Best Evidence Summaries of Topics in Mental Healthcare

BEST *in* MH *clinical question-answering service*

Question

Do health trusts/services/clinics that are research active (intensive), have better health outcomes (mortality/reduced symptoms/reduced recovery time) than trusts/services/clinics that do less or no research?

Clarification of question using PICO structure

Population: Health trusts/services/clinics
Intervention: Higher levels of research activity
Comparison: Lower levels of research activity
Outcome: Better health outcomes

Clinical and research implications

No definite clinical implications can be made from the available evidence. It does appear, however, that lower mortality rates are observed in institutions that are involved in clinical trials although this does not necessarily demonstrate a causal relationship. The authors of a systematic review suggested that there might also be beneficial effects for patients who receive non-trial treatment from practitioners or in institutions that take part in trials. They stated that the reasons for this difference were unclear, and the relatively small amount of research on this subject and the possible influence of confounding by patient characteristics mean that this conclusion should be viewed with caution and is not robust enough to influence practice.

The authors of the systematic review also suggested that more research is needed to identify and minimise factors that might influence differences between patients treated by trial practitioners or in trial institutions compared to those treated elsewhere. They also suggested that larger numbers of patients, practitioners and institutions should be included in future studies to have sufficient power to detect moderate differences.

What does the evidence say?

Number of included studies/reviews (number of participants)
We identified one systematic review (SR) (n=13 studies) (Clarke et al. 2011) and one observational study (n=174 062 patients from 494 hospitals) (Majumdar et al. 2008) that met the inclusion criteria.

Main Findings

Four studies included in the SR reported outcomes that were relevant to this BEST summary. One of these four studies is also included as non-RCT evidence in this BEST summary: Majumdar et al. 2008. In this observational study, hospitals were classified into tertiles by percentage of patients concurrently enrolled in non–ST segment elevation acute coronary syndrome trials. They reported that all-cause (hospital) mortality decreased in hospitals that had increased trial participation: 5.9% (no) vs. 4.4% (low) vs. 3.5% (high) (adjusted *P*=.003). Patients treated at hospitals that participated in trials had significantly lower mortality than patients treated at non-participating hospitals (low enrolment adjusted odds, 0.9 [95% CI, 0.8-1.0, *P*=.04]; and high enrolment adjusted odds, 0.8 [95% CI, 0.7-0.9, *P*=.003]).

Two other studies included in the SR also reported on mortality. One study in Canada evaluated five groups of myocardial infarction patients; four of these groups were participants (and non-participants) in hospitals taking part in thrombolysis studies (GUSTO and LATE); the fifth group consisted of patients from other hospitals not taking part in these studies. The authors reported that hospital mortality was higher at non-trial hospitals (17.4%) than it was for trial participants at the trial hospitals (6.9% and 6.6%) but similar to that for non-participants in those hospitals (16.8% and 19.7%). A study of gynaecological departments in 165 German hospitals sought data on the treatment and two year survival of ovarian cancer patients. Eighty hospitals were involved in clinical trials and 85 were not. The authors found that treatment in a *non-trial* hospital was associated with a significantly increased risk of death (P = 0.001) after adjustment for baseline factors.

The last study included in the SR reported that following participation in a RCT of chemotherapy regimens for women with high-risk breast cancer, 80% of centres reported an improvement in professional knowledge relevant to breast cancer and 31% of centres found that patient care improved.

Authors Conclusions

The authors of the SR concluded that the existing research suggests that there might be a 'trial effect' of better outcomes, greater adherence to guidelines and more use of evidence by practitioners and institutions that take part in trials. However, the consequences for patient health are uncertain and the most robust conclusion may be that there is no apparent evidence that patients treated by practitioners or in institutions that take part in trials do worse than those treated elsewhere. The authors of the observational study concluded that compared with hospitals that do not participate in trials, those hospitals that do participate in trials seem to provide better care and to have lower mortality.

Reliability of conclusions/Strength of evidence

The SR was generally well-conducted and the cautious conclusions are likely to be reliable, although the types of studies included in this review, and their quality, were not always fully reported. While the observational study was well-conducted, this type of design is prone to bias.

What do guidelines say?

