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Rehabilitation for cognitive deficits after central nervous system malaria in Ugandan children

Submission date	Recruitment status	[_] Prospectively registered
10/04/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/07/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
28/02/2019	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Paul Bangirana

Contact details
Department of Psychiatry
Makerere University Medical School
Kampala
Uganda
7072
+256 (0)772 673 831
pbangirana@yahoo.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
NCT00658450

Secondary identifying numbers
2006/HD11/4748U

Study information

Scientific Title
A randomised trial to investigate the effect of a rehabilitation program for cognitive deficits in Ugandan children after central nervous system malaria

Study objectives
Current hypothesis as of 05/02/2009:
Malaria with central nervous system (CNS) involvement affects several children in sub-Saharan Africa leaving some survivors with cognitive problems especially in attention and memory. There are currently no tested interventions for such deficits resulting from infectious diseases like malaria or other causes. Providing such interventions will go a long way in helping these children achieve their full potential.

The purpose of this study is to determine whether computerised cognitive rehabilitation training improves cognition in children who have had CNS malaria.

Initial hypothesis at time of registration:
Children receiving cognitive rehabilitation will have better cognitive outcomes than those not receiving cognitive rehabilitation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Makerere University Faculty of Medicine Research and Ethics Committee on the 31st October 2007
2. Uganda National Council of Science and Technology on the 11th December 2007

In addition to the proposal being reviewed on the above two dates, another approval for the new changes was given on the 14th Nov 2008.

Study design
Randomised controlled single centre trial (multicentre as of 05/02/2009)

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Malaria with CNS involvement

Interventions
A computerised cognitive training package (named Captain's Log) will be the main intervention. Children assigned to the intervention will be given cognitive training for 45 minutes, twice a week for 8 weeks (16 sessions in all). The hope is that continued use of certain cognitive functions during the training will strengthen them leading to improvement in these areas.

Duration of the treatment in the intervention arm is 16 sessions each lasting 45 minutes bi-weekly for 8 weeks (2 months). This intervention will start at 3 months post-discharge.

The control group will receive the standard post-discharge care for cerebral malaria at Mulago Hospital, the study site (treatment as usual). This includes follow up visits at the Paediatric neurology clinic if child had neurological complications at discharge. No cognitive rehabilitation takes place at this clinic.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Attention measured by the Test of Variables of Attention (TOVA).

Primary and secondary outcomes will be measured at 3 months post-discharge (just before intervention starts) and at 6 months post-discharge (a month after intervention).

Secondary outcome measures
Amended as of 20/10/2010:
1. Memory, visual spatial ability, learning and reasoning measured by the Kaufmann Assessment Battery for children second edition
2. Parental rating of behaviour measured by the child behaviour checklist
3. Academic functioning measured by the wide range achievement test, third edition

Primary and secondary outcomes will be measured at 3 months post-discharge (just before intervention starts) and at 6 months post-discharge (a month after intervention).

Initial information at time of registration:
1. Memory, planning and reasoning measured by the Kaufmann Assessment Battery for children second edition
2. Parental rating of behaviour measured by the child behaviour checklist
3. Academic functioning measured by the wide range achievement test, third edition

Primary and secondary outcomes will be measured at 3 months post-discharge (just before intervention starts) and at 6 months post-discharge (a month after intervention).

Overall study start date
01/02/2008

Completion date
01/10/2010

Eligibility

Key inclusion criteria
Current information as of 05/02/2009:
Study will recruit children with central nervous system malaria (CNS) and healthy controls (HC).

Inclusion criteria for CNS group:
1. Aged five to 15 years, either sex
2. Presenting with asexual forms of P. falciparum malaria on a peripheral blood smear
3. Unarousable coma (not able to localise a painful stimulus) and no other cause for coma (normal cerebrospinal fluid [CSF])
4. A history of seizures for the present illness
5. Impaired consciousness

Inclusion criteria for HC group:
1. Aged five to 15 years, either sex
2. No other illness at present
3. Within two years of the CNS child (for CNS children aged 5 and 6 years, the HC's age won't go below 5 and for CNS children aged 14 and 15, the HC's age won't go above 15 years)

Initial information at the time of registration:
Study will recruit children with cerebral malaria (CM) and healthy controls (HC).

Inclusion criteria for CM group:
1. Aged five to 15 years, either sex
2. Presenting with asexual forms of P. falciparum malaria on a peripheral blood smear
3. Unarousable coma (not able to localise a painful stimulus) and no other cause for coma (normal cerebrospinal fluid [CSF])

Inclusion criteria for HC group:
1. Aged five to 15 years, either sex
2. No other illness at present
3. Within two years of the CM child (for CM children aged 5 and 6 years, the HCs age won't go below 5 and for CM children aged 14 and 15, the HCs age won't go above 15 years)

Participant type(s)
Patient

Age group
Child

Lower age limit
5 Years

Upper age limit
15 Years

Sex
Both

Target number of participants
124

Key exclusion criteria
Amended as of 20/10/2010:
Please note that the exclusion of HIV children has been removed as of 20/10/2010, meaning that children infected with HIV will now be allowed to participate in this trial.

Initial information at time of registration:
Exclusion criteria for CNS* group:
1. History of or present meningitis, encephalitis, prior CNS*, sickle cell disease (SCD), human immunodeficiency virus (HIV) infection, epilepsy, multiple seizures
2. Developmental delay
3. History of hospitalisation for malnutrition

Exclusion criteria for HC group:
1. History of or present bacterial meningitis, encephalitis, CNS, SCD, HIV infection
2. History of hospitalisation for malnutrition
3. Any chronic illness for which the patient is currently taking medication

* Please note that this changed from CM to CNS on 05/02/09 in response to updates from the Principal Investigator)

Date of first enrolment
01/02/2008

Date of final enrolment
01/10/2010

Locations

Countries of recruitment
Uganda

Study participating centre
Makerere University Medical School
Kampala
Uganda
7072

Sponsor information

Organisation
Swedish International Development Cooperation Agency (SIDA) (Sweden)

Sponsor details
Valhallavägen 199
Stockholm
Sweden
105 25
+46 (0)8 698 50 00
sida@sida.se

Sponsor type
Government

Website
http://www.sida.se

ROR
https://ror.org/01fn7me06

Funder(s)

Funder type
Government

Funder Name
Department for Research Cooperation (SAREC) of the Swedish International Development Cooperation Agency (SIDA) (Sweden)

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?
Results article	results	04/08/2011	28/02/2019	Yes	No