

# The Ready to Use Complementary Food (RUCF) Study

<b>Submission date</b> 08/11/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 28/04/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 19/06/2012	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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Fond Tasnier 6  
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## Additional identifiers

**Protocol serial number**  
N/A

## Study information

### Scientific Title

The impact of high nutrient dense Ready to Use Complementary Food (RUCF) on growth of children below 2 years in South Kivu, Eastern Democratic Republic of Congo: a randomised controlled interventional trial

**Acronym**  
S-RUCF

## **Study objectives**

This study will test the hypothesis that the use of a specially designed fortified spread (a specific Ready to Use Complementary Food [RUCF]) containing 500 kcal per 100 g as a complementary food for 12 months (from 6 months to 18 months of age) will reduce the incidence and prevalence of underweight and stunting.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

1. Ethics Committee of the Free University of Brussels approved on the 10th March 2009 (ref: P2009/060/B40620095963)
2. Ethics Committee of the Centre de Recherche of Science Naturelles (CRSN) approved on the 28th September 2008

## **Study design**

Randomised controlled interventional trial

## **Primary study design**

Interventional

## **Study type(s)**

Quality of life

## **Health condition(s) or problem(s) studied**

Underweight/stunting

## **Interventions**

Intervention group: infants enrolled in the intervention group will receive 50 g of RUCF providing 250 kcal/day during 12 months (from the age of 6 to 18 months). The RUCF will be administered daily by the mother. Extension health workers serving the villages of participating children will visit the couples mother-infant biweekly.

Control group: Infants enrolled in the control group will receive 1 kg of UNIMIX flour per week. The porridge offered to infant should provide 250 kcal/day.

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome(s)**

Prevalence of stunting at 12, 18 and 24 months of age.

## **Key secondary outcome(s)**

1. Average daily breast milk intake at 6 and 9 months of age
2. Prevalence of exclusive breast feeding at 6 months of age
3. Mean change in anthropometric indices at 12, 18 and 24 months of age
4. Risks factors of stunting at 12 months of age

5. Incidence of diarrhoea at 12 months of age
6. Incidence of malaria at 12 months of age
7. Incidence of severe acute malnutrition at 12, 18 and 24 months of age
8. Proportion of children standing independently at 9 and 12 months of age
9. Proportion of children walking unassisted at 12 months of age
10. Mean cholesterol at 12 and 18 months of age
11. Mean triglycerides at 12 and 18 months of age
12. Mean haemoglobin at 12, 18 and 24 months of age

**Completion date**

30/12/2011

## Eligibility

**Key inclusion criteria**

1. Full term born infants (gestational age greater than 37 weeks and birth weight greater than 2500 g)
2. Consent given

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Child

**Sex**

All

**Key exclusion criteria**

1. Bottle-fed children
2. Children with any malformations or neurological impairment

**Date of first enrolment**

15/11/2009

**Date of final enrolment**

30/12/2011

## Locations

**Countries of recruitment**

Belgium

Congo, Democratic Republic

**Study participating centre**  
**Fond Tasnier 6**  
Genval  
Belgium  
1332

## Sponsor information

**Organisation**  
Irish Aid (Ireland)

**ROR**  
<https://ror.org/03kyawa63>

## Funder(s)

**Funder type**  
Charity

**Funder Name**  
Irish Aid (Ireland)

## Results and Publications

**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?
<a href="#">Results article</a>	results	01/05/2012		Yes	No