Effectiveness of general practice based, practice nurse led telephone coaching on glycaemic control of type 2 diabetes: the Patient Engagement And Coaching for Health (PEACH) pragmatic cluster randomised controlled trial

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Research: Effectiveness of a diabetes education and self management programme (DESMOND) for people with newly diagnosed type 2 diabetes mellitus (*BMJ* 2012;344:e2333)

STUDY QUESTION

How effective is goal focused telephone coaching by practice nurses in real world general practice in improving glycaemic control in patients with type 2 diabetes in Australia?

SUMMARY ANSWER

A practice nurse led telephone coaching intervention implemented in a primary care setting in Australia had no significant effect on glycaemic control compared with usual care, after adjusting for baseline glycated haemoglobin (HbA_{1c}) and the clustering.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Telephone coaching by highly trained nurses can improve glycaemic, blood pressure, and lipid outcomes in type 2 diabetes. This study showed that translating a telephone coaching intervention into the real world general practice setting using existing generalist nurses employed within general practice was ineffective.

Design

Prospective, cluster randomised controlled trial, with general practices as the unit of randomisation. A statistician blinded to the identity of the general practices carried out randomisation using computer generated permuted block sizes of two and four, stratified based on the organisation and financial arrangements of the general practice. Practice nurses in the intervention group received two days training in an empowerment based pragmatic educational telephone coaching programme designed to enhance patients' self management and engagement with their general practitioners to achieve lifestyle goals and biochemical targets by intensifying treatment with medications. Intervention practice nurses were trained to deliver eight telephone coaching sessions and one face to face session for each intervention patient. Patients in the control group received usual general practice care.

Participants and setting

473 patients with type 2 diabetes (HbA_{1c} >7.5% in the past 12 months) from 59 general practices in Victoria, Australia (236 from 30 intervention practices and 237 from 29 control practices).

Primary outcome

The mean absolute change in HbA_{1c} between baseline and 18 months in the intervention group compared with the control group.

Main results and the role of chance

Glycated haemoglobin (HbA_{1c}) did not differ significantly between the intervention and control groups (mean difference 0.02, 95% confidence interval −0.20 to 0.24, P=0.84, adjusted for HbA_{1c} measured at baseline). The study used a cluster randomised controlled design to reduce risk of contamination within the general practices. To minimise selection bias, randomisation occurred after all baseline data were collected. The study was powered to detect change in the primary outcome, with an attrition rate of 20% at 18 months.

Harms None identified.

Bias, confounding, and other reasons for caution

The intensity and fidelity of the intervention was compromised. 25% (58/236) of intervention patients did not receive telephone coaching. The quality of data on medications collected from general practices may vary and we did not measure medication adherence.

Generalisability to other populations

Characteristics of participants and non-participants were comparable and this indicates generalisability to people with poorly controlled type 2 diabetes in Australia.

Study funding/potential competing interests

This study was supported by the Australian National Health and Medical Research Council (ID 359374 and 566586). The funder was not involved in the study design, data collection, analysis, and interpretation.

Trial registration number

Current Controlled Trials ISRCTN50662837.

Difference in mean change from baseline to 18 months follow-up in serum glycated haemoglobin (HbA_{1c}) between study groups

	Intervention group		Control group			
Serum HbA_{1c} (%)	No	Mean (SD)	No	Mean (SD)	Difference* (95% CI)	P value
Baseline	235	7.98 (1.22)	236	8.13 (1.34)		0.84
Follow-up	221	7.85 (1.24)	219	7.91 (1.42)	0.02 (−0.20 to 0.24)	

*Difference in mean change in outcome before and after intervention between study groups with 95% confidence intervals and P values calculated using linear regression adjusted for baseline outcome measure, practice type, and Australian Primary Care Collaboratives programme. Analysis does not adjust for clustering because the estimated intracluster correlation for fitted model using generalised estimating equations was negative.

Effectiveness of interdisciplinary primary care approach to reduce disability in community dwelling frail older people: cluster randomised controlled trial

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Research: Effectiveness of a multifaceted podiatry intervention to prevent falls in community dwelling older people with disabling foot pain (*BMJ* 2011;342:d3411)

STUDY QUESTION Is an interdisciplinary primary care approach for community dwelling frail older people more effective than usual care in reducing disability and preventing (further) functional decline?

SUMMARY ANSWER No significant differences were seen between the interdisciplinary primary care approach and care as usual with regard to disability at 24 months' follow-up.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS Various community based interventions aiming at reduction of disability have been developed during the past few decades; however, only a small number of interventions have shown beneficial effects on disability, and most studies did not report on the long term effects. The non-effective results of this study mean that more research is needed to optimise the effectiveness of community based interventions for frail older people.

