

Community based lifestyle intervention for blood pressure reduction in children and young adults in developing country: cluster randomised controlled trial

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STUDY QUESTION Does family based home health education delivered by trained lay health workers have a beneficial impact on blood pressure levels of children and young adults residing in communities in Karachi, Pakistan?

SUMMARY ANSWER Simple, family based home health education delivered by trained lay health workers significantly ameliorates the usual increase in blood pressure with age in children and young adults in the general population of Pakistan, a low income developing country.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS Community based strategies to achieve blood pressure lowering in the general population have not yielded promising results. A strategy of home health education had a beneficial impact on blood pressure and is potentially feasible for up-scaling within the existing healthcare systems of Indo-Asia.

Design

This was a cluster randomised controlled trial in 12 randomly selected communities, with six clusters randomly assigned to home health education and six to no home health education. Trained lay health workers delivered family based home health education over six weeks by using a case based curriculum on healthy lifestyle to prevent high blood pressure. The nutritional recommendations were modelled on the dietary approaches to stop hypertension (DASH) diet, adapted to the dietary patterns of the study population. Separate teams of field staff masked to randomisation status measured blood pressure with a calibrated automated device at baseline and two years after randomisation.

Participants and setting

The participants were 4023 people aged 5 to 39 years residing in the randomised clusters in Karachi, Pakistan.

Primary outcomes

The primary outcome was change in systolic blood pressure from baseline to the final follow-up visit at two years. The secondary outcome was change in diastolic blood pressure from baseline to the final visit.

Main results and role of chance

Mean blood pressure at baseline was 115/74 in the control group and 114/74 in the home health education group. Final mean systolic and diastolic blood pressure levels were significantly greater in the control group (116/76 mm Hg) than in the home health education group (114/74 mm Hg) ($P=0.02/0.005$). When analysed using the intention to treat principle, the change in blood pressure from baseline to follow-up was significantly greater in the intervention group than in the control group (table). Sen-

CHANGE IN BLOOD PRESSURE (95% CI) FROM BASELINE TO FOLLOW-UP

Blood pressure	Home health education (n=2008)	No home health education (n=2015)	P value
Systolic (mm Hg)*	0.1 (-0.3 to 0.5)	1.5 (1.1 to 1.9)	0.02
Diastolic (mm Hg)†	0.6 (0.3 to 0.9)	2.1 (1.8 to 2.4)	0.002

*Adjusted for clustering, age, sex, and baseline systolic blood pressure.

†Adjusted for clustering, age, sex, and baseline diastolic blood pressure.

sitivity analysis using a per protocol approach ($n=2878$) and subgroup analysis stratified by age group (5-14 years and 15-39 years) yielded consistent results. These findings have considerable relevance to global public health, as even a modest shift in mean blood pressure at the level of the population has been shown to have a marked beneficial effect on the primary prevention of stroke and cardiovascular disease.

Harms

As with any health promotion, the possibility of "warning fatigue" exists, whereby people pay no attention to repeated advice and the observed benefit is lost during trial. This could be a problem if the intervention continued for a much longer duration or indefinitely.

Bias, confounding, and other reasons for caution

The main limitation of the study was a short duration of follow-up of two years, so that we cannot tell to what extent blood pressure changes can be sustained. In addition, follow-up blood pressure readings were not available on 28% of the study population.

Generalisability to other populations

Models of service by lay health workers are operational in several under-resourced countries including India, Kenya, Uganda, Ghana, Ethiopia, South Africa, and China. Our results suggest that a similar vehicle can be used for health promotion with effective lowering of blood pressure levels in the population.

Study funding/potential competing interests

The study was financially supported by a research award (070854/Z/03/Z) from the Wellcome Trust, UK.

Trial registration number

Clinical trials NCT00327574.



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Exercise therapy after corticosteroid injection for moderate to severe shoulder pain: large pragmatic randomised trial

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STUDY QUESTION How effective is subacromial corticosteroid injection combined with timely exercise and manual therapy compared with exercise and manual therapy alone in patients with subacromial impingement syndrome?

