

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

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<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 19/08/2015	<b>Condition category</b> 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

**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 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

## 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