

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

Submission date 30/09/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 19/08/2015	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

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 et 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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes