RESEARCH

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ERIC SCHREMPP/SPL

THIS WEEK'S RESEARCH QUESTIONS

869 Compared with selective serotonin reuptake inhibitors, how effective are tricyclic antidepressants in treating headaches and what are the adverse effects?

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871 How is ethnic mix in a neighbourhood associated with the prevalence of common mental disorders?

872 What were the early lessons from the England-wide implementation of detailed electronic health records?

Neighbourhood ethnic mix and mental health

Last week the UK Equality and Human Rights Commission (which the government hasn't thrown on to the bonfire of the quangos but which, it reckons, needs "substantial reform") reported that "Pakistani and Bangladeshi groups are more likely to experience poor mental health, more likely to report a disability or limiting long term illness, and more likely to find it hard to access and communicate with their GPs than other groups...It was unclear how far these outcomes are related to relatively poor socioeconomic position" (http://bit.ly/9URMuG).

Jayati Das-Munshi and colleagues provide some of that missing detail in their multi-level logistic regression analysis of a cross sectional, nationally representative survey of adults in England in 2000 (p 871). They looked at self reported ethnicity in geographical areas with a mean population of about 7200 people. For each 10 percentage point rise in "own group ethnic density" in these areas—which, for an individual, is the percentage of people of the same ethnic group living in the same area—there was a decreased risk of common mental disorders for all local people from ethnic minorities (odds ratio 0.94, 95% CI 0.89 to 0.99) after adjustment for age, social class, educational level, sex, marital status, and level of deprivation in the area. The reduced risk was most striking for Bangladeshi and Irish groups. Living in areas of higher own group density was also associated with less discrimination and with improved social support for some groups.


JACKY CHAPMAN/ALAMY

Editorialist Helen Lester says we've known for nearly a century that living in areas with people of the same ethnicity may be protective for mental health (p 843). The strengths of this study, she says, include its nationally representative data and the ways it highlights "the messy complexity of the relationship." The authors agree: "There were no neat conclusions from our analyses [and] we were not able to definitively unpack the meaning of ethnic density" (doi:10.1136/bmj.c5367). For more discussion of this intriguing work, listen to our podcast interview with Dr Das-Munshi at www.bmj.com/podcasts.

Interventions to promote cycling


ALEX SEGRE/ALAMY

The Mayor of London's cycle hire scheme, which provides (almost) free bicycles for 30 minute journeys in the city, was launched amid much fanfare in July this year. However, mayor Boris Johnson might be dismayed to read Lin Yang and colleagues' systematic review of interventions to promote cycling, including in the United Kingdom and the United States (p 870).

Of the 25 published and unpublished studies assessed, those that evaluated interventions to promote cycling at population level reported net increases of only 3.4 percentage points in the population prevalence of cycling or the proportion of trips made by bicycle.

Student BMJ also has a less than positive report on interventions to promote cycling, specifically the London bike hire scheme (doi:10.1136/sbmj.c5621). Harry Rutter and Nick Cavill question whether the public health benefits of the scheme outweigh the associated risks of injury and long term exposure to air pollution.

Nevertheless, editorialists Nanette Mutrie and Fiona Crawford argue that an increase in everyday cycling could generate a considerable public health gain and that better measurement of the impacts of interventions is necessary . . . to strengthen the case that promoting cycling is good value for money (p 842).

LATEST RESEARCH: For this and other new research articles see http://www.bmj.com/channels/research.dtl

Antidepressants and publication bias

Last week a meta-analysis in the *BMJ* reported that the antidepressant reboxetine is ineffective and potentially harmful, and that published literature on the drug is skewed by publication bias (doi:10.1136/bmj.c4737). The research has received considerable coverage, much of it focusing on the "serious obstacles" the authors encountered when they tried to get unpublished clinical trial information from Pfizer, which sells the drug in Europe (doi:10.1136/bmj.c5641).

"Scientists accuse Pfizer of holding back studies which reveal drug sold as Edronax to be ineffective and potentially harmful," wrote the Guardian (http://bit.ly/dbJ1ll), while the BBC stated that the public had been "'misled' by drug trial claims" (http://bbc.in/abCvsY).

