

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	<input type="checkbox"/> Prospectively registered
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 14/10/2014	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Paul Little

Contact details

Primary Medical Care Group
Faculty of Medicine
Southampton University
Aldermoor Health Centre
Southampton
United Kingdom
SO16 5ST
psl3@soton.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Other

Participant information sheet

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 measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/1999

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

45 Years

Sex

Female

Target number of participants

Not provided at time of registration

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

England

United Kingdom

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)

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	01/08/2001		Yes	No