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RESEARCH

Subacromial ultrasound guided or systemic steroid injection for rotator cuff disease: randomised double blind study

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ABSTRACT

Objective To compare the effectiveness of ultrasound guided corticosteroid injection in the subacromial bursa with systemic corticosteroid injection in patients with rotator cuff disease.

Design Double blind randomised clinical trial.

Setting Outpatient clinic of a physical medicine and rehabilitation department in Oslo, Norway.

Patients 106 patients with rotator cuff disease lasting at least three months.

Interventions Ultrasound guided corticosteroid and lidocaine injection in the subacromial bursa and lidocaine injection in the gluteal region (local group); corticosteroid and lidocaine injection in the gluteal region and ultrasound guided lidocaine injection in the subacromial bursa (systemic group).

Main outcome measures Difference in improvement in the overall shoulder pain and disability index score after six weeks.

Results Six weeks after the intervention, the mean difference in improvement in overall shoulder pain and disability index score between the local group and the systemic group was −5.2 (95% confidence interval −13.9 to 3.5); it was −4.1 (−12.3 to 4.1, P=0.32) after adjustment for baseline score. A small but statistically significant difference in improvement between groups occurred in favour of the local group for two secondary outcome measures: the Western Ontario rotator cuff index (8.1, 0.7 to 15.6) and change in main complaint (2.0, 0 to 4).

Conclusions No important differences in short term outcomes were found between local ultrasound guided corticosteroid injection and systemic corticosteroid injection in rotator cuff disease.

Trial registration Clinical trials NCT00640575.

INTRODUCTION

Non-operative treatment for rotator cuff disease primarily consists of active physiotherapy, which may be supplemented with non-steroidal anti-inflammatory drugs, steroid injections, and electrotherapy.[1] Despite extensive research, evidence for the effectiveness of steroid injections for rotator cuff disease is unconvincing. Conclusions of systematic reviews and meta-analyses are inconsistent.[2-4] Corticosteroids are potent anti-inflammatory and pain modulating drugs with both systemic and local effects. The precise mechanism of local corticosteroid injections is not well understood.

Thirty per cent to 80% of subacromial injections are reported to reach the subacromial bursa or the subacromial space when a blind injection technique is used.[5] High frequency ultrasonography is a safe, readily available technique for guiding musculoskeletal aspiration and infiltration. Recently, two small randomised trials reported that ultrasonographically guided injections were significantly more effective than blind injections for short term pain relief and improved function.[6 7] However, participants were not blinded for treatment group, raising the possibility of a bias favouring ultrasound guided injections.

We did a randomised controlled study comparing the effectiveness of a systemic corticosteroid injection in the gluteal region with an ultrasound guided injection in the subacromial bursa in patients with rotator cuff disease. We used a double blind design.

METHODS

This study was a prospective, double blind, randomised controlled trial. We recruited patients between April 2005 and October 2006. We invited general practitioners in Oslo, serving a population of half a million, to refer patients with rotator cuff disease. We included patients who had all of the following: shoulder pain for more than three months; pain on abduction; less than a 50% reduced glenohumeral range of motion in no more than one direction of external rotation, internal rotation, or abduction; pain on two of three isometric tests for abduction, external rotation, and internal rotation; and a positive Hawkins-Kennedy impingement sign.[8]

We excluded patients who had symptomatic acromioclavicular arthritis, indicators of glenohumeral joint pathology, referred pain, generalised muscular pain syndrome, inflammatory arthritis, diabetes mellitus type 1, previous fractures or surgery to the shoulder, or contraindications to or use in the last month of local steroid injections and patients with a shoulder pain and disability index score below 30 points.

Study protocol—At baseline we recorded magnetic resonance imaging results or diagnostic ultrasonography. We randomised patients to either local or systemic steroid injection treatment groups. Patients and the outcome assessor were blinded for treatment assignment. The consultant physician administering the injections was not blinded.

Treatment—Both treatment groups received injections of local anaesthetic in the shoulder and the gluteal region

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to improve blinding by pain relief. The "local" group received a sonographically guided injection of 2 ml (10 mg/ml) triamcinolone and 5 ml (10 mg/ml) lidocaine hydrochloride to the subacromial bursa and an intramuscular injection of 4 ml (10 mg/ml) lidocaine hydrochloride to the upper gluteal region. The "systemic" group received a sonographically guided injection of 5 ml (10 mg/ml) lidocaine hydrochloride to the subacromial bursa and an intramuscular injection of 2 ml (10 mg/ml) triamcinolone and 2 ml (10 mg/ml) lidocaine hydrochloride to the upper gluteal region. We allowed patients to use analgesics and to continue physiotherapy in the trial period.

Outcome measures—We recorded baseline demographics and clinical characteristics. Blind follow-up measures were carried out at two and six weeks after treatment. We asked patients to report additional treatment. The main outcome measure was the self administered shoulder pain and disability index.[9] Secondary outcome measures were the Western Ontario rotator cuff index[10]; active range of abduction and flexion; the participant's assessment of change in the main complaint compared with baseline; and pain at rest and during activity.[11]

Statistical analysis—We analysed data according to the principle of intention to treat. We calculated differences in improvement between groups in shoulder pain and disability index score, Western Ontario rotator cuff index score, change in main complaint, and pain at rest and during activity. We used an analysis of covariance model with adjustment for baseline differences.[12]

RESULTS

Of the 312 patients evaluated for inclusion, we randomised 106. Four patients (local n=1, systemic n=3) did not attend follow-up either at two weeks or at six weeks. One patient in the systemic group withdrew from the study after the two week follow-up. We included these results in the intention to treat analyses.

The two groups were similar across all baseline variables. Eight patients were not able or willing to have magnetic resonance imaging and had diagnostic ultrasonography. Eight patients in the local group and five patients in the systemic group attended physiotherapy between baseline and the six week follow-up. The groups did not differ in drug use, and no patient reported attending for other treatments in the trial period.

The table shows the improvement in shoulder pain and disability index scores for both groups over the six week period. The mean difference from baseline to the six week follow-up was 24.4 (SD 22.5, P<0.001) for the local group and 19.2 (SD 22.7, P<0.001) for the systemic group. The results at the six week follow-up were slightly in favour of the group receiving local injections for all outcome measures. The difference in effectiveness of

