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A randomised trial of educational interventions for women taking the combined oral contraceptive pill (COCP)

Submission date
23/01/2004

Recruitment status
No longer recruiting

Registration date
23/01/2004

Overall study status
Completed

Last Edited
14/10/2014

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Pregnancy and childbirth: Pregnancy

Interventions
The interactive questions were itemised, and the doctor or practice nurse posed each item to the patient and ticked the box as appropriate. If the women could not respond the correct answer was discussed. We aimed for an interactive rather than a simple didactic approach. The interactive questions took 2-5 minutes depending on the woman's level of knowledge. We used two kinds of leaflet. The first was a laminated leaflet, the size of a credit card, that contained a summary of the pill rules. The card was developed from discussions with women who took the contraceptive pill, doctors, nursing colleagues, and our advisors. The second leaflet was the latest one produced by the Family Planning Association. The leaflets were given to the women without explanation, but with a simple endorsement by the doctor or practice nurse. The management sheets and the answers to the interactive questions were all well completed.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s))
Not provided at time of registration

Completion date
31/12/1999

Eligibility

Key inclusion criteria
Women aged 18-45 years attending check up appointment for repeat prescription of the combined contraceptive pill.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
45 years

Sex
Female

Key exclusion criteria
1. Aged 17 or under, owing to the sensitivity of collecting the postal outcome measures
2. Unable to complete the questionnaire (learning disability, schizophrenia, major current manic or depressive episode, or both)
3. or if the consultation was their first for the contraceptive pill (this created the ethical dilemma of randomising such patients to a control group where they would receive no education on the pill rules)

Date of first enrolment
01/01/1999

Date of final enrolment
31/12/1999

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Primary Medical Care Group
Southampton

United Kingdom
SO16 5ST

Sponsor information

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

Funder(s)

Funder type
Government

Funder Name
NHS Executive South West (UK)

Results and Publications

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	01/08/2001		Yes	No