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Improving teenagers understanding of emergency contraception (EC)

Submission date	Recruitment status	[ ] Prospectively registered
23/01/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/01/2004	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
12/01/2010	Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
S/13/Graham/98

Study information

Scientific Title

Study objectives
Principle research questions:
1. To determine the availability of EC in Avon for the under 16s
2. To develop an intervention in schools, delivered by teachers, to increase teenagers knowledge about EC
3. To evaluate the effectiveness of the intervention in a randomised controlled trial (RCT) in schools in Avon, using a cluster based design

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Pregnancy; emergency contraception

Interventions
Added 12/01/10:
Teachers gave a single lesson on emergency contraception to year 10 pupils. The teachers had previously received in-service training on giving the lesson. The pupils were actively involved during the lesson.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
To improve awareness of EC amongst 14/15 year olds in Avon

Secondary outcome measures
1. To map the provision of EC for the under 16s in Avon
2. To evaluate the effectiveness of a school based, teacher led, intervention to improve knowledge of the time limits for use of EC
3. To obtain data on pupils knowledge and attitudes towards EC; where they believe EC can be obtained, what they believe the side effects to be, how effective EC is, and how they view the safety of EC
4. To obtain data within this sample, of rates of sexual activity and use of EC

Overall study start date
01/10/1998

Completion date
01/10/2001

Eligibility

Key inclusion criteria
Year 10 pupils (age 14-15 years) in 24 schools from the four Local Education Authorities that make up Avon Health Authority

Participant type(s)
Patient

Age group
Child

Lower age limit
14 Years

Upper age limit
15 Years

Sex
Both

Target number of participants
3794 (1974 boys; 1820 girls; 24 schools) (added 12/01/10, see publication)

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/10/1998

Date of final enrolment

01/10/2001

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Bristol
Bristol
United Kingdom
BS8 2PR

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name

NHS Executive South West (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	18/05/2002		Yes	No