Outcome measures

Measure	Local group (n=53)	Systemic group (n=53)	Difference in improvement (95% CI)	Adjusted difference (95% CI)	P value
Shoulder pain and disability index—mean (SD)					
Baseline	53 (18)	51 (17)	–	–	–
2 weeks	32 (25)	28 (23)	0.8 (−7.9 to 9.4)	–	–
6 weeks	29 (21)	32 (23)	−5.2 (−13.9 to 3.5)	−4.1 (−12.3 to 4.1)	0.32
Western Ontario rotator cuff index*—mean (SD)					
Baseline	45 (17)	47 (16)	–	–	–
2 weeks	64 (23)	63 (22)	3.0 (−4.6 to 10.6)	–	–
6 weeks	67 (21)	60 (22)	9.0 (1.2 to 16.8)	8.1 (0.7 to 15.6)	0.032
Abduction†—median (interquartile range)					
Baseline	131 (98-144)	126 (88-144)	–	–	–
2 weeks	140 (130-148)	133 (108-146)	−2 (−11 to 7)	–	–
6 weeks	141 (122-150)	121 (99-144)	−4 (−12 to 4)	−6 (−15.9 to 3.8)	0.23
Flexion†—median (interquartile range)					
Baseline	151 (132-160)	150 (129-158)	–	–	–
2 weeks	158 (148-164)	150 (134-161)	−4 (−10 to 1)	–	–
6 weeks	156 (148-166)	152 (132-160)	−2 (−8 to 5)	−4.4 (−14.7 to 5.9)	0.40
Pain at rest†—median					
Baseline	6.0	7.0	–	–	–
2 weeks	4.0	4.0	0 (−1.0 to 1.0)	–	–
6 weeks	3.0	5.0	1.0 (0 to 2.0)	−0.6 (−1.5 to 0.2)	0.13
Pain in activity†—median					
Baseline	6.0	7.0	–	–	–
2 weeks	3.0	2.0	0 (−1.0 to 1.0)	–	–
6 weeks	2.0	3.0	1.0 (0 to 2.0)	−0.5 (−1.1 to 0.2)	0.19
Change in main complaint†—median					
2 weeks	5.0	4.0	1.0 (0 to 2.0)	–	–
6 weeks	6.0	2.0	2.0 (0 to 4.0)	–‡	0.009§

*Local group n=52; systemic group n=52.
†Non-parametric statistics.
‡No adjustment possible for baseline score.
§Mann-Whitney test of hypothesis of difference between medians *v* no difference.

WHAT IS ALREADY KNOWN ON THIS TOPIC

Insufficient evidence exists for the efficacy of corticosteroid injections in rotator cuff disease of the shoulder

Recent studies have shown favourable results with ultrasound guided injections in the subacromial bursa

Corticosteroids are potent anti-inflammatory and pain modulating drugs and may act through both local and systemic mechanisms

WHAT THIS STUDY ADDS

Local ultrasound guided corticosteroid injection is unlikely to be substantially more effective than systemic corticosteroid injection for short term improvement of pain and disability in rotator cuff disease

The study did not include a sham injection group, so whether either treatment is superior to placebo could not be determined

treatment between the two groups in the primary outcome measure was small and not statistically significant at any time point, even after adjustment for baseline difference in shoulder pain and disability index score (mean difference −4.1, 95% confidence interval −12.3 to 4.1, P=0.32) (table).

After adjusting for baseline difference in Western Ontario rotator cuff index score, we found a significant difference between groups of 8.1 (95% confidence interval 0.7 to 15.6, P=0.032) points at the six week follow-up in favour of patients receiving local injections. The participants' reported change in main complaint from baseline to six week follow-up was 6 (range 3-7) versus 2 (range 0-7), and the median difference between the groups was 2 (95% confidence interval 0 to 4, P=0.009) in favour of the local group. We found no significant difference between groups in range of abduction, range of flexion, or the two separate pain questions at two week and six week follow-ups (table).

Nine patients from both groups reported mild adverse effects. One patient in the local group and four patients in the systemic group reported post-injection pain in the shoulder. No serious side effects were reported.

DISCUSSION

We compared the effectiveness of ultrasound guided subacromial injection and systemic gluteal injection of corticosteroids in patients with rotator cuff disease. We did not find significant between group differences in the primary outcome measure. A recent estimate of the minimal clinically important difference in shoulder pain and disability index of 13.2 points suggests that our observed results are not clinically important.[13]

We reported statistically significant, but clinically small, group differences for two secondary outcome measures. The observed inconsistency between outcome measures may be due to the effects of multiple testing. With Bonferroni corrections, no results remained statistically significant. We cannot rule out the possibility that the Western Ontario rotator cuff index is a more sensitive outcome measure than the shoulder pain and disability index. In addition, the two scores may measure different constructs.

Comparison with existing literature

Previous randomised trials and systematic reviews have reported contradictory results on the effectiveness of corticosteroid injections for rotator cuff disease.[2 4 14] Considerable placebo effects have been seen with various treatments for shoulder disease.[15-17] Thus, our results could be attributed to the systemic effect of corticosteroids, injections of lidocaine into the subacromial bursa, and placebo effects.

We cannot rule out the possibility that the use of ultrasound for better placement of lidocaine injections contributed to the results of our study. Limited evidence exists for better efficacy with higher corticosteroid dosage.[3] We used 20 mg of triamcinolone, generally regarded as a low dose for systemic treatment. However, a higher dosage would be likely to reduce the difference between groups and increase adverse effects.

Possible confounders and weaknesses

The effectiveness of corticosteroid injections might be influenced by the duration of rotator cuff disease. Naredo et al found a favourable result of ultrasound guided corticosteroid injections in patients with a first flare of shoulder pain.[7] A large portion of patients in our study had had symptoms for more than six months.

A weakness in the design of the study was the lack of blinding of the physician who gave the injections. Even though we standardised the procedure, bias may have been introduced.

We set the period of time between treatment and follow-up testing to optimise the anticipated pharmacological effect of the injected steroid. Evidence of the effectiveness of long term treatment is scant.[18] Recent studies have reported better short term and inferior long term results from corticosteroid intervention than from physiotherapy and no intervention.[19 20]

Conclusion

The modest improvements seen in this and previous studies suggest that steroid injection is not a sufficient treatment strategy for patients with rotator cuff disease. The results of this study do not indicate that local corticosteroid injection is more effective than systemic corticosteroid injection for short term improvement in rotator cuff disease.

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Clinical effectiveness of health visitor training in psychologically informed approaches for depression in postnatal women: pragmatic cluster randomised trial in primary care

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ABSTRACT

Objective To evaluate benefits for postnatal women of two psychologically informed interventions by health visitors.
Design Prospective cluster trial randomised by general practice, with 18 month follow-up.
Setting 101 general practices in Trent, England.
Participants 2749 women allocated to intervention, 1335 to control.
Intervention Health visitors (n=89 63 clusters) were trained to identify depressive symptoms at six to eight weeks postnatally using the Edinburgh postnatal depression scale (EPDS) and clinical assessment and also in providing psychologically informed sessions based on cognitive behavioural or person centred principles for an hour a week for eight weeks. Health visitors in the control group (n=49 38 clusters) gave usual care.
Main outcome measures Score ≥12 on the Edinburgh postnatal depression scale at six months. Secondary outcomes were mean Edinburgh postnatal depression scale, clinical outcomes in routine evaluation-outcome measure (CORE-OM), state-trait anxiety inventory (STAI), SF-12, and parenting stress index short form (PSI-SF) scores at six, 12, 18 months.
Results 4084 eligible women consented and 595 women had a six week EPDS score ≥12. Of these, 418 had scores available at six weeks and six months. At six months, 34% (93/271) of women in the intervention group and 46% (67/147) in the control group had a score ≥12. The odds ratio for score ≥12 at six months was 0.62 (95% confidence interval 0.40 to 0.97, P=0.036) for women in the intervention group compared with women in the control group. After adjustment for covariates, the odds ratio was 0.60 (0.38 to 0.95, P=0.028). At six months, 12.4% (234/1880) of all women in the intervention group and 16.7% (166/995) of all women in the control group had scores ≥12 (0.67, 0.51 to 0.87, P=0.003). Benefit for women in the intervention group with a six week score ≥12 and for all women was maintained at 12 months postnatally. There was no differential benefit for either psychological approach over the other.
Conclusion Training health visitors to assess women, identify symptoms of postnatal depression, and deliver psychologically informed sessions was clinically effective at six and 12 months postnatally compared with usual care.
Trial registration ISRCTN92195776.