SUMMARY ANSWER Injection plus exercise and exercise only have similar effectiveness at 12 weeks.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Shoulder pain is common, persistent, and often caused by subacromial impingement syndrome. At 12 weeks corticosteroid injection combined with exercise is of similar effectiveness to exercise only. Earlier improvement in pain and function is seen with corticosteroid injection combined with exercise and manual therapy.

Design

In this pragmatic randomised clinical trial simple block randomisation was performed for seven sites based on a computer generated randomisation list.

Participants and setting

Adults aged 40 or over with subacromial impingement syndrome who reported moderate or severe shoulder pain and were referred from primary care.

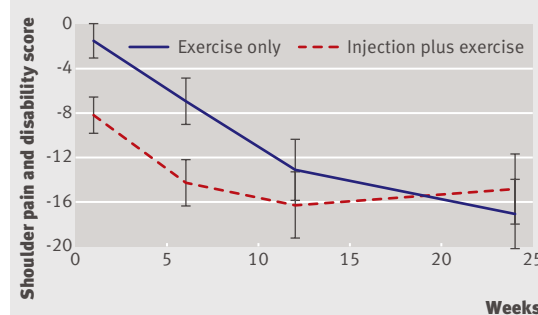
Primary outcome

Primary outcome was the difference in improvement in the total shoulder pain and disability index at 12 weeks.

Main results

Of the 232 participants included, 115 were randomised to injection plus exercise and 117 to exercise only. The mean age was 56 (range 40–78), over half (127) were women, and all had had shoulder pain for a median of 16 weeks (interquartile range 12–28 weeks). At week 12 there was no significant difference between the groups in change in total score on the shoulder pain and disability index (mean difference between change in groups 3.26 (95% confidence interval –0.81 to 7.34), $P=0.116$). Improvement was significantly greater in the injection plus exercise group at week 1 (6.56, 4.30 to 8.82) and week 6 (7.37, 4.34 to 10.39) for the total score on the shoulder pain and disability index ($P<0.001$), with no differences at week 24 (–2.26, –6.77 to 2.25, $P=0.324$). In terms of secondary outcomes (global assessment of change compared with baseline), at week 1, 50/104

CHANGE IN SCORES IN PATIENTS WITH SUBACROMIAL IMPINGEMENT SYNDROME



(48%) reported recovery or improvement in the exercise only group compared with 75/97 (77%) in the injection plus exercise group. At week 6, 78/100 (78%) reported recovery or improvement in the exercise only group compared with 86/94 (92%) in the combined injection plus exercise group. By week 12 and 24 the proportion of participants reporting recovery or improvement was similar in both groups. At 12 weeks, however, there was still a higher complete recovery rate in the injection plus exercise group than in the exercise only group (15/101 v 8/104). No adverse events were reported in either group.

Bias, confounding, and other reasons for caution

There are certain limitations to this study. Because of the pragmatic design, participants were not blinded to their interventions and there might have been a placebo or non-specific effect caused by the injection. The total treatment response probably includes both the treatment and associated placebo effects, as is the case in routine clinical practice.

Generalisability to other populations

These findings should not be generalised to adults aged under 40, those with mild shoulder pain, or with shoulder pain not caused by subacromial impingement syndrome.

Study funding/potential competing interests

The study was funded by a project grant 17236 from Arthritis Research UK. No competing interests declared by all authors.

Trial registration number

ISRCTN 25817033; EudraCT No 2005-003628-20.

Mobile phone base stations and early childhood cancers: case-control study

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STUDY QUESTION Is there an increased risk of early childhood cancers associated with exposure to macrocell mobile phone base stations during pregnancy?

SUMMARY ANSWER There was no association of early childhood cancers with mobile phone base station exposure during pregnancy.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS Reports of apparent cancer clusters near a mobile phone base station are difficult to interpret because of small numbers and possible selection and reporting biases. We based our study on national registers of cancers and births, thus avoiding such biases. Our findings should help place any future reports of cancer clusters near mobile phone base stations in wider public health context.

Participants and setting

We included children aged 0-4 from the national cancer registry in Great Britain and controls from the national birth register, individually matched by sex and date of birth (four controls per case).

