Randomised controlled trial of a lay-led self-management programme for Bangladeshi patients with chronic disease

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ABSTRACT

Background
Reducing the impact of chronic disease in minority ethnic groups is an important public health challenge. Lay-led education may overcome cultural and language barriers that limit the effectiveness of professionally–led programmes. We report the first randomised trial of a lay-led self-management programme — the Chronic Disease Self-Management Programme (CDSMP) (Expert Patient Programme) — in a south Asian group.

Aim
To determine the effectiveness of a culturally-adapted lay–led self-management programme for Bangladeshi adults with chronic disease.

Design of study
Randomised controlled trial.

Setting
Tower Hamlets, east London.

Method
We recruited Bangladeshi adults with diabetes, cardiovascular disease, respiratory disease or arthritis from general practices and randomised them to the CDSMP or waiting-list control. Self-efficacy (primary outcome), self-management behaviour, communication with clinician, depression scores, and healthcare use were assessed by blinded interviewer-administered questionnaires in Sylheti before randomisation and 4 months later.

Results
Of the 1363 people invited, 476 (34%) agreed to take part and 92% (439/476) of participants were followed up. The programme improved self-efficacy (difference: 0.67, 95% confidence interval [CI] = 0.08 to 1.25) and self-management behaviour (0.53; 95% CI = 0.01 to 1.06). In the 51% (121/238) of intervention participants attending three or more of the 6-weekly education sessions the programme led to greater improvements in self-efficacy (1.47; 95% CI = 0.50 to 1.82) and self-management behaviour (1.16; 95% CI = 0.50 to 1.82), and reduced HADS depression scores (0.64; 95% CI = 0.07 to 1.22). Communication and healthcare use were not significantly different between groups. The programme cost £123 (€181) per participant.

Conclusion
A culturally-adapted CDSMP improves self-efficacy and self-care behaviour in Bangladeshi patients with chronic disease. Effects on health status were marginal. Benefits were limited by moderate uptake and attendance.

Keywords
chronic disease; ethnic groups; self care

INTRODUCTION

Minority ethnic groups often experience higher morbidity and mortality than majority populations for a range of chronic diseases.[1] For example, compared with the majority white population, people of South Asian origin in the UK have a higher prevalence of diabetes,[2] are almost twice as likely to die from cardiovascular disease,[3] and have three times the hospital admission rate for asthma.[4] Ethnic diversity is increasing in most industrialised countries. The need to reduce inequalities in health outcomes between majority and minority groups is widely recognised by governments [5] and physician groups.[6] Education programmes that promote self-management of chronic disease can reduce morbidity.[7,8]

Increasing ethnic diversity of populations means that the development and evaluation of cultural adaptations of such programmes are a priority. Minority ethnic groups are often under-represented in trials of self-management programmes[9] and culturally adapted self-management programmes are rare. Trials of self-management education in populations of ethnic diversity suggest that minority groups derive less benefit than majority groups.[10,11] Promoting partnerships between empowered or 'expert' patients

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How this fits in

Reducing the impact of chronic disease in minority ethnic groups is an important public health challenge. Culturally adapted, lay-led health education may overcome barriers that limit the effectiveness of professionally-led programmes. The impact of the CDSMP (Expert Patient Programme) in the UK is unknown. A culturally-adapted, lay-led self-management education programme improves self-efficacy, self-care behaviour and health status in Bangladeshis with chronic disease. Benefits were limited by moderate uptake and attendance. Effects on healthcare use and physiological and metabolic markers of disease control are unclear.

and physicians is seen as a fundamental part of modern chronic disease management.[12] Minority ethnic groups may have difficulty establishing such partnerships.[13] Lay, or peer-led educational programmes, notably the Chronic Disease Self-management Programme (CDSMP),[14] aim to promote patient expertise and are becoming an established part of chronic disease management in the US, Australia and the UK, the latter as the UK Expert Patient Programme.[15] Culturally-adapted versions of lay-led programmes have the potential to overcome cultural and language barriers that may limit the effectiveness of professionally-led educational programmes, but have been tested only in Hispanic minority groups.[16,17]

The Bangladeshi community in the UK are a marginalised ethnic group. They experience marked socioeconomic deprivation, have poor access to care and services and report the highest levels of chronic disease of any ethnic group in the UK.[18,19] We tested the hypothesis that a culturally-adapted version of the CDSMP (the Expert Patient Programme) would improve the health of Bangladeshi patients with diabetes, heart disease, respiratory disease or arthritis, living in Tower Hamlets, east London. We report the first randomised trial to test the benefit of any self-management education programme for any South Asian group and the first randomised trial to test the effectiveness of the CDSMP in Europe.