INTRODUCTION

About 13% of women experience depression during the first postnatal year,[1] yet there are problems in recognition because its clinical assessment is complex. Psychosocial and psychological intervention might be an effective treatment option, but the long term effectiveness remains unclear.[2] In this pragmatic trial we examined outcomes of special training for health visitors compared with usual care.

METHODS

Setting and participants—The pragmatic cluster trial took place from April 2003 to March 2006 in

101 general practices (clusters) in 29 primary care trusts in the former Trent Regional Health Authority, comprising a blend of urban and rural areas, with a population of about 5.2 million people. Health visitors recruited eligible women antenatally if they were registered with participating practices, were aged 18 or more, were able to give informed consent, and had no severe mental health problems.

Health visitor training—Health visitors in the intervention group were trained to identify depressive symptoms using the Edinburgh postnatal depression scale (EPDS)[3] and to use clinical assessment skills to assess a mother's mood, including suicidal thoughts. The EPDS is a self report measure with a score ranging from 0 to 30 (the highest symptom level). These health visitors were also trained to deliver psychologically informed sessions based on either cognitive behavioural principles[4] or on person centred principles.[5]

Baseline measurement and identification of women with six week score ≥12—Women were sent a postal questionnaire at six weeks postnatally to collect demographic details, measure depressive symptoms using the EPDS, and measure social support, stressful life events using the measure of social relationships[6] and list of threatening experiences,[7] and previous depression.[8] We used the recommended EPDS threshold score of 12 to identify women with symptoms of depression.[3 9]

Intervention group—In intervention clusters the psychologically informed approach comprised a package of health visitor training, combining three main elements of assessing women, identifying depressive symptoms, and delivering either a cognitive behavioural[4] or a person centred approach.[5] See bmj.com for details on the training and support of the health visitors.

Women eligible for psychologically informed sessions—In the intervention group the health visitors re-administered the EPDS face to face at eight weeks postnatally to all women with a six week score ≥12. Those who still had a score ≥12 were offered either cognitive behavioural or person centred sessions according to the cluster randomisation. The health visitor delivered weekly one hour sessions in the woman's home for up to eight weeks, focusing on the woman's needs, starting around eight weeks postnatally.

Usual care—In the UK, general practitioners, midwives, and hospital obstetricians meet women early in pregnancy to plan care. UK health visitors have routine contact with women at a new birth visit and at well baby clinics. (See bmj.com.)

Outcomes—We measured outcomes using a postal questionnaire at six, 12, and 18 months postnatally. The patient centred primary outcome was the proportion of women with an EPDS score ≥12 at six months. Secondary outcomes included the mean EPDS score at six and 12 months postnatally. (See bmj.com for full details.)

Statistical analysis—All analyses were by intention to treat, analysed as randomised, irrespective of receipt of psychologically informed sessions, with P<0.05 regarded as significant. (See bmj.com.)

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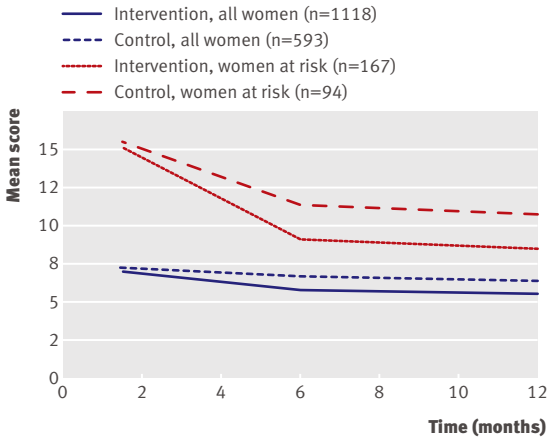

Mean EPDS scores over time by intervention and control group for women at risk (score ≥12 on EPDS at six weeks) and for all women

RESULTS

Among 241 interested practices, 101 consented to take part. The 101 clusters yielded 7649 eligible women of whom 4084 (53%) with a live baby consented to take part.

Six week response and identification of women with six week score ≥12

Of all the women, 85% (3449/4084) completed a six week questionnaire: 16% (191/1172) in the control group and 18% (404/2277) in the intervention group scored ≥12 on the EPDS.

Six month follow-up and analysis for women with six week score ≥12

Seventy per cent (418/595) of women with a six week EPDS score ≥12 from 86 clusters had a six week and a six month score available for analysis; 77% (147/191) in the control group *v* 67% (271/404) in the intervention group. For the primary outcome, 46% (67/147) in the control group and 34% (93/271) in the intervention group scored ≥12 on the six month EPDS (table 1). The difference of 11.7% (95% confidence interval 0.4 to 22.9) was significant (P=0.039). This means that we would need to treat nine women with a six week EPDS score ≥12 for one additional woman to have a score <12 at six months.

For women with a six week EPDS score ≥12, the mean score at six months was 11.3 (SD 5.8) in the control group and 9.2 (SD 5.4) in the intervention group (table 2).

Six month follow-up and analysis for all women as randomised

Of all the women who returned a six week questionnaire, 77% (2659/3449) also returned a six month questionnaire: 78% (914/1172) in the control group and 77% (1745/2277) in the intervention group.

At six month follow-up 16% (150/914) of all women in the control group and 12% (205/1745) of all women in the intervention group had a six week EPDS score ≥12, an absolute difference of 4.7% (0.7% to 8.6%, P=0.003). The difference was still significant (P=0.002)

after we adjusted for living alone, history of postnatal depression, stressful life events, and six week score (table 1).

Comparison of the cognitive behavioural approach and person centred approach

Examination of the two intervention groups separately showed that 33% (46/140) of women with a six week EPDS score ≥12 in the cognitive behavioural group and 35% (46/131) in the person centred group had a six month score ≥12 (P=0.74).

Secondary outcomes at 12 and 18 months

The figure shows how the mean EPDS score changed over time from six weeks to 12 months for women with a six week score ≥12 and all women by group. See bmj.com for all results.

DISCUSSION

This pragmatic cluster trial provides evidence of the effectiveness of a package of training for health visitors to identify symptoms of postnatal depression and to provide psychologically informed sessions.[10] In the intervention group we found a reduction in depressive symptoms in postnatal women as measured by the EPDS and by secondary outcomes at six and 12 months postnatally among women with a six week EPDS score ≥12 as well as among all women as randomised.

There was also some evidence of a benefit in favour of the intervention group for some of the secondary outcomes at the 18 month follow-up. As fewer women were sent a follow-up questionnaire at 18 months, however, more uncertainty surrounds these outcomes.

Strengths of the study

The trial has good internal and external validity and, with more than twice as many participants as the previous largest study,[11] provides more evidence than before of the benefit of psychologically informed approaches for women with postnatal depression.[2] We followed postnatal women to 18 months, whereas the final outcome in most previous studies of postnatal depression was measured at one to three months postnatally.[12] (See bmj.com.)

Limitations and potential sources of bias

One limitation in the interpretation of the results arises from the differential loss to follow-up at six months among the women with a six week score ≥12: 23% (44/191) in the control group and 33% (133/404) in the intervention group did not complete both the six week and the six month questionnaire. In the control group there was no difference between the mean scores at six weeks in those women who did (15.4) and did not (15.1) complete a six month questionnaire. The corresponding scores in the intervention group were 15.1 and 16.2. The potential impact of this on our results is unclear, although we did adjust the six month scores for the baseline six week score.