Design

We used a computer generated list to randomise 12 general practices to two groups. Practices in the control group delivered care as usual. Those in the intervention group implemented the "Prevention of Care" approach, in which frail older people receive a multidimensional assessment and interdisciplinary care based on a tailor made treatment plan and regular evaluation and follow-up. Whereas older people and healthcare professionals were aware of the allocated arm (intervention or control), outcome assessors were kept blinded to the allocation.

Participants and setting

We selected all general practices in the region of Sittard (the Netherlands) and its surrounding areas that had no current active and systematic policy for the detection and follow-up of frail older people. A postal questionnaire, the Groningen Frailty Indicator, was sent to 3498 of their community dwelling older patients (≥70 years). The response rate was 80% (n=2790). Of 1101 older people who were willing to participate in the study, 393 (36%) were frail (frailty score ≥5) and were eligible for the study. Finally, 346 frail older people were included and 270 (78%) completed the study.

Primary outcome

Outcomes were measured at the level of the patient. We assessed the primary outcome, disability, at 24 months by means of the Groningen Activity Restriction Scale.

Main results and the role of chance

One hundred and ninety three older people in the intervention group (six practices) received the Prevention of Care approach, and 153 in the control group (six practices) received care as usual. Follow-up rates for patients were 91% (n=316) at six months, 86% (n=298) at 12 months, and 78% (n=270) at 24 months. Mixed model multilevel analyses showed no significant differences between the two groups with regard to disability at 24 months. Pre-planned subgroup analyses confirmed these results.

Harms

No harms were reported.

Bias, confounding, and other reasons for caution

Firstly, significant baseline differences existed between the intervention and control groups with regard to frailty and disability, and the sample size distribution was skewed. Secondly, the completion rate differed significantly between the intervention and control groups. Thirdly, some parts of the Prevention of Care approach were not implemented as planned.

Generalisability to other populations

The findings can be generalised to community dwelling frail older people.

Study funding/potential competing interests

This research is funded by the Dutch National Care for the Elderly Programme by the Netherlands Organisation for Health Research and Development (ZonMw 311070301).

Trial registration

Current Controlled Trials ISRCTN31954692.

Disability scores on Groningen Activity Restriction Scale* at baseline and 24 months' follow-up

	Mean (SD) at baseline (n=346)		Mean (SD) at 24 months' follow-up (n=310)		Adjusted mean difference (95% CI)
Scale	Control group	Intervention group	Control group	Intervention group	
GARS	30.58† (10.62)	33.09† (11.52)	31.50 (10.92)	34.39 (11.58)	1.18 (-0.35 to 2.71)
GARS ADL	16.54† (5.35)	17.97† (6.14)	16.73 (5.73)	18.31 (5.82)	0.77 (-0.05-1.59)
GARS IADL	14.03 (5.86)	15.12 (5.96)	14.77 (5.86)	16.08 (6.35)	0.40 (-0.54-1.34)

ADL=activities of daily living; IADL=instrumental activities of daily living.
*Range 18-78; higher scores indicate more disability.
†Significant difference: P=0.03.

Feasibility and effectiveness of a low cost campaign on antibiotic prescribing in Italy: community level, controlled, non-randomised trial

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Research: Improving antibiotic prescribing in acute respiratory tract infections (*BMJ* 2013;347:f4403)

bmj.com/multimedia

Watch a video abstract for this paper at http://bit.ly/18QUVL0

STUDY QUESTION

How effective and feasible is a multifaceted, local public campaign on antibiotic prescribing for outpatients in Italy?

SUMMARY ANSWER

A local low cost information campaign targeted at citizens, combined with a newsletter on local antibiotic resistance targeted at doctors and pharmacists, was associated with a moderate decrease in total antibiotic prescribing. Potential savings may outweigh the initial investment.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Systematic reviews show that multifaceted information campaigns may be moderately effective in limiting the excessive use of antibiotics. A local population campaign on antibiotics, including local data on antimicrobial resistance targeted at prescribers, may be feasible and may influence doctors' prescribing.

Design and setting

A social marketing approach was sought for designing a public campaign, including collaboration from a group of general practitioners and paediatricians in the intervention area. Campaign materials included posters, brochures, advertisements on local media, plus a newsletter on antibiotic resistance targeted at doctors and pharmacists. The campaign was implemented from November 2011 to February 2012 in the Provinces of Modena and Parma (in Emilia-Romagna, Northern Italy, about 1 150 000 residents). Provinces in the same region where no campaign had been implemented (about 3 250 000 residents) were used as the control group.

Primary outcome

Average change in prescribing rates of antibiotics for outpatients in five months, measured as defined daily doses per 1000 inhabitants/day.

Main results and the role of chance

Antibiotic prescribing was reduced in the intervention area compared with control area (−4.3%, 95% confidence interval −7.1% to −1.5; P=0.008). A higher decrease was observed for penicillins resistant to β lactamase and a lower decrease for penicillins susceptible to β lactamase, consistently with contents of the newsletter on antibiotic resistance directed at health professionals.

Harms

Differences in antibiotic prescribing were not linked to differences in hospital admissions for upper respiratory tract infections during and after the campaign.