Box 1. Components of the Sylheti Adaptation of the Chronic Disease Self Management Programme.

Session 1:	Course overview; acute and chronic conditions compared; cognitive symptom management; better breathing; introduction to action plans
Session 2:	Feedback; dealing with anger, fear and frustration; introduction to exercise; making an action plan
Session 3:	Feedback; distraction; muscle relaxation; fatigue management; monitoring exercise; making an action plan
Session 4:	Feedback/making an action plan; healthy eating; communication skills; problem solving
Session 5:	Feedback/making an action plan; medication usage; depression management; self-talk; treatment decisions; guided imagery
Session 6:	Feedback; informing the healthcare team; working with your health care professional; looking forward

METHOD

Participants

We recruited Bangladeshi adults (aged over 20 years) with diabetes, arthritis, respiratory or cardiovascular disease, by writing to people listed on disease registers of 10 general practices serving large Bangladeshi populations in Tower Hamlets. Letters were in English as the Sylheti dialect has no commonly used written form, but younger family members may read English. Letters were followed by a telephone call by Sylheti-speaking research assistants (one male, one female) to ascertain interest in the study. Those interested in taking part were invited to meet the research assistants to learn more about the study. For cultural reasons the researchers saw only participants of their own sex. If they gave written informed consent to take part the researcher recorded demographic data and carried out a baseline study questionnaire.

Programme

The education programme was a culturally adapted version of the CDSMP, a lay-led self-management programme developed at Stanford University and based on Bandura's theoretical model of self-efficacy.[20,21] This sociocognitive theory proposes a multifaceted model where an individuals' beliefs about self-efficacy operate with their goals and expectations about outcome of their actions to influence self-care behaviour. Self-efficacy has proved a reliable predictor of behaviour change in studies of self-management.[22]

Scales assessing self-efficacy have been translated into at least 26 languages. Cross-cultural validity of self-efficacy has been widely confirmed, although not specifically in Syheti-speaking Bengalis.[23] Self-efficacy is a concept applicable to management of a wide range of chronic diseases.[14] Social Action for Health, a local community group, adapted the CDSMP into the Sylheti dialect and Islamic culture: (http://www.ichs.qmul.ac.uk/research/gppc/respiratory/adaption.html), omitting culturally inappropriate topics such as instructions relating to power of attorney (living wills). A supporting videocassette was provided for participants in place of written material. The programme comprised 6-weekly, 3-hour sessions, and took place in general practices or community centres. The six sessions covered topics including symptom management, communication with health professionals, managing medication, exercise, and decision-making (Box 1).

The programmes were led by pairs of trained and accredited Bangladeshi lay tutors, who themselves had chronic diseases (mainly diabetes), who acted as facilitators. They used strategies including mastering self-management skills, role-modelling and reinterpretation of symptoms. Over a 2-year period we ran seven programmes for men and eight

programmes for women, with tutors of the appropriate sex. We invited groups of about 25 intervention participants to each programme.

Randomisation

The details of consenting participants were passed to a researcher who randomised them using a computer minimisation programme to attend the education programme immediately or to a waiting list control group. Randomisation was stratified by main condition (diabetes, asthma, cardiovascular disease or arthritis), age and sex.

Invitations and incentives to attend education programme

Names and contact details of participants randomised to the intervention groups were passed to an administrator who sent written invitations by post to participants with details of the venue and times of sessions. To encourage attendance, we offered transport to and from the venue by taxi, and gave people who attended five or more sessions a certificate of attendance and a supermarket voucher.

Outcomes questionnaire

The primary outcome was self-efficacy.[20,24] Self-efficacy was measured using six items (addressing general condition management, distress, non-medication management, discomfort, fatigue, and interference) from the Chronic Disease Self-Efficacy Scale.[25] Self-management behaviour and communication with physician were assessed using scales from the same instrument, measuring use of cognitive symptom self-management and communication strategies respectively;[25] health status was measured using: the Hospital Anxiety and Depression Scale,[26] 5-point Likert scales for pain, fatigue and breathlessness, and the EuroQol EQ5D.[27] Healthcare use and costs were measured using six simple questions. We cross-culturally adapted these scales using forward and back translations with professional and lay bilingual (Sylheti mother tongue) panels.[28]

The questionnaire was administered face to face to participants by researchers before randomisation and 4 months later, prior to the control group receiving the programme. Interviewers were blinded to treatment allocation. We decided against including physiological measures such as serum measures of glycaemic control or cholesterol since their inclusion would compromise recruitment.