Another limitation is our use of the threshold score ≥12 to assess the level of depressive symptoms at six months postnatally. As the sensitivity of the EPDS at this threshold is 86%, the presence of these self reported symptoms might not necessarily have met the psychiatric criteria for a primary diagnosis of depression. Conversely, some women with a score below the threshold of 12 might have had symptoms of depression not included in the questionnaire (specificity 78%) or might have chosen to conceal their symptoms.[13]

The mechanism of action is unclear because the improvement in the intervention group was despite the unexpectedly low uptake of the psychologically informed sessions. In the intervention group 404 women had a six week score ≥12, but 173 were not eligible for sessions as they had an eight week score <12. However, 49% (199/404) of women were offered sessions and 60% (120/199) of these accepted. Of the 404 women, 271 (67%) returned a six month questionnaire. Of these, 46% (124/271) were offered sessions and 62% (77/124) accepted. The median number of sessions accepted was four (interquartile range two to seven). The women might have had practical reasons, such as lack of time, for not accepting the sessions.[14]

We found a significant reduction in depressive symptoms in all the women in the intervention clusters, including the 2241 with a six week EPDS score <12, of whom 11% (83/767) in the control group and 8% (113/1474) in intervention group had a six month score <12. These results suggest that non-specific effects of the health visitor intervention were operating to generate the improvement extending beyond the women with a six week score ≥12. As this was a pragmatic rather than explanatory trial, we can only speculate about the cause of the positive outcomes.

Because the health visitor intervention combined different training components, it is difficult to disentangle which elements might have been more effective. Importantly, the health visitors used their skills acquired during training to assess women, identify

Table 1 | Primary outcome: numbers (percentages) of women with score ≥12 on Edinburgh postnatal depression scale at six months among 418* with score ≥12 at six weeks, all women (n=2659*), and 2241 with score <12 at six weeks

				Odds ratio (95% CI)	
	Control	Intervention	% Difference (95% CI)	Unadjusted	Adjusted†
Score ≥12 at six weeks	67/147 (45.6)	92/271 (33.9)	11.7 (0.4 to 22.9)	0.62 (0.40 to 0.97), P=0.036	0.60 (0.38 to 0.95), P=0.028
All women	150/914 (16.4)	205/1745 (11.7)	4.7 (0.7 to 8.6)	0.67 (0.51 to 0.87), P=0.003	0.67 (0.52 to 0.86), P=0.002
Score <12 at six weeks	83/767 (10.8)	113/1474 (7.7)	3.1 (0.4 to 5.9)	0.68 (0.51 to 0.92), P=0.016	—

*For adjusted odds ratio, n=409 for women with score ≥12 at six weeks and 2624 for all women.
†Adjusted for score at six weeks, living alone, history of postnatal depression, any life events.

Table 2 | Secondary outcomes at six months for women with score ≥12 on Edinburgh postnatal depression scale (EPDS) at six weeks and all women, for control group versus intervention group

	Control		Intervention		Unadjusted		Adjusted*	
	No of women	Mean (SD)	No of women	Mean (SD)	Difference (95% CI)	P value	Difference (95% CI)	P value
Women with score ≥12 at six weeks (n=418):								
EPDS	147	11.3 (5.8)	271	9.2 (5.4)	−2.1 (−3.4 to −0.8)	0.002	−2.1 (−3.3 to −0.9)	0.001
CORE-OM	146	1.05 (0.69)	269	0.82 (0.62)	−0.23 (−0.39 to −0.07)	0.006	−0.22 (−0.36 to −0.09)	0.001
STATE anxiety	136	45.5 (12.5)	254	41.7 (11.8)	−3.8 (−6.6 to 1.0)	0.008	−3.9 (−6.1 to −1.4)	0.003
SF-12 MCS	142	37.8 (11.8)	263	42.3 (10.8)	4.7 (1.8 to 7.6)	0.001	5.2 (2.5 to 7.8)	0.001
SF-12 PCS	142	54.3 (9.0)	263	53.0 (7.6)	−1.4 (−3.5 to 0.7)	0.204	−1.7 (−3.6 to 0.1)	0.069
PSI-SF total stress	106	139.6 (20.4)	211	148.9 (17.0)	9.2 (4.8 to 13.7)	0.001	9.3 (5.2 to 13.4)	0.001
All women (n=2659):								
EPDS	914	6.4 (5.2)	1745	5.5 (4.7)	−1.0 (−1.5 to −0.4)	0.001	−0.8 (−1.2 to −0.4)	0.001
CORE-OM	906	0.53 (0.53)	1736	0.45 (0.46)	−0.09 (−0.15 to −0.04)	0.001	−0.07 (−0.11 to −0.03)	0.001
STATE anxiety	858	34.3 (11.7)	1634	33.2 (10.9)	−1.3 (−2.7 to −0.1)	0.042	−1.3 (−2.5 to −0.1)	0.033
SF-12 MCS	885	47.6 (10.5)	1694	48.9 (9.5)	1.5 (0.3 to 2.6)	0.010	1.4 (0.5 to 2.3)	0.003
SF-12 PCS	885	54.5 (6.8)	1694	54.7 (6.1)	0.2 (−0.3 to 0.7)	0.469	0.0 (−0.4 to 0.5)	0.871
PSI-SF total stress	698	155.9 (16.9)	1310	157.9 (15.3)	2.1 (0.3 to 3.9)	0.021	2.3 (0.6 to 3.9)	0.007

CORE-OM=clinical outcomes in routine evaluation-outcome measure; SF-12 MCS=short form 12 mental component summary; SF-12 PCS=short form 12 physical component summary; PSI-SF=parenting stress index short form. Better health represented by lower score in EPDS, CORE-OM, and STATE anxiety; higher score in others.
*Adjusted for six week EPDS score, living alone, history of postnatal depression, any life events.

those with postnatal depressive symptoms, and offer support and deliver specific psychologically informed sessions. Health visitors have a unique opportunity to engage with all postnatal women on their caseload. The unexpected effect might have arisen because the training equipped the health visitors with the confidence in their skills, which they were motivated to generalise beyond the original protocol specification for the women with a six week score ≥12.[15] That is, as a result of their training, health visitors in the intervention group might have extended enhanced relationship skills, such as warmth and empathy, thereby improving engagement with all women on their caseload antenatally and postnatally.

The intervention comprised other components, which might also have affected the emotional status of the new mothers. These were antenatal contact, the early development of the mother-health visitor relationship, and emphasis on focusing on the woman rather than solely the baby.

For those women who were offered but declined the psychologically informed sessions, the knowledge that the health visitor was aware of their emotional state and the offer in itself might have been perceived as support. Having someone in whom to confide has been identified as one of the main functional elements of social support for coping with stressful situations, and there is evidence of an association between absence of such a close relationship and symptoms.[16] The health visitors remained in contact with women on their caseload and there were opportunities for observation and support when the women attended baby clinics, baby massage, or postnatal groups. The women could also ask for further follow-up support when they thought they needed it.

The key to the effect of this psychological approach might therefore lie in the generalisation of the training outcomes across all women on their caseload, beyond the scope for which the training was originally developed, providing benefit from the health visitors' enhanced input and ongoing supportive engagement.

WHAT IS ALREADY KNOWN ON THIS TOPIC

Postnatal depression is a global problem that can persist beyond the first postnatal year

There are problems in recognising the condition and difficulties with using antidepressants in postnatal women

Psychologically informed interventions provide a practical, acceptable alternative

WHAT THIS STUDY ADDS

Health visitors can be trained to develop skills in the assessment of women and the detection of postnatal depressive symptoms and in the provision of psychologically informed interventions based on person centred or cognitive behavioural principles

The training was effective in reducing the proportion of women with postnatal depressive symptoms at six and 12 months postnatally

Both person centred and cognitive behavioural approaches were equally beneficial in bringing out sustained change in postnatal women

Conclusion

This large trial of treatment for postpartum depression is unique in the comparison of the cognitive behavioural approach and person centred approach. The trial indicates that training in psychologically informed approaches can be recommended for health visitors to enable them to identify postnatal depressive symptoms and enhance the psychological care of postnatal women.

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Effect of peer support on prevention of postnatal depression among high risk women: multisite randomised controlled trial

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ABSTRACT

Objective To evaluate the effectiveness of telephone based peer support in the prevention of postnatal depression.
Design Multisite randomised controlled trial.
Setting Seven health regions across Ontario, Canada.
Participants 701 women in the first two weeks postpartum identified as high risk for postnatal depression with the Edinburgh postnatal depression scale and randomised with an internet based randomisation service.
Intervention Proactive individualised telephone based peer (mother to mother) support, initiated within 48-72 hours of randomisation, provided by a volunteer recruited from the community who had previously experienced and recovered from self reported postnatal depression and attended a four hour training session.
Main outcome measures Edinburgh postnatal depression scale, structured clinical interview-depression, state-trait anxiety inventory, UCLA loneliness scale, and use of health services.
Results After web based screening of 21 470 women, 701 (72%) eligible mothers were recruited. A blinded research nurse followed up more than 85% by telephone, including 613 at 12 weeks and 600 at 24 weeks postpartum. At 12 weeks, 14% (40/297) of women in the intervention group and 25% (78/315) in the control group had an Edinburgh postnatal depression scale score >12 (χ^2=12.5, P<0.001; number need to treat 8.8, 95% confidence interval 5.9 to 19.6; relative risk reduction 0.46, 95% confidence interval 0.24 to 0.62). There was a positive trend in favour of the intervention group for maternal anxiety but not for loneliness or use of health services. For ethical reasons, participants identified with clinical depression at 12 weeks were referred for treatment, resulting in no differences between groups at 24 weeks. Of the 221 women in the intervention group who received and evaluated their experience of peer support, over 80% were satisfied and would recommend this support to a friend.
Conclusion Telephone based peer support can be effective in preventing postnatal depression among women at high risk.
Trial registration ISRCTN68337727.

INTRODUCTION

Studies show a significant increase in the risk of postnatal depression in women who do not have someone to talk openly with who has shared and understood a similar problem,[1] lack an intimate confidante or friend,[1-4] do not receive support without having to ask for it,[1] and feel socially isolated.[5] We evaluated the effect of telephone based peer (mother to mother) support on preventing postnatal depression among women identified as high risk within the first two weeks postpartum.

METHODS

Participants

Women were recruited from seven health regions across Ontario, Canada, between November 2004 and September 2006. In Ontario, as part of standard postpartum care, each mother receives a telephone call from a public health nurse often in the 24-48 hours after hospital discharge. At this time, a public health nurse briefly assessed mothers and looked for potential participants by screening for low mood (scoring >9 on the Edinburgh postnatal depression scale using a web based screening system). The trial coordinator downloaded the contact information daily and telephoned potential participants. Eligible participants were all new mothers about two weeks postpartum or less who were at least 18 years of age, able to speak English, had a live birth, and were discharged home from hospital.

Design and procedures

We carried out a multisite randomised controlled trial. The trial coordinator obtained baseline data and randomised eligible participants with stratification based on self reported history of depression, a known risk factor for postnatal depression.[6 7] Women allocated to the control group had access to standard community postpartum care. Women allocated to the intervention group had access to all standard postpartum care in addition to being matched with a peer volunteer. Research nurses blinded to group allocation telephoned all participants at 12 and 24 weeks postpartum to assess trial outcomes. At 12 weeks, women in the intervention group answered questions regarding their experience with the peer volunteer via a mailed questionnaire.[8] Health professionals and providers of standard community postpartum care were not informed of any mother's participation in the trial.

Intervention

The volunteer coordinator matched participants and peer volunteers based on residency and ethnicity if the mother desired. Telephone contact was to be initiated in the 48-72 hours after trial randomisation. The peer volunteers were requested to make a minimum of four contacts. The volunteer coordinator interacted with the peer volunteer one week after matching to confirm that contact was made with the participant. All peer volunteers were requested to complete an activity log[8 9] up to 12 weeks postpartum.

Peer volunteer recruitment and training—Following local advertising, 204 women from the community volunteered and met the selection criteria: ability to speak and understand English and self reported history of and recovery from postnatal depression. We employed a paid volunteer coordinator to organise recruitment of peer volunteers; conduct training sessions; match women with an appropriate peer volunteer; and monitor implementation of the intervention. All peer volunteers participated in four training sessions. On average, the 175 peer volunteers who were actually matched with a participant supported two mothers (mean 1.97, SD 1.50), with a range from one to seven.

Outcome measures

Postnatal depression was assessed using the Edinburgh postnatal depression scale[10] and the structured clinical interview for depression (SCID).[11] A cut-off score of >12 on the depression scale was used to indicate probable depression.[10] The clinical interview is a diagnostic measure for depression and has excellent evidence of reliability and validity when administered face to face. Our secondary outcomes included the state-trait anxiety inventory, the short version UCLA loneliness scale, and the health service utilisation and cost of care questionnaire. See bmj.com.

From our sample size calculation we required a sample of 586 (293 per group). We planned to enrol 700 to allow for losses to follow-up.

Statistical analysis

All data were collected by phone interview. We used a significance level of 0.05 for the primary outcome of postnatal depression and 0.01 for secondary outcomes to account for multiple comparisons. To assess the change over time across groups for the primary outcome, we ran generalised estimating equation models, with one model looking at the change from baseline to 12 weeks and the second looking at the change from baseline to 24 weeks.

We used multiple logistic regression analysis to assess the effect of the intervention on postnatal depression at 12 weeks after controlling for baseline characteristics. See bmj.com.

RESULTS

Flow of participants, follow-up, and sample characteristics

Of the 14 101 women who agreed to be screened, 1740 (12.3%) scored >9 and 1430 (82.2%) agreed to be contacted by the trial coordinator; 973 were eligible

Mean (SD) scores for postnatal depression, anxiety, loneliness, and use of health services at 12 and 24 weeks according to group

Time (weeks)	Peer support	Control	t	P value
EPDS:				
12*	7.93 (4.68)	8.89 (5.24)	2.37	0.02
24†	7.00 (4.66)	7.61 (4.59)	1.62	0.10
State-trait anxiety inventory:				
12	35.10 (11.85)	36.88 (12.84)	1.77	0.08
24	33.63 (11.01)	34.40 (12.07)	0.82	0.41
UCLA loneliness scale:				
12	19.59 (6.16)	20.14 (6.31)	1.08	0.28
24	18.76 (6.34)	19.44 (6.00)	1.35	0.17
Health service use:				
12	4.97 (1.62)	4.85 (1.52)	0.90	0.37
24	2.83 (1.53)	2.86 (1.62)	0.21	0.83

EPDS=Edinburgh postnatal depression scale.
*n=297 for peer support group, 315 for control group.
†n=289 for peer support group, 311 for control group.

