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The psychological effects of completing daily diary cards for patients receiving chemotherapy

Submission date	Recruitment status	[ ] Prospectively registered
30/09/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/09/2004	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/08/2015	Signs and Symptoms	[ ] Record updated in last year

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
N0255127859

Study information

Scientific Title
The psychological effects of completing daily diary cards for patients receiving chemotherapy

Study objectives
There is a relationship between the use of daily diary cards and an increase in the incident of nausea/vomiting and anxiety in patients receiving chemotherapy. The sample size calculation is based upon RSCL normative data for chemotherapy patients provided in the manual (De-Hanes eta al 1996). This information was not available within the literature for the HAD scale therefore it was decided to base the sample size on RSCL characteristics. Using the normative data from the RSCL manual I assumed: control group mean = 25; standard deviation = 22; treatment group standard deviation = 22. Based on these assumptions and requiring a statistical power of 0.8; using a 2-sided test at alpha = 0.05 to discern a 15 point difference between treatment and control groups the calculations indicated a sample size of 34 patients per group (total 68) would be sufficient.

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)
Not specified

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Signs and Symptoms: Nausea and vomiting

Interventions
Daily diary cards vs standard practice

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. Hospital Anxiety and Depression (HAD) questionnaire
2. Rotterdam Symptom CheckList (RSCL)
3. Diary cards

Secondary outcome measures
Not provided at time of registration

Overall study start date
08/09/2003

Completion date
08/10/2004

Eligibility

Key inclusion criteria
Patient receiving chemotherapy and using daily diary cards

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
68

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
08/09/2003

Date of final enrolment
08/10/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Princess Alexandra Hospital NHS Trust
Harlow
United Kingdom
CM20 1QX

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
The Princess Alexandra Hospital NHS Trust (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