Study power

We needed at least 98 participants in each group to complete the self-management programme (defined as attending at least three of six sessions). We increased the recruitment target to 108 per group, to allow for 10% loss to follow up. The study was powered to detect a 40% standard deviation change in self-efficacy with 80% power and 5% significance, chosen because it was equivalent to an effect size associated with improvements in behaviour, health status and healthcare use found in trials of similar programmes.[14,29]

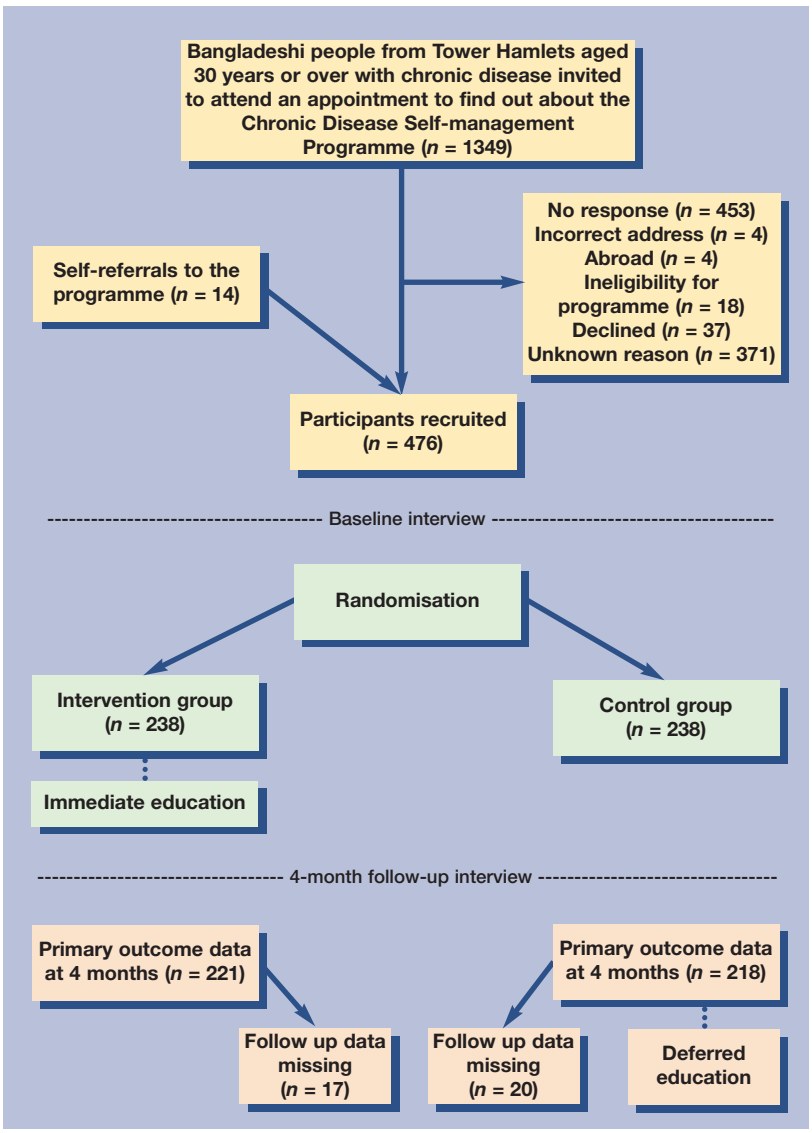

Figure 1. Participant flow. Effectiveness of a lay-led self-management programme for Bangladeshis in the UK with chronic disease: A randomised controlled trial.

Analysis

Our primary analysis was by intention to treat, blinded to allocation. Since we expected limited attendance at education sessions we also pre-specified a per-protocol analysis, which included intervention group participants who had attended three or more of the six education sessions. All control group participants were included in this analysis. We used STATA software to analyse data using linear multiple regression for continuous outcomes, proportional odds ordered logistic regression for outcomes measured on Likert scales, and poisson regression for health care use

Table 1. Characteristics of participants in intervention and control groups.