WHAT IS ALREADY KNOWN ON THIS TOPIC

About 13% of women from diverse cultures will experience postnatal depression

Social deficiencies significantly increase the risk of postnatal depression

Preventative interventions are more likely to be successful if they are individually based, initiated postnatally, and target high risk women

WHAT THIS STUDY ADDS

Telephone based peer support might be effective in preventing postnatal depression among women at high risk

Women are receptive to receiving telephone based peer support and are satisfied with their experience

Lay people who have experienced a similar health problem or stressor can have a positive effect on psychological wellbeing

and could be contacted by the trial coordinator, and 701 agreed to participate, resulting in a 72% acceptance rate. See bmj.com.

There were no clinically important differences between the two groups. The mean depression scores at baseline were 12.50 (SD 2.80) in the intervention group and 12.62 (SD 2.76) in the control group. At 12 weeks postpartum, 613 (87.4%) participants completed the follow-up telephone interview, and 600 (85.6%) at 24 weeks. There were no baseline differences between women included in the analyses and those lost to follow-up at 12 weeks.

Clinical outcomes

Women in the intervention group were significantly less likely to have symptoms of postnatal depression at the 12 week assessment than those in the control group (odds ratio 2.1, 95% confidence interval 1.38 to 3.20). Specifically, 14% (40/297) of women in the intervention group had a score >12 compared with 25% (78/315) in the control group (χ^2=12.5, P<0.0014; number needed to treat 8.8, 5.9 to 19.6; relative risk reduction 0.46, 0.24 to 0.62). These results suggest women who received the peer support intervention were at half the risk of developing postnatal depression at 12 weeks postpartum than those in the control group. We found no significant group differences at 24 weeks (χ^2=2.53, P=0.11), when 11% (33/289) of women in the intervention group and 14% (43/311) in the control group had a score >12 (odds ratio 1.22, 0.75 to 1.98). This 24 week finding was expected considering that this was a prevention trial and for ethical reasons any participants identified at 12 weeks with clinical depression or who had a depression score >20 were referred for treatment.

Only 37 (6%) women in the whole sample were identified with clinical depression at 12 weeks postpartum using the structured clinical interview (14/297 (5%) in intervention group and 23/315 (7%) in control group). This prevalence is significantly lower than the overall 13% reported by O'Hara and Swain.[6] It is also inconsistent with research suggesting women with depressive symptoms in the early postpartum period are at significantly higher risk of developing postnatal depression. The uncertain accuracy of our data should highlight the problems associated with using generalist nurses as data collectors, and using a shortened version of the depression interview over the telephone with a multicultural sample.

At 12 weeks postpartum, 61 (21%) women in the intervention group had a score >44 on the state-trait anxiety inventory compared with 86 (27%) in the control group (odds ratio 1.44, 0.99 to 2.10; χ^2=3.66, P=0.055); we found no significant group differences at 24 weeks postpartum. The table shows mean scores related to all trial outcomes including loneliness and total use of health services. At 12 weeks comparable numbers of women in the intervention (n=11, 4%) and control (n=19, 6%) groups were taking antidepressants (χ^2=1.70, P=0.19). At 24 weeks there was no significant difference in antidepressant use between the groups (16 (6%) *v* 29 (10%), χ^2=3.05, P=0.08).

We used multiple regression analysis to assess the effect of the peer support intervention on postnatal depression after controlling for baseline characteristics that were significantly related to the screening depression score in univariate analysis, including non-Canadian ethnicity (χ^2=16.16, P<0.001), not born in Canada (χ^2=13.93, P=0.002), and less than five years in Canada (χ^2=5.19, P=0.02). The final model included the variables trial group status (P<0.001), history of depression (P<0.001), and no other individual to talk to who has a baby or young children (P<0.001).

Application of intervention

Out of the 349 women randomised to the intervention group, there was clear documentation of some form of initiation of the intervention in 328 (94%). Among these women, 219 (67%) had activity logs completed by their peer volunteer. Mothers received a mean of 8.8 (SD 6.0) contacts with their peer volunteers. In total, 1921 contacts were documented. Half (n=951) were telephone conversations initiated by the peer volunteer, with a mean duration of 14.1 minutes (SD 18.5, range 1-180). Almost a third (n=95, 29%) of the peer volunteer-mother matches actively continued past 12 weeks.

Scores at 12 weeks postpartum were correlated to total number of peer volunteer contacts (r=0.25, P<0.001) and number of conversations (r=0.25, P<0.001). In particular, women who had a depression score >12 at 12 weeks had significantly more contacts with their peer volunteer than those with a score ≤12 (11.96 (SD 6.96) *v* 8.30 (SD 5.86); t=2.97, P=0.003); we found similar results with total number of conversations (t=3.61, P<0.001).

Maternal satisfaction with intervention

Two hundred and twenty one (63%) women in the intervention group returned mailed evaluations of their experiences with peer volunteers. Overall, 81% (n=161) of women were satisfied with their experience. Maternal overall satisfaction was weakly correlated with total number of peer volunteer contacts (r=0.35, P<0.001), number of conversations (r=0.29, P=0.001), and number of messages left (r=0.29, P=0.001).

DISCUSSION

Telephone based peer support might be effective in preventing postnatal depression among women identified as high risk immediately postpartum. In particular, women who received peer support were at half the risk of developing postnatal depression at 12 weeks postpartum than those in the control group. Our results suggest that eight women would need to receive the peer support intervention to prevent one case of postnatal depression. On average women received eight contacts from their peer volunteer, and over 80% of women were satisfied with their peer support experience and would recommend it to a friend.

Strengths and weaknesses

The intervention was piloted and standardised, postnatal depression was assessed with the Edinburgh postnatal depression scale, data collection nurses were trained and blinded, and our losses to follow-up were below 15%.

Our results are limited in that the clinical diagnostic data for postnatal depression might be questionable. While the structured clinical interview was developed to be administered face to face by a mental health specialist, in our trial it was only feasible for generalist nurses to administer a shortened version of the depression module by telephone. This had not been formally validated. Furthermore, our sample was significantly more ethnically diverse than one previous study that administered the interview by telephone.[12] The results of the Edinburgh postnatal depression scale were consistent with our power analysis, previous research,[6] and recent work that supports the use of the scale in multiethnic samples.[13] Other limitations include the pragmatic exclusion of women who did not speak English and that for appreciable proportion of women in the intervention group peer volunteers did not return activity logs. Furthermore, the intervention was not initiated in a few cases.

Our results are consistent with research linking depressive symptoms with smaller social networks, fewer close relationships, and lower perceived adequacy of social support.[14 15] Our findings provide evidence that lay people who have experienced a similar health problem or stressor can have a positive effect on psychological wellbeing.[16 17]

Anxiety often occurs with depression,[18] and in our trial there was a trend for women in the intervention group to have lower levels of anxiety at 12 weeks postpartum.