Perhaps surprisingly, given that reboxetine has not been licensed in the United States, the research also got plenty of coverage across the pond. American writer Scott Hensley describes reboxetine as "the crummiest antidepressant you've never heard of" in his health blog on the National Public Radio website (http://n.pr/axvkSP), whereas *Genetic Engineering and Biotechnology News* asks "Did sneaky publication tactics help Pfizer's reboxetine slip through to market?" (http://bit.ly/bNfZt0)

The responses to this research certainly indicate how concerned people are about pharmaceutical companies sitting on data about their drugs, but what can be done? The *BMJ* has taken the first steps to uncovering the extent of the problem and will devote a special theme issue to the topic in late 2011.

CME

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Tricyclic antidepressants and headaches: systematic review and meta-analysis

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EDITORIAL by Holroyd and Bendtsen

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Recent research with CME
- Association of cerebral palsy with Apgar score in low and normal birthweight infants (*BMJ* 2010;341:c4990)
- Effect of preventive (β blocker) treatment, behavioural migraine management, or their combination on outcomes of optimised acute treatment in frequent migraine (*BMJ* 2010;341:c4871)
- Antipsychotic drugs and risk of venous thromboembolism (*BMJ* 2010;341:c4245)
- Effects of glucosamine, chondroitin, or placebo in patients with osteoarthritis of hip or knee (*BMJ* 2010;341:c4675)

STUDY QUESTION

Compared with selective serotonin reuptake inhibitors, how effective are tricyclic antidepressants in treating migraine, tension-type, and mixed headaches and what are the adverse effects?

SUMMARY ANSWER

Tricyclics are effective in preventing migraine and tension-type headaches and are more effective than selective serotonin reuptake inhibitors, although with more adverse effects. The effectiveness of tricyclics seems to increase over time.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Tricyclics are effective in treating tension-type and migraine headaches. This study showed that tricyclics are more effective than selective serotonin reuptake inhibitors for both tension-type and migraine headaches and are more effective over time.

Selection criteria for studies

We searched Medline, Embase, the Cochrane Trials Registry, and PsycLIT for randomised trials of adults receiving tricyclics as the only treatment (other than analgesics) for migraine, tension-type, and mixed headaches.

Primary outcome(s)

Outcome measures were headache frequency, intensity of headache, and headache index. For this analysis we classified trials of mixed headache as migraine trials.

Main results and role of chance

Thirty seven studies met the inclusion criteria. Tricyclics significantly reduced the number of days with tension-type headache and number of headache attacks from migraine than did placebo (average standardised mean difference −1.29, 95% confidence interval −2.18 to −0.39 and −0.70, −0.93 to −0.48) but not compared with selective serotonin reuptake inhibitors (−0.80, −2.63 to 0.02 and −0.20, −0.60 to 0.19). The effect of tricyclics increased with longer duration of treatment (β=−0.11, 95% confidence interval −0.63 to −0.15; P<0.0005). Tricyclics were also more likely to reduce the intensity of headaches by at least 50% than either placebo (tension-type: relative risk 1.41, 95% confidence interval 1.02 to 1.89; migraine: 1.80, 1.24 to 2.62) or selective serotonin reuptake inhibitors (1.73, 1.34 to 2.22 and 1.72, 1.15 to 2.55). Tricyclics were more likely to cause adverse effects than placebo (1.53, 95% confidence interval 1.11 to 2.12) and selective serotonin reuptake inhibitors (2.22, 1.52 to 3.32), including dry mouth (P<0.0005 for both), drowsiness (P<0.0005 for both), and weight gain (P<0.001 for both), but did not increase dropout rates (placebo: 1.22, 0.83 to 1.80, selective serotonin reuptake inhibitors: 1.16, 0.81 to 2.97).

Bias, confounding, and other reasons for caution

Most studies in this analysis were of low quality, but the results of high and low quality studies did not differ. Although our analysis showed greater efficacy with longer treatment, most trials were of short duration (mean 11 weeks), thus this finding should be considered exploratory. We could not determine the optimal tricyclic dose. Lastly, owing to the limited number of studies, we could not determine the effectiveness of tricyclics compared with other therapies other than selective serotonin reuptake inhibitors.

Study funding/potential competing interest

We received no external funding for this study and have no potential competing interests.

