

ALLograft INformation EXchange (ALLINEX): Standard care versus standard care plus access to the ALLINEX website

Submission date 16/03/2012	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 16/03/2012	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 17/08/2015	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/a-study-looking-support-website-people-who-have-had-stem-cell-transplant-allinex>

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

11496

Study information

Scientific Title

ALlograft INformation EXchange (ALLINEX) - phase three: A randomised pilot study of standard care versus standard care plus access to the ALLINEX website

Acronym

ALLINEX

Study objectives

Survival for adult patients receiving allogeneic Haemopoietic Stem Cell Transplant (HSCT) is improving but many will experience challenges particularly associated with chronic Graft versus Host Disease (cGvHD). Allogeneic HSCT patients are followed up in tertiary care, being seen less frequently as they recover. Although recommendations have been made for assessment and support for HSCT patients on follow up, some patients do not access the care they want or need. There has been an increase in the use of technologies in providing support in health care. Allogeneic HSCT patients tend to be under the age of 65 years and therefore are likely to be users of the internet. This is a group of patients who might benefit from a specifically designed website for use as an adjunct to their standard follow up care. Such a website could include information endorsed by their clinical team, the means to contact their clinical team and the facility for them to chat to each other via a secure forum.

The aim of this study is to assess the acceptability and feasibility of introducing a specifically designed website for use in the allogeneic adult HSCT service as an adjunct to standard care.

In this pilot we will aim to recruit sufficient participants to allow for a minimum of 20 patients in each arm to complete the study to fulfil minimum requirements of a total of 30 participants recommended by Browne for randomised pilot studies. We will aim to recruit more than this minimum to provide the best estimate for primary outcome for a larger trial.

More details can be found at <http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=11496>

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee East Midlands - Nottingham 1 First MREC approval date 08/11/2011, ref: 11/EM/0407

Primary study design

Interventional

Study design

Randomised; Interventional; Design type: Not specified

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Topic: National Cancer Research Network; Subtopic: Haematological Oncology; Disease: All

Interventions

Intervention (access to website) plus standard care versus standard care.

Consenting patients will complete baseline measures prior to randomisation. Participation time is twelve weeks. Consultations with the clinician will be audio-recorded. Website activity will be tracked. At six weeks the intervention arm will complete a Patient Technology Acceptance Survey. After twelve weeks all will complete outcome measures and a use of service questionnaire. The intervention arm will complete a feedback questionnaire concerning the website. Clinicians will take part in a debriefing interview concerning use of the website as an adjunct to standard care. Contact between patients and clinicians will be reviewed during the study period.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Feasibility and acceptability - Establish feasibility and acceptability of a specifically designed website as an adjunct to routine measured at 12 weeks

Key secondary outcome(s)

1. Patient behaviour - Demonstrate change in patient behaviour
2. Patient well-being - Enhancement of patient well-being compared to standard care group. Measured at 6 weeks

Completion date

29/06/2012

Eligibility**Key inclusion criteria**

1. Having undergone allogeneic HSCT
2. Under specialist HSCT care
3. English literate
4. Aged 18 or over
5. Access to the internet

Target Gender: Male & Female ; Lower Age Limit 18 no age limit or unit specified

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Unable to provide informed consent to participate
2. Have cognitive impairment or communication difficulties which are incompatible with the study
3. Participation in the study is judged to be inappropriate on clinical grounds

Date of first enrolment

18/01/2012

Date of final enrolment

29/06/2012

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

St James's Institute of Oncology

Leeds

United Kingdom

LS9 7TF

Sponsor information**Organisation**

University of Leeds (UK)

ROR

<https://ror.org/024mrxd33>

Funder(s)**Funder type**

Charity

Funder Name

Macmillan Cancer Support (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2014		Yes	No
Results article	results	01/05/2016		Yes	No