## SAM Photo Diagnosis App Project

Submission date	Recruitment status  No longer recruiting	<ul><li>Prospectively registered</li></ul>		
24/09/2018		☐ Protocol		
Registration date 29/10/2018	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	[] Individual participant data		
09/09/2020	Nutritional, Metabolic, Endocrine			

#### 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 lifethreatening 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 lmedialdea@accioncontraelhambre.org

## **Contact information**

#### Type(s)

Scientific

#### Contact name

Ms Laura Medialdea

#### Contact details

C/ Duque de Sevilla, 3 Madrid Spain 28003 +34913915300, ext. 1345 lmedialdea@achesp.org

## Additional identifiers

#### Protocol serial number

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

#### Study type(s)

Diagnostic

#### 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.

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(s)

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)

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)

#### Key secondary outcome(s))

N/A

#### 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

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

### Healthy volunteers allowed

No

#### Age group

Child

#### Lower age limit

6 months

### Upper age limit

59 months

#### Sex

All

#### 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

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

#### **ROR**

https://ror.org/00jfgrn87

## Funder(s)

## Funder type

Charity

#### **Funder Name**

Children's Investment Fund Foundation

#### Alternative Name(s)

The Children's Investment Fund Foundation, The Children's Investment Fund Foundation (UK), 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, gchallenges, Grand Challenges Canada / Grands Défis Canada, grandchallengescanada, GCC

#### **Funding Body Type**

Government organisation

#### **Funding Body Subtype**

National government

#### Location

Canada

#### **Funder Name**

Agencia Española de Cooperación

## **Results and Publications**

### 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?
Results article	results	01/04/2019	09/07/2019	Yes	No
Participant information sheet		18/10/2018	02/04/2019	No	Yes
Participant information sheet		18/10/2018			Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes