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SAM Photo Diagnosis App Project

Submission date
24/09/2018

Recruitment status
No longer recruiting

Registration date
29/10/2018

Overall study status
Completed

Last Edited
09/09/2020

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Action against Hunger (ACH) is an international humanitarian organization that fights against the causes and effects of hunger. We save lives of malnourished children and guarantee families access to safe water, food, training and basic health care. The SAM Photo Diagnosis App® project has developed an innovative easy-to-use smartphone tool which can quick and accurately diagnose nutritional status in children aged 6-59 months by means of a photo (body shape analysis). Our innovation responds to the need to improve screening, diagnosis and management of malnutrition, providing a unique opportunity to address it at scale at community level.
Despite significant progress over recent decades, maternal and child undernutrition remains a significant problem throughout the developing world, with 45% of deaths of children younger than five years old attributed to malnutrition. Acute malnutrition (wasting) in children is the life-threatening result of hunger and/or disease. Children suffering from acute malnutrition face an increased risk of morbidity and mortality, and therefore require urgent treatment to survive. In 2016, over 52 million children under five years of age suffered from acute malnutrition, with almost 17 million of these children experiencing the most severe form. Only 3.2 million children were successfully diagnosed and treated in 2016, leaving over 80% of children in need but unable to access treatment. It is important that health centres are equipped with the tools and expertise they need to be able to diagnose and manage cases of acute malnutrition. By the same token, it's important that caretakers are also empowered to continue the treatment and regularly monitor the condition until the child is fully recovered.
Historically, two methods of anthropological measurement have been used for the diagnosis of moderate and severe acute malnutrition – weight-for-height (WHZ) and mid-upper arm circumference (MUAC). While these techniques provide an accurate diagnosis of acute malnutrition, there are still significant operational challenges for their use at scale. We have demonstrated that image-based techniques can be applied as an alternative diagnosis approach. This project reinforces decentralization and sustainability of community management of malnutrition by empowering caretakers to diagnose and monitor the nutrition status of their children. It also presents a great opportunity for governments and local health systems to revolutionize nutrition assessments and improve the impact and coverage of nutrition programs.

Who can participate?
Children aged 6-59 months with severe acute malnutrition

What does the study involve?
Phase 1 is the pilot phase. This phase is complete and involved developing an innovative smartphone tool which could quick and accurately diagnose nutritional status, by analysing the child's body shape registered in photos taken by the device. The development of the algorithm required taking photographs of a sample of well-nourished children in Spain and well-nourished and malnourished children in Senegal. The sample was composed of 107 Spanish children, 154 Senegalese well-nourished children and 142 Senegalese children with severe acute malnutrition. Overall, the Phase 1 project collected over 2,060 images across the sample of children in the study. These images captured the full body photos in different views and allowed the study of both the whole body and split body regions. These images provided the information needed to generate the templates used for diagnosis.
Phase 2 involves adapting the technology to the users. Here the aim is to reinforce both dimensions of the App as a research and diagnostic tool. At conception, it was recognised that a second phase of the project would be needed to further develop the tool and expand its use to different contexts and explore further use of the tool at scale. Thus, as both the programming of the App and the first preliminary results were being generated, new research questions and concerns were arising and opening-up potential future App functionality and usability paths to be developed.
Phase 3 will be a scaling up phase and is currently under development.

What are the possible benefits and risks of participating?
Both Spanish and Senegalese children receive a personalised report (written for Spanish children and both written and/or oral for Senegalese children) regarding their nutritional status, as well as important information related to health and nutrition care practices. All malnutrition diagnosis (both under and overnutrition) are reported directly to the families, informing them of next steps. In Senegal, when a MAM or SAM child is identified, they are immediately referred to the health system. All participants families are informed of the associated technology that was going to be created and the important role they were carrying out for that population in risk or suffering malnutrition by allowing their children to participate. They are also informed that such technology would be available for free in the near future for everyone who wishes to use it. However, the possible risk is that children do not always wish to participate, even if their parents do, especially babies. Children may get tired during the sampling process.

