Health promotion for adolescents in primary care: randomised controlled trial

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Abstract

Objectives To evaluate the effectiveness of inviting teenagers to general practice consultations to discuss health behaviour concerns and appropriate follow up care.

Design Randomised controlled trial, with participants randomised to a consultation (intervention) or usual care (control). Questionnaires completed at baseline, 3 months, and 12 months.

Setting Eight general practices in Hertfordshire, England.

Participants 1516 teenagers aged 14-15 years.

Intervention Consultations with practice nurses to discuss health concerns and develop plans for healthier lifestyles.

Main outcome measures Mental and physical health, "stage of change" for health related behaviour, and use of health services.

Results At baseline 970 teenagers completed questionnaires; 25% smoked, 35% had been drunk in the previous three months, 64% considered they ate unhealthily, 39% took little exercise, and 36% had possible depression. 41% (304) of teenagers invited attended for a consultation; over one third (112) were offered follow up care. More intervention group teenagers reported positive movement in stage of change for diet and exercise and in at least one of four behaviours (diet, exercise, smoking, drinking alcohol) at 3 months (41% v 31%, P<0.01), but this did not persist at 12 months. There was marginally more positive change in actual behaviour by intervention teenagers at 3 months (16% v 12%, P=0.06). Recognition of possible depression resulted in improved mental health outcomes at 3 and 12 months. 97% of attenders said they would recommend the intervention to a friend.

Conclusions Change in behaviour was slight but encouraging, and the intervention was well received and relatively cheap.

Introduction

Government policy in Britain is focused on preventing heart disease and stroke, accidents, cancer, and mental illness. Adolescents have a high prevalence of risk factors associated with each of these priority areas, but few receive any health promotion from general practice. Consultations with teenagers are shorter than for other age groups. Very few reports of health promotion or screening for teenagers in the general practice setting have been published. Any such initiatives have been welcomed by both health professionals and teenagers, but no controlled evaluations have been conducted to determine outcomes. Studies of primary care interventions with adults have reported small but significant effects on health behaviour. Health professionals are known to have credibility with adolescents, and the advice they give may be important for teenage behaviour. This paper reports the first UK randomised controlled trial to evaluate the effectiveness of inviting teenagers to general practice for a health consultation and appropriate follow up care. Our hypotheses were that the intervention would provide a useful service, enable mental and physical health problems to be identified and addressed with appropriate information, and encourage healthy lifestyles. The intervention was based on models of self efficacy and behaviour change and teenagers' attitudes to general practice services. The intervention followed the structure suggested by the American Medical Association for consultations promoting self efficacy for healthy lifestyles with adolescents and was informed by the views of teenagers elicited from local surveys and focus groups. The study was approved by the local research ethics committees of East and North Hertfordshire and West Hertfordshire and was first piloted in one practice.

Methods

Participants and randomisation

We identified teenagers aged 14 or 15 years on 1 January 1999 from eight general practice registers in Hertfordshire. The general practitioners sent letters to parents asking for consent. We then gave the teenagers a study number, stratified them according to sex, and randomised them by household with SPSS "random number seed," within the practice, to the intervention or control group.

Intervention

After parental consent had been obtained, teenagers in the intervention group received an appointment for a 20 minute consultation with the practice nurse to discuss health concerns and develop plans for healthier lifestyles.
Primary care

discuss their health and health related behaviour, focusing on topics of their choice. Twelve nurses received training in the study protocol, which aimed to improve adolescent self efficacy for behaviour change.

Researchers (ZW and LO) observed two consultations for each nurse, to see how this was interpreted in practice. Teenagers who attended completed baseline and satisfaction questionnaires and provided saliva samples for measurement of cotinine to validate self reported smoking status. Teenagers who did not attend after two invitations were sent health promotion leaflets and baseline questionnaires at home. The control group received usual care and were sent baseline questionnaires at home. Both intervention and control teenagers were asked to complete follow up questionnaires at three months and 12 months and were invited for a consultation at 12 months to provide saliva samples for cotinine and have physical measurements taken. Up to three reminders were sent for all questionnaires. Mental and physical health, “stage of change” for four health related behaviours (diet, exercise, smoking, drinking alcohol), and use of general practice services were compared between groups. We used the Center for Epidemiological Studies depression scale for children to assess mental health.

Masking

Because of the nature of the intervention, teenagers could not be blinded to their intervention status. However, both groups completed identical questionnaires, and the coding and entry of data were blinded to intervention status.

Analysis

We calculated the sample size needed to detect an effect size of a 10% reduction in the prevalence of smoking (defined as smoking at least one cigarette a week). We aimed to recruit 1200 teenagers, assuming a statistical power of 80%, a 60% response rate, and a 30% loss to follow up, resulting in a minimum of 254 teenagers in each of the two groups at follow up. We analysed the data with SPSS (version 10.0) by using Student’s t test, Mann-Whitney U test, and χ² analysis as appropriate. Analysis was by intention to treat, and we assumed that teenagers who completed baseline questionnaires but did not return follow up questionnaires had made no changes. The main endpoints were health behaviour and stage of change for health related behaviours at 12 months; secondary endpoints were these outcomes at three months.

Results

Participant flow

We identified 1516 teenagers from the practice registers. All teenagers not withdrawn from the study were invited to complete questionnaires at baseline, three months, and 12 months, irrespective of whether they had completed earlier questionnaires. The figure illustrates the progress of participants through the trial. Of the 739 intervention group teenagers invited to a baseline consultation, 304 attended—173 (49%) of the girls and 131 (35%) of the boys. One was withdrawn at this stage because of learning difficulties. A further 200 intervention teenagers and 466 control teenagers completed baseline questionnaires at home. At three months 378 of the intervention group and 357 of the control group completed questionnaires.

At one year the 1358 teenagers remaining in the study were invited to attend a consultation (158 of the original sample had withdrawn from the study; 67 teenagers withdrew consent, 28 parents refused consent, 60 had moved house, and three withdrew for other reasons). Three hundred and ninety three (29%) attended, and non-attenders were sent questionnaires at home. Questionnaires were completed by 322 (49%) of the intervention group and 337 (48%) of the control group.

Baseline results

Demographic data

Respondents were aged 14-16 years (mean 14.8 years). Approximately half (478, 49%) were male. Most (868, 89%) were white, and 466 (48%) were in professional, managerial, or technical socioeconomic groups. Six hundred and forty eight (67%) lived in privately owned accommodation. Three quarters (706, 73%) lived with both natural parents.

Physical and mental health problems

One hundred teenagers (10.3%) reported a “major health problem”; asthma was the most common problem. Problems varied from sexual abuse to acne. More girls than boys reported problems—13% (64) v 8% (36); χ²=5.23, df=1, P<0.02).

Girls scored significantly higher than boys on the depression scale, indicating poorer mental health (17.1 v 11.9; 95% confidence interval for mean difference −6.49 to −4.01; t=−8.32, P<0.01). (A score of 16 indicates probable depression.)

Flow of participants in study

Enrolment

Eligible (n=1516) Excluded (n=28) Randomised (n=1488)

Parental consent refused (n=22) Moved out of area (n=6)

Allocation

Allocated to intervention (n=746) Allocated to control (n=742)

Withdrawable (n=7) Received usual care (n=466)

Invited for consultation (n=739) Baseline data collected (n=466)

Attended and received intervention (n=704) Withdrawn (n=19)

Did not attend (n=432) Baseline data collected (n=584)

Follow up

Three month follow up

questionnaire sent (n=680) Three month follow up

questionnaire sent (n=723)

Completed (n=378) Completed (n=357)

Withdrawn (n=19) Withdrawn (n=26)

Did not respond (n=233) Did not respond (n=347)

Analysis

12 month follow up

questionnaire sent (n=661) 12 month follow up

questionnaire sent (n=697)

Completed (n=337) Completed (n=337)

Did not respond (n=339) Did not respond (n=360)
mental health on the depression scale (t-test). The numbers of these behaviours were associated with poorer mental health. Girls reported significantly more health damaging behaviours than boys (mean 1.5 for intervention and control groups or between attenders. Girls reported significantly more health damaging behaviours measured (current smoking, drinking alcohol more than once a week, not eating healthily, not exercising regularly), and 128 (14%) reported at least three. No significant differences existed in the number of behaviours reported between intervention and control groups or between attenders and non-attenders. Girls reported significantly more health damaging behaviours than boys (mean 1.5 for girls, 1.2 for boys; 95% confidence interval for mean difference 0.25 to 0.51; n=5,8, P<0.01). Increased numbers of these behaviours were associated with poorer mental health on the depression scale (r=0.31, P<0.01).