One unique finding was the importance of self reported non-Canadian ethnicity and living in Canada for less than five years in the presentation of depressive symptoms in the immediate postpartum period. Among the few studies that have examined immigrant status, all have found this variable to be significantly related to postnatal depression.[19-21]

Women positively evaluated their experience of telephone based peer support. Traditionally, support has been provided through groups, but these tend to be poorly attended by new mothers and those who are feeling depressed. Telephone based support interventions are not only flexible, private, and non-stigmatising but they also reduce differences related to socioeconomic status, access, or geography.[22 23]

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Impact of presumed consent for organ donation on donation rates: a systematic review

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FAST TRACK

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ABSTRACT

Objectives To examine the impact of a system of presumed consent for organ donation on donation rates and to review data on attitudes towards presumed consent.

Design Systematic review.

Data sources Studies retrieved by online searches to January 2008 of Medline, Medline In-Process, Embase, CINAHL, PsycINFO, HMIC, PAIS International, and OpenSIGLE.

Studies reviewed Five studies comparing donation rates before and after the introduction of legislation for presumed consent (before and after studies); eight studies comparing donation rates in countries with and without presumed consent systems (between country comparisons); 13 surveys of public and professional attitudes to presumed consent.

Results The five before and after studies represented three countries: all reported an increase in donation rates after the introduction of presumed consent, but there was little investigation of any other changes taking place concurrently with the change in legislation. In the four best quality between country comparisons, presumed consent law or practice was associated with increased organ donation—increases of 25-30%, 21-26%, 2.7 more donors per million population, and 6.14 more donors per million population in the four studies. Other factors found to be important in at least one study were mortality from road traffic accidents and cerebrovascular causes, transplant capacity, gross domestic product per capita, health expenditure per capita, religion (Catholicism), education, public access to information, and a common law legal system. Eight surveys of attitudes to presumed consent were of the UK public. These surveys varied in the level of support for presumed consent, with surveys conducted before 2000 reporting the lowest levels of support (28-57%). The most recent survey, in 2007, reported that 64% of respondents supported a change to presumed consent.

Conclusion Presumed consent alone is unlikely to explain the variation in organ donation rates between countries. Legislation, availability of donors, organisation and infrastructure of the transplantation service, wealth and investment in health care, and public attitudes to and awareness of organ donation may all play a part, but their relative importance is unclear. Recent UK surveys show support for presumed consent, though with variation in results that may reflect differences in survey methods.

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INTRODUCTION

There is currently an insufficient supply of donor organs to meet the demand for organ transplantations in the United Kingdom and worldwide. There were 13.2 dead organ donors per million population in the UK in 2007, lower than in several other European countries, especially Spain, which had a rate of 34.3 per million population in 2007.[1]

In 2006 the UK Organ Donation Taskforce was established with the task of identifying barriers to donation and making recommendations for increasing organ donation and procurement within the current legal framework. Its recommendations were published in November 2008 (www.dh.gov.uk/en/Healthcare/Secondarycare/Transplantation/Organdonation/index.htm).[2] An explicit or informed consent system operates in the UK and requires that individuals authorise organ removal after death by carrying a donor card or joining a national registry.

Several countries, including Spain, Austria, and Belgium, have opted for a change in legislation and introduced presumed consent, whereby organs can be used for transplantation after death unless individuals have objected during their lifetime (an opt out system).

To inform the work of the taskforce, a systematic review was commissioned of the best available evidence of the effect of presumed consent legislation on organ donation rates. A secondary objective was to assess the literature on public attitudes to presumed consent.

METHODS

Search strategy

We searched seven electronic databases from inception to January 2008 without language restrictions. Internet searches were carried out using the specialist engine Intute (www.intute.ac.uk/healthandlifes

ciences/) and the meta-search engine Copernic (www.copernic.com) and browsed relevant websites and checked the reference lists. See full report.[3]

Study selection and inclusion criteria

Eligible studies were those which compared organ donation rates before and after the introduction of presumed consent or where organ donation rates were compared in countries with and without systems of presumed consent. See bmj.com for details.

We assessed public and professional attitudes to organ donation and presumed consent. Only studies using survey methods and that focused explicitly on organ donation and presumed consent were included.

Two reviewers independently screened and reviewed papers, and disagreements were resolved by discussion and consensus. We extracted relevant data from the included studies and assessed study quality.

Data synthesis

We undertook a narrative synthesis. Studies were grouped based on study design, and the results were interpreted in the context of their methodological strengths and weaknesses and any contextual factors. The data from surveys were synthesised, taking into account issues of importance identified during the quality assessment.

RESULTS

Twenty six studies met inclusion criteria. Of these, five assessed organ donation rates before and after the introduction of presumed consent legislation in a single country,[w1-w5] eight compared organ donation rates in countries with presumed consent systems with rates in countries with explicit or informed consent or similar systems,[w6-w13] and 13 surveys addressed attitudes towards presumed consent[w14-w26] (see web extra on bmj.com for reference list). Of the 13 surveys identified, full details were obtained for nine.

Impact of presumed consent on organ donation rates in before and after studies

All five studies, which represented the experience of three countries, found an increase in organ donation rates following the introduction of presumed consent legislation (see bmj.com). In Austria the 4.6 donors per million population per year before legislation increased to 10.1 per million in the four years after the introduction of presumed consent and to 27.2 per million in the five years after introduction of infrastructure changes including full time transplant coordinators.[w1] In Belgium kidney donation increased from 18.9 to 41.3 per million population per year over a three year period,[w3] and in Singapore kidney procurement increased from 4.7 to 31.3 per million population, also over a three year period.[w4]

However, there was limited exploration of other changes such as increased publicity and organisational and infrastructure changes that might have taken place at the same time as the change in legislation.

Impact of presumed consent on organ donation rates in between country comparisons

The eight studies that compared organ donation rates in countries with presumed consent systems with those in countries with explicit or informed consent or other similar systems were based on secondary analyses of published data. We focus here on the findings of the more robust studies (see table).[w6 w8 w9 w11]

Three of the four studies showed a significant association between presumed consent and increased organ donation rates.[w6 w8 w11] The fourth study reported a positive but not significant association.[w9] The size of the increase in organ donation rates with presumed consent varied: 25-30% higher,[w6] 21-26% higher,[w11] 2.7 more donors per million population,[w9] and 6.14 more donors per million population.[w8]

Impact of other factors on organ donation rates

In the three studies where it was considered, mortality from road traffic accidents showed a significant association with donation rate.

In the one study that considered transplant coordination, transplant capacity (defined as the number of transplant centres per million population) was positively associated with higher donation rates and within the statistical model it was the factor with the greatest predictive strength.[w8]

Three of the four studies investigated the influence of wealth or healthcare expenditure.[w6 w9 w11] Gross domestic product per capita and health expenditure per capita were the strongest predictors of donation rates in one model, stronger than presumed consent law.[w11]

The only religion investigated was Catholicism. It officially recognises organ transplantation as a "service of life." It was a significant positive predictor of donation rates in one study[w8] and of importance in some sections of the regression model in another,[w11] but not in a study that specifically included only Western Catholic and Protestant countries.[w6]

Two studies investigated the legislative system (common law versus civil law).[w6 w11] Common law was significantly associated with increased donation rates in both studies.

Internet access was used in one study as a proxy measure for access to information.[w11] The percentage of the population with internet access correlated significantly with organ donation rate in some areas of the statistical model.