Where is the study run from?
Action Against Hunger (Spain)

When is the study starting and how long is it expected to run for?
November 2015 to December 2021

Who is funding the study?
1. Children's Investment Fund Foundation (UK)
2. World Food Programme (Italy)
3. Grand Challenges Canada (GCC, Canada)
4. Agencia Española de Cooperación (AECID, Spain)

Who is the main contact?
Laura Medialdea Marcos, Principal Researcher
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Contact information

Type(s)
Scientific

Contact name
Ms Laura Medialdea

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28003
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lmedialdea@achesp.org

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ES/SAMphotoD/01

Study information

Scientific Title
Severe Acute Malnutrition (SAM) Photo Diagnosis Application Project for nutritional assesment

Acronym
SAMphotoD

Study objectives
The starting hypothesis this project was that it is possible to develop an innovative smartphone tool which can quick and accurately diagnose nutritional status, by analysing morphometrically the child's body shape, registered in photos taken by the device.
Once this hypothesis was verified, a second phase of the project was designed in order to answer the following hypotheses:
1. Shape variations between this two-extreme nutritional status are also measurable if considering Moderate Acute Malnutrition (MAM) and underweight
2. Children's body shape with SAM present homogeneous growth and body shape pattern among populations with different contexts and culture
3. Chronic malnutrition approach is possible using SAM Photo Diagnosis® methodology
4. A user centred design is possible for addressing community management of malnutrition

Ethics approval required
Old ethics approval format

Ethics approval(s)

1. Clinical Research Ethical Committee, San Carlos Clinical Hospital, Madrid, Spain, 15/01/2016, reference number: C.P. CMAM 2.0 - C.I. 16/013-E
2. National Ethics Committee for Health Research, Dakar, Senegal, 23/11/2016, reference number: SEN16/35

Study design
Observational epidemiological study with pilot phase and validation phase

Primary study design
Observational

Secondary study design
Epidemiological study

Study setting(s)
Other

Study type(s)
Diagnostic

Participant information sheet
See additional files (available in Spanish and French)

Health condition(s) or problem(s) studied
Acute and chronic malnutrition in children aged 6-59 months

Interventions
Current intervention as of 07/09/2020:
Phase I of this study was the pilot phase, with the following objectives:
1. Validate geometric morphometric (GM) techniques for use in children under 5 years of age
2. Validate the use of a morphometric model to diagnose severe acute malnutrition (SAM) in a high-prevalence context
3. Document the lessons and knowledge on the application and its use as a diagnostic tool to inform future operational and research use
The development of the algorithm required taking photographs of a sample of well-nourished children in Spain and well-nourished and malnourished children in Senegal. Overall, 2,060 images were collected across the sample of 450 children in the study. These images captured the full body photos in different views and allowed the study of both the whole body and split body regions. These images provided the information needed to generate the templates used for diagnosis. According to bioethical considerations as well as personal data protection policies (Senegalese 2008/12 and European GDPR 16/679), all health data, including images, were treated under a high-level data protection framework. Furthermore, required ethical clearances and consent forms were obtained prior to data collection. Regarding the app development, since the images of body regions are used to diagnose malnutrition with SAM Photo Diagnosis App®, children will not be identifiable from the photos taken and all images will be deleted from mobiledevices once the diagnosis has been provided.

Phase II is the validation phase, with the following objectives:
1. Technical validation of SAM Photo Diagnosis App in two selected pilot countries, Senegal and Guatemala
2. Integration of machine learning technology to allow automated diagnosis of malnutrition

3. Validation of a user-centered design approach in pilot countries
Pictures of body regions are being taken with SAM Photo Diagnosis App®, applying the same ethical considerations used in Phase I. Surveys are being conducted to legal guardians of participants to assess nutritional, familiar and context information related to undernutrition and provide useful information for final users. Focal groups are being constructed to carry out workshops and get useful feedbacks to develop the app's interface.

Phase III is the scaling up phase is still under ideation. One of the main objectives in this stage is to create a platform where SAM Photo Diagnosis App® is integrated with national health systems to provide a holistic community-based management of malnutrition.