	Intervention group (*n* = 238)	Control group (*n* = 238)
Main chronic condition (%):		
Diabetes	156 (66)	169 (71)
Asthma	46 (19)	33 (14)
Arthritis	22 (9)	24 (10)
Cardiovascular disease	14 (6)	12 (5)
Bangladeshi ethnicity	238	238
Mean age in years (SD)	48.9 (9.9)	48.0 (9.5)
Mean age in years when education completed (SD)	12.2 (6.7)	12.4 (7.0)
Female sex (%)	133 (56)	139 (58)
In employment (%)	18 (8)	21 (9)
Marital status (%):		
Married	204 (85)	208 (87)
Widowed	26 (11)	24 (10)
Single	4 (2)	2 (1)
Divorced	2 (1)	0 (0)
Separated	2 (1)	4 (2)

outcomes measured as number of visits.

RESULTS

Characteristics of participants

Participant flow is given in Figure 1. Of 1349 Bangladeshi people approached by letter 462 (34%) agreed to take part. A further 14 volunteered after hearing about the programme by word of mouth or local media. Participants allocated to the intervention and control groups were well matched (Table 1). Three hundred and twenty-five (68%) participants reported diabetes as their main condition; 79 (17%) asthma, 46 (10%) arthritis and 26 (5%) heart disease; 390 (82%) had more than one condition. Despite a mean age of 49 years, only 8% were employed; education was completed on average by 12 years of age.

Attendance at the education programme

One hundred and twenty-one (51%) of intervention participants attended three or more of six sessions; 48 (20%) attended one or two sessions and 50 (21%) attended none. Attenders and non-attenders did not differ with respect to condition, sex, age, employment or marital status.

Table 2. Effect of education programme on primary and secondary outcomes: baseline and 4-month values. Intention to treat analysis.

Outcome	Baseline		4 months		Effect size (95% CI)	*P*-value
	Control	Intervention	Control	Intervention		
Self efficacy (scale 5–30, ↑ better)	16.39	16.31	17.62	18.22	0.67[a] (0.08 to 1.25)	0.025
Self care behaviour (scale 5–25, ↑ better)	7.16	7.23	8.31	8.95	0.53[a] (0.01 to 1.06)	0.047
Communication with physician (scale 5–20, ↑ better)	6.68	6.49	7.49	7.60	0.15[a] (-0.23 to 0.54)	0.435
Health status						
Depression (scale 0–21, ↓ better)	8.64	8.84	8.49	8.55	-0.22[a] (-0.71 to 0.28)	0.392
Anxiety (scale 0–21, ↓ better)	8.41	8.66	8.08	8.23	-0.09[a] (-0.55 to 0.35)	0.682
Pain (scale 1–5, ↓ better)	3.49	3.36	3.23	3.07	-0.13[b] (-0.48 to 0.22)	0.462
Fatigue (scale 1–5, ↓ better)	3.33	3.40	3.17	3.25	0.06[b] (-0.22 to 0.12)	0.721
Shortness breath (scale 1–5, ↓ better)	2.29	2.45	2.23	2.26	-0.22[b] (-0.60 to 0.16)	0.249
Health status EQ5D	0.59	0.61	0.65	0.66	0.005[a] (-0.044 to 0.054)	0.827
Healthcare use						
Visits to GP/practice nurse in last 3 months	4.12	3.97	3.71	3.53	0.99[c] (0.90 to 1.10)	0.893

In all analyses, age, sex, main condition at baseline and baseline values of outcome are adjusted for. In the Poisson regression baseline value of outcome is included as an offset. The coefficients presented are: [a]adjusted difference in means, [b]coefficient on logistic scale, [c]incidence rate ratio. The coefficient on the logistic scale presented for the proportional odds ordered logistic regression model is similar to the coefficient from a logistic regression model. For a logistic model the coefficient can be directly converted to an easily interpretable odds ratio. This is not the case for the coefficients from the proportional odds ordered logistic model. Negative coefficients for the proportional odds ordered model indicate that symptom scores are lower in the intervention group.

Effect of the education programme

We obtained follow up data for 439/476 (92%) of participants. Intention-to-treat analysis showed improvements in self-efficacy with weak (P <0.05, secondary outcome) evidence of improved self-management behaviour in those randomised to receive the education programme, compared to those allocated to the waiting list (Table 2); other outcomes were not significantly different between groups. Per-protocol analysis (including intervention participants attendance at three or more of six sessions) showed similar improvements but of a greater magnitude, and improved depression scores. Other outcomes were not significantly different between groups (Table 2). Characteristics of the participants from the intervention group attending three or more sessions were broadly similar to those attending fewer sessions and those in the control group (Tables 1 and 3).