Bias, confounding, and other reasons for caution

Since information campaigns have different components, their evaluation and the generalisation of their results may be somewhat complex. The non-randomised design is a limitation of this study and caution is required in interpreting the results.

Generalisability to other populations

Although antibiotic consumption also depends on cultural and organisational factors, public campaigns have generally shown their effectiveness in different contexts. A social marketing approach would facilitate context sensitive strategies, by assessing factors influencing antibiotic prescribing; patients' understanding, attitudes, and expectations; and doctors' difficulties in implementing a delayed or no prescription strategy when appropriate. Doctors' involvement in the design of campaigns may favour their own endorsement, and the availability of information in a proper context may in itself favour change in decision making.

Study funding/potential competing interests

This study was supported by a public grant from the Italian Medicines Agency (Bando AIFA 2008).

Trial registration number ClinicalTrials.gov NCT01604096.

Change in antibiotic consumption in geographical areas of Italy in five months

Geographical area	Defined daily doses per 1000 inhabitant/day		% difference
	Nov 2010–Mar 2011	Nov 2011–Mar 2012	
Intervention provinces	22.7	20.0	−11.9
Control provinces	22.7	21.0	−7.4
Rest of Italy	27.0	26.1	−3.2

"Hardly worth the effort"? Medical journals' policies and their editors' and publishers' views on trial registration and publication bias: quantitative and qualitative study

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Research: Assessment of publication bias, selection bias, and unavailable data in meta-analyses using individual participant data (*BMJ* 2012;344:d7762)

bmj.com/multimedia

Watch a video abstract for this paper at http://bit.ly/1ahygLe

STUDY QUESTION

How many journals make trial registration a requirement for publication and why do they adopt such policies?

SUMMARY ANSWER

Only 55/200 journals required trial registration according to their instructions; not wanting to lose out to rival journals was the commonest reason for journals not requiring registration.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Trial registration may reduce publication bias and has been required by the major medical journals since 2005. However, many editors and publishers seem unconvinced of the benefits of trial registration and reluctant to adopt a policy that might put them at a competitive disadvantage by reducing submissions.

Rationale, design, data collection method

Quantitative survey of journal websites, followed by semistructured interviews with journal editors and publishers.

Participants and setting

Random sample of 200 journals taken from the Cochrane CENTRAL database. Interviews with 13 journal editors and three publishers.

Recruitment/sampling strategy

Potential interviewees were identified from the quantitative survey to provide a sample of journals with different policies on trial registration, including some that had recently changed their policy.

Data analysis method

Descriptive statistics for quantitative survey. Framework analysis for qualitative interviews.

Main findings

Most journals do not require trial registration. Many editors seem unconvinced of the importance of trial registration. Interviewees explained their journals' reluctance to require registration in terms of not wanting to lose out to rival journals, not wanting to reject otherwise sound articles or submissions from developing countries, and perceptions that such policies were not relevant to all journals. Some interviewees considered that registration was unnecessary for small or exploratory studies.

Implications

Registering clinical trials before recruitment starts can highlight subsequent non-publication and selective publication of findings. It may also reduce misleading reporting (for example, switching endpoints). If all journals made registration a requirement for publication this would be an important incentive for researchers. By failing to require registration, editors are missing an opportunity to improve reporting standards in their journals and reduce the problem of publication bias which distorts the medical evidence base.

Bias, limitations, generalisability

The qualitative work was limited to 16 interviewees, most of whom edited or published journals that require registration, although some had only recently adopted such a policy.

Study funding/potential competing interests

This study was part of the OPEN project (Overcome failure to Publish nNEgative fiNdings) which was funded from the European Union Seventh Framework Programme (FP7-HEALTH.2011.4.1-2) under grant agreement No 285453. EW is a member of the advisory board of the International Standard Randomised Controlled Trial Number (ISRCTN) scheme, this is an unpaid position; she was also a member of the World Health Organization Scientific Advisory Group on trial registration (2005-07) and received expenses to attend occasional meetings.

Journal requirements for trial registration in current and previous studies. Values are numbers (percentages) unless stated otherwise

Study	Search date	Journals	Source	No in sample	Registration	
					Required	Encouraged
Matarese[9]	2006/7	Italian; UK	Medline; Medline	76; 76	0; 21 (28)	—; —
Meerpohl[23]	2008	Paediatric	*Journal Citation Report*	69	11 (16)	5 (7)
Meerpohl[24]	2009	Open access paediatric	*Directory of Open Access Journals*	41	9 (22)	4 (10)
Krleza-Jeric[25]	2009	WAME members	WAME membership list	102	35 (34)	—
Kunath[6]	2010	Urology	*Journal Citation Report*	55	18 (33)	2 (4)
Wager	2012	Random sample	Cochrane CENTRAL database	200	55 (28)	3 (2)

WAME=World Association of Medical Editors.