60 (0.32)	0.01	-0.08 to 0.10	0.81

[a]Mean difference of 1-month and 3-month scores with baseline score covaried out. [b]Range = 0 to 4 (higher scores indicate greater dysfunction). [c]Data from patients with complete actual datasets. [d]Data from patients with last observation carried forward. [e]Range = 0 to 100 (higher scores indicate greater mental health). [f]Range = -0.59 to 1.00 (full health = 1.00, unconscious = -0.40).

3–month follow-ups by applying stringent criteria for reliable and clinical change. This is defined as an end-of-treatment score, which is below clinical cut-off, and a pre-post change score, which is significantly greater than the error of the measurement of the instrument (for details see Evans *et al*[23]). Patients in the self-help group were more than twice as likely to achieve reliable and clinical change at 1 month compared to the ordinary care group but this difference had disappeared by 3 months.

Satisfaction

Table 3 shows that patients in the self-help group were significantly more satisfied with their treatment than patients in the ordinary care group.

Additional resource use

Data were available for 47 people who were allocated to the self-help group, and 40 who were allocated to ordinary care. In the self-help group two people were referred to secondary services. In the ordinary care group five were referred to other services: three to secondary care, one to complementary therapy and one to inpatient psychiatric care. In addition, two people in the self-help group were referred to a practice-based counsellor and one person to a primary care mental health worker compared to nine people referred to counselling in the ordinary care group. One person in the ordinary care group attended an accident and emergency department. The remainder of the notes were unavailable at the time of the researchers' surgery visits.

Economic results

Table 4 shows that there were no overall differences between the two groups' mental healthcare costs in the year following intake into the study. General practice costs for the ordinary care group were significantly higher than the self-help group, but these costs were offset by the costs of increased practice nurse time. One person in the ordinary care group had an inpatient episode. However, this was excluded from the economic analysis owing to the disproportionate weighting it would have given to that group.

Table 2. Reliable and clinical change data.

Domains	Self-help group n (%)	Ordinary care group n (%)
Reliable and clinically significant change[a]		
1 month	10 (29)	4 (12)
3 months	10 (29)	11 (33)
Reliable change only[b]		
1 month	4 (12)	5 (15)
3 months	6 (18)	3 (9)
Non-reliable change[c]		
1 month	19 (56)	21 (64)
3 months	16 (47)	17 (52)
Reliable deterioration[d]		
1 month	1 (3)	3 (9)
3 months	2 (6)	2 (6)
Total	34 (100)	33 (100)

[a]Change that is both reliable (statistically significant) and clinically significant (changed from a clinical to a non-clinical population). [b]Change that is statistically significant, i.e. unlikely to be owing to measurement error. [c]Change that is either non-reliable improvement or non-reliable deterioration. [d]Deterioration that is statistically significant.

Table 3. Satisfaction data.

Outcome measure	Self-help group		Ordinary care group		Mean difference	95% CI	Significance
	n	Mean (SD)	n	Mean (SD)			
Consultation satisfaction questionnaire score (scale 1–5[a])							
1 month	32	3.81 (0.62)	33	3.28 (0.54)	0.54	0.17 to 0.92	0.005
3 months	32	3.73 (0.59)	33	3.25 (0.80)	0.48	0.13 to 0.83	0.008

[a]Higher scores denote greater satisfaction.

Discussion

This trial shows that patients with common mental health problems treated by practice nurse-supported cognitive behavioural-based self-help attained similar clinical outcomes for similar costs, were more satisfied, and were referred on to other services less frequently than patients treated by GPs with ordinary care.

Although there were no statistically significant differences between the group means on outcome measures, in the self-help group more than twice as many patients for whom actual follow-up data was available were either below clinical cut-off or had achieved clinical and reliable change after 1 month of treatment compared to the ordinary care group. Even though the differences between the groups had disappeared after 3 months, self-help patients remained more satisfied.