In exploratory hypothesis-generating analyses, we found no evidence of differences in effect by sex or by condition (available from authors). These analyses lacked statistical power.

Table 3. Characteristics of participants the intervention group who attended zero to two out of six sessions, and who attended three to six out of six sessions.

	Intervention group attending 0–2 sessions (n = 116)	Control group attending 3–6 sessions (n = 238)
Main chronic condition (%)		
Diabetes	60 (52)	86 (70)
Asthma	24 (21)	18 (15)
Arthritis	10 (9)	11 (9)
Cardiovascular disease	6 (5)	7 (6)
Mean age in years (SD)	43.8 (10.5)	48.5 (9.5)
Mean age in years when education completed (SD)	12.1 (6.1)	12.3 (7.1)
Female sex (%)	52 (45)	59 (48)
In employment (%)	9 (8)	8 (7)
Marital status (%)		
Married	91 (78)	98 (80)
Widowed	7 (6)	18 (15)
Single	2 (2)	2 (1.6)
Divorced	0 (0)	2 (1.6%)
Separated	0 (0)	2 (1.6%)

SD = standard deviation.

Cost of the programme

Pairs of tutors were paid £587.10 (€865) per tutor to facilitate each of the six week courses, making the tuition costs £17 613 (€25 953) for the fifteen intervention educational programmes. Similar costs accrued for the control participants. Administration costs were £20 400 (€30 060) per year over the two year project — a total of £40 800 (€60 119), comprising the salary of an administrator and administrative costs. The total cost of the course was thus £58 413 (€86 072). With 476 participants, the cost of the programme was therefore £123 (€181) per participant.

DISCUSSION

Summary of main findings

We found that Bangladeshi people with chronic disease benefited from a 6-week chronic disease self-management programme, delivered by trained and accredited lay Bangladeshi tutors, who themselves had chronic disease. The programme improved participants' confidence (self-efficacy) to control chronic disease and probably altered their behaviour, increasing their use of self-management skills. The combination of improved confidence and altered self-care behaviour is important since both are associated with better health outcomes.[8]

Recruitment and attendance of Bangladeshi patients at education sessions was only moderate despite providing incentives and support, and compared poorly with that of other groups in similar studies.[14,16,30] We approached unselected Bangladeshi patients directly in primary care. A third of those approached agreed to take part and only half of these attended three or more sessions. The impact of the programme on people who attended the majority of the education sessions is reflected by the per-protocol analysis, where we found larger changes in confidence and use of self-management skills and improved depression scores, although other measures of health status were unaltered. Qualitative interviews with attenders and non-attenders (reported elsewhere) suggest that there were social and spiritual barriers to attendance.[31] These included responsibilities relating to social roles and health (care for family and guests, attending other healthcare appointments), and views that predetermination ('takdir' or destiny) of the Islamic life-course made attendance futile.[31] Initiatives to improve attendance need to address these factors.

Strengths and limitations of the study

This is the first randomised trial to test the effectiveness of any self-management educational programme in a South Asian group, and the first to test the effectiveness of the chronic disease self-management programme in Europe. To date all data on the CDSMP in Europe has either been anecdotal or exploratory.[32] Strengths of this study include: a pragmatic design with adequate statistical power, close involvement from the local Bangladeshi community in the design and execution, concealed treatment allocation, blinded outcome assessment and analysis, and high rates of follow up. We chose a relatively short (4-month) period of follow up since the Bangladeshi population is highly mobile and we considered that a long delay would discourage

Table 4. Effect of education programme on primary and secondary outcomes: baseline and 4-month values. Per protocol analysis — intervention participants attending at least three of six education sessions and all control participants.