COMPARISON OF EFFICACY AND ADVERSE EFFECTS BETWEEN TRICYCLICS AND PLACEBO

Outcome	Tricyclics *v* placebo
Difference (95% CI):	
Tension-type headache (days)	−1.3 (−2.2 to −0.39)
No of migraine attacks	−0.70 (−0.93 to −0.48)
Relative risk (95% CI):	
Intensity of tension-type headache reduced >50%	1.4 (1.02 to 1.9)
Intensity of migraine headache reduced >50%	1.8 (1.2 to 2.6)
Adverse effects	1.5 (1.1 to 2.1)

Differences >0.80 are considered large clinical effects.

Interventions to promote cycling: systematic review

Lin Yang, Shannon Sahlqvist, Alison McMinn, Simon J Griffin, David Ogilvie

EDITORIAL
by Mutrie and Crawford

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STUDY QUESTIONS

What interventions are effective in promoting cycling, what is the size of their effects, and are there any associated benefits in terms of overall physical activity or anthropometric measures?

SUMMARY ANSWER

Community-wide promotional activities, individualised marketing of "environmentally friendly" modes of transport to households, and improving infrastructure for cycling have the potential to increase cycling by modest amounts, but whether interventions result in an increase in overall physical activity or changes in anthropometric measures remains unclear.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Cycling is a form of physical activity that could be incorporated into many people's daily routines as a mode of transport, resulting in both health and environmental benefits. A variety of approaches to promoting cycling were found to be associated with increases in cycling, but overall the available evidence is of limited quantity and validity and suggests that interventions have produced relatively modest absolute increases in cycling at population level.

Selection criteria for studies

Published and unpublished controlled trials and "before and after" experimental or observational studies of the effect of any type of intervention on cycling behaviour were identified by searching electronic databases, websites, reference lists, and existing systematic reviews, and by contacting experts.

Primary outcomes

The primary outcomes were any specific measure of cycling both before and after the intervention at either individual or population level. These included prevalence of cycling, time spent cycling, distance cycled, cycling trip frequency, or proportion of trips made by bicycle (mode share).

Main results and role of chance

Twenty five studies from seven countries were included. Four interventions aimed specifically at promoting cycling (an intensive individual intervention in obese women, high quality improvements to a cycle route network, and two multifaceted cycle promotion initiatives at town or city level) were associated with increases in cycling. Of these, the interventions applied at population level were associated with increases of up to 3.4 percentage points in the population prevalence of cycling or the proportion of trips made by bicycle. Sixteen studies assessing individualised marketing of "environmentally friendly" modes of transport (walking, cycling, and public transport) to interested households reported an average of eight additional cycling trips per person per year. Most studies did not report tests of statistical significance for changes in cycling. Only two studies assessed effects of interventions on physical activity: one reported a positive shift in the population distribution of overall physical activity during the intervention.

Bias, confounding, and other reasons for caution

Most studies relied on self reported measures of cycling of unknown validity or reliability, and many were unclear about the comparability of control groups or the method of adjusting for changes in control groups.

Study funding/potential competing interests

This work was supported by the Centre for Diet and Activity Research (CEDAR), a UK Clinical Research Collaboration (UKCRC) Public Health Research Centre of Excellence. Funding from the British Heart Foundation, the Economic and Social Research Council, the Medical Research Council, the National Institute for Health Research (NIHR), and the Wellcome Trust, under the auspices of the UK Clinical Research Collaboration, is gratefully acknowledged (www.esrc.ac.uk/publichealthresearchcentres). SJG also receives support from the Department of Health NIHR Programme Grant funding scheme (RP-PG-0606-1259). The views expressed in this publication are those of the authors and not necessarily those of the Department of Health or other funders. The authors declare no competing interests.