Design, size, and duration

This was a case-control study among 1397 children with cancer and 5588 matched birth controls, 1998-2001. The four national mobile phone operators provided data on 76 890 antennas.

Primary outcomes, risks, exposures

We investigated risks of brain and central nervous system cancers (International Classification of Disease C71-C72), leukaemia and non-Hodgkin's lymphomas (C91-95, C82-85), and all cancers combined (C00-C96), adjusted at small area level for education, socioeconomic deprivation, population density, and population mixing. Three exposure metrics were estimated for the fetal period at registered birth address for each case and control: distance (m) from nearest mobile phone base station; total power output (kW) from summation across all base stations within 700 m; and

modelled power density (dBm/m²) for base stations within 1400 m, using a semi-Gaussian propagation model. Estimated exposures were categorised into three groups and were also analysed as continuous measures.

Main results and the role of chance

Mean distance of birth address from a macrocell base station was similar for cases (1107 (SD 1131) m) and controls (1073 (SD 1130) m, $P=0.31$), as was total power output of base stations within 700 m of birth address (2.89 (SD 5.9) and 3.00 (SD 6.0) kW, respectively, $P=0.54$) and modelled power density (-30.3 (SD 21.7) and -29.7 (SD 21.5) dBm/m², respectively, $P=0.41$). Compared with the lowest exposure category, the adjusted odds ratios in the highest exposure category of modelled power density were 1.02 (95% confidence interval 0.88 to 1.20) for all cancers ($P=0.79$ for trend), 0.76 (0.51 to 1.12) for brain and central nervous system cancer ($P=0.33$ for trend), and 1.03 (0.79 to 1.34) for leukaemia and non-Hodgkin's lymphoma ($P=0.51$ for trend). For the continuous measures, adjusted risks per 15th to 85th centile change ranged from 0.82 (0.55 to 1.22, modelled power density) to 1.12 (0.91 to 1.39, distance from nearest base station) for cancer of the brain and central nervous system.

Bias, confounding, and other reasons for caution

We were unable to take account of migration during pregnancy or attenuation of radiofrequency exposures within the home, and our models did not include information on other sources of radiofrequency exposure.

Generalisability to other populations

This was a national study and results should be broadly generalisable to other countries.

Study funding/potential competing interests

The study was funded through the UK Mobile Telecommunications Health Research (MTHR) Programme. Data analysis and interpretation were independent of the funders. PE and DJB obtained funding in support of this work from MTHR. PE was a member of the MTHR programme management committee.

ODDS RATIO* (95% CI) FOR CANCER ACCORDING TO MOTHER'S EXPOSURE TO MOBILE PHONE BASE STATIONS IN PREGNANCY

Cancer in child	Cases	Distance from nearest base station (per decrease of 1212 m)	Total power output (per increase of 6.75 kW)	Modelled power density (per increase of 57.2 dBm/m ²)
All	1397	1.0 (0.9 to 1.1)	1.0 (0.9 to 1.1)	1.0 (0.8 to 1.2)
Brain and central nervous system	251	1.1 (0.9 to 1.4)	0.9 (0.7 to 1.1)	0.8 (0.6 to 1.2)
Leukaemia and non-Hodgkin's lymphoma	527	1.0 (0.9 to 1.1)	1.0 (0.9 to 1.2)	1.0 (0.8 to 1.3)

*Adjusted for % of population with education to degree level or higher, Carstairs deprivation score, population density, and population mixing.

Postoperative pneumonia in elderly patients receiving acid suppressants: a retrospective cohort analysis

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STUDY QUESTION Do gastric acid suppressants increase the risk of postoperative pneumonia after elective surgery?

SUMMARY ANSWER No, after adjustment for patient and surgical characteristics, acid suppressants are not associated with an increased risk of postoperative pneumonia among elderly patients admitted for elective surgery.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS Gastric acid suppressants may increase patients' risk of pneumonia after major surgery. This study found that patients who received gastric acid suppressants were at increased risk of postoperative pneumonia but were also predisposed by independent risk factors to postoperative pneumonia. Adjustment for these risk factors revealed no direct association between gastric acid suppressants and a patient's risk of postoperative pneumonia.

