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Long-term outcomes of severe childhood malnutrition study

Submission date 07/06/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 08/06/2021	**Overall study status** Completed	
Last Edited 19/02/2024	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Childhood malnutrition is widespread in low-resource settings such as Malawi and results in significant morbidity and mortality. Furthermore, the 'double burden of malnutrition' (undernutrition of nutritionally rich foods and overnutrition with food of low nutritional value) is being increasingly recognised as a major health problem in these settings.

The ChroSAM cohort was an exploratory study in 2007 which recruited children admitted to Queen Elizabeth Central Hospital (QECH) in Blantyre, Malawi with severe childhood malnutrition. This study followed up 320 children in 2013 who had survived seven years post-discharge (median age: 9). The children from this initial cohort are now in adolescence (median age: 17).

We aim to measure several medium- and long-term outcomes in survivors from the ChroSAM cohort in comparison to (previously recruited) sibling and community controls.

Who can participate?
We will contact all previous participants (cases, sibling controls and community controls) to participate in the study. We will recruit additional community controls if there is high loss to follow-up.

What does the study involve?
We will ask participants to come for a half-day of assessments. Follow-up of participants in the cohort will generate long-term survival data and add to previously collected longitudinal growth data.

What are the possible benefits and risks of participating?
There are no direct benefits to participating in the study. If any health problems are detected at follow-up we will refer participants to the appropriate health services. There are minor risks involved in the study as this is an observational study. There are some risks due to general community COVID-19 transmission, which we will minimise through use of personal protective

equipment, masks, distancing and ventilation during assessments. We will compensate participants for the small discomfort of taking blood samples and fasting for oral glucose tolerance tests.

Where is the study run from?
Queen Elizabeth Central Hospital (QECH) in Blantyre (Malawi)

When is the study starting and how long is it expected to run for?
June 2021 to December 2022

Who is funding the study?
Wellcome Trust (UK)

Who is the main contact?
Dr Amir Kirolos, a.kirolos@liverpool.ac.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Medium- and long-term health outcomes of adolescents and young adults following severe malnutrition in childhood: A longitudinal cohort study

Acronym
LOSCM Study

Study objectives
Our overarching research question is 'How does severe malnutrition in childhood affect physical and mental development and how persistent is this effect into later life?'

Our proposed follow-up of a previously established cohort of survivors of severe childhood malnutrition aims to describe medium- and long-term health outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval pending.
Currently under ethics review with College Of Medicine Research Ethics Committee (COMREC) Malawi.
The proposal will also be reviewed by University of Liverpool and London School of Tropical Medicine & Hygiene ethics committees.

Study design
Longitudinal cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Community

Study type(s)
Other

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Health outcomes of severe childhood malnutrition

Interventions
We will contact all previous participants (cases, sibling controls and community controls with additional controls if required) to ask them to come for a half-day assessment in Blantyre, Malawi. Recruitment is anticipated to last one year and we aim to recruit as many of the previous 320 children since the last study, anticipating that there will be some level of loss to follow-up

since the last study. Follow-up of children in the cohort will generate long-term survival data and add to previously collected longitudinal growth data.

Intervention Type
Other

Primary outcome measure
Survival is measured using a follow-up questionnaire of participants 8 years following the previous ChroSAM study

Secondary outcome measures
1. Body composition is measured using body impedance analysis and skinfold thickness at 8 year follow-up
2. Growth is measured using anthropometry (mean upper arm circumference, weight, height, hip circumference, sitting height) at 8 year follow-up
3. Cardiovascular disease risk is measured using resting blood pressure at 8 year follow-up
4. Cardiovascular disease risk is measured using lipidomic analysis at 8 year follow-up
5. Metabolic disease risk is measured using oral glucose tolerance test at 8 year follow-up
6. Metabolic disease risk is measured using metabolomics at 8 year follow-up
7. Chronic stress is measured using hair cortisol at 8 year follow-up
8. Motor function is measured by hand grip strength, exercise tolerance and rapid consequential movements at 8 year follow-up
9. Cognition is measured by a tablet-based cognition assessment (CANTAB) and school performance at 8 year follow-up.
10. Cognition and inattention is measured with EEG and eye tracking at 8 year follow-up
11. Mental health & behaviour is measured using strengths & difficulties, GAD-7, PHQ-9 and child behaviour checklist questionnaires at 8 year follow-up

Overall study start date
07/06/2021

Completion date
30/12/2022

Eligibility

Key inclusion criteria
1. Previous recruitment to the ChroSAM study

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
350

Total final enrolment
380

Key exclusion criteria
1. Controls that have significant health issues
2. Previous participants that are unavailable (for example, have moved far from previous recruitment area in Blantyre) since last follow-up

Date of first enrolment
01/08/2021

Date of final enrolment
30/08/2022

Locations

Countries of recruitment
Malawi

Study participating centre
Malawi-Liverpool-Wellcome Trust Clinical Research Programme
Chichiri
Blantyre
Malawi
PO Box 30096

Sponsor information

Organisation
University of Liverpool

Sponsor details
Brownlow Hill
Liverpool
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United Kingdom
L69 3BX
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Sponsor type
University/education

Website
http://www.liv.ac.uk/

ROR
https://ror.org/04xs57h96

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust

Alternative Name(s)
Wellcome, WT

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Results will be included as part of the PhD thesis of the prinicpal investigator. Results will be subsequently prepared and submitted for publication in open-access peer-reviewed journals.

Results of this study will be presented in national forums such as the College of Medicine Research Dissemination day. We will also present results at international meetings.

We will provide findings in writing to the local paediatric department, QECH and COMREC committees to disseminate findings locally.

Intention to publish date
01/12/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository.
University of Liverpool Data Repository. Anonymised data with removal of potentially identifiable information, with inclusion of health outcomes data, data will be held for at least 10

years after completion of the study, data will be available after a year following study completion. Access can be shared with other researchers and access will be controlled by the study investigators, request through the University of Liverpool.

IPD sharing plan summary

Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v1.1		08/07/2021	No	Yes
Protocol file		14/05/2021	08/07/2021	No	No
Results article		15/02/2024	19/02/2024	Yes	No