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Previous intervention:
Phase I of this study was the pilot phase, with the following objectives:
1. Validate geometric morphometric (GM) techniques for use in children under 5 years of age
2. Validate the use of a morphometric model to diagnose severe acute malnutrition (SAM) is a high-prevalence context
3. Document the lessons and knowledge on the application and its use as a diagnostic tool to inform future operational and research use
The development of the algorithm required taking photographs of a sample of well-nourished children in Spain and well-nourished and malnourished children in Senegal. Overall, 2,060 images were collected across the sample of children in the study. These images captured the full body photos in different views and allowed the study of both the whole body and split body regions. These images provided the information needed to generate the templates used for diagnosis. According to bioethical considerations as well as personal data protection policies (Senegalese 2008/12 and European GDPR 16/679), all health data, including images, were treated under a high-level data protection framework. Furthermore, required ethical clearances and consent forms were obtained prior to data collection. Regarding the app development, since the images of body regions are used to diagnose malnutrition with SAM Photo Diagnosis App®, children will not be identifiable from the photos taken and all images will be deleted from mobile devices once the diagnosis has been provided.

Phase II is the validation phase, with the following objectives:
1. Technical validation of SAM Photo Diagnosis App in two selected pilot countries, Senegal and the Democratic Republic of the Congo
2. Creation of a platform where SAM Photo Diagnosis App(R) is integrated integration for holistic community-based management of malnutrition
3. Integration of machine learning technology to allow automated diagnosis of malnutrition
4. Validation of the approach in pilot countries
Pictures of body regions were taken with SAM Photo Diagnosis App(R), and the same ethical considerations applied in Phase I were applied to Phase II. Surveys were conducted to assess nutritional, familiar and context information related to undernutrition and provide useful information for final users.

Phase III is the scaling up phase and has not yet been designed.

Intervention Type
Device

Primary outcome measure

Current primary outcome measures as of 07/09/2020:
1. Anthropometric measurements:
1.1. Weight (kg), assessed using a portable electronic scale (phases I & II)
1.2. Height (cm), assessed using (phases I & II):
1.2.1. Portable infantometer for children under 87 cm
1.2.2. Anthropometer GPM for children over 87 cm
1.3. Mid-upper arm circumference (MUAC, cm), assessed using a self-rectracting flat metal tape with a blank lead-in strip (phases I & II)
1.4. Sitting height (cm), assessed using (phase I):
1.4.1. Portable infantometer for children under 87 cm
1.4.2. Anthropometer GPM for children over 87 cm
1.5. Cephalic perimeter (cm), assessed using a self-rectracting flat metal tape with a blank lead-in strip (phase I)
2. Determination of which photographic angles would provide better image information regarding body shape, assessed through anatomically identifying and marking 68 points on the child's body and analysing the images (phase I)
3. Information regarding the health, nutrition and origin of the child participating in the study, assessed using a survey completed by the parents (phases I & II)
4. Feedback obtained in user-centered design activities carried out with focal groups (phase II)

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Previous primary outcome measures:
1. Anthropometric measurements, taken during phase I of the study:
1.1. Weight (kg), assessed using a portable electronic scale
1.2. Height (cm), assessed using:
1.2.1. Portable infantometer for children under 87 cm
1.2.2. Anthropometer GPM for children over 87 cm
1.3. Mid-upper arm circumference (cm), assessed using a self-rectracting flat metal tape with a blank lead-in strip
1.4. Sitting height (cm), assessed using:
1.4.1. Portable infantometer for children under 87 cm
1.4.2. Anthropometer GPM for children over 87 cm
1.5. Cephalic perimeter (cm), assessed using a self-rectracting flat metal tape with a blank lead-in strip
2. Determination of which photographic angles would provide better image information regarding body shape, assessed through anatomically identifying and marking 68 points on the child's body and analysing the images. This was done during phase I of the study
3. Information regarding the health, nutrition and origin of the child participating in the study, assessed using a survey completed by the parents at the point of photographs being taken (during phase I)

Secondary outcome measures
N/A

Overall study start date
16/11/2015

Completion date
31/12/2021

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 07/09/2020:
Phase I
1. Aged 6-59 months
2. Normal weight: p30 - p70 weight-for-height Z-score (WHZ) or mid-upper arm circumference Z-score (MUACZ)
3. Severe acute malnourishment (WHZ and MUACZ <-3 SD

Phase II
1. Aged 6-59 months
2. Any nutritional condition estimated by WHZ and MUACZ following WHO criteria

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Previous participant inclusion criteria:
1. Aged 6-59 months
2. Normal weight: p30 - p70 weight-for-height Z-score (WHZ) or mid-upper arm circumference Z-score (MUACZ)
3. Severe acute malnourishment (WHZ and MUACZ <-3 SD

Participant type(s)
Mixed

Age group
Child

Lower age limit
6 Months

Upper age limit
59 Months

Sex
Both

Target number of participants
Phase I: n= 450. 2 countries (150 Spain, 300 Senegal), nutritional status (normalweight: 150 Spanish, 150 Senegalese; SAM: 150 Senegalese). Phase II: n=1800 (1200 Senegal, 600 Guatemala), Senegal= 4 nutritional conditions decribed by WHO (25% each), Guatemala= wasting (presence /absence) + stunting (presence/absence) equally distributed. Phases I & II: 2 sexes (50% each group), 2 age groups (50% each group)

Key exclusion criteria
Current participant exclusion criteria as of 07/09/2020:
1. No signed consent
2. Billateral oedema.
3. Unwilling to participate
4. Health complications other than malnutrition

5. Morphological abnormalities

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Previous participant exclusion criteria:
1. No signed consent
2. Unwilling to participate
3. Health complications
4. Morphological abnormalities

Date of first enrolment
01/02/2016

Date of final enrolment
31/12/2020

Locations

Countries of recruitment
Guatemala

Senegal

Spain

Study participating centre
Action against Hunger HQ in Madrid, Complutense University of Madrid, schools and nurseries in Madrid, Casse de tous petites in Senegal, community level at Senegal and Guatemala.
AAH, HQ Madrid: C/ Duque de Sevilla 3
Madrid
Spain
28003

Study participating centre
CEIP San Juan Bautista
Calle Sorzano 1
Madrid
Spain
28043

Study participating centre
CEIP Amorós
Calle Gómez de Arteche 31
Madrid
Spain
28044

Study participating centre
CEIP Lorenzo Luzuriaga
Calle Valencia de Don Juan 19
Madrid
Spain
28034

Study participating centre
Guardería Cuatro Pecas
Calle Capitán Salazar Martínez 9
Madrid
Spain
28005

Study participating centre
Guardería Escuela el Girasol
Calle del General Aranaz 54
Madrid
Spain
28027

Study participating centre
Guardería Coco
Calle de Monseñor Oscar Romero 72
Madrid
Spain
28025

Study participating centre
Guardería Diabolo
Calle de Cáceres 8
Madrid
Spain
28045

Study participating centre
Guardería EL Arlequín
Calle los Yébenes 69

Madrid
Spain
28047

Study participating centre
Guardería el Arullo
Calle de Montes de Barbanza
Madrid
Spain
28031

Study participating centre
Guardería Los Nanos Chiflados
Calle de Marcenado 46
Madrid
Spain
28002

Study participating centre
Universidad Complutense de Madrid
Av. Séneca 2
Madrid
Spain
28040

Study participating centre
Diela
Kanel
Matam
Diela
Senegal
N/A

Study participating centre
CTP - Kanel
Kanel
Matam
Senegal
N/A

Study participating centre
Danthiady
Kanel
Matam
Senegal
N/A

Study participating centre
Douloul
Kanel
Matam
Senegal
N/A

Study participating centre
Orndolde
Kanel
Matam
Senegal
N/A

Study participating centre
Ounare
Kanel
Matam
Senegal
N/A

Study participating centre
Polel Diaoube
Kanel
Matam
Senegal
N/A

Study participating centre
Sinthiou Bamambe
Kanel

Matam
Senegal
N/A

Study participating centre
Sinthiou Garba
Kanel
Matam
Senegal
N/A

Study participating centre
Wodaberé
Kanel
Matam
Senegal
N/A

Study participating centre
Younouferé
Kanel
Matam
Senegal
N/A

Study participating centre
Bockisabundu
Matam
Matam
Senegal
N/A

Study participating centre
Boinadji
Matam
Matam
Senegal
N/A

Study participating centre
CTP - Matam
Matam
Matam
Senegal
N/A

Study participating centre
CTP - Sedo Sebe
Matam
Matam
Senegal
N/A

Study participating centre
CTP Fété Niébé
Matam
Matam
Senegal
N/A

Study participating centre
Diamel
Matam
Matam
Senegal
N/A

Study participating centre
Maternelle - Gourel Sérigne
Matam
Matam
Senegal
N/A

Study participating centre
Maternelle - Matam 1
Matam
Matam
Senegal
N/A

Study participating centre
Maternelle - Ndouloumadji
Matam
Matam
Senegal
N/A

Study participating centre
Ogo
Matam
Matam
Senegal
N/A

Study participating centre
Ourossogui
Matam
Matam
Senegal
N/A

Study participating centre
Soubalo
Matam
Matam
Senegal
N/A

Study participating centre
Badagor
Ranerou
Matam
Senegal
N/A

Study participating centre
CTP - Ranerou
Ranerou

Matam
Senegal
N/A

Study participating centre
Fourdou
Ranerou
Matam
Senegal
N/A

Study participating centre
Lougueré Thiolly
Ranerou
Matam
Senegal
N/A

Study participating centre
Loumbol Samba Abdoul
Ranerou
Matam
Senegal
N/A

Study participating centre
Mbem mbem
Ranerou
Matam
Senegal
N/A

Study participating centre
Nawré
Ranerou
Matam
Senegal
N/A

Study participating centre
Salalatou
Ranerou
Matam
Senegal
N/A

Study participating centre
Thionokh
Ranerou
Matam
Senegal
N/A

Study participating centre
Velingara
Ranerou
Matam
Senegal
N/A

Study participating centre
Guardería Projardín Praga
Calle de Antonio López 67
Madrid
Spain
28019

Study participating centre
Guardería Projardín Delicias
Paseo de las Delicias 65
Madrid
Spain
28045

Sponsor information

Organisation
Children's Investment Fund Foundation

Sponsor details
7 Clifford Street
London
United Kingdom
W1S 2FT

Sponsor type
Charity

Website
https://ciff.org/

ROR
https://ror.org/00jfgrn87

Funder(s)

Funder type
Charity

Funder Name
Children's Investment Fund Foundation

Alternative Name(s)
CIFF

Funding Body Type
Private sector organisation

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

Location
United Kingdom

Funder Name
United Nations World Food Programme

Funder Name
Grand Challenges Canada

Alternative Name(s)
Grands Défis Canada, GCC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Funder Name
Agencia Española de Cooperación

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 07/09/2020:
We have produced a promotional video of the project (https://www.youtube.com/watch?v=y0VlLxYKpZY&feature=youtu.be) and a general diffusion article (https://www.ennonline.net//fex/57/samphotodiagnosisapp).
A manuscript is under review with the American Journal of Physical Anthropology.
We aim to prepare another two manuscripts to be sent to peer-reviewed journals in December 2020 and March 2021

Previous publication and dissemination plan:
We have produced a promotional video of the project (https://www.youtube.com/watch?v=y0VlLxYKpZY&feature=youtu.be) and a general diffusion article (https://www.ennonline.net//fex/57/samphotodiagnosisapp).
A manuscript is under review with the American Journal of Physical Anthropology.
We aim to prepare another two manuscripts to be sent to peer-reviewed journals in December 2018 and March 2019

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		18/10/2018	02/04/2019	No	Yes
Participant information sheet		18/10/2018	02/04/2019	No	Yes
Results article	results	01/04/2019	09/07/2019	Yes	No