Participants and setting

Consecutive patients aged >65 years admitted for an elective operation to Canadian acute care hospitals between 1 April 1992 and 31 March 2008.

Design, size, duration

This population-wide, retrospective cohort analysis covered 16 years and included 593 265 patients.

Main results

About 21% of patients (121 850/471 415) were receiving an acid suppressant (most commonly omeprazole or ranitidine). The two groups were similar in mean age, fitness for surgery, and duration of surgery, but other risk factors for postoperative pneumonia were imbalanced against the acid suppressant group (including a history of chronic obstructive pulmonary disease, heart failure, Parkinson's disease, and prior pneumonia; nasogastric tubes; and prescriptions of antipsychotics).

Overall, 6389 patients developed postoperative pneumonia, with a rate significantly higher for those taking acid suppressants (13 per 1000) than controls (10 per 1000), (odds ratio 1.30 (95% confidence interval 1.23 to 1.38), $P<0.001$). However, after adjustment for confounders, no increase in risk was observed (odds ratio 1.02 (0.96 to 1.09), $P=0.48$). The general safety of acid suppressants extended to those patients prescribed proton pump inhibitors, experiencing long term treatment, receiving high doses, and undergoing high risk procedures. The table shows significant predictors of postoperative pneumonia.

Bias, confounding, cautions

The most important limitation is that this study is not a randomised trial that eliminates all confounding. Prospective data collection would also provide information about microbiology, radiology, medication compliance, clinical course, long term outcomes, milder cases, and other evidence lack-

POTENTIAL PREDICTORS OF POSTOPERATIVE PNEUMONIA AMONG PATIENTS UNDERGOING ELECTIVE SURGERY

Characteristic	Odds ratio (95% CI)*
Age, per decade increase	1.54 (1.47 to 1.61)
Sex, men relative to women	1.29 (1.22 to 1.37)
Past diagnoses:	
Chronic obstructive pulmonary disease	1.48 (1.38 to 1.59)
Asthma	0.76 (0.69 to 0.83)
Heart failure	1.25 (1.16 to 1.35)
Parkinson's disease	1.36 (1.12 to 1.66)
Pneumonia	1.67 (1.55 to 1.79)
Chronic treatments:	
Systemic corticosteroid	1.16 (1.01 to 1.33)
Inhaled β agonist	1.18 (1.05 to 1.33)
Inhaled anticholinergic	1.21 (1.06 to 1.38)
Inhaled corticosteroid	1.24 (1.11 to 1.38)
Benzodiazepine	1.14 (1.06 to 1.30)
Antipsychotic	1.61 (1.34 to 1.92)
Antidepressant	1.18 (1.07 to 1.30)
Inpatient admissions, ≥ 1 in past 3 years	1.02 (1.01 to 1.03)
Charlson score, per unit increase	1.18 (1.16 to 1.19)
Type of surgery, relative to abdominal surgery:	
Cardiac	1.26 (1.14 to 1.38)
Thoracic	2.72 (2.46 to 3.00)
Vascular	1.38 (1.25 to 1.52)
Musculoskeletal	0.75 (0.69 to 0.82)
Lower urogenital	0.30 (0.26 to 0.34)
Breast and skin	0.21 (0.16 to 0.28)
Ophthalmological	0.07 (0.04 to 0.12)
Postoperative care:	
Nasogastric tube present	1.24 (1.12 to 1.38)
Hypoalbuminaemia present	5.74 (4.64 to 7.10)
Duration of surgery, per 30 minute increase	1.14 (1.13 to 1.14)

*Results from fully adjusted multivariate analysis accounting for all baseline characteristics.

ing in administrative databases. In addition, negative studies are sometimes prone to biases related to over-adjustment, outcome heterogeneity, and misclassification error.

Generalisability

The study's large sample size provides statistical power. The multicentred sampling provides a rigorous test free of referral bias or selective recruitment. In addition, the statistical analyses corroborate predictors of pneumonia reported in other studies, including use of benzodiazepines and nasogastric tubes.