Not applicable

Date question received: 24/04/2012
Date searches conducted:
Date answer completed: 18/05/2012

References

1. Clarke M, Loudon K. Effects on patients of their healthcare practitioner's or institution's participation in clinical trials: a systematic review. 2011 Clarke and Loudon; licensee BioMed Central Ltd. http://www.trialsjournal.com/content/pdf/1745-6215-12-16.pdf (Accessed 30/4/2012)

2. Majumdar S, Roe M, Peterson E, Chen A, Gibler W, Armstrong P. Better Outcomes for Patients Treated at Hospitals That Participate in Clinical Trials. *Arch Intern Med. 2008;168(6)*:657-662.

Results

Reviews

Author (year)	Search Date	Inclusion criteria	Number of included studies	Summary of results	Risk of bias
Clarke et al (2011)	January 2009	Studies were included that compared treatment in a research active institution with treatment in a non-research institution. The groups were not necessarily randomised. Cohort studies were also included in this review. All types of institution providing health care, all types of healthcare practitioner, and all types of patient (including people who were healthy and, for example receiving interventions to prevent illness) were eligible. The primary outcome in this review was the health of patients, secondary outcomes included the use of research findings, and adherence to clinical guidelines	13 studies (study type not clearly presented for all studies)	Five studies compared patient-care related outcomes for ***practitioners*** who took part in clinical research versus outcomes for practitioners who had not taken part in clinical research. Outcomes evaluated included prescription rates, prescribing practice, nurses attitudes to research/research use, adherence to guidelines, and discharge decisions on mean length of hospital stay. These have not been data extracted as they do not meet the outcome inclusion criteria of this BEST summary. Seven studies compared patient-care related outcomes for ***institutions*** that had taken part in clinical research versus outcomes for institutions that had not taken part in clinical research: One study reported that in-hospital mortality was lower in high trial participation hospitals compared to low participation and non-trial hospitals (data extracted below). Another study reported the hospital mortality was higher at the non-trial hospitals (17.4%) than it was for trial	Low

				participants (GUSTO: 6.9%; LATE: 6.6%) at the trial hospitals but similar to that for non-participants in those hospitals (GUSTO: 16.8%; LATE: 19.7%). A study of gynaecological departments in 165 German hospitals sought data on the treatment and two year survival of ovarian cancer patients. Treatment in a non-trial hospital was associated with a significantly increased risk of death (hazard ratio 1.82, 95% CI 1.27 to 2.61, P = 0.001) after adjustment for baseline factors. Following their participation in ADEBAR (randomised trial of chemotherapy regimens for women with high-risk breast cancer), 80% of centres reported an improvement in professional knowledge relevant to breast cancer and 31% of centres found that patient care improved. Other outcomes evaluated were adherence to guidelines, use of drugs, and treatment type (not data extracted and these outcomes were not relevant to this BEST summary).	

Primary studies

Author (year)	Inclusion criteria	Number of participants	Summary of results	Risk of bias
Majumdar (2008)	*Participants* -	174 062 patients with non–ST-	In-hospital (all-cause) mortality decreased with increasing trial participation*: 5.9% (no) vs. 4.4% (low) vs. 3.5% (high)	Well-

	hospitals that were included in an early study (494 CRUSADE) concerning treatment of non-ST-segment elevation acute coronary syndrome. *Intervention* – High levels of research participation at an institutional level *Comparison* – Low levels of institutional at an institutional level *Outcomes* – Clinical guideline adherence and mortality were the reported outcomes of this study.	segment elevation acute coronary syndrome treated at 494 hospitals; of these patients, 4590 were enrolled in trials	(adjusted *P*=.003). Patients treated at hospitals that participated in trials had significantly lower mortality than patients treated at non-participating hospitals (low enrolment adjusted odds, 0.9 [95% CI, 0.8-1.0, *P*=.04]; and high enrolment adjusted odds, 0.8 [95% CI, 0.7-0.9, *P*=.003]). Hospitals that participated in trials had higher adjusted guideline adherence than non-participating hospitals (low enrolment, 0.8% greater [95% CI −0.9% to 2.6%]; and high enrolment, 2.5% greater [95% CI, 0.5%-4.5%, *P*=.01]). *'Trial participation' was considered as a hospital-level characteristic and defined by the proportion of CRUSADE patients who were concomitantly enrolled in a clinical trial during hospitalisation.	conducted study, but study design has inherent bias

Risk of Bias: SRs

Author (year)	Risk of Bias				
	Inclusion criteria	Searches	Review Process	Quality assessment	Synthesis
Clarke et al (2011)	☺	☺	☺	☺	☺