Consistent with other psychological therapies literature,[26] patients receiving the self-help intervention were more likely to be below caseness thresholds in the short term only. The availability of treatment options that alleviate short-term distress is an important consideration for primary care. Treatments that use cognitive behavioural techniques are both effective[27] and recommended,[4] but when delivered in traditional ways have not always translated the effect sizes seen in clinical trials into primary care effectiveness.[26] In contrast, patients may benefit from accessible cognitive behavioural-based psychological treatment delivered at an early stage, particularly as many people are reluctant to use

psychopharmacology.[5] Patients saw GPs less often in the self-help group, and the levels of satisfaction with practice nurses in this study is similar to that in other areas of nurse-provided care,[10] suggesting that patients like this option.

Limitations

This was a pragmatic trial with a commitment that 'practice' was the driver in which the 'trial' was being conducted. As such, the study was only powered to detect large-scale main effects. Nonetheless, it was limited by small numbers because of poor recruitment rates and substantial attrition at both 1- and 3-month follow-ups, introducing a potential bias to our original sample. These high levels of attrition mean that the results should be interpreted cautiously.

The higher levels of satisfaction reported in the self-help group also need to be interpreted with caution as they may reflect the positive effects of seeing the practice nurse for a longer period of time. In future research this could be controlled for with a control arm in which the patient receives unstructured support from the nurse.

A further limitation is the use of distress rather than diagnostic criteria for study inclusion. Although 96% of patients included in the study were above the GHQ-12 caseness threshold, we were unable to confirm diagnostic prevalence rates for anxiety and depression. Therefore, the patients in this sample represent people with psychological distress commonly seen in primary care.

Table 4. Resource allocation referral to one year.

Resources	Unit cost[a]	Self-help group Mean in £ (SD) n = 47	Ordinary care group Mean in £ (SD) n = 40	Mean difference	95% CI	P value
GPs	£18 per 9.36 minute consultation	57.45 (43.87)	84.60 (55.92)	-27.15	-48.44 to -5.87	0.013
Practice nurses	£32 per hour of client contact	19.94 (12.63)	NA	NA	NA	NA
Medication	Cost per tablet from the *Monthly Index of Medical Specialities*: December 2001	70.79 (127.32)	109.03 (134.62)	-38.24	-94.15 to 17.68	0.178
Counselling	£30 per hour	13.26 (64.91)	23.25 (71.73)	-9.99	-39.84 to 19.84	0.509
Mental health worker	£72 per hour of client contact	1.27 (6.12)	0.00	1.28	-0.65 to 3.20	0.191
Outpatient	Psychologist: £62 per hour of client contact Psychiatrist: £277 per hour of client contact	27.26 (132.67)	14.55 (57.75)	12.71	-32.56 to 57.99	0.578
Self-help costs[b]	Cost per booklet	3.50	NA	NA	NA	NA
Total		191.80 (220.86)	231.43 (184.64)	-39.62	-127.33 to 48.07	0.372
Contacts						
Primary care contacts		5.02 (2.67)	4.65 (3.15)	0.37	-0.87 to 1.61	0.560

[a]All rates include qualification costs. [b]The additional training cost per nurse was £500, calculated on the basis of similar courses in primary health care (this was not included, as per patient cost was dependent on the number of patients seen by the nurse, and added value of training persists beyond the study). NA = not applicable.

Implications

The finding that practice nurse-facilitated self-help conferred some short-term clinical benefit, that it costs no more than ordinary care, and that patients were more satisfied than with ordinary care has implications for mental health in primary care. Practice nurses can deliver a brief cognitive behavioural intervention that is effective, no more costly than usual care, and that patients like. Although both treatments have identical outcomes at 3 months, patients receiving practice nurse-facilitated self-help are likely to have their distress alleviated in a shorter time.

The use of practice nurses to deliver cognitive behavioural-based self-help has the potential to improve primary care mental health services by ensuring patients have a choice of effective psychological as well as pharmacological treatments. Primary care might consider training practice nurses to deliver cognitive behavioural self-help as an alternative to ordinary care. Unfortunately, practice nurses may have neither the inclination nor the time to take on this role. Replicating this study is necessary in order to see if the same results can be achieved by other non-mental health professionals in primary care using the same or other self-help materials.

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