Study funding/potential conflicts of interest

This project was supported by the Canada Research Chair in Medical Decision Sciences, Canadian Forces Health Services, the Physicians Services Incorporated Foundation of Ontario, the Alberta Heritage Foundation for Medical Research, and the University of Toronto Comprehensive Research Experience for Medical Students programme. These organisations had no role in the design and conduct of the study, collection and management of the data, or preparation of the manuscript. The authors report no competing interests.

Modified intention to treat reporting in randomised controlled trials: systematic review

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STUDY QUESTION Are medical journals increasingly publishing trials in which use of a modified intention to treat approach is reported, and what is intended by the approach, as reported by the trialists?

SUMMARY ANSWER Publication of trials in which use of a modified intention to treat approach is reported is significantly increasing. Modified intention to treat is characterised by multiple and different types of deviation from a standard intention to treat approach; these descriptions are unpredictable and may cover missing data and deviation from protocol.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS Despite the single and clear definition of intention to treat, authors label it differently. The increasingly used modified intention to treat approach with multiple and ambiguous descriptions should be replaced by an explicit description of post-randomisation exclusions.

Selection criteria for studies

We searched PubMed, Embase, the Cochrane Library, ISI Web of Knowledge, and eight full text electronic databases (to December 2006) for randomised controlled trials that reported use of a modified intention to treat approach for at least one analysis.

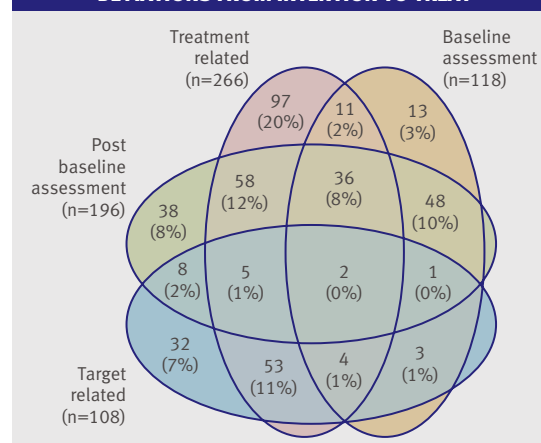
Primary outcome(s)

The primary outcome was incidence and characteristics of randomised controlled trials in which use of modified intention to treat was reported. We also examined the descriptions of the modified intention to treat approach and classified types of deviation from a standard intention to treat.

Main results and role of chance

Of 1010 records identified, 475 trials met our inclusion criteria. The incidence of randomised controlled trials that reported use of a modified intention to treat analysis published in journals indexed by Medline increased significantly over time. In 266 (55%) of the trials, the type of deviation from the intention to treat approach was related to the treatment received, in 196 (40%) to the presence of a post-baseline assessment, in 118 (24%) to the presence of a baseline assessment, in 108 (22%) to a target condition—participants were randomised but subsequently excluded from the analysis if found to lack the specific outcome or diagnosis at entry (either factor being difficult to determine or only suspected at enrolment), and in 23 (5%) to a lack of follow-up or participants failed to return for follow-up appointments. Whereas 192 (40%) trials reported one type of deviation, 256 (55%) reported two or more types. Post-randomisation exclusions occurred in 381 (80%) of the randomised controlled trials although it was not always possible to discern cases of missing data from protocol deviation

FOUR MOST COMMON TYPES OF DEVIATIONS FROM INTENTION TO TREAT



given the multiple and ambiguous descriptions of the modified intention to treat approach. The drug industry was involved in 91% of the trials. Of the 352 superiority trials, 77% reported results that favoured the drug under investigation.

Bias, confounding, and other reasons for caution

Our search strategy may have missed trials that are not hosted in electronic databases or those labelled as using an intention to treat analysis when they are using a modified intention to treat one on the basis of the type of deviation described. Therefore, we may have underestimated the incidence of trials in which use of a modified intention to treat was reported.

Study funding/potential competing interests

No funding was received for this study. We have no competing interests.

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