STUDIES OF INTERVENTIONS TO PROMOTE CYCLING INCLUDED IN THE SYSTEMATIC REVIEW, GROUPED BY TYPE OF INTERVENTION

Type of intervention	Mean validity score (range 0-5)	Sample size (range)	Duration of follow-up (range)	Summary of net effects on cycling (range)
Interventions primarily to promote cycling (n=6)	3.8	99-2000	5-36 months	Change in proportion of trips made by bicycle: 0% to +3.4%
Individualised marketing of "environmentally friendly" modes of transport (n=16)	1.9	227-1959	1-10 months	Change in cycling trip frequency: −0.7 per week to +21 per year
Interventions to change travel behaviour in general (n=3)	0.3	220-1807	9-36 months	Change in proportion of trips made by bicycle: −11.6% to +1.1%

Understanding the effect of ethnic density on mental health: multi-level investigation of survey data from England

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EDITORIAL by Lester

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bmj.com/podcasts
Jayati Das-Munshi talks about the accompanying research paper in a *BMJ* podcast. Find out more at bmj.com/podcasts/

STUDY QUESTION Is living in an area where high proportions of people of the same ethnicity reside protective for common mental disorders, and is any protective effect mediated by reduced exposure to racism and improved social support?

SUMMARY ANSWER For Bangladeshi people, Irish people, and the combined ethnic minority sample, living in areas of higher own-group ethnic density was associated with a decreased risk of common mental disorders; some of the ethnic minority groups were less likely to report discrimination and limited social support, but these associations did not fully account for the density effects.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS Living in areas of higher own-group ethnic density has been associated with a decreased risk of health problems for some ethnic minority groups, and with reduced discrimination. This study confirmed that, for all ethnic minority groups combined and for Bangladeshi and Irish groups in particular, ethnically dense areas may protect residents of the same ethnicity from common mental disorders. Higher own-group ethnic density was also associated with improved social support and reduced experiences of discrimination for some groups, but these associations did not account for observed ethnic density effects.

Participants and setting

In a nationally representative survey, 4281 participants of Irish, black Caribbean, Indian, Pakistani, Bangladeshi, and white British ethnicity aged 16–74 years were randomly sampled from 892 middle layer super output areas in England.

Design

Multi-level logistic regression analysis of national survey data, with own-group ethnic density at the area level modelled as the main exposure.

Primary outcome(s)

Common mental disorders, determined via validated structured interviews.

Main results and the role of chance

The sample comprised people from two earlier surveys who agreed to be re-contacted. Of this sample, 4281 (68.2%) took part. Although the most ethnically dense areas were also the poorest, for each 10 percentage point increase in own-group ethnic density, there was evidence of a decreased risk of common mental disorders for the full ethnic minority sample (odds ratio 0.94 (95% CI 0.89 to 0.99)), for the Irish group (odds ratio 0.21 (0.06 to 0.74)), and for the Bangladeshi group (odds ratio 0.75 (0.62 to 0.91)), after adjusting for a priori confounders (see table). Living in areas of higher own-group density was also associated with fewer reported experiences of discrimination or racism and with improved social support and improved social networks for some of the groups. When the variables for interpersonal racism, social support, and social networks were individually added into final models and then added together, the effects for ethnic density with common mental disorders were not fully attenuated (table).

Bias, confounding, and other reasons for caution

Residual confounding by area-level deprivation or individual-level socioeconomic position may have masked protective density effects. Estimates of mediation may have been biased by measurement error in the mediation variables. Insufficient power may have accounted for the apparent lack of effect for some of the groups. This was an analysis of a cross sectional dataset, therefore temporality cannot be assumed.

Generalisability to other populations

These are findings from a nationally representative survey of England, making the findings highly generalisable to the experiences of ethnic minority groups living in England—with the caveat that the survey was completed in 2000, so it is possible that the effects reported may no longer be relevant to some of the groups included in this study or to some of the more recent migrant groups to England.

Study funding/potential competing interests
JD-M is funded by the MRC. LB was partially funded by the ESRC. The Institute of Social Psychiatry provided a small funds grant to enable retrieval of area-level data. No competing interests are declared.