Non-RCTs

Study	RISK OF BIAS					
	Aims and objectives clearly stated?	Is the study design appropriate?	Adequate description of groups?	Objective and reliable measures?	Power calculation/ justification of numbers?	Appropriate statistical analysis?
Majumdar et al. (2008)	☺	?	☺	☺	☺	☺

☺Low Risk ☹High Risk ? Unclear Risk

Search Details

Source	Search Strategy	Number of hits	Relevant evidence identified
SRs and Guidelines			
DARE	1 research 19444 2 MeSH DESCRIPTOR Biomedical Research EXPLODE ALL TREES 26 3 MeSH DESCRIPTOR Clinical Nursing Research EXPLODE ALL TREES 31 4 MeSH DESCRIPTOR Community-Based Participatory Research EXPLODE ALL TREES 4	331	0

	5 MeSH DESCRIPTOR Empirical Research EXPLODE ALL TREES 55 6 MeSH DESCRIPTOR Health Services Research EXPLODE ALL TREES 465 7 MeSH DESCRIPTOR Nursing Administration Research EXPLODE ALL TREES 10 8 MeSH DESCRIPTOR Peer Review, Research EXPLODE ALL TREES 3 9 MeSH DESCRIPTOR Qualitative Research EXPLODE ALL TREES 37 10 MeSH DESCRIPTOR Research EXPLODE ALL TREES 951 11 MeSH DESCRIPTOR Research Design EXPLODE ALL TREES 1979 12 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 20116 13 MeSH DESCRIPTOR Trust EXPLODE ALL TREES 1 14 mental health trust* 6 15 trust* 448 16 mental health service* 313 17 MeSH DESCRIPTOR Community Mental Health Services EXPLODE ALL TREES 102 18 MeSH DESCRIPTOR Mental Health Services EXPLODE ALL TREES 557 19 clinic* 24249 20 MeSH DESCRIPTOR Outpatient Clinics, Hospital EXPLODE ALL TREES 71 21 #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 24573		

	22 #12 AND #21 13773 23 reseach adj 2 active 0 24 research active 1 25 research act* 20 26 research adj2 act* 46 27 research adj2 intensive 5 28 #25 OR #26 OR #27 51 29 #21 AND #28 31 30 (research):TI 499 31 (trust*):TI 3 32 (service*):TI 517 33 #31 OR #32 520 34 #30 AND #33 18 35 (nhs):TI 32 36 #30 AND #35 1 37 nhs 13158 38 #22 AND #37 3928 39 mental 1921 40 #38 AND #39 331 Delete		
Primary studies			
CENTRAL	#1 "Clinical trial":ti,ab,kw 59320 edit delete #2 participation 7485 edit delete #3 outcomes 159917 edit delete #4 "research intensive" 10 edit delete #5 (#1 OR #4) 59330 edit delete #6 (#2 AND #3 AND #5) 371 Clinical trials 300	300	2
PsycINFO	8. PsycINFO; "clinical trial*".ti,ab; 15709 results. 9. PsycINFO; participation.ti,ab; 52560 results. 10. PsycINFO; outcomes.ti,ab; 111169 results. 11. PsycINFO; 8 AND 9 AND 10; 96 results.	96	

MEDLINE	1. MEDLINE; "clinical trial*".ti,ab; 176364 results. 2. MEDLINE; participation.ti,ab; 79593 results. 3. MEDLINE; outcomes.ti,ab; 298306 results. 4. MEDLINE; 1 AND 2 AND 3; 357 results. 5. MEDLINE; "research intensive".af; 124 results. 6. MEDLINE; 1 OR 5; 176484 results. 7. MEDLINE; 2 AND 3 AND 6; 358 results.	358	
EMBASE	2. EMBASE; participation.ti,ab; 92421 results. 3. EMBASE; outcomes.ti,ab; 388855 results. 5. EMBASE; "research intensive".ti,ab; 144 results. 6. EMBASE; "clinical trial*".ti,ab; 225391 results. 7. EMBASE; 5 OR 6; 225533 results. 8. EMBASE; 2 AND 3 AND 7; 502 results	502	
Methods studies From Cochrane	#1 "Clinical trial":ti,ab,kw 59320 edit delete #2 participation 7485 edit delete #3 outcomes 159917 edit delete #4 "research intensive" 10 edit delete #5 (#1 OR #4) 59330 edit delete #6 (#2 AND #3 AND #5) 371 edit delete Methods Studies 41	41	
Summary	**NA**	**NA**	

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