Variable	Baseline		4 months		Effect size (95% CI)	*P*-value
	Control	Intervention	Control	Intervention		
Self-efficacy (scale 5–30, ↑ better)	16.39	16.42	17.62	18.96	1.47[a] (0.76 to 2.20)	<0.001
Self care behaviour (scale 5–25, ↑ better)	7.16	7.36	8.31	9.59	1.16[a] (0.50 to 1.82)	0.047
Communication with physician (scale 5–20, ↑ better)	6.68	6.31	7.49	7.56	0.37[a] (-0.09 to 0.83)	0.112
Health status						
Depression (scale 0–21, ↓ better)	8.64	9.07	8.49	8.29	-0.64[a] (-1.22 to -0.07)	0.028
Anxiety (scale 0–21, ↓ better)	8.41	8.58	8.08	8.24	-0.14[a] (-0.89 to 0.62)	0.724
Pain (scale 1–5, ↓ better)	3.49	3.32	3.23	3.03	-0.20[b] (-0.44 to 0.40)	0.360
Fatigue (scale 1–5, ↓ better)	3.33	3.45	3.17	3.26	-0.02[b] (-0.44 to 0.40)	0.922
Shortness breath (scale 1–5, ↓ better)	2.29	2.38	2.23	2.30	-0.22[b] (-0.60 to 0.16)	0.249
Health status EQ5D	0.59	0.61	0.65	0.66	0.009[a] (-0.05 to 0.069)	0.751
Healthcare use						
Visits to GP/practice nurse in last 3 months	4.14	4.08	3.71	3.56	0.97[c] (0.86 to 1.09)	0.625

In all analyses, age, sex, main condition at baseline and baseline values of outcome are adjusted for. In the poisson regression baseline value of outcome is included as an offset. The coefficients presented are: [a]adjusted difference in means, [b]coefficient on logistic scale, [c]incidence rate ratio. The coefficient on the logistic scale presented for the proportional odds ordered logistic regression model is similar to the coefficient from a logistic regression model. For a logistic model the coefficient can be directly converted to an easily interpretable odds ratio. This is not the case for the coefficients from the proportional odds ordered logistic model. Negative coefficients for the proportional odds ordered model indicate that symptom scores are lower in the intervention group.

participation in a waiting list control design. Weaknesses include the lack of physiological measures of disease control, short follow up, and lack of quantitative assessment of validity of the cross culturally adapted outcome scales. Interpretation of clinical relevance of changes in cross-culturally adapted scales is difficult, particularly where constructs originate in Western psychological or sociocognitive theory. Furthermore, minimal important differences, if known, may not be transferable. Some experts recommend *de novo* development of scales. Although our preparatory work included focus groups to determine needs of local Bangladeshis, consideration of the relevance of theoretical constructs of the intervention to the target group, careful cross-cultural adaptation of the intervention, and pilot work to assess feasibility and usefulness of delivering the intervention, we did not follow all steps recommended in the development of a complex intervention.[33]

Comparison with existing literature

The magnitude of this improvement in self-efficacy (roughly 10%) is similar to that seen in trials of the chronic disease self-management programme in other settings and populations.[14,16,30] Unlike these studies, we did not find changes in a wide range of health status measures and health care use. This may reflect a weaker effect of the intervention in Bangladeshi people, lack of sensitivity in our instruments or perhaps differences in the disease characteristics of the trial populations — in our case comprising few people with musculoskeletal or respiratory conditions and over two-thirds with diabetes.

Despite high rates of primary care use at recruitment we found no reduction in visit frequency and no improvement in reported communication with a physician. This is disappointing and suggests that the programme may not impact on the doctor–patient relationship in this group. Differences in healthcare organisation and reimbursement between the US and UK may underlie the differences between the reductions seen in healthcare use seen in evaluations in the US and our results. However, decreased healthcare use is a highly debatable outcome, particularly in communities with high prevalence of chronic disease, and consequent increased morbidity and mortality. Longer-term assessments of healthcare use are needed. Low

attendance at the programme may reflect our method of recruitment — directly approaching patients in primary care practices — rather than advertising for volunteers as used in other studies.[14,16,30] With only one-third of primary care patients approached agreeing to join the programme and poor attendance among some of those that did, expectations of the benefits and in particular the cost savings of the CDSMP for the NHS and its patients may need to be tempered if these findings are replicated in majority ethnic populations of the UK.

Implications for further research and clinical practice

Our results give grounds for cautious optimism about the benefits of such a programme in minority ethnic groups in the UK, but also raise important questions about the capacity of this programme which has been promoted comprehensively across the NHS, to deliver improved health status, reduced healthcare use and costs which might justify taxpayers funds committed to it. Further work should determine ways of improving uptake, and longer-term impact of the programme on health status, metabolic and physiological outcomes, and healthcare use.

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Ethics committee

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Competing interests

None

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