ASSOCIATION OF COMMON MENTAL DISORDERS PER 10 PERCENTAGE POINT INCREASE IN OWN-GROUP ETHNIC DENSITY

	Adjusted for confounders*		Adjusted for confounders, with mediators added†	
Ethnic group	Odds ratio (95% CI)	P value for trend	Odds ratio (95% CI)	P value for trend
White British	1.13 (0.97 to 1.30)	0.10	1.16 (1.00 to 1.36)	0.05
Irish	0.21 (0.06 to 0.74)	0.01	0.19 (0.05 to 0.72)	0.01
Black Caribbean	0.92 (0.61 to 1.40)	0.71	0.82 (0.52 to 1.28)	0.37
Bangladeshi	0.75 (0.62 to 0.91)	0.005	0.80 (0.65 to 0.99)	0.04
Indian	0.89 (0.73 to 1.10)	0.28	0.91 (0.74 to 1.10)	0.33
Pakistani	0.92 (0.81 to 1.04)	0.20	0.93 (0.82 to 1.06)	0.30
Combined ethnic minority density	0.94 (0.89 to 0.99)	0.02	0.93 (0.88 to 0.98)	0.007

*A priori confounders: area-level deprivation, social class, education, marital status, age, and sex
†Mediators: discrimination and social support measures

Implementation and adoption of nationwide electronic health records in secondary care in England: qualitative analysis of interim results from a prospective national evaluation

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Response on bmj.com

"The rigidity of analysable electronic records has been underestimated. No standardisation of terminology and flow patterning of electronic questions exist thus far. Yet every time duplicate data is re-recorded, the human resources available for direct patient care are reduced."
Susan Bewley, Rupert Fawdry, Grant Cummings, and Helga Perry, London

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STUDY QUESTION

What are the lessons from the first hospitals to join the government's programme for an England-wide implementation of detailed electronic health records?

STUDY ANSWER

The type of detailed electronic record systems and the scale of data sharing that would be clinically useful urgently require clarification. Hospitals seek flexibility and local adaptability in the systems to accommodate technological developments and changing local and national NHS priorities.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

The national programme to implement centrally procured, standardised, detailed electronic health record systems throughout all secondary care NHS trusts by 2010 is considerably behind schedule. Interim results from "early adopter" trusts indicate that the top-down approach to deliver records systems has contributed to deployment delays and frustrations. The approach has had to evolve to permit greater flexibility and local choice. The immediate priority is to clarify the type and scale of detailed electronic health records that are wanted and affordable.

Rationale and design

The nationwide implementation of electronic health records in England (the NHS Care Records Service) is the cornerstone of the government £12.7bn Programme for IT for the NHS. We were commissioned to evaluate the implementation of detailed electronic health records to inform their subsequent rollout. Our longitudinal, socio-technical, multisite case study will end in 2011.

Recruitment/sampling strategy

We used purposive sampling to recruit 11 diverse "early adopter" secondary care NHS trusts and to include implementations of each of three centrally procured NHS Care Records Service systems (Lorenzo and Cerner Millennium for acute hospitals and RiO for mental health). Within each case study, purposive sampling aimed to recruit diverse interviewees, including a wide range of NHS staff.

Settings

The reported research is set in five of our 11 early adopter sites.

Data collection and analysis

We collected public and trust documents, and conducted semi-structured interviews and on site observations. Data collection and analysis were iterative. Analysis combined top-down, thematic coding with coding categories that emerged from the data.

Main findings

The NHS Care Records Service had evolved substantially since its launch in 2002. Although most NHS staff still believed in the vision of electronic health records, the type of detailed record and scale of data sharing they wanted were far less clear. There were considerable uncertainties about the programme's future. Interviewees identified adverse consequences of centrally negotiated contracts to deliver the NHS Care Records Service to hospitals; trusts wanted systems that could be tailored to their own organisations.

Implications

A priority at this critical juncture, when a new coalition government is planning public spending cuts and NHS reorganisation, is to agree the appropriate national goals for detailed electronic health records. Specifically, the type of digital record it is now hoped to achieve, on what scale, and at what cost need clarification. Greater consistency in the Department of Health's leadership could alleviate some of trusts' concerns. Trusts need to be able to communicate changing local and national NHS priorities directly to those working with them to implement electronic health record systems.

Bias, limitations, generalisability

The comprehensive nature of our longitudinal evaluation should enhance the transferability of our findings and conclusions. When the evaluation is completed, we will be able to compare experiences of implementing these systems in a wider range of local contexts, reporting from 11 diverse secondary care settings. Early adopters may differ in important ways from NHS trusts that plan to join the NHS Care Records Service later or not at all.

Study funding/competing interests

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