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Managing pain in HIV/AIDS: investigating the effectiveness of an education intervention for Malawian people living with HIV/AIDS and their family carers

Submission date
31/08/2012

Recruitment status
No longer recruiting

Registration date
09/10/2012

Overall study status
Completed

Last Edited
10/11/2016

Condition category
Signs and Symptoms

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims:
The study aims to investigate the effects of an educational programme on managing pain among people living with HIV/AIDS. Pain is frequently experienced and difficult to manage in HIV infection, so we want to assess if providing people living with HIV/AIDS and their family carers with a short educational package will help the way pain is managed is effective. It is hoped that this will assist in reducing the pain experienced.

Who can participate?
The study aims to recruit 179 people with HIV/AIDS (stage III or IV) and their family carers. Both patient and carer need to be aged 18 years and above and write in English or Tumbuka.

What does the study involve?
The study involves randomly allocating patients with HIV/AIDS and their family carers into two groups. This allocation is determined by a computer (which has no information about participants). Initial assessments will be conducted before group allocation. In one group participants will receive health education via a face-to-face meeting with pain education nurse and a leaflet about pain assessment and management. The other group will receive usual care. After eight weeks a staff nurse will conduct follow-up assessments with participants using the same questionnaire used for initial assessments. Participants allocated to usual care will still receive the educational package about pain, but not until after they have completed the follow-up assessments.

What are the possible benefits and risks of participating?
There are no direct benefits for those taking part in the study. However this may be an opportunity for patients and family carers to learn ways of assessing the pain experienced and how to better manage that pain. There are no risks involved to those taking part in the study and every effort will be made not to inconvenience patients or their family carers.

Where is the study run from?
Ekwendeni Hospital (Malawi)

When is the study starting and how long is it expected to run for?
The study will start in October 2012 and participants will be followed-up for assessments after two months

Who is funding the study?
The University of Nottingham School of Nursing, Midwifery and Physiotherapy and the Malawi Government

Who is the main contact?
Dr Tony Arthur
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Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
An educational intervention to reduce pain and improve pain management for Malawian people living with HIV/AIDS and their family carers in Malawi: randomised controlled trial

Study objectives
Compared with standard care:
1. Patients who receive the pain education intervention will show reduced pain, improved knowledge and skills in managing pain, improved quality of life
2. Carers who receive pain education intervention will show improved knowledge and skill in managing pain, improved quality of life and improved motivation in providing care

Ethics approval required
Old ethics approval format

Ethics approval(s)
1.The University of Nottingham Medical School Ethics Committee, 27/04/2012, ref: SNMP11042012
2.The National Health Sciences Research Committee in Malawi, 18/06/2012, ref: NHSRC 1023

Primary study design
Interventional

Study design
Two-arm randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pain in HIV/AIDS

Interventions
Usual care versus a structured leaflet based education intervention that includes:
1. 30 minutes face-to-face meeting with the patient and family carer
2. A leaflet designed for HIV/AIDS patients and their family carers
3. Follow-up telephone at two weeks

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Average pain intensity, measured by Brief pain inventory at baseline and two months after randomisation

Key secondary outcome(s)
PLWHA
1. Pain knowledge, measured by patient pain questionnaire at baseline and two months after intervention
2. Quality of life, measured by African palliative care outcome scale at baseline and two months after intervention

Family carers
1. Pain knowledge, measured by family pain questionnaire at baseline and two months after intervention
2. Quality of life, measured African palliative care outcome scale at baseline and two months after intervention
3. Motivation, measured by Picot caregiver rewards scale at baseline and two months after intervention

Completion date
29/03/2013

Eligibility

Key inclusion criteria
People living with HIV/AIDS (PLWHA):
1. Diagnosis of HIV/AIDS
2. Stages III or IV of HIV/AIDS

Carers:
Living with the person infected with HIV/AIDS and be most involved in their care

PLWHA and carers:
1. Both PLWHA and their carers will be able to read and write in English or Tumbuka (this is the vernacular language used in the northern part of Malawi)
2. Aged 18 years and above

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Unable to give informed consent
2. PLWHA will be excluded if they have any other health problems that may hinder communication
3. Carers of patients with conditions other than HIV/AIDS

Date of first enrolment
01/10/2012

Date of final enrolment
29/03/2013

Locations

Countries of recruitment
United Kingdom

England

Malawi

Study participating centre
University of Nottingham
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
University of Nottingham (UK)

ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
University/education

Funder Name
University of Nottingham (UK)

Alternative Name(s)
The University of Nottingham

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
Malawi Government (Malawi)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2015		Yes	No
Protocol article	protocol	13/07/2013		Yes	No