ISRCTN82960239 https://doi.org/10.1186/ISRCTN82960239

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

Contact name
Ms Noreen Cushen

Contact details
Galen House
The Princess Alexandra Hospital NHS Trust
Hamstel Road
Harlow
United Kingdom
CM20 1QX
+44 (0)1279 694937/28
abc@email.com

Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Quality of life

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

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

Completion date
08/10/2004

Eligibility

Key inclusion criteria
Patient receiving chemotherapy and using daily diary cards

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

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

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
The Princess Alexandra Hospital NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration