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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 16/03/2012	**Overall study status** Completed	
Last Edited 17/08/2015	**Condition category** Cancer	

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 65years 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 suffiicent 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

Study design
Randomised; Interventional; Design type: Not specified

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

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

Secondary outcome measures
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

Overall study start date
18/01/2012

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 40; UK Sample Size: 40

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
England

United Kingdom

Study participating centre
St James's Institute of Oncology
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation
University of Leeds (UK)

Sponsor details
Faculty of Medicine and Health
Academic Unit of Musculoskeletal and Rehabilitation Medicine
36 Clarendon Road
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Sponsor type
University/education

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Charity

Funder Name
Macmillan Cancer Support (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 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