**Health related behaviour**

Table 1 shows the prevalence of health damaging behaviour at baseline. No significant differences existed between intervention and control groups. Self reported smoking behaviour was validated by a saliva cotinine test for attenders. Four samples (2%) provided by the 234 self reported non-smokers contained cotinine levels greater than 15 ng/ml, which suggested probable smoking or high exposure to passive smoking.2

Seven hundred and twenty six (78%) of the 930 teenagers who answered reported at least one of the health damaging behaviours measured (current smoking, drinking alcohol more than once a week, not eating healthily, not exercising regularly), and 128 (14%) reported at least three. No significant differences existed in the number of behaviours reported between intervention and control groups or between attenders and non-attenders. Girls reported significantly more health damaging behaviours than boys (mean 1.5 for girls, 1.2 for boys; 95% confidence interval for mean difference 0.25 to 0.51; n=5,8, P<0.01). Increased numbers of these behaviours were associated with poorer mental health on the depression scale (r=0.31, P<0.01).

**Sexual health knowledge**

One quarter (236, 24%) of the respondents did not know where to go for contraception without their parent knowing, and 30% (293) did not know where to get confidential advice. Almost one third (292, 30%) did not know that emergency contraception is effective for 72 hours, and two thirds (645) did not know that chlamydia is a sexually transmitted infection.

**Use of health services**

In the year before baseline, 709 (73%) of the teenagers had visited their general practitioner and 226 (23%) had visited their practice nurse at least once. Girls were significantly more likely to have visited, but there was no significant difference by age, ethnic group, or socioeconomic group. Forty one per cent (398) had visited their school nurse, and one fifth (202) had visited another health professional. Teenagers who had seen their general practitioner were more likely to report health damaging behaviour and poorer mental and physical health. This was most marked for current smokers and for teenagers who reported having been drunk in the previous three months, taking drugs or knowing someone who takes drugs, considering themselves overweight, or having a depression scale score indicating probable depression.

**Consultation**

Of the 290 attenders who answered the question, three quarters (230) wished to discuss at least one health behaviour topic with a practice nurse (table 2). A quarter (77) wished to discuss body shape and diet; 12% (35—half the smokers) wished to discuss smoking. Three quarters (225) indicated at least one behaviour they would like to work on changing; the most common were diet (144, 50%), exercise (104, 36%), dealing with stress (68, 23%), and smoking (59, 13%). Three quarters (204) of the teenagers set a health related behaviour target. Sixty three planned to tackle more than one area; the most common topics were diet or nutrition (101), exercise (95), and smoking (29). Two hundred and sixty eight (85%) teenagers completed satisfaction questionnaires, and all but one were satisfied or fairly satisfied with their consultations. Most (246, 95%) said they had felt able to talk about all the issues they wanted to, 116 (45%) found the consultation better than they had expected, 242 (94%) thought the consultation was very useful or fairly useful, and 252 (97%) would recommend the service to a friend.

The nurses identified 48 (16%) teenagers as having some mental health problems, such as anxieties related to family, school, or friends. They identified 12 (4%) as likely to be depressed and a further 17 (6%) as possibly depressed; 21 teenagers were offered mental health follow up care.

Overall, more than one third (112) of the teenagers were offered follow up care. Thirty two were referred to the general practitioner, mostly (81%) for physical health problems. Twenty seven teenagers were offered follow up appointments with the nurse for 45 different problems; these appointments tended to be to discuss health related behaviour (25, 56%) or mental health (15, 33%). In addition, four teenagers were referred to the asthma clinic, eight were offered counselling, and all but one were satisfied or fairly satisfied with their consultations. Most (246, 95%) said they had felt able to talk about all the issues they wanted to, 116 (45%) found the consultation better than they had expected, 242 (94%) thought the consultation was very useful or fairly useful, and 252 (97%) would recommend the service to a friend.

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**Table 1** Prevalence of self reported health related behaviour at baseline. Values are numbers (percentages)

<table>
<thead>
<tr>
<th>Behaviour</th>
<th>Prevalence (n=970)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smoking:</td>
<td></td>
</tr>
<tr>
<td>Current smoker</td>
<td>225 (23)</td>
</tr>
<tr>
<td>Never smoked</td>
<td>613 (63)</td>
</tr>
<tr>
<td>Alcohol:</td>
<td></td>
</tr>
<tr>
<td>Drinks alcohol more than once a week</td>
<td>98 (10)</td>
</tr>
<tr>
<td>Never drunk alcohol</td>
<td>231 (24)</td>
</tr>
<tr>
<td>Been drunk in past three months</td>
<td>342 (35)</td>
</tr>
<tr>
<td>Drugs:</td>
<td></td>
</tr>
<tr>
<td>Has taken drugs</td>
<td>145 (15)</td>
</tr>
<tr>
<td>Knows someone who takes drugs</td>
<td>617 (64)</td>
</tr>
<tr>
<td>Has been offered drugs or encouraged to try drugs</td>
<td>299 (31)</td>
</tr>
<tr>
<td>Thinks will be tempted to take drugs in the future</td>
<td>122 (13)</td>
</tr>
<tr>
<td>Diet and exercise:</td>
<td></td>
</tr>
<tr>
<td>Does not exercise regularly</td>
<td>378 (39)</td>
</tr>
<tr>
<td>Does not eat healthily</td>
<td>617 (64)</td>
</tr>
<tr>
<td>Believes is overweight</td>
<td>264 (27)</td>
</tr>
<tr>
<td>Believes is underweight</td>
<td>99 (10)</td>
</tr>
</tbody>
</table>

**Table 2** Topics teenagers most wanted to discuss. Values are numbers (percentages)

<table>
<thead>
<tr>
<th>Topic</th>
<th>All (n=290)</th>
<th>Boys (n=122)</th>
<th>Girls (n=168)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body size or shape</td>
<td>77 (27)</td>
<td>26 (21)</td>
<td>51 (30)</td>
</tr>
<tr>
<td>Acne</td>
<td>77 (27)</td>
<td>38 (31)</td>
<td>39 (23)</td>
</tr>
<tr>
<td>Diet</td>
<td>75 (26)</td>
<td>28 (23)</td>
<td>47 (28)</td>
</tr>
<tr>
<td>Exercise</td>
<td>62 (21)</td>
<td>28 (23)</td>
<td>34 (20)</td>
</tr>
<tr>
<td>Stress</td>
<td>59 (20)</td>
<td>15 (12)</td>
<td>44 (26)</td>
</tr>
<tr>
<td>General health</td>
<td>58 (20)</td>
<td>21 (17)</td>
<td>37 (22)</td>
</tr>
<tr>
<td>Smoking</td>
<td>35 (12)</td>
<td>17 (14)</td>
<td>18 (11)</td>
</tr>
<tr>
<td>Periods</td>
<td>34 (12)</td>
<td>NA</td>
<td>34 (20)</td>
</tr>
<tr>
<td>Contraception</td>
<td>32 (11)</td>
<td>6 (5)</td>
<td>26 (15)</td>
</tr>
<tr>
<td>Depression</td>
<td>24 (8)</td>
<td>9 (7)</td>
<td>15 (9)</td>
</tr>
<tr>
<td>Cancer</td>
<td>23 (8)</td>
<td>9 (7)</td>
<td>14 (8)</td>
</tr>
<tr>
<td>Alcohol</td>
<td>22 (8)</td>
<td>16 (13)</td>
<td>6 (4)</td>
</tr>
<tr>
<td>Sex</td>
<td>22 (8)</td>
<td>6 (5)</td>
<td>16 (10)</td>
</tr>
<tr>
<td>School</td>
<td>19 (7)</td>
<td>9 (7)</td>
<td>10 (6)</td>
</tr>
<tr>
<td>Nothing</td>
<td>60 (21)</td>
<td>33 (27)</td>
<td>27 (16)</td>
</tr>
</tbody>
</table>

NA—not applicable.
Change in mental health score

We found no significant difference in change in mental health score overall between intervention and control group teenagers at three or 12 months. However, attending teenagers who scored 16 or more on the depression scale and who were identified by a nurse as having possible depression reduced their mental health score significantly more than did controls with these scores. The difference was significant both at three months ($-8.14 \div 1.35$; 95% confidence interval for mean difference $-3.20$ to $-13.26$; $t = -2.10$, $P = 0.04$) and at one year ($-1.58 \div 4.42$; $-0.53$ to $-11.48$; $t = -2.20$, $P = 0.03$), indicating significantly improved mental health relative to controls.

Use of health services

Significantly more of the teenagers who were offered follow up had returned to the practice within three months compared with those offered no specific follow up—41% (46/112) vs 28% (54/192); $\chi^2=8.82$, df=1, $P=0.03$. In the follow up year intervention group teenagers reported fewer visits to their general practitioner than did controls (1.74 vs 2.05; $-0.64$ to 0.02; $P=0.06$). No difference existed between groups in the number of visits to practice nurses or school nurses.

At 12 months significantly more intervention group teenagers than controls knew where to go for confidential advice (83% (257/311) vs 77% (249/325); $\chi^2=4.30$, df=1, $P=0.04$) and for information on contraception (88% (273/311) vs 80% (259/325); $\chi^2=5.65$, $P=0.02$).

Discussion

The results of the trial are disappointing in that benefits (even where significant) were small. In this the results confirm the findings of trials of health promotion among adults and suggest that more needs to be offered to make a real difference. However, although the sample size was met, the analysis by intention to treat and assumptions of no change for the considerable number of non-responders is likely to have resulted in a considerable underestimate of the real effects of the intervention, especially at 12 months, when non-response was highest. Considering these factors, and that changing behaviour is notoriously difficult, the results provide an encouraging start, in terms of both actual behaviour change and stage of change. They suggest the need for a larger study with greater power as well as a more sustained intervention to help to maintain the short term gains and the positive intentions.

The trial confirmed the broad range of topics that adolescents would like the opportunity to discuss with a health professional. Nearly three quarters of teenagers visit their general practitioner each year—over half attend by themselves—and these visits provide an opportunity to develop an adult relationship with health professionals and to discover the range of services available through the NHS. Confidentiality is a major issue that may stop this age group seeking health. In consultations, neither teenagers nor health

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**Table 3** Number (percentage) of teenagers in intervention and control groups who reported positive behaviour change at three month follow up

<table>
<thead>
<tr>
<th>Positive change at three months</th>
<th>Intervention group (n=504)</th>
<th>Control group (n=466)</th>
<th>$\chi^2$</th>
<th>df</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diet</td>
<td>21 (4.2)</td>
<td>10 (2.1)</td>
<td>3.32</td>
<td>1</td>
<td>0.07</td>
</tr>
<tr>
<td>Exercise</td>
<td>18 (3.6)</td>
<td>12 (2.6)</td>
<td>0.80</td>
<td>1</td>
<td>0.37</td>
</tr>
<tr>
<td>Smoking</td>
<td>33 (6.5)</td>
<td>23 (4.9)</td>
<td>1.16</td>
<td>1</td>
<td>0.28</td>
</tr>
<tr>
<td>Drinking</td>
<td>32 (6.3)</td>
<td>22 (4.7)</td>
<td>1.22</td>
<td>1</td>
<td>0.27</td>
</tr>
<tr>
<td>Any of four areas</td>
<td>82 (16.3)</td>
<td>56 (12.0)</td>
<td>3.59</td>
<td>1</td>
<td>0.06</td>
</tr>
</tbody>
</table>

**Table 4** Comparison at three month follow up between intervention and control groups in number (percentage) of teenagers reporting positive movement along the stage of change continuum

<table>
<thead>
<tr>
<th>Positive movement at three months</th>
<th>Intervention group (n=504)</th>
<th>Control group (n=466)</th>
<th>$\chi^2$</th>
<th>df</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diet</td>
<td>89 (17.6)</td>
<td>55 (11.6)</td>
<td>6.57</td>
<td>1</td>
<td>0.01</td>
</tr>
<tr>
<td>Exercise</td>
<td>86 (17.1)</td>
<td>54 (11.6)</td>
<td>5.88</td>
<td>1</td>
<td>0.01</td>
</tr>
<tr>
<td>Smoking</td>
<td>41 (8.1)</td>
<td>25 (5.4)</td>
<td>2.93</td>
<td>1</td>
<td>0.09</td>
</tr>
<tr>
<td>Drinking</td>
<td>65 (12.9)</td>
<td>61 (13.1)</td>
<td>0.91</td>
<td>1</td>
<td>0.35</td>
</tr>
<tr>
<td>Any of four areas</td>
<td>206 (40.9)</td>
<td>143 (30.6)</td>
<td>10.91</td>
<td>1</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>

Further 16 were encouraged to return if they wanted to follow up on any of the issues discussed.

Observation of a sample of clinics confirmed that the nurses were following the protocol, explaining the code of confidentiality, and trying to build a rapport with the teenagers. Mean length of consultations was 22.6 (SD 8.7) minutes. Most teenagers (288/304, 95%) saw the nurse alone.

Follow up

**Health related behaviour**

At three months marginally more teenagers in the intervention group than in the control group reported positive change in at least one of the four areas of health related behaviour (16% v 12%; $\chi^2=3.59$, df=1, $P=0.06$) (table 3). We found no significant difference between intervention and control group teenagers in the proportion who reported unhealthy lifestyles for the four areas measured individually at three month follow up, although the intervention group reported more positive movement in each case, except for drinking alcohol where change was similar for both groups. No significant difference existed at 12 months.

**Stage of change for health related behaviour**

Positive movement along the stage of change continuum indicates increased intention to improve the behaviour and assesses attempted as well as maintained change. At three months significantly more of the teenagers in the intervention group (41%) than in the control group (31%) indicated some positive movement in stage of change for at least one of the four key behaviours ($\chi^2=10.91$, df=1, $P<0.01$) (table 4). For individual behaviours, significantly more teenagers in the intervention group than in the control group made positive movement in stage of change for diet and for exercise. For smoking, the difference between the groups was of marginal significance (8% v 5%; $\chi^2=2.93$, df=1, $P=0.09$). No difference in drinking alcohol was found (table 4). At 12 months, no significant differences existed in the proportion showing positive movement in stage of change in at least one area.
What is already known on this topic

Teenagers have a high prevalence of health damaging behaviour and have expressed a wish to discuss a broad range of health related issues with a health professional.

- Few teenagers receive health promotion advice or information from their general practice teams.

What this study adds

General practice based health promotion consultations are welcomed by teenagers who attend.

- Such consultations provide an effective opportunity to identify and tackle mental and physical health problems and encourage healthy lifestyles.

The effect on teenagers’ actual lifestyles is modest.

Attendance did not vary by risk behaviour, age, or ethnic group. The practices included large and small practices in town based and rural locations. Lower attendance rates were recorded in the more deprived areas, but a higher proportion of teenagers who attended at these practices reported serious health concerns. Our findings may not be generalisable to inner city or very rural settings with particular problems of access but would be likely to apply to a wide range of practice settings and could be considered as part of a broad approach to providing health promotion and advice to this age group.

Recruitment to behaviours with health risks tends to be high at this age, so any reduction in uptake is important. Nurses expected to discuss sexual and mental health, drugs, and alcohol, and the teenagers did raise these concerns. But teenagers’ greatest concern was about diet and exercise, both important factors in heart disease and stroke, while half the smokers wished to discuss smoking.

Interest in training about teenage health issues is increasing, but no specific financial incentives for adolescent care are available, and a recent survey reported that only one in 10 health authorities had a policy on adolescents. The intervention reported in this study was brief and inexpensive and possibly offset by reduced consultations in the following year. With minor financial outlay and some publicising of policies on confidentiality, practices can at least create an atmosphere that welcomes teenagers.

Conclusion

The consultations enabled the mental and physical health concerns of adolescents to be identified and addressed, were well received, and helped the teenagers to develop healthier lifestyles. A larger study with more substantial intervention is needed.

We thank all the teenagers and nurses for their essential contribution to this project.

Contributors: ZW and JT developed the research question. ZW, JT, CD, HS, JB, ZH, and SM developed the study design. ZW, LO, CD, HS, JB, ZH, and SM developed and led the training. SM and JB were among the 12 nurses who held clinics for teenagers in their practices. ZW undertook the day to day running of the trial, with the help of LO. All authors attended regular meetings to oversee the development and management of the trial. ZW and LO carried out data collection, coding, and cleaning. ZW carried out data analysis in discussion with all authors. ZW wrote the first draft of the paper, and all authors have reviewed successive drafts. JT is guarantor for the study.

Funding: NHS Executive—Eastern Region, and HertNet (Hertfordshire Primary Care Research Network).

Competing interests: None declared.

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(Accepted 9 July 2002)