Attitudes to presumed consent

We obtained data from eight UK surveys—four from full reports[w15 w17 w19 w22] and four from secondary sources.[w23-w26] The surveys obtained through secondary sources could not be fully quality assessed because of insufficient information. The surveys took place between the mid-1970s and 2007. Details of sampling

methods were not available for four surveys.[w23-w26] The four surveys that did provide information about their methods varied in how they phrased the questions on presumed consent.[w15 w17 w19 w22]

Among the four full surveys, the two earliest (conducted in 1976[w19] and 1999[w25]) reported the lowest levels of support, with 34% and 28% in favour of presumed consent, respectively. With the exception of one survey conducted in Scotland, in which 37% agreed that doctors should be allowed to take organs automatically,[w17] surveys conducted from 2000 onwards reported at least 60% of respondents being in support of presumed consent.[w15 w22]

Two UK surveys investigated demographic differences in attitudes.[w17 w22] The most recent found similar levels of support across age, sex, social class, and geographic region.[w22] The other survey found that those who stated they were unwilling to donate all their organs tended to be men, aged over 65 years, and from the least privileged social group.[w17]

With the exception of one survey from Belgium,[w21] where there is presumed consent legislation, most respondents in surveys from outside the UK seemed opposed to presumed consent (full details reported elsewhere[3]).

DISCUSSION

Principal findings

We conducted a systematic review investigating the impact of presumed consent legislation on organ donation rates; to our knowledge this is the first review to address this question. We found four good quality studies comparing organ donation rates between countries with and without systems of presumed consent. All four found an association between presumed consent legislation and higher organ donation rates, and in three this was statistically significant, but there was evidence that factors other than presumed consent contributed to the variation in organ donation rates. Five before and after studies also showed an increase in organ donation rates following the introduction of presumed consent.

We investigated public attitudes towards presumed consent through surveys carried out in the UK and elsewhere. The eight UK surveys suggest variation in the level of support for presumed consent, with earlier surveys finding lower levels of support. The most recent survey reported that 64% of respondents supported a change to presumed consent.

Strengths and weakness of the study

We followed systematic review methods to identify relevant studies, appraise their quality, and synthesise the results in a transparent, unbiased, and reproducible manner. We searched a wide range of sources for both published and unpublished studies, but it was not feasible to contact relevant bodies in countries with presumed consent for information about any missed evaluations.

We found only five studies comparing organ donation rates before and after the introduction of presumed consent legislation in a single country. Notably we did not find any studies focusing on Spain, the country with the highest donation rates, or Brazil, a widely cited example of an unsuccessful law change to presumed consent. Others have noted the difficulties in obtaining documentation about the effects of national-level initiatives[4] and the fact that

Details of analysis and results for between country comparison studies of legislation for presumed consent for organ donation that had a robust analysis

	Statistical significance of factors considered in regression analysis										
Type of analysis	PC law (or practice)	CVA mortality	RTA mortality	GDP	Healthcare expenditure	Transplant capacity	Religion (Catholicism)	Education	Legislative system	Blood donation rate	Internet access
Abadie (2006)[w6]											
Fixed regression with panel (longitudinal) data*	P≤0.05	P≤0.05	P≤0.05	P≤0.05	NS	—	NS	—	P≤0.05	NS	—
Neto (2007)[w11]											
Quantile regression for panel (longitudinal) data†	P≤0.05	P≤0.05¶	P≤0.05	P≤0.05	P≤0.05	—	P≤0.05**	—	P≤0.05	—	P≤0.05††
Healy (2005)[w9]											
Linear mixed-effects regression using time series data‡	NS	NS	P≤0.05	NS	NS	—	—	—	—	—	—
Gimbel (2003)[w8]											
Linear ordinary least squares regression using single data point per country§	P≤0.05	—	—	—	—	P≤0.05	P≤0.05	P≤0.05	—	—	—

PC=presumed consent, CVA=cerebrovascular, RTA=road traffic accident, GDP=gross domestic product, NS=not significant.
*Different combinations of variables considered in a series of models.
†Analysis based on Koenker 2004.[8] Two models were used—one with GDP and one with health expenditure (these were highly collinear). A generalised least squares regression was also performed for comparison.
‡The initial model did not fit the data, and the analysis was repeated excluding outliers (Spain and Italy).
§This study classified countries based on whether there was presumed consent in practice rather than whether presumed consent legislation was in place.
¶Significant in model using health expenditure per capita but not GDP per capita.
**Significant at 25th centile only on one model and 25th and 50th centiles but not the 75th.
††Significant for 25th and 75th centiles.

WHAT IS ALREADY KNOWN ABOUT THIS TOPIC

The supply of donor organs is insufficient to meet the need for transplantation in the UK, and a change in legislation to one of presumed consent has been proposed

The introduction of presumed consent legislation in other countries is thought to have led to increased donation rates

WHAT THIS STUDY ADDS

The evidence suggests that presumed consent law is associated with increased organ donation rates

Other factors such as availability of potential donors, infrastructure for transplantation, investment in health care, and public attitudes may all have a role, but the relative importance of these factors is unclear

strategic policies tend not to receive the same evaluative attention as, for example, medical procedures.[5]

The available studies had methodological weaknesses. We evaluated three different types of research evidence—before and after studies, between country comparisons using secondary data, and surveys. Unlike evaluations of medical interventions, the "hierarchy" of evidence is not clear when evaluating a policy such as a change in legislation (see bmj.com).

The countries represented in the studies were mainly Western European. Although this increases the likelihood that the findings are generalisable to the UK, it resulted in considerable overlap between the samples used. This duplication means that the studies are naturally biased towards giving similar results.

Although presumed consent is not a binary variable, it has been treated as such in the between country comparisons. Countries vary in the nature of their legislation and how the legislation is interpreted. Of key importance is the extent of consultation about donation with relatives of the deceased. This was partly addressed in one study that compared countries on the basis of how legislation was implemented in practice, rather than the actual legislation in place.[w8]

The surveys provided useful information about public attitudes to presumed consent, but important methodological detail was not available in four of the surveys and caution is needed in the interpretation of the findings. This is already reflected in the gap between high levels of support for organ donation in UK surveys and lower rates of registration on the organ donor register.

Conclusions

The available evidence suggests that presumed consent is associated with increased organ donation rates, even when other factors are accounted for. However, it cannot be inferred from this that the introduction of presumed consent legislation per se will lead to an increase in organ donation rates. The availability of potential donors, the underpinning infrastructure for transplantation, wealth and investment in health care, and underlying public attitudes may all have a role.

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Ethical approval: Not required.

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Encouraging the use of cycle helmets—effect of a brief intervention

Debate continues about whether cyclists should wear helmets and, if so, whether legislation should compel them to do so. I tend to wear my cycle helmet only when in the mood to do so.

Recently, I was cycling home bareheaded after an afternoon surgery. A car pulled up alongside me, and the driver looked across to catch my eye before tapping his head significantly two or three times and then driving off. My immediate reaction was irritation at this intrusion into my ride—cyclists would be much safer if fewer people drove motor vehicles, and helmet wearing is a matter of personal choice.

As I rode on, however, I calmed down and reflected on the wider issues. I accepted that I would almost certainly derive a significant net benefit from wearing a helmet, as long as I resisted the temptation to ride less carefully because of the sense of protection that helmet wearing can induce.

This intervention by the unknown driver has been successful in encouraging me to use my helmet more consistently. Perhaps the setting of the encounter was important—as not only did I think about the evidence base, but, with traffic pounding past me, I also reflected on the reality of life after a head injury.

Is this is the first report of a brief intervention to encourage cycle helmet wearing?

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