

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 09/10/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/11/2016	Condition category Signs and Symptoms	<input type="checkbox"/> 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

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Study design

Two-arm randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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 measure

Average pain intensity, measured by Brief pain inventory at baseline and two months after randomisation

Secondary outcome measures

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

Overall study start date

01/10/2012

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

Participant type(s)

Mixed

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

179 patient/carer dyads

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**

England

Malawi

United Kingdom

Study participating centre

University of Nottingham

Nottingham

United Kingdom

NG7 2UH

Sponsor information**Organisation**

University of Nottingham (UK)

Sponsor details

c/o Paul Cartledge, Head of Contracts

Research and Graduate Services

King's Meadow Campus

Lenton Lane

Nottingham

England

United Kingdom

NG7 2NR

Sponsor type

University/education

Website

<http://www.nottingham.ac.uk/>

ROR

<https://ror.org/01ee9ar58>

Funder(s)

Funder type

University/education

Funder Name

University of Nottingham (UK)

Alternative Name(s)**Funding Body Type**

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

Funder Name

Malawi Government (Malawi)